State of Iowa
Board of Pharmacy

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BOARD MEMBERS
LADONNA GRATIAS
EDWARD McKENNA
EDWARD MAIER

JAMES MILLER
Board Chair

ANDREW FUNK
Executive Director

BOARD MEMBERS
JASON HANSEL
SHARON MEYER
JUDITH TRUMPY

MINUTES

August 31 - September 2, 2015

The Iowa Board of Pharmacy met on August 31 - September 2, 2015, in the conference room at 400 SW Eighth Street, Des Moines, Iowa.

MONDAY, AUGUST 31, 2015

MEMBERS PRESENT
Edward L. Maier, Chairperson
James Miller, Vice-Chair
LaDonna Gratias
Jason Hansel
Edward J. McKenna
Sharon K. Meyer
Judith M. Trumpy

SPEAKERS
AnthonyPudlo, IPA
Brett Barker, NuCara
Evan Arnold, Centor
Anthony Crofoot, STATdispense
Jordan Esbrook, AAG
Adam Chesler, PTCB
Megan Myers, IPA
Dale Woolery, ODCP
Roby Miller, TelePharm
Ed Dalashmutt, Midwest Respiratory Care Inc.

STAFF PRESENT
Therese Witkowski, Interim Director/Executive Officer
Meghan Gavin, Esq., Assistant Attorney General
Laura Steffensmeier, Esq., Assistant Attorney General
Debbie Jorgenson, Administrative Assistant
Becky Hall, Secretary
Andrew Funk, Compliance Officer
Curt Gerhold, Compliance Officer
Mark Mather, Compliance Officer
Sue Mears, Compliance Officer
Jean Rhodes, Compliance Officer
Jennifer Tiffany, Compliance Officer
Jennifer O'Toole, Compliance Officer

Call to Order & Announcements

At 10:00 a.m., Edward Maier, Chairperson, called the meeting of the Iowa Board of Pharmacy to order on Monday, August 31, 2015.

Public Comments

No public comments.

Approval of Minutes

The minutes of the June 23-24, 2015, meeting were reviewed.

Motion by James Miller, seconded by Judith Trumpy, to approve the open session minutes of the June 23-24, 2015, meeting as presented. Motion approved unanimously.

Election of Officers

Motion by Jason Hansel, seconded by Edward McKenna, to nominate James Miller for Chair. Motion approved unanimously.

Motion by Judith Trumpy, seconded by Edward McKenna, to nominate Sharon Meyer for Vice-Chair. Motion approved unanimously.

Reports

1. Interim Executive Director's Report – August 31, 2015.

   A. Financials

   ***Board Account*:**

Total Revenues FY15:	$ 3,927,802.79 (includes FY14 carry-over $1,504,636.79)
Expenditures:	$ 2,380,037.84
Carry-over to FY16:	$ 1,547,764.95

   ***IPRN*:**

Expenditures:	$ 107,358.53
Carry-over to FY16:	$ 7,465.47
Transfer from Board CO:	$ 106,034.53

   ***PMP*:**

Expenditures:	$ 102,000
No Carry-over to FY16:	---
Transfer from Board CO:	$ 106,800

2. Office/Program Updates.

A. Information Technology Specialist Position – The Office of Chief Information Officer (OCIO) did not approve filling this position at this time. OCIO is working to consolidate all IT positions within OCIO. Board staff is currently working with OCIO to assess the needs of the Board.

B. Prescription Monitoring Program (PMP) Interconnect – The Iowa PMP is actively sharing information with neighboring states. Iowa is able to exchange data with Kansas, Illinois, and South Dakota. Iowa users can obtain prescription records from Minnesota and Wisconsin, but these two states are waiting for their software vendor to authorize their PMP users to obtain information from Iowa. Nebraska and Missouri do not currently have a sharable PMP.

C. Website Redesign - Debbie Jorgenson has been converting information from the current Board website to the redesign website and anticipates switching to the new website around October 1, 2015.

3. Meetings.

A. The NABP/AACP District Five Annual Meeting was held in Fargo, North Dakota, on August 6-8, 2015. Edward Maier, Jim Wolfe, Curt Gerhold, Andrew Funk, and Terry Witkowski attended the meeting. Lloyd Jessen will be continuing his District Five duties as secretary, and agreed to work with the Board and both Iowa colleges when Iowa hosts the District Five Meeting in August of 2017.

B. Mark Mather and Andrew Funk will be attending the Council on Licensure, Enforcement, and Regulation (C.L.E.A.R.) investigator training in Boston, Massachusetts, on September 13-16, 2015.

C. Jennifer O'Toole, Jennifer Tiffany, and Terry Witkowski will be providing a presentation at the Iowa Veterinary Medicine Association's annual meeting on September 18, 2015, in Ames. Topics of discussion with include history and overview of Board of Pharmacy functions and responsibilities, Iowa PMP, veterinary compounding, and issues relating to controlled substances, record keeping, and security requirements.

D. Meghan Gavin will be attending the Federal Associations of Regulatory Boards (FARB) Regulatory Law Seminar in Denver, Colorado, on October 1-4, 2015.

E. The Tri-Regulator Symposium is schedule for October 6-7, 2015, in Arlington, Virginia. Representatives of state Medical, Nursing, and Pharmacy Boards have been invited to attend the Symposium.

F. The Annual Meeting of the National Association of State Controlled Substances Authorities (NASCSA) is scheduled for October 19-23, 2015, in Scottsdale, Arizona. Jim Wolfe and Terry Witkowski plan to attend the meeting.

G. The November board meeting is scheduled for November 3-4, 2015, in Des Moines. A committee of the Board will meet with the Iowa Pharmacy Association Board of Trustees for an annual dinner meeting on the evening of November 3, at the Iowa Pharmacy Association's office in Urbandale.

4. Miscellaneous.

The National Association of Boards of Pharmacy (NABP) recently announced the task forces and committees for 2016, and the individuals appointed to those committees. Edward Maier has been appointed to the Task Force on VPP Implementation.

5. Litigation Update Meghan Gavin.

   The Board currently has one judicial review in District Court.

6. Pharmacy Benefit Managers Lawsuit – Jordan Esbrook, Assistant Attorney General.

   In 2014, the Iowa Legislature passed a statue regulating Pharmacy Benefit Managers (PBM), adding to Section 510B of the Iowa Code. It imposed some requirements on PBM that they provide an avenue appeal for pharmacies, and that they use nationally recognized and locally available standards for setting MAC pricing. The Pharmaceutical Care Management (PCM) Association filed suit in September of 2014. PCM originally filed an ERISA Preemption Claim, a Dormant Commerce Clause Claim, and claimed that the statue enacted unconstitutional taking of their property. Ms. Esbrook on behalf of the State moved to dismiss the Takings Claim and the ERISA Claim. Judge Jarvey of the United States District Court for the Southern District of Iowa dismissed the claims last year. The Dormant Commerce Clause Claim still exists, under the United States Constitution states cannot interfere with the flow of goods through Interstate Commerce. PCM is alleging that Section 510B interferes with Interstate Commerce Clause. PCM added another claim that the statue is unconstitutionally vague. In June 2015, Ms. Esbrook moved to dismiss the Dormant Commerce Clause Claim and the Vagueness Claim, that motion is pending, if granted the entire case will be dismissed. PCM has the right to appeal to the Eighth Circuit Court of Appeals. If the motion is not granted, the case will continue to trial in July of 2016.

7. Iowa Pharmacy Recovery Network (IPRN) Report.

   The IPRN Report was provided for review.

8. IPRN Statement of Financial Position.

   The IPRN Statement of Financial Position was provided for review.

9. Iowa TakeAway Medication Disposal Program 2014-2015 Annual Report.

   The Iowa TakeAway Medication Disposal Program 2014-2015 Annual Report was provided for review.

10. Hy-Vee Pharmacy Fulfillment Center – 2nd Quarter 2015 Error Report.

    Hy-Vee Pharmacy Fulfillment Center submitted their 2nd Quarter Error Report for review.

11. Patient Safety & Medication Error Prevention for Pharmacists – Kenneth Wells, Continuing Education Department, Oregon State University, College of Pharmacy.

    The Patient Safety and Medication Error Prevention for Pharmacists is an online continuing education course. The course provides pharmacists with the tools to identify problems, reduce risks, and improve communication, leading to increased patient safety within the pharmacy environment. The course was developed collaboratively by Oregon State University's College of Pharmacy and the Oregon Patient Safety Commission.

12. NuCara Pharmacy, Zearing - 2nd Quarter 2015 Telepharmacy Report.

    NuCara Telepharmacy provided their 2nd Quarter Telepharmacy Report for review.

13. NuCara Pharmacy, State Center - 2nd Quarter 2015 Telepharmacy Report.

    NuCara Telepharmacy provided their 2nd Quarter Telepharmacy Report for review.

14. State Board Position on Protecting Citizens – Evan Arnold, Centor.

    Evan Arnold with Centor provided a presentation. Centor is a supplier of regulatory compliant prescription containers for medication dispensing. Topics of discussion were (1) drug abuse with container/closure prescription solution, (2) labeling the prescription container, and (3) moisture protection for the prescription container.

15. STATdispense – Creative Strategies US.

    Anthony Crofoot provided a presentation via the Internet. STATdispense is a first-dose and emergency medication management software solution providing real-time billing and tracking information and can be used in conjunction with a "tackle-box" system. This item was referred to the Rules Committee.

16. Advancing Patient Safety – Adam Chesler, Pharmacy Technician Certification Board.

    Adam Chesler provided a presentation on Advancing Patient Safety and discussed changes with the Pharmacy Technician Certification Board (PTCB). New PTCB requirements include (1) any continuing education earned after January 1, 2015, must be in pharmacy technician-specific subject matter, and (2) by 2020, PTCB candidates seeking certification will be required to complete an ASHP/ACPE-accredited training program.

17. Rx Return Box Service – Announces Community Anti-Drug Coalitions of America (CADCA) Membership.

    Informational item.

18. New Practice Model Project Phase One and Phase Two Quarter Reports – Megan Myers, Iowa Pharmacy Association.

    Phase One Quarter Five Report and Phase Two Quarter Two Report for the New Practice Model Project were provided for review.

19. Response to Tech Check Tech Memo from Board Compliance Officers – Megan Myers, Iowa Pharmacy Association.

    Board compliance officers visited Phase One and Phase Two Tech Check Tech program sites and provided the Board with their individual observations and concerns. A response to the concerns regarding the pilot project was provided for review.

20. Opioid Overdose Prevention Toolkit – National Association of Boards of Pharmacy.

    Informational item.

Requests

1. Request for Internship Credit – Ali Hassan El-Sayad, Pharmacist Intern No. 6369, Mason City.

   Motion by Jason Hansel, seconded by Judith Trumpy, to grant credit for 500 hours of internship in lieu of life experience requiring Mr. El-Sayad to complete an additional 1,000 hours of internship. Motion approved unanimously.

2. Request for Amendment to 2015-2016 Medication Disposal Contract – Iowa Pharmacy Association.

   This item was tabled.

3. Proposals for Renewing Phase One New Practice Model Pilot – Megan Myers, Iowa Pharmacy Association.

   Motion by James Miller, seconded by Judith Trumpy, to approve an 8 month extension for the pilot program. Motion approved unanimously.

4. NuCara Health Solutions Application for Limited Use Pharmacy License.

   Motion by James Miller, seconded by LaDonna Gratias, to approve the Application for Limited Use Iowa Pharmacy License. Motion approved unanimously.

5. Joint Telepharmacy Pilot Project Proposal – Tel-Pharm and NuCara Pharmacies.

   Roby Miller presented a proposal for a pilot/search demonstration project to establish telepharmacies in rural Iowa communities. TelePharm requested to create pilot projects in Lake Park, Nora Springs, Wayland, and Winfield.

   Motion by LaDonna Gratias, seconded by Judith Trumpy, to table this request and refer to the Rules Committee. Motion approved unanimously.

Rules & Legislation

1. Removal of [123I] Ioflupane from Schedule II of the Controlled Substances Act.

   Informational item.

2. Notice of Intended Action to Amend Various Chapters: Chapter 6, "General Pharmacy Practice," Chapter 8, "Universal Practice Standards," Chapter 10, "Controlled Substances," and Chapter 22, "Unit Dose, Alternative Packaging, and Emergency Boxes."

   Motion by Judith Trumpy, seconded by Edward McKenna, to approve for Notice of Intended Action. Motion approved unanimously. Copies are attached as Addendum A (Chapter 6), Addendum B (Chapter 8), Addendum C (Chapter 10), and Addendum D (Chapter 22).

3. Proposed for Adoption and Filing - Chapter 3, "Pharmacy Technicians," Chapter 6, "General Pharmacy Practice," and Chapter 7, "Hospital Pharmacy Practice," rescinds Chapter 13, "Sterile Compounding Practices," and rescinds Chapter 20, "Pharmacy Compounding Practices," and adopts new Chapter 20, "Compounding Practices."

   Motion by Judith Trumpy, seconded by Sharon Meyer, to approve for Adoption and Filing. Motion approved unanimously. A copy is attached as Addendum E.

4. Proposed for Adoption and Filing - Chapter 6, "General Pharmacy Practice," Chapter 7, "Hospital Pharmacy Practice," Chapter 15, "Correctional Pharmacy Practice," and Chapter 16, "Nuclear Pharmacy Practice."

   Motion by Judith Trumpy, seconded by Sharon Meyer, to approve for Adoption and Filing. Motion approved unanimously. A copy is attached as Addendum F.

5. Proposed for Adoption and Filing - Chapter 7, "Hospital Pharmacy Practice," and Chapter 23, "Long-Term Care Pharmacy Practice."

   Motion by Jason Hansel, seconded by Judith Trumpy, to approve for Adoption and Filing. Motion approved unanimously. A copy is attached as Addendum G.

6. Proposed for Adoption and Filing - Chapter 10, "Controlled Substances."

   Motion by Judith Trumpy, seconded by Jason Hansel, to approve for Adoption and Filing. Motion approved unanimously. A copy is attached as Addendum H.

Licensure/Registration

1. NR & V Drugs, Inc., d/b/a Wyandotte Drugs, Nonresident Pharmacy Application, Wyandotte, Michigan.

   Motion by Judith Trumpy, seconded by James Miller, to approve the Licensure by Consent Agreement. Motion approved unanimously. A copy of the Licensure by Consent Agreement is attached as Addendum I.

2. Han. Sam. Corp., d/b/a River's Edge Pharmacy, Nonresident Pharmacy Application, Palm Desert, California.

   Motion by James Miller, seconded by Judith Trumpy, to approve the Preliminary Notice of Intent to Deny License. Motion approved unanimously. A copy of the Preliminary Notice of Intent To Deny License is attached as Addendum J.

3. Professional Partners, Inc., Nonresident Pharmacy Application, Newport Beach, California

   This item was tabled.

4. Best Care Pharmacy Inc., Nonresident Pharmacy Application, Miami, Florida.

   Motion by Jason Hansel, seconded by Judith Trumpy, to approve the Application for Nonresident Iowa Pharmacy License. Motion approved unanimously.

5. Jay Pharmacy of Jay Fla, Inc., Nonresident Pharmacy Application, Jay, Florida.

   Motion by Sharon Meyer, seconded by Judith Trumpy, to approve the Application for Nonresident Iowa Pharmacy License. Motion approved unanimously.

6. Perform Specialty, Nonresident Pharmacy Application, Orlando, Florida.

   Motion by Sharon Meyer, seconded by Judith Trumpy, to approve the Application for Nonresident Iowa Pharmacy License. Motion approved unanimously.

7. US Specialty Care, Nonresident Pharmacy Application, Lakeland, Florida.

   Motion by Judith Trumpy, seconded by LaDonna Gratias, to approve the Application for Nonresident Iowa Pharmacy License. Motion approved unanimously.

8. OptiMed Pharmacy, Nonresident Pharmacy Application, Kalamazoo, Michigan.

   Motion by Sharon Meyer, seconded by Judith Trumpy, to approve the Application for Nonresident Iowa Pharmacy License. Motion approved unanimously.

9. Veterinary Enterprises of Tomorrow, Nonresident Pharmacy Application, Mount View, Oklahoma.

   Motion by Judith Trumpy, seconded by Sharon Meyer, to approve the Application for Nonresident Iowa Pharmacy License. Motion approved unanimously.

10. Dawn Farrell, Pharmacy Support Person Registration Application, Des Moines.

    Motion by James Miller, seconded by Judith Trumpy, to approve the Application for Pharmacy Support Person Registration. Motion approved unanimously.

Complaints Against Non-Licensees

1. 2009-146, ANEWrx, Pittsburgh, Pennsylvania.

   Motion by James Miller, seconded by Judith Trumpy, to close with no action. Motion approved unanimously.

2. 2015-139, Midwest Respiratory Care Inc., Iowa Wholesale Drug License Application - Grimes.

   Motion by James Miller, seconded by LaDonna Gratias, to approve the Application for Iowa Wholesale Drug License and close complaint 2015-139. Motion approved unanimously.

Discussion on Vacant Executive Director Position

The Board will conduct interviews of the two final candidates for the Executive Director's position on Wednesday, September 2, 2015, at the board office.

Closed Session Minutes

Motion by James Miller, seconded by Edward McKenna, to approve the Closed Session Minutes and Deliberations of the June 23-24, 2015, meeting. Motion approved unanimously.

Closed Session

At 3:15 p.m., motion by Judith Trumpy, seconded by Jason Hansel, the Board voted unanimously by roll call vote to move into closed session for the following reasons:

For Follow-Up Investigative Information pursuant to Iowa Code § 21.5(1)(d) to discuss whether to initiate licensee disciplinary investigations or proceedings and pursuant to Iowa Code § 21.5(1)(a) to review or discuss records which are required or authorized by state or federal law to be kept confidential, specifically to review or discuss information that is confidential under Iowa Code § 272C.6(4).

For Settlement Agreement and Final Orders pursuant to Iowa Code § 21.5(1)(f) to discuss the decision to be rendered in a contested case.

For Notice of Hearings and Statement of Charges pursuant to Iowa Code § 21.5(1)(d) to discuss whether to initiate licensee disciplinary investigation or proceedings.

At 3:52 p.m., while still in closed session, James Miller moved that the Board go into open session, seconded by Judith Trumpy. Motion approved unanimously.

In open session, the following actions were taken:

1. Close With No Action.

   Motion by Jason Hansel, seconded by Sharon Meyer, to close with no further action the following investigative files in complaint numbers: 2014-79, 2013-81, 2013-129, 2013-201, 2014-151, and 2015-54. Motion approved unanimously.

2. Close With Referral to Another Agency.

   Motion by Sharon Meyer, seconded by Judith Trumpy, to close 2015-10 and refer to another agency. Motion approved unanimously.

3. Draft Statement of Charges.

   Motion by Judith Trumpy, seconded by Edward McKenna, to draft Statement of Charges against the pharmacy in 2015-6. Motion approved unanimously.

4. Settlement Agreement and Final Order.

   Motion by Edward McKenna, seconded by Judith Trumpy, to approve the Settlement Agreement and Final Order in the following cases. Motion approved unanimously.

   A. Thomas B. Dodds, Pharmacist License No. 12951 of Dakota Dunes, South Dakota. A copy of the Settlement Agreement and Final Order is attached as Addendum K.

   B. Rxtra Solutions, Nonresident Pharmacy License No. 4203 of Southfield, Michigan. A copy of the Settlement Agreement and Final Order is attached as Addendum L.

   C. LDI Integrated Pharmacy Services, Nonresident Pharmacy License No. 3816 of Creve Coeur, Missouri. A copy of the Settlement Agreement and Final Order is attached as Addendum M.

5. Notice of Hearing and Statement of Charges.

   Motion by Jason Hansel, seconded by Edward McKenna, to approve the Notice of Hearing and Statement of Charges against Karen Bean, Pharmacy Support Person No. 3456 of Cedar Rapids. Motion approved unanimously. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum N.

6. Order to Show Cause.

   Motion by Judith Trumpy, seconded by Sharon Meyer, to approve the Order to Show Cause for David H. Marcowitz, D.O., Controlled Substance Registration No. 1305770 of Chariton. A copy of the Order to Show Cause is attached as Addendum O.

Closed Session

At 3:56 p.m., motion by Judith Trumpy, seconded by Sharon Meyer, the Board voted unanimously by roll call vote to move into closed session for the following reason:

For Complaints and Investigative Reports pursuant to Iowa Code § 21.5(1)(d) to discuss whether to initiate licensee disciplinary investigations or proceedings and pursuant to Iowa Code § 21.5(1)(a)

to review or discuss records which are required or authorized by state or federal law to be kept confidential, specifically information that is confidential under Iowa Code § 272C.6(4).

At 4:28 p.m., while still in closed session, James Miller moved that the Board go into open session, seconded by Edward McKenna. Motion approved unanimously.

In open session, the following actions were taken:

1. Non IBP Disciplinary.

   Motion by Judith Trumpy, seconded by Edward McKenna to take no further action and close pursuant to reason No. 13, regarding out–of-state discipline in cases reference as 13.1, 13.2, 13.3, 13.4, 13.5, 13.7, 13.8, 13.9, 13.10, 13.11 a.k.a. 2015-17, 13.12, and 13.13. Motion approved unanimously.

2. Open a Complaint to Investigate.

   Motion by Jason Hansel, seconded by Sharon Meyer, to open a complaint to investigate 13.6, 2015-05, and 2015-127. Motion approved unanimously.

At 4:32 p.m. the Board recessed.

The meeting reconvened in open session on Tuesday, September 1, 2015, at 9:00 a.m.

TUESDAY, SEPTEMBER 1, 2015

MEMBERS PRESENT
Edward L. Maier, Chairperson
James Miller, Vice-Chair
LaDonna Gratias
Jason Hansel
Edward J. McKenna
Sharon K. Meyer
Judith M. Trumpy

STAFF PRESENT
Therese Witkowski, Interim Director/Executive Officer
Meghan Gavin, Esq., Assistant Attorney General
Laura Steffensmeier, Esq., Assistant Attorney General
Debbie Jorgenson, Administrative Assistant
Becky Hall, Secretary
Andrew Funk, Compliance Officer
Curt Gerhold, Compliance Officer
Mark Mather, Compliance Officer
Sue Mears, Compliance Officer
Jean Rhodes, Compliance Officer
Jennifer Tiffany, Compliance Officer
Jennifer O'Toole, Compliance Officer

Call to Order and Announcements

At 9:00 a.m., Edward Maier, Chairperson, called the meeting of the Iowa Board of Pharmacy to order.

Administrative Hearing

1. Amanda L. Latta, Pharmacist License No. 19669 of Springville.

   At 9:00 a.m., Laura Lockard, Administrative Law Judge, Department of Inspections and Appeals opened the record. Assistant Attorney General Meghan Gavin represented the State. Ms. Latta appeared without counsel. The hearing was conducted in the presence of the Board. The hearing was closed to the public.

   The Board heard testimony of a witness and examined exhibits.

   At 9:30 a.m., the record was closed.

   At 9:30 a.m., motion by Judith Trumpy, seconded by Sharon Meyer, the Board voted unanimously by roll call vote to move into closed session in accordance with Iowa Code Section 21.5(1)(f) to discuss the decision to be rendered in a contested case.

   At 9:40 a.m., while still in closed session, LaDonna Gratias moved that the Board go into open session, seconded by Judith Trumpy. Motion approved unanimously.

   Motion by James Miller, seconded by Judith Trumpy, to direct Administrative Law Judge Lockard to draft the Order consistent with the Board's deliberations in case 2011-43, Amanda L. Latta.

Closed Session

At 9:45: a.m., motion by Judith Trumpy, seconded by Edward McKenna, the Board voted unanimously by roll call vote to move into closed session for the following reason:

For Complaints and Investigative Reports pursuant to Iowa Code § 21.5(1)(d) to discuss whether to initiate licensee disciplinary investigations or proceedings and pursuant to Iowa Code § 21.5(1)(a) to review or discuss records which are required or authorized by state or federal law to be kept confidential, specifically information that is confidential under Iowa Code § 272C.6(4).

At 11:55 p.m., while still in closed session, Judith Trumpy moved that the Board go into open session, seconded by LaDonna Gratias. Motion approved unanimously.

In open session, the following actions were taken:

1. Letter of Education.

   Motion by LaDonna Gratias, seconded by Sharon Meyer, to issue a Letter of Education to the pharmacy and pharmacist in charge in 2015-140. Motion approved unanimously. Jason Hansel recused.

2. Letter of Education.

   Motion by Judith Trumpy, seconded by Edward McKenna, to issue a Letter of Education to the pharmacy in 2015-120, and two CSA registrants in 2015-134. Motion approved unanimously.

3. Close With No Action.

   Motion by LaDonna Gratias, seconded by Jason Hansel, to close with no further action the investigative files in complaint numbers: 2015-128, 2015-114, 2015-126, 2015-131, 2015-68, 2015-77, 2015-78, 2014-202, 2015-62, 2015-76, 2015-82, 2015-129, 2015-113, 2015-133, and 2015-136. Motion approved unanimously.

4. Draft Statement of Charges.

   Motion by Judith Trumpy, seconded by Jason Hansel, to draft Statement of Charges against the pharmacy in 2015-37, pharmacy and pharmacist in 2015-81, and pharmacy and pharmacist in charge in 2015-123. Motion approved unanimously.

5. Draft Statement of Charges.

   Motion by Sharon Meyer, seconded by Jason Hansel, to draft Statement of Charges against the pharmacy and pharmacist in charge in 2015-110. Motion approved unanimously. Edward McKenna recused.

6. Notice of Intent to Rescind License.

   Motion by Judith Trumpy, seconded by Jason Hansel, to issue Notice of Intent to Rescind License to the Wholesaler in 2015-100 and Wholesaler in 2015-115. Motion approved unanimously.

7. Referral to Another Agency.

   Motion by Sharon Meyer, seconded by Edward McKenna, to refer 2015-37 to the Board of Medicine. Motion approved unanimously.

Meghan Gavin and Laura Steffensmeier left the room.

Presentation on Website Redesign

Debbie Jorgenson provided an update and visual presentation on the new website redesign.

Rules Review Planning and Assignment

Assignments to review chapters of the board rules were issued.

Discussion on Vacant Executive Director Position

The Board discussed interview questions, comments, and scoring sheets from the Board's Search Committee Members and board staff. The Board finalized their goals for the position, interviewing process, interview questions, and scoring sheet.

Closed Session

At 3:00 p.m., motion by Judith Trumpy, seconded by Jason Hansel, the Board voted unanimously by roll call vote to move into closed session for the following reason:

For findings of Fact, Conclusions of Law, Decision and Order pursuant to Iowa Code § 21.5(1)(f) to discuss the decision to be rendered in contested case.

At 3:01 p.m., while still in closed session, James Miller moved that the Board go into open session, seconded by LaDonna Gratias. Motion approved unanimously.

In open session, the following actions were taken:

A. Settlement Agreement and Final Order.

Motion by Edward McKenna, seconded by Judith Trumpy, to approve the Settlement Agreement and Final Order for Ashley Henson, Pharmacy Technician Registration No. 8907 of Cherokee. A copy of the Settlement Agreement and Final Order is attached as Addendum P.

B. Findings of Fact, Conclusions of Law, Decision and Order.

Motion by Edward McKenna, seconded by Jason Hansel, to approve the Findings of Fact, Conclusions of Law, and Decision and Order for Sherri Marshall, Pharmacy Technician Registration No. 18129 of Des Moines. A copy of the Findings of Fact, Conclusions of Law, Decision and Order is attached as Addendum Q.

At 3:07 p.m. the Board recessed.

The meeting reconvened in open session on Wednesday, September 2, 2015, at 8:20 a.m.

WEDNESDAY, SEPTEMBER 2, 2015

MEMBERS PRESENT
Edward L. Maier, Chairperson
James Miller, Vice-Chair
LaDonna Gratias
Jason Hansel
Edward J. McKenna
Sharon K. Meyer
Judith M. Trumpy

VISITORS
Anthony Pudlo, IPA
Joshua Roehrick, IPA
Erin Beal, IPA

STAFF PRESENT
Therese Witkowski, Interim Director/Executive Officer
Meghan Gavin, Esq., Assistant Attorney General
Laura Steffensmeier, Esq., Assistant Attorney General
Debbie Jorgenson, Administrative Assistant
Becky Hall, Secretary
Andrew Funk, Compliance Officer
Curt Gerhold, Compliance Officer
Mark Mather, Compliance Officer
Sue Mears, Compliance Officer
Jean Rhodes, Compliance Officer
Jennifer Tiffany, Compliance Officer
Jennifer O'Toole, Compliance Officer

Call to Order and Announcements

At 8:20 a.m., Edward Maier, Chairperson, called the meeting of the Iowa Board of Pharmacy to order.

Executive Director Interviews

The Board conducted in-person interviews with the following candidates:

- Andrew Funk - 8:20 a.m.
- David Sinnwell - 10:00 a.m.

Executive Director Discussion and Decision

Members of the Board asked each candidate the same series of questions. Board members independently completed score sheets and comments following the interviews.

Following the interviews, candidate's responses to the questions were discussed and score ratings were accumulated. A list of those questions and scoring sheet are attached as Addendum R.

Motion by Sharon Meyer, seconded by James Miller, to offer Andrew Funk the Executive Director's Position. Motion approved unanimously.

Motion by Edward McKenna, seconded by Judith Trumpy, should Mr. Funk decline the Executive Director's Position David Sinnwell will be offered the position. Motion approved unanimously.

The Board discussed the salary range and having a 6 month performance evaluation for the Executive Director's Position.

Motion by Judith Trumpy, seconded by Jason Hansel, the staring salary for the Executive Director's Position be $92,000 annually. Motion approved unanimously.

The Board offered Andrew Funk the Executive Director's Position and discussion was held regarding salary range, a comprehensive benefits program, and a starting date for the position.

Motion by James Miller, seconded by Sharon Meyer, to amend the previous motion to increase the Executive Director's starting salary from $92,000 to $100,000 annually. Motion approved unanimously.

Motion by Judith Trumpy, seconded by LaDonna Gratias, to adjourn at 1:45 p.m. on September 2, 2015.

_____
Becky Hall
Recording Secretary

_____	_____
Andrew Funk	James Miller
Executive Director	Board Chair

APPROVED THIS _____ DAY OF _____, 20____.

ADDENDUM A

NOTICE OF INTENDED ACTION

CHAPTER 6, "GENERAL PHARMACY PRACTICE," AND CHAPTER 8, "UNIVERSAL PRACTICE STANDARDS"

AUGUST 31, 2015

PHARMACY BOARD [657]

Notice of Intended Action

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 6, "General Pharmacy Practice," and Chapter 8, "Universal Practice Standards," Iowa Administrative Code.

The amendments were approved at the August 31, 2015, regular meeting of the Board of Pharmacy.

The proposed amendments are intended to implement 2015 Iowa Acts, Senate File 462, which authorizes the prescribing of epinephrine auto-injectors in the name of a facility as defined in 135.185(1), a school district, or an accredited nonpublic school. The proposed amendments exclude such a prescription from the requirement for a preexisting patient-prescriber relationship and establish the unique prescription label and recordkeeping requirements for a prescription issued to a facility, school district, or accredited nonpublic school as authorized by Senate File 462.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on November 17, 2015. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by E-mail to terry.witkowski@iowa.gov.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code section 155A.27 and 2015 Iowa Acts, Senate File 462.

The following amendments are proposed.

Item 1. Amend subrule 6.10(1) as follows:

6.10(1) *Required information.* The label affixed to or on the dispensing container of any prescription drug or device dispensed by a pharmacy pursuant to a prescription drug order shall bear the following:

a. to *b.* No changes.

c. ~~The~~ Except as provided in subrule 657—8.19(7) for epinephrine auto-injectors, the name of the patient or, if such drug is prescribed for an animal, the species of the animal and the name of its owner;

d. through h. No changes.

Item 2. Amend subrule 8.19(1) as follows:

8.19(1) *Requirements for a prescription.* A valid prescription drug order shall be based on a valid patient-prescriber relationship except as provided in subrule 8.19(7) for epinephrine auto-injectors.

a. Written, electronic, or facsimile prescription. In addition to the electronic prescription application and pharmacy prescription application requirements of this rule, a written, electronic, or facsimile prescription shall include:

(1) The date issued.

(2) The name and address of the patient except as provided in subrule 8.19(7) for epinephrine auto-injectors.

(3) The name, strength, and quantity of the drug or device prescribed.

(4) The name and address of the prescriber and, if the prescription is for a controlled substance, the prescriber's DEA registration number.

(5) The written or electronic signature of the prescriber.

b. through d. No changes.

Item 3. Amend subrule 8.19(5) as follows:

8.19(5) *Legitimate purpose.* The pharmacist shall ensure that the prescription drug or medication order, regardless of the means of transmission, has been issued for a legitimate medical purpose by an authorized practitioner acting in the usual course of the practitioner's professional practice. A pharmacist shall not dispense a prescription drug if the pharmacist knows or should have known that the prescription was issued solely on the basis of an Internet-based questionnaire, an Internet-based consultation, or a telephonic consultation and without a valid preexisting patient-practitioner relationship except as provided in subrule 8.19(7) for epinephrine auto-injectors.

Item 4. Adopt new subrule 8.19(7) as follows:

8.19(7) *Epinephrine auto-injector prescription issued to school or facility.* A physician, advanced registered nurse practitioner, or a physician assistant may issue a prescription for one or more epinephrine auto-injectors in the name of a facility as defined in Iowa Code subsection 135.185(1), a school district, or an accredited nonpublic school. The prescription shall comply with all requirements of subrule 8.19(1) as applicable to the form of the prescription except that the prescription shall be issued in the name and address of the facility, the school district, or the accredited nonpublic school in lieu of the name and address of a patient. Provisions requiring a preexisting patient-prescriber relationship shall not apply to a prescription issued pursuant to this subrule.

a. The pharmacy's patient profile and record of dispensing of a prescription issued pursuant to this subrule shall be maintained in the name of the facility, school district, or accredited nonpublic school to which the prescription was issued and the drug was dispensed.

b. The label affixed to an epinephrine auto-injector dispensed pursuant to this subrule shall

identify the name and address of the facility, school district, or accredited nonpublic school to which the prescription is dispensed.

ADDENDUM B

NOTICE OF INTENDED ACTION

CHAPTER 8,
"UNIVERSAL PRACTICE STANDARDS"

AUGUST 31, 2015

PHARMACY BOARD [657]

Notice of Intended Action

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 8, "Universal Practice Standards," Iowa Administrative Code.

The amendment was approved at the August 31, 2015, regular meeting of the Board of Pharmacy.

The proposed amendment requires that the initial record or report of a continuous quality improvement program event shall be documented no later than three days following the date the error or event was discovered.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

Any interested person may present written comments, data, views, and arguments on the proposed amendment not later than 4:30 p.m. on November 17, 2015. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by E-mail to terry.witkowski@iowa.gov.

After analysis and review of this rule making, no impact on jobs has been found.

This amendment is intended to implement Iowa Code section 155A.41.

The following amendment is proposed.

Amend subrule 8.26(5) as follows:

8.26(5) *CQI program records.* All CQI program records shall be maintained on site at the pharmacy or shall be accessible at the pharmacy and be available for inspection and copying by the board or its representative for at least two years from the date of the record. When a reportable program event occurs or is suspected to have occurred, the program event shall be documented in a

written or electronic storage record created solely for that purpose. Records of program events shall be maintained in an orderly manner and shall be filed chronologically by date of discovery.

a. The program event shall initially be documented as soon as practicable but no more than three days following discovery of the event by the staff member who discovers the event or is informed of the event.

b. No change.

ADDENDUM C

NOTICE OF INTENDED ACTION

CHAPTER 10, "CONTROLLED SUBSTANCES"

AUGUST 31, 2015

PHARMACY BOARD [657]

Notice of Intended Action

Pursuant to the authority of Iowa Code section 124.201, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 10, "Controlled Substances," Iowa Administrative Code.

The amendment was approved at the August 31, 2015, regular meeting of the Board of Pharmacy.

The proposed amendment rescinds current rule 10.38(124) and adopts new rule 10.38(124), temporarily designating certain identified substances as controlled substances, subject to the applicable security and control requirements and penalties provided for in the Iowa Controlled Substances Act (CSA), and removing one substance from the CSA, in conformance with recent scheduling actions of the federal Drug Enforcement Administration (DEA). The substances affected by this action include three synthetic cannabinoids and acetyl fentanyl, all of which are temporarily placed into Schedule 1 of the CSA. Synthetic cannabinoids are chemicals synthesized in laboratories and mimic the biological effects of THC, the main psychoactive ingredient in marijuana. These chemicals are much more potent than marijuana and are often marketed as herbal incense or potpourri. They have no accepted medical use in the United States, and have been reported to produce adverse health effects, including acute and chronic abuse, addiction, and withdrawal. Acetyl fentanyl, a synthetic opioid, has been linked to at least 39 fatalities nationwide in 2013 and 2014 and poses an imminent hazard to public safety. There is currently no approved medical use for acetyl fentanyl and should be appropriately classified as a Schedule 1 controlled substance.

Also affected by this temporary action is naloxegol, a new molecular entity and derivative of naloxone. The Food and Drug Administration (FDA) recently approved naloxegol for marketing for the treatment of opioid-induced constipation in adults with chronic non-cancer pain. Based on the

FDA's approval of naloxegol for marketing for an identified medical purpose, and the lack of evidence of a high potential for abuse of this product, the Board concurs with the DEA's decision to remove naloxegol from control under the CSA.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

Any interested person may present written comments, data, views, and arguments on the proposed amendment not later than 4:30 p.m. on November 17, 2015. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by E-mail to terry.witkowski@iowa.gov.

After analysis and review of this rule making, no impact on jobs has been found.

This amendment is intended to implement Iowa Code section 124.201.

The following amendment is proposed.

Rescind current rule 10.38(124) and adopt the following new rule in lieu thereof:

657—10.38 (124) Temporary designation of controlled substances.

10.38(1) Amend Iowa Code subsection 124.204(9) by adding the following new paragraphs "g," "h," "i," and "j":

g. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts, and salts of isomers. Oher names: AB-CHMINACA.

h. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts, and salts of isomers. Other names: AB-PINACA.

i. [1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone, its optical, positional, and geometric isomers, salts, and salts of isomers. Other names: THJ-2201.

j. N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide, its optical, positional, and geometric isomers, salts, and salts of isomers. Other names: acetyl fentanyl.

10.38(2) Amend Iowa Code subsection 124.206(2), paragraph "a," as follows

a. Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, naloxegol, naloxone, and naltrexone, and their respective salts, but including the following:

ADDENDUM D

NOTICE OF INTENDED ACTION

CHAPTER 22,
"UNIT DOSE, ALTERNATIVE PACKAGING, AND EMERGENCY BOXES"

AUGUST 31, 2015

PHARMACY BOARD [657]

Notice of Intended Action

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 22, "Unit Dose, Alternative Packaging, and Emergency Boxes," Iowa Administrative Code.

The amendment was approved at the August 31, 2015, regular meeting of the Board of Pharmacy.

The proposed amendment eliminates the requirement for a record, on the prescription, identifying the patient med pak in which the prescription drug is packaged. The patient med pak record requires identification of each prescription included in the patient med pak. Requiring the complimentary record on the prescription is duplicative and unnecessary. The amendment further clarifies that the unique identification number of the current prescription drug order must be included in the patient med pak record. The removal of paragraph "b" results in the organization and renumbering of the components of the subrule.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

Any interested person may present written comments, data, views, and arguments on the proposed amendment not later than 4:30 p.m. on November 17, 2015. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by E-mail to terry.witkowski@iowa.gov.

After analysis and review of this rule making, no impact on jobs has been found.

This amendment is intended to implement Iowa Code sections 126.10, 126.11, and 155A.28.

The following amendment is proposed.

Amend subrule 22.5(8) as follows:

22.5(8) *Record keeping.*

~~*a.*~~ The record of each patient med pak shall contain, at a minimum:

~~(1)~~ a. The name and address of the patient;

~~(2)~~ b. ~~A~~ The unique identification number for each of the current prescription drug orders for each of the drug products contained therein;

~~(3)~~ c. A unique identification number for the patient med pak;

~~(4)~~ d. Information identifying or describing the design, characteristics, or specifications of the patient med pak sufficient to allow subsequent preparation of an identical patient med pak for the patient;

~~(5)~~ e. The date of preparation of the patient med pak and the beyond-use date that was assigned;

~~(6)~~ f. Any special labeling instructions; and

~~(7)~~ g. The name, unique identification, or initials of the responsible pharmacist.

~~*b.* The record of the individual prescription drug orders for each of the drug products packaged in a patient med pak shall include the unique identification number for the patient med pak wherein the prescription drug is dispensed.~~

ADDENDUM E

ADOPTED AND FILED

CHAPTER 3, "PHARMACY TECHNICIANS," CHAPTER 6, "GENERAL PHARMACY PRACTICE," CHAPTER 7, "HOSPITAL PHARMACY PRATICE"; RESCINDS CHAPTER 13, "STERILE COMPOUNDING PRACTICES"; AND RESCINDS CHAPTER 20, "PHARMACY COMPOUNDING PRACTICES" AND ADOPTS NEW CHAPTER 20, "COMPOUNDING PRACTICES"

AUGUST 31, 2015

PHARMACY BOARD [657]

Adopted and Filed

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby amends Chapter 3, "Pharmacy Technicians," Chapter 6, "General Pharmacy Practice," and Chapter 7, "Hospital Pharmacy Practice"; rescinds Chapter 13, "Sterile Compounding Practices"; and rescinds Chapter 20, "Pharmacy Compounding Practices," and adopts new Chapter 20, "Compounding Practices," Iowa Administrative Code.

The amendments combine the requirements currently in Chapters 13 and 20 for the compounding of drug products into a single chapter, Chapter 20, that fully adopts national minimum practice standards for compounding found in General Chapters 795 and 797 of the United States Pharmacopeia (USP). The amendments also incorporate new federal regulations as established in the Drug Quality and Security Act of 2013, also known as the Compounding Quality Act, with respect to compounding and outsourcing facilities. Current Chapter 13 is rescinded and reserved.

Requests for waiver or variance of the discretionary provisions of these rules will be considered pursuant to 657—Chapter 34.

Notice of Intended Action was published in the April 29, 2015, Iowa Administrative Bulletin as ARC 1979C. The Board received numerous written comments regarding the proposed amendments. Comments from one national pharmacy chain questioned the need to include all identified information on the label of a compounded drug product prepared for general pharmacy or outpatient dispensing. In response to those comments, the Board determined that there is no need to include the FDA contact information on the prescription label as such information can be provided in or on auxiliary information provided to the patient with the prescription. The Board did not agree that other required information, such as the identification of the product as a compounded product, was

unnecessary.

Other comments suggested realigning and adding verbiage in the definition of "compounding" to ensure understanding of the exceptions identified in the definition. The Board determined that the definition, as proposed, accurately defines the term and identifies the exceptions to the definition. The Board also received comments from practitioners objecting to the stated restrictions regarding the compounded of nonpatient-specific products for practitioner administration to patients (office use). The Board is unable to authorize Iowa pharmacies to compound and distribute nonpatient-specific products for office use unless the Iowa pharmacy is registered with the FDA as a 503B outsourcing facility. The federal Compounding Quality Act specifically addresses this issue and the Board may not adopt less stringent requirements.

The adopted amendments differ from those published under Notice. In response to comments identified above, paragraph "e" in subrule 20.19(1) is removed and subsequent paragraphs are appropriately renumbered. The removed paragraph would have required pharmacies to include, on the prescription label of a compounded drug product packaged for general pharmacy or outpatient dispensing, FDA contact information including the FDA website address or toll-free telephone number.

The amendments were approved during the August 31, 2015, meeting of the Board of Pharmacy.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code sections 124.302, 124.303, 124.306, 124.308, 124.501, 126.9, 126.10, 126.18, 155A.2, 155A.13, 155A.28, 155A.33, and 155A.35.

These amendments will become effective on November 18, 2015.

The following amendments are adopted.

ITEM 1. Amend rule 657—3.22(155A) as follows:

657—3.22(155A) Technical functions. At the discretion of the supervising pharmacist, the following technical functions, in addition to any of the functions authorized for a pharmacy support person pursuant to 657—Chapter 5, may be delegated to a pharmacy technician as specified in the following subrules.

3.22(1) *Certified pharmacy technician.* Under the supervision of a pharmacist, a certified pharmacy technician may perform technical functions delegated by the supervising pharmacist including, but not limited to, the following:

a. to *h.* No change.

i. Perform drug compounding processes ~~for nonsterile compounding~~ as provided in 657—Chapter 20.

~~*j.* Perform drug compounding processes for sterile compounding as provided in 657—Chapter 13.~~

~~*k.*~~ *j.* As provided in rule 657—3.24(155A), accept new prescription drug orders or medication orders communicated to the pharmacy by a prescriber or by the prescriber's agent.

3.22(2) *Pharmacy technician trainee.* Under the supervision of a pharmacist, a pharmacy technician trainee may perform only the following technical functions delegated by the supervising pharmacist:

a. to *g.* No change.

h. Under the supervision of a pharmacist who provides training and evaluates and monitors trainee competence in the compounding processes, perform drug compounding processes ~~for nonsterile compounding~~ as provided in 657—Chapter 20.

~~*i.* Under the supervision of a pharmacist who provides training and evaluates and monitors trainees, and contingent on successful completion of appropriate media fill testing processes, perform~~

~~drug compounding processes for sterile compounding as provided in 657—Chapter 13.~~

ITEM 2. Amend subrule 6.10(2) as follows:

6.10(2) *Exceptions.* The requirements of subrule 6.10(1) do not apply to unit dose dispensing systems, 657—22.1(155A)~~; sterile products, 657—Chapter 13;~~, and patient med paks, 657—22.5(126,155A).

ITEM 3. Amend paragraph **7.8(1)"b"** as follows:

b. Pharmacy personnel shall, except as specified in policies and procedures, prepare all sterile products in conformance with 657—Chapter ~~13~~ 20.

ITEM 4. Rescind and reserve **657—Chapter 13**.

ITEM 5. Rescind 657—Chapter 20 and adopt the following **new** chapter in lieu thereof:

CHAPTER 20

COMPOUNDING PRACTICES

657—20.1(124,126,155A) Purpose and scope. The requirements of this chapter apply to compounded preparations that are dispensed, distributed, or administered to an ultimate user in the state of Iowa, regardless of the location of the pharmacy or outsourcing facility where the preparation was compounded. This chapter applies to compounded preparations intended for humans and animals. In addition to the requirements in this chapter, all pharmacies and outsourcing facilities engaged in compounding shall comply with all applicable federal laws and regulations governing compounding and all applicable state laws, rules and regulations governing the practice of pharmacy. In the event the requirements in this chapter directly conflict with any federal law or regulation, the federal law or regulation shall supersede the requirements in this chapter. The requirements of 657—Chapter 16 apply to the compounding of radiopharmaceuticals.

657—20.2(124,126,155A) Definitions. For purposes of this chapter, the following definitions apply:

"Anticipatory compounding" means the compounding of preparations in advance of the pharmacy's receipt of patient-specific prescriptions.

"Batch preparation compounding" means anticipatory compounding, compounding preparations intended for multiple disbursements, or compounding preparations in a multiple-dose container for administration to more than one patient.

"Beyond-use date" means the date after which a compounded preparation should not be used, determined from the date that the preparation is compounded.

"Bulk drug substance" means any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug. The term does not include intermediates used in the synthesis of such substances.

"Compounding" means the combining, mixing, diluting, pooling, flavoring, or otherwise altering of a drug or bulk drug substance to create a drug. Compounding includes the preparation of drugs or devices in which all bulk drug substances and components are nonprescription products. Compounding does not include the use of a flavoring agent to flavor a drug pursuant to rule 657—20.13(124,126,155A), nor does it include mixing or reconstituting a drug according to the product's manufacturer label.

"FDA" means the Food and Drug Administration of the U.S. Department of Health and Human Services.

"Flavoring agent" means a therapeutically inert, nonallergenic substance consisting of inactive ingredients that is added to a drug to improve the drug's taste and palatability.

"Outsourcing facility" means a facility that is located at a single geographic location and has registered with the FDA as an outsourcing facility in accordance with Section 503B of the Federal

Food, Drug, and Cosmetic Act.

"USP" means United States Pharmacopeia.

657—20.3(124,126,155A) Nonsterile compounding. Iowa-licensed pharmacies that compound nonsterile preparations for ultimate users in the state of Iowa shall follow the current revision of USP Chapter 795 standards. Additional USP chapters incorporated by reference into USP Chapter 795 shall also be followed.

657—20.4(124,126,155A) Sterile compounding. Iowa-licensed pharmacies that compound sterile preparations for ultimate users in the state of Iowa shall follow the current revision of USP Chapter 797 standards. Additional USP chapters incorporated by reference into USP Chapter 797 shall also be followed.

657—20.5(126,155A) Delayed compliance. A pharmacy that is unable to meet the requirements for full compliance with these rules and with USP Chapter 795 or USP Chapter 797 by May 18, 2016, shall, prior to that date, request and obtain from the board a waiver of the specific requirement or requirements that the pharmacy is unable to meet. A pharmacy that cannot meet the requirements for full compliance with these rules, including applicable USP chapters, and that has not obtained from the board a waiver of the specific requirement or requirements shall not engage in compounding until the pharmacy is in full compliance with all requirements or the board has approved a waiver of the specific requirement or requirements.

657—20.6(126,155A) Compounding standards for outsourcing facilities. An FDA-registered outsourcing facility shall be properly licensed in Iowa and shall follow the FDA's current good manufacturing practices (cGMPs) for outsourcing facilities when compounding preparations for hospitals, practitioners, or patients in the state of Iowa.

657—20.7 and **20.8** Reserved.

657—20.9(124,155A) Prescriber/patient/pharmacist relationship. All compounded preparations shall be dispensed pursuant to a patient-specific prescription unless the compounded preparation is distributed pursuant to rule 657—20.15(124,126,155A) or 657—20.16(124,126,155A). A prescription for a compounded preparation shall be authorized by the prescriber for a specific patient. Prescriptions for all compounded preparations shall be maintained on file at the dispensing pharmacy.

657—20.10(126,155A) Anticipatory compounding.

20.10(1) *Outsourcing facilities.* Outsourcing facilities are authorized to engage in anticipatory compounding. Outsourcing facilities are not required to obtain patient-specific prescriptions in order to distribute compounded preparations.

20.10(2) *Pharmacies.* Pharmacies may engage in anticipatory compounding only if the anticipatory compounding is based on a history of receiving valid prescriptions generated solely within an established prescriber/patient/pharmacist relationship, so long as each compounded preparation is dispensed pursuant to a patient-specific prescription.

657—20.11(126,155A) Prohibition on resale of compounded preparations. The sale of compounded preparations to other pharmacies, prescribers, or facilities, except as explicitly authorized by this chapter, is considered manufacturing.

657—20.12(126,155A) Compounding copies of an approved drug. A pharmacy or outsourcing facility may only compound preparations that are essentially copies of approved drugs if the compounded preparation is changed to produce for an individual patient a clinically significant difference to meet a medical need as determined and authorized by the prescriber. A pharmacy or outsourcing facility may compound a preparation that is essentially a copy of an approved drug if the approved drug is identified as currently in shortage on the FDA drug shortages database published on

the FDA Web site, http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

657—20.13(124,126,155A) Use of flavoring agents. A flavoring agent may be added to a drug at the discretion of the pharmacist or upon the request of the prescriber, the patient, or the patient's agent. The pharmacist may add flavoring agents not to exceed 5 percent of the total volume of the drug to which the flavoring agents are added. The pharmacist shall label the flavored drug with a beyond-use date no greater than 14 days past the date the flavoring agent is added if the drug is required to be stored in a refrigerator. A different beyond-use date or alternate storage conditions may be indicated if such variation is supported by peer-reviewed medical literature. The pharmacist shall electronically or manually document that a flavoring agent was added to a drug, and such documentation shall be made available for inspection and copying upon the request of the board or an agent of the board.

657—20.14 Reserved.

657—20.15(124,126,155A) Compounding for office use.

20.15(1) *Human compounded preparations.* Only an FDA-registered outsourcing facility properly licensed in Iowa may distribute to a practitioner for office use human compounded preparations without a patient-specific prescription.

20.15(2) *Veterinary compounded preparations.* Veterinary compounded preparations may be sold to a practitioner for office use if compounded by an Iowa-licensed pharmacy and sold directly to the practitioner by the compounding pharmacy.

20.15(3) *Office administration.* Compounded preparations distributed for office use pursuant to subrule 20.15(1) or 20.15(2) and in accordance with the labeling requirements of subrule 20.15(4) do not require a patient-specific prescription but do require that the compounded preparation be administered to an individual patient in the practitioner's office. Compounded preparations

distributed for office use pursuant to this rule shall not be further distributed to other practitioners or to patients for administration outside of the office.

20.15(4) *Labeling.* Compounded preparations for office use, in addition to the labeling requirements specified in rule 657—20.19(124,126,155A), shall include on the prescription label the practitioner's name in place of the patient's name. The label shall state "For Office Use Only—Not for Resale." If the sterility or integrity of the compounded preparation cannot be maintained after the initial opening of the container, the label shall state "Single-Dose Only."

657—20.16(124,126,155A) Compounding for hospital use. Compounded preparations distributed or dispensed to a hospital or hospital pharmacy pursuant to this rule shall be administered to an individual patient in the hospital.

20.16(1) *By an FDA-registered outsourcing facility.* Only an FDA-registered outsourcing facility properly licensed in Iowa may distribute human compounded preparations to a hospital or hospital pharmacy in the absence of a patient-specific prescription. The compounded preparation shall be labeled in compliance with subrule 20.19(3).

20.16(2) *By a pharmacy that is not an FDA-registered outsourcing facility.* Human compounded preparations that are not compounded at an FDA-registered outsourcing facility may be dispensed to a hospital or hospital pharmacy by an Iowa-licensed pharmacy pursuant to a prescriber's authorization for administration to a specific patient. The compounded preparation shall be labeled in compliance with subrule 20.19(2).

657—20.17 and **20.18** Reserved.

657—20.19(124,126,155A) Labeling. The label, or attached auxiliary labeling if necessary, affixed to the container of any compounded preparation dispensed or distributed into or within Iowa shall contain at least the information identified in one of the following subrules, as applicable.

20.19(1) *General pharmacy or outpatient dispensing.* The label shall meet the labeling requirements of 657—subrule 6.10(1) and shall include the following additional information:

a. The name and concentration of each active ingredient.

b. The date that the preparation was compounded.

c. The beyond-use date of the compounded preparation.

d. Special storage and handling instructions, if applicable.

e. The statement "COMPOUNDED PREPARATION" or a reasonable comparable alternative statement that prominently identifies the drug as a compounded preparation.

f. If the compounded preparation is sterile, the word "STERILE."

g. If the compounded preparation was prepared from batch preparation compounding, the batch identification or control number.

20.19(2) *Hospital pharmacy or inpatient administration.* The label shall meet the labeling requirements of 657—subrule 22.1(3) and shall include the following additional information:

a. The name and concentration of each active ingredient.

b. The date that the preparation was compounded.

c. The beyond-use date of the compounded preparation.

d. If the compounded preparation was prepared from batch preparation compounding, the batch identification or control number.

e. Special storage and handling instructions, if applicable.

20.19(3) *Outsourcing facility distribution or dispensing.* The label, or auxiliary labeling if necessary, shall include the following information:

a. The statement "THIS IS A COMPOUNDED DRUG" or a reasonable comparable alternative statement that prominently identifies the drug as a compounded preparation.

b. The name, address, and telephone number of the outsourcing facility that compounded the preparation.

c. The established name of the preparation.

d. The dosage form and strength.

e. The quantity of the preparation.

f. The date that the preparation was compounded.

g. The beyond-use date of the compounded preparation.

h. Storage and handling instructions.

i. The lot or batch identification or control number.

j. The national drug code number, if available.

k. The statement "Not for resale" and, if the preparation is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement "OFFICE USE ONLY."

l. The following additional information, which can be included on the labeling of a container (such as a plastic bag containing individual product syringes) from which individual units of the drug are removed for dispensing or for administration if there is not space on the label for such information:

(1) Directions for use including, as appropriate, dosage and administration;

(2) A list of the active and inactive ingredients, identified by established name and quantity or proportion of each ingredient;

(3) FDA contact information (www.fda.gov/medwatch and 1-800-FDA-1088 or successor Web site or telephone number) to facilitate adverse event reporting.

m. If the preparation is compounded pursuant to a prescription for a specific patient, the label shall also include the label requirements in 657—subrule 6.10(1).

n. If the preparation is compounded for office use, the label shall also include the label requirements in subrule 20.15(4).

657—20.20(126,155A) Labeling for batch preparation compounding. Compounded preparations resulting from batch preparation compounding shall be labeled with the following information until such time as the preparations are labeled pursuant to rule 657—20.19(124,126,155A) for distribution to hospitals or practitioners or for dispensing or administration to patients:

1. The date that the preparation was compounded.
2. Compounded preparation name or formula.
3. Dosage form.
4. Strength.
5. Quantity per container.
6. Unique internal batch identification or control number.
7. Beyond-use date.
8. Special storage and handling instructions, if applicable.

657—20.21 and **20.22** Reserved.

657—20.23(124,126,155A) Records. All records required by this chapter shall be retained as original records of the pharmacy or outsourcing facility and shall be readily available for inspection and photocopying by agents of the board or other authorized authorities for at least two years following the date of the record. Records shall allow for the identification of all ingredients used in compounding, all personnel involved in compounding, and all personnel involved in reviewing compounded preparations. The pharmacy or outsourcing facility shall maintain records documenting the disbursements from each batch of a compounded preparation.

These rules are intended to implement Iowa Code sections 124.302, 124.303, 124.306, 124.308,

124.501, 126.9, 126.10, 126.18, 155A.2, 155A.13, 155A.28, 155A.33, and 155A.35.

ADDENDUM F

ADOPTED AND FILED

CHAPTER 6, "GENERAL PHARMACY PRACTICE,"
CHAPTER 7, "HOSPITAL PHARMACY PRATICE,"
CHAPTER 15, "CORRECTIONAL PHARMACY PRACTICE,"
AND
CHAPTER 16, "NUCLEAR PHARMACY PRACTICE"

AUGUST 31, 2015

PHARMACY BOARD [657]

Adopted and Filed

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby amends Chapter 6, "General Pharmacy Practice," Chapter 7, "Hospital Pharmacy Practice," Chapter 15, "Correctional Pharmacy Practice," and Chapter 16, "Nuclear Pharmacy Practice," Iowa Administrative Code.

The amendments eliminate the requirements that pharmacies maintain the *Iowa Pharmacy Law and Information Manual* and authorize pharmacies to utilize other sources, including electronic or Internet-based sources, for Iowa pharmacy laws, rules, and regulations.

Requests for waiver or variance of the discretionary provisions of these rules will be considered pursuant to 657—Chapter 34.

Notice of Intended Action was published in the July 22, 2015, Iowa Administrative Bulletin as ARC 2065C. The Board received numerous written comments regarding the proposed amendments. Comments were split between support of the amendments and opposition or suggestions for alternatives to the amendments. The adopted amendments differ from those published under Notice. In response to suggestions from commenters, the Board has clarified that an acceptable law reference will include all pertinent Iowa laws, rules, and regulations that impact the pharmacy's practice.

The amendments were approved during the August 31, 2014, meeting of the Board of Pharmacy.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code section 155A.31.

These amendments will become effective on November 18, 2015.

The following amendments are adopted.

ITEM 1. Amend rule 657—6.3(155A) as follows:

657—6.3(155A) Reference library. References may be printed or computer-accessed. A reference library shall be maintained which includes, as a minimum, one current reference from each of the following categories, including access to current periodic updates.

1. ~~The Iowa Pharmacy Law and Information Manual~~ A reference including all pertinent Iowa laws, rules, and regulations that impact the pharmacy's practice.

2. to 8. No change.

ITEM 2. Amend rule 657—7.3(155A) as follows:

657—7.3(155A) Reference library. References may be printed or computer-accessed. A reference library shall be maintained which includes, as a minimum, one current reference from each of the following categories, including access to current periodic updates.

1. ~~The Iowa Pharmacy Law and Information Manual~~ A reference including all pertinent Iowa laws, rules, and regulations that impact the pharmacy's practice.

2. to 9. No change.

ITEM 3. Amend rule 657—15.4(155A) as follows:

657—15.4(155A) Reference library. References may be printed or computer-accessed. Each correctional pharmacy shall have on site, at a minimum, one current reference from each of the following categories, including access to current periodic updates.

1. ~~The Iowa Pharmacy Law and Information Manual~~ A reference including all pertinent Iowa laws, rules, and regulations that impact the pharmacy's practice.

2. to 8. No change.

ITEM 4. Amend rule 657—16.5(155A) as follows:

657—16.5(155A) Library. Each nuclear pharmacy shall have access to the following references. References may be printed or computer-accessed and shall be current editions or revisions.

1. No change.

2. ~~The Iowa Pharmacy Law and Information Manual~~ A reference including all pertinent Iowa laws, rules, and regulations that impact the pharmacy's practice;

3. and 4. No change.

ADDENDUM F

ADOPTED AND FILED

CHAPTER 6, "GENERAL PHARMACY PRACTICE," CHAPTER 7, "HOSPITAL PHARMACY PRACTICE," CHAPTER 15, "CORRECTIONAL PHARMACY PRACTICE," AND CHAPTER 16, "NUCLEAR PHARMACY PRACTICE"

AUGUST 31, 2015

PHARMACY BOARD [657]

Adopted and Filed

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby amends Chapter 7, "Hospital Pharmacy Practice," and Chapter 23, "Long-Term Care Pharmacy Practice," Iowa Administrative Code.

The amendments permit, as authorized by federal law, the administration of any influenza or pneumococcal vaccine to a hospital or long-term care facility patient pursuant to physician-approved hospital or facility policy after the patient has been assessed for contraindications. Current subrules limit this authority to the administration of influenza and pneumococcal polysaccharide vaccines only.

Requests for waiver or variance of the discretionary provisions of these rules will be considered pursuant to 657—Chapter 34.

Notice of Intended Action was published in the July 22, 2015, Iowa Administrative Bulletin as ARC 2063C. The Board received no written comments regarding the proposed amendments. The adopted amendments are identical to those published under Notice.

The amendments were approved during the August 31, 2015, meeting of the Board of Pharmacy.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code sections 155A.13, 155A.15, 155A.23, and 155A.35.

These amendments will become effective on November 18, 2015.

The following amendments are adopted.

ITEM 1. Amend subrule 7.8(14) as follows:

7.8(14) *Influenza and pneumococcal vaccines.* As authorized by federal law, a written or verbal

patient-specific medication administration order shall not be required prior to administration to an adult patient of influenza and pneumococcal ~~polysaccharide~~ vaccines pursuant to physician-approved hospital policy and after the patient has been assessed for contraindications. Administration shall be recorded in the patient's medical record.

ITEM 2. Amend subrule 23.9(4) as follows:

23.9(4) *Influenza and pneumococcal vaccines.* As authorized by federal law, a written or verbal patient-specific medication administration order shall not be required prior to administration to an adult patient of influenza and pneumococcal ~~polysaccharide~~ vaccines pursuant to physician-approved facility policy and after the patient has been assessed for contraindications. Administration shall be recorded in the patient's record. The facility shall submit to the provider pharmacy a listing of those residents or staff members who have been immunized utilizing vaccine from each vial supplied by the provider pharmacy.

ADDENDUM H

ADOPTED AND FILED

CHAPTER 10, "CONTROLLED SUBSTANCES"

AUGUST 31, 2015

PHARMACY BOARD [657]

Adopted and Filed

Pursuant to the authority of Iowa Code section 124.2, the Board of Pharmacy hereby amends Chapter 10, "Controlled Substances," Iowa Administrative Code.

The amendment rescinds rule 657—10.41(124A) in which certain substances are identified and classified as imitation controlled substances. Those substances have been identified and classified by legislative action as controlled substances subject to Iowa Code chapter 124. Rescinding the designation of those substances as imitation controlled substances eliminates the confusion created by their dual classification as imitation controlled substances, subject to the penalties for unlawful possession of imitation controlled substances, and their classification as controlled substances, subject to different penalties for unlawful possession of controlled substances.

Requests for waiver or variance are not addressed because there are no provisions from which to request a waiver or variance.

Notice of Intended Action was published in the July 22, 2015, Iowa Administrative Bulletin as ARC 2064C. The Board received no written comments regarding the proposed amendments. The adopted amendment is identical to that published under Notice.

The amendment was approved during the August 31, 2015, meeting of the Board of Pharmacy.

After analysis and review of this rule making, no impact on jobs has been found.

This amendment is intended to implement Iowa Code section 124A.2.

This amendment will become effective on November 18, 2015.

The following amendment is adopted.

Rescind and reserve rule **657—10.41(124A)**.

ADDENDUM I

LICENSURE BY CONSENT AGREEMENT

NR & V DRUGS, INC.,
d/b/a WYANDOTTE DRUGS
WYANDOTTE, MICHIGAN

BEFORE THE IOWA BOARD OF PHARMACY

Re: Application for Nonresident Pharmacy Licensure of **NR & V DRUGS, INC., d/b/a WYANDOTTE DRUGS,** Applicant	)	**LICENSURE BY CONSENT AGREEMENT**

COMES NOW the Iowa Board of Pharmacy ("Board") and N R & V Drugs, Inc., doing business as Wyandotte Drugs ("Applicant"), 364 Eureka Road, Wyandotte, Michigan 48192, and enter into this Licensure by Consent Agreement ("Agreement") pursuant to Iowa Code section 17A.10 (2015).

1. Applicant has applied for a nonresident pharmacy license.

2. Applicant provided pharmacy services to Iowa patients prior to licensure.

3. The Board has authority to deny an application for nonresident pharmacy licensure for violations of Iowa Code section 155A.13A and rules of the Board. *See* Iowa Code section 155A.13A(3) and 657 IAC 19.10.

4. It is a violation of Iowa Code section 155A.13A(1) and 657 IAC 19.2 and 36.1(4)"v" to provide pharmacy services to Iowa patients prior to obtaining a nonresident pharmacy license from the Board.

5. THEREFORE, **IT IS HEREBY ORDERED** that the Applicant shall be issued an Iowa nonresident pharmacy license with the following conditions:

   a. Applicant's license shall be placed on **PROBATION** for a period of two (2) years.

   b. Applicant shall pay a civil penalty in the amount of one-thousand dollars ($1000). This civil penalty shall be made payable to the Treasurer of Iowa and mailed to the Executive Director of the Board within thirty (30) days of the Board's approval of this Agreement. All civil penalty payments shall be deposited into the State of Iowa general fund.

6. Applicant shall fully and promptly comply with this Agreement. Should Applicant violate the terms of this Agreement, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 155A and 272C and 657 IAC 36.

7. By entering into this Agreement, the Applicant voluntarily waives any right to a contested case hearing regarding this matter. Once entered, this Agreement shall have the force and effect of a disciplinary order entered following a contested case hearing.

8. Applicant acknowledges that it has read this Agreement in its entirety, that it understands its content, and that it executed this Agreement freely and voluntarily.

9. The State's legal counsel may present this Agreement to the Board *ex parte*.

10. Applicant acknowledges that it has a right to be represented by counsel on this matter.

11. This Agreement is subject to approval by a majority of the full Board. If the Board fails to approve this Agreement, it shall be of no force or effect to either the Board or Applicant. If the Board approves this Agreement, it shall be the full and final resolution of this matter.

12. Applicant understands that this Agreement is a public record available for inspection and copying in accordance with Iowa Code chapter 22.

13. Applicant acknowledges and understands that this Agreement will be reported to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse.

This Licensure by Consent Agreement is voluntarily submitted by Applicant to the Board for its consideration on the ___ day of _____, 2015.

N R & V Drugs, Inc., d/b/a Wyandotte Drugs
Applicant

By this signature, Nehal R. Patel acknowledges s/he is the President for N R & V Drugs, Inc., and is authorized to sign this Agreement on behalf of N R & V Drugs, Inc.

This Licensure by Consent Agreement is accepted by the Iowa Board of Pharmacy on the 31st day of August, 2015.

EDWARD MAIER, Chairperson
Iowa Board of Pharmacy
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

Copy to:

Laura Steffensmeier
Assistant Attorney General
Hoover Building, 2nd Floor
Des Moines, IA 50319

ADDENDUM J

PRELIMINARY NOTICE OF INTENT TO DENY LICENSE

HAN. SAM. CORP.,
d/b/a RIVER'S EDGE PHARMACY
PALM DESERT, CALIFORNIA

BEFORE THE IOWA BOARD OF PHARMACY

Re: The Application for Nonresident Pharmacy License of **HAN. SAM. CORP.,** **d/b/a RIVER'S EDGE PHARMACY** Applicant.	)))))))	**PRELIMINARY NOTICE OF INTENT TO DENY LICENSE**

TO: Han. Sam. Corp.
d/b/a River's Edge Pharmacy
36919 Cook Street, Suite 102
Palm Desert, CA 92211

YOU ARE HEREBY NOTIFIED that on the 31st day of August, 2015, the Iowa Board of Pharmacy ("Board") voted to deny your application for an Iowa nonresident pharmacy license. The intent to deny licensure is based upon the following:

FACTUAL CIRCUMSTANCES

1. On April 3, 2015, the Board received an Iowa nonresident pharmacy license application from Han. Sam. Corp., d/b/a River's Edge Pharmacy.

2. On the license application, Applicant answered "No" to the question "Does the pharmacy, the pharmacy's owner, any officer or partner, or the pharmacist in charge have any charges, or knowledge of any complaints or investigations, pending before any licensing authority?"

3. On the license application, Applicant answered "No" to the question "Does the pharmacy engage in compounding?"

4. On January 23, 2015, the California Board of Pharmacy issued an Accusation against Applicant's California retail pharmacy permit. The Accusation is currently pending.

5. Applicant's California inspection reports indicate that Applicant engages in sterile compounding.

LEGAL GROUNDS

6. Applicants for an Iowa nonresident pharmacy license must apply in accordance with Iowa Code section 155A.13A and 657 IAC 19.2.

7. The Board has the authority to deny an Iowa nonresident pharmacy application for licensure for violations of rules of the Board. *See* Iowa Code section 155A.13A(3).

8. It is a violation of 657 IAC 36.1(4)"a" to engage in fraud in procuring a license.

NOTICE OF APPEAL RIGHTS

Pursuant to the provisions of 657 IAC 36.16, you may appeal the Board's preliminary notice of denial of licensure by serving a written notice of appeal and request for hearing upon the Board not more than thirty (30) days following the date of service of this notice. Applicant's written notice of appeal and request for a hearing should be directed to Terry Witkowski, Acting Executive Director, Iowa Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. The written notice of appeal and request for hearing shall specifically describe the facts to be contested and determined at the hearing. The hearing shall be a contested case conducted pursuant to the procedures outlined at 657 IAC 35.

If a written notice of appeal and request for hearing is not timely filed, this preliminary notice of intent to deny licensure will become final, and the Iowa nonresident pharmacy license application for Han. San. Corp. d/b/a River's Edge Pharmacy will be DENIED.

DATED this 31st day of August, 2015.

Chairperson
Iowa Board of Pharmacy

cc: Laura Steffensmeier
Assistant Attorney General
Hoover Building, 2nd Floor
Des Moines, IA 50319

ADDENDUM K

SETTLEMENT AGREEMENT AND FINAL ORDER

THOMAS B. DODDS
PHARMACIST LICENSE NO. 12951
DAKOTA DUNES, SOUTH DAKOTA

BEFORE THE IOWA BOARD OF PHARMACY

Re: Pharmacist License of **THOMAS B. DODDS** License No. 12951 Respondent.	))))))	CASE NO. 2014-86 **SETTLEMENT AGREEMENT AND FINAL ORDER**

Pursuant to Iowa Code sections 17A.10 and 272C.3(4) (2013), the Iowa Board of Pharmacy ("Board") and Thomas B. Dodds ("Respondent") enter into the following Settlement Agreement and Final Order ("Order") to settle a contested case pending before the Board.

The allegations contained in a Statement of Charges against Respondent shall be resolved without proceeding to hearing, as the Board and Respondent stipulate as follows:

1. Respondent's license #12951 is currently active, but on probation until January 12, 2016.

2. The Board has jurisdiction over the parties and the subject matter of these proceedings.

3. A Statement of Charges was filed against Respondent on November 19, 2014.

4. Respondent admits the allegations contained in the Statement of Charges and acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order.

5. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's actions, by freely and voluntarily entering into this Settlement Agreement. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.

6. Respondent is freely and voluntarily entering into this Order.

7. Respondent acknowledges that he has the right to be represented by counsel on this matter.

8. Respondent agrees that the State's counsel may present this Order to the Board and may have *ex parte* communications with the Board while presenting it.

9. This Order is subject to approval by a majority of the full Board. If the Board fails to approve this Order, it shall be of no force or effect to either the Board or Respondent. If the Board approves this Order, it shall be the full and final resolution of this matter.

10. This Order shall be part of the permanent record of Respondent and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

11. Respondent acknowledges and understands that this Order will be reported to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse, as applicable.

12. This Order, when fully executed, is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapters 22 and 272C.

13. The Board's approval of this Order shall constitute a **FINAL ORDER** of the Board.

IT IS THEREFORE ORDERED:

14. Respondent is hereby **CITED** for violating the duties of a pharmacist-in-charge and **WARNED** that Respondent's failure to comply with the laws governing the practice of pharmacy in the future could result in further discipline.

15. Respondent agrees not to serve as a pharmacist-in-charge (PIC) without the express, written consent of the Board.

16. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A and 657 Iowa Administrative Code chapter 36.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 11 day of May, 2015.

THOMAS B. DODDS
Respondent

This Settlement Agreement and Final Order is accepted by the Iowa Board of Pharmacy on the 31st day of August, 2015.

Chairperson
Iowa Board of Pharmacy
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

cc: Meghan Gavin
Assistant Attorney General
Hoover Building, 2nd Floor
Des Moines, IA 50319

Connie Diekema
FINLEY, ALT, SMITH, SCHARNBERG,
CRAIG, HILMES & GAFFNEY, P.C.
699 Walnut Street, Ste. 1900
Des Moines, IA 50309
ATTORNEY FOR THE RESPONDENT

ADDENDUM L

SETTLEMENT AGREEMENT AND FINAL ORDER

RXTRA SOLUTIONS
NONRESIDENT PHARMACY LICENSE NO. 4203
SOUTHFIELD, MICHIGAN

BEFORE THE IOWA BOARD OF PHARMACY

Re: Nonresident Pharmacy License of **RXTRA SOLUTIONS** License No. 4203 Respondent.	))))))	CASE NO. 2015-34 **SETTLEMENT AGREEMENT AND FINAL ORDER**

Pursuant to Iowa Code sections 17A.12(5) and 272C.3(4) (2015), and 657 IAC 36.6, the Iowa Board of Pharmacy ("Board") and Rxtra Solutions ("Respondent") enter into the following Settlement Agreement and Final Order ("Order") to settle a contested case currently pending before the Board.

The allegations contained in the Statement of Charges against Respondent shall be resolved without proceeding to hearing, as the Board and Respondent stipulate as follows:

1. The Board filed a Notice of Hearing and Statement of Charges on April 29, 2015.

2. The Board has jurisdiction over the parties and the subject matter of these proceedings.

3. Respondent now does business under the name "Creams 'N Caps". A hearing regarding the Notice of Intent to Deny Licensure to Creams 'N Caps is currently scheduled for September 1, 2015.

4. Respondent does not admit the allegations in the Statement of Charges. Respondent does, however, acknowledge that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order.

5. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's actions, by freely and voluntarily entering into this Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.

6. Respondent acknowledges that it has the right to be represented by counsel on this matter.

7. Respondent agrees that the State's counsel may present this Order to the Board and may have *ex parte* communications with the Board while presenting it.

8. This Order is subject to approval by a majority of the full Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.

9. This Order shall be part of Respondent's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

10. This Order shall not be binding as to any new complaints received by the Board.

11. Respondent understands the Board is required by federal law to report any adverse action to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank.

12. This Order, when fully executed, is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapters 22 and 272C.

13. The Board's approval of this Order shall constitute a FINAL ORDER of the Board.

IT IS THEREFORE ORDERED:

14. Respondent agrees to **VOLUNTARILY SURRENDER** its Iowa nonresident pharmacy license and to withdraw its request for hearing regarding the Notice of Intent to Deny Licensure to Creams 'N Caps, which will result in the denial of such application, to resolve this matter.

15. This voluntary surrender, when accepted by the Board, has the same force and effect as an order of revocation under 657 IAC 36.15 for purposes of reinstatement. Reinstatement requests are governed by 657 IAC 36.13. Respondent agrees not to perform any activities that would require an Iowa nonresident pharmacy license unless its license is reinstated.

16. Respondent shall return its Iowa nonresident pharmacy license to the Board on or before October 1, 2015, but in any event within thirty (30) days of this Order.

17. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 147, 155A, and 272C and 657 IAC 36.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 28th day of August, 2015.

RXTRA SOLUTIONS, now d/b/a
CREAMS 'N CAPS
Respondent

By this signature, Wisam Arawish acknowledges s/he is the principal for Rxtra Solutions, now d/b/a Creams 'N Caps, and is authorized to sign this Settlement Agreement and Final Order on behalf of Rxtra Solutions, now d/b/a Creams 'N Caps.

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the 31st day of August, 2015.

Chairperson
Iowa Board of Pharmacy

Copy to:

Nicholas Nahorski and Kim J. Sveska
Foley, Baron, Metzger & Juip, PLLC
38777 Six Mile Rd., Suite 300
Livonia, MI 48152
ATTORNEYS FOR RESPONDENT

Laura Steffensmeier
Assistant Attorney General
Licensing & Administrative Law Division
Iowa Department of Justice
Hoover Building, 2nd Floor
Des Moines, IA 50319
ATTORNEY FOR THE STATE

ADDENDUM M

SETTLEMENT AGREEMENT AND FINAL ORDER

LDI INTEGRATED PHARMACY SERVICES
NONRESIDENT PHARMACY LICENSE NO. 3816
CREVE COEUR, MISSOURI

BEFORE THE IOWA BOARD OF PHARMACY

Re: Pharmacy License of **LDI INTEGRATED PHARMACY SERVICES** License No. 3816 Respondent.	)))))))	CASE NO. 2015-44 **SETTLEMENT AGREEMENT AND FINAL ORDER**

Pursuant to Iowa Code sections 17A.10 and 272C.3(4) (2015), the Iowa Board of Pharmacy ("Board") and LDI Integrated Pharmacy Services ("Respondent") enter into the following Settlement Agreement and Final Order ("Order") to settle a contested case pending before the Board.

The allegations contained in a Statement of Charges against Respondent shall be resolved without proceeding to hearing, as the Board and Respondent stipulate as follows:

1. Respondent's license #3816 is currently active.

2. The Board has jurisdiction over the parties and the subject matter of these proceedings.

3. A Statement of Charges was filed against Respondent on June 23, 2015.

4. Respondent has chosen not to contest the allegation contained in the Statement of Charges and acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order.

5. The allegations in this case centered on out-of-state discipline which occurred in 2014. This Order thus constitutes reciprocal discipline based on events already reported to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and National Practitioner Data Bank.

6. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's actions, by freely and voluntarily entering into this Settlement Agreement. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.

7. Respondent is freely and voluntarily entering into this Order.

8. Respondent acknowledges that it has the right to be represented by counsel on this matter.

9. Respondent agrees that the State's counsel may present this Order to the Board and may have *ex parte* communications with the Board while presenting it.

RECEIVED
AUG 25 2015
IOWA BOARD OF PHARMACY

10. This Order is subject to approval by a majority of the full Board. If the Board fails to approve this Order, it shall be of no force or effect to either the Board or Respondent. If the Board approves this Order, it shall be the full and final resolution of this matter.

11. This Order shall be part of the permanent record of Respondent and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

12. Respondent acknowledges and understands that this Order will be reported to the National Practitioners Data Bank and National Association of Boards of Pharmacy's Disciplinary Clearinghouse, as applicable.

13. This Order, when fully executed, is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapters 22 and 272C.

14. The Board's approval of this Order shall constitute a **FINAL ORDER** of the Board.

IT IS THEREFORE ORDERED:

15. Respondent is hereby **CITED** for violating the pharmacy laws of another state and failing to timely notify the Board of the violation and **WARNED** that Respondent's failure to comply with the laws governing the practice of pharmacy in the future could result in further discipline.

16. Respondent agrees to pay a civil penalty in the amount of one-thousand dollars ($1000.00). This civil penalty shall be made payable to the Treasurer of Iowa and paid within thirty (30) days of the Board's approval of this Settlement Agreement and Final Order. All civil penalty payments shall be deposited into the State of Iowa general fund.

17. The civil penalty though payable to the general fund shall be submitted to the Board by mailed—Iowa Board of Pharmacy, Attn: Debbie Jorgenson, 400 SW Eighth Street, Suite E, Des Moines, IA 50309.

18. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A and 657 Iowa Administrative Code chapter 36.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 1st day of S, 2015.

LDI Integrated Pharmacy Services
Respondent

By his signature Leonard S. Dino, Jr. acknowledges he is authorized to this Settlement Agreement and Final Order on behalf of LDI Integrated Pharmacy Services.

This Settlement Agreement and Final Order is accepted by the Iowa Board of Pharmacy on the 31st day of August, 2015.

Chairperson
Iowa Board of Pharmacy
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

cc: Meghan Gavin
Assistant Attorney General
Hoover Building, 2nd Floor
Des Moines, IA 50319

Connie Diekema
FINLEY, ALT, SMITH, SCHARNBERG,
CRAIG, HILMES & GAFFNEY, P.C.
699 Walnut Street, Ste. 1900
Des Moines, IA 50309
ATTORNEY FOR THE RESPONDENT

ADDENDUM N

NOTICE OF HEARING
AND
STATEMENT OF CHARGES

KAREN BEAN
PHARMACY SUPPORT PERSON NO. 3456
CEDAR RAPIDS, IOWA

BEFORE THE IOWA BOARD OF PHARMACY

Re: Pharmacy Support Person Registration of **KAREN BEAN** Registration No. 3456 Respondent.	))))))	CASE NO. 2015-43 **NOTICE OF HEARING & STATEMENT OF CHARGES**

COMES NOW the Iowa Board of Pharmacy (Board) and files this Notice of Hearing and Statement of Charges pursuant to Iowa Code sections 17A.12(2) and 17 A.18(3) (2015). Respondent was issued Iowa pharmacy support person registration number 3456. Respondent's license is currently active.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on November 3, 2015, before the Iowa Board of Pharmacy. The hearing shall be held during the morning session, beginning at 9:00 a.m. and shall be located in the Board conference room located at 400 S. W. 8'h Street, Des Moines, Iowa.

Presiding Officer. The Board shall serve as presiding officer, but the Board may request an Administrative Law Judge from the Department of Inspections and Appeals make initial rulings on prehearing matters, and be present to assist and advise the board at hearing.

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 Iowa Administrative Code rule 35.19. At hearing you will be allowed the opportunity to respond to the charges against you, to produce evidence on your behalf, cross-examine witnesses, and examine any documents introduced at hearing. You may appear personally or be represented by counsel at your own expense. The hearing may be open to the public or closed to the public at your discretion.

Prosecution. The office of the Attorney General is responsible for representing the public interest (the State) in this proceeding. Pleadings shall be filed with the Board and copies should be provided to counsel for the State at the following address.

Meghan Gavin
Assistant Attorney General
Iowa Attorney General's Office
2nd Floor Hoover State Office Building
Des Moines, Iowa 50319

Ms. Gavin can also be reached by phone at (515)281-6736 or e-mail at Meghan.Gavin@iowa.gov.

Communications. You may contact the Board office (515)281-5944 with questions regarding this notice and other matters relating to these disciplinary proceedings. However, you may NOT contact individual members of the Board to discuss these proceedings by phone, letter, facsimile, email, or in person. Board members can only receive information about the case when all parties have notice and an opportunity to participate, such as at the hearing or in pleadings you file with the Board office and serve upon all parties in the case. You may also direct questions relating to settlement of these proceedings to Assistance Attorney. General Meghan Gavin at (515)281-6736.

B. LEGAL AUTHORITY AND JURISDICTION

Jurisdiction. The Board has jurisdiction in this matter pursuant to Iowa Code chapters 17A, 147, 155A, and 272C.

Legal Authority. If any of the allegations against you are founded, the Board has authority to take disciplinary action against you under Iowa Code chapters 17A, 14 7, 148C, and 272C and 657 Iowa Administrative Code chapter 36.

Default. If you fail to appear at the hearing, the Board may enter a default decision or proceed with the hearing and render a decision in your absence, in accordance with Iowa Code section 17A.12(3) and 657 Iowa Administrative Code rule 35.21.

C. CHARGES

Count I
UNETHICAL CONDUCT OR PRACTICE HARMFUL OR DETRIMENTAL TO THE PUBLIC

Respondent is charged with engaging in unethical conduct or practice harmful or detrimental to the public in violation of Iowa Code sections 147.55(3) and 155A.6B(5) and 657 Iowa Administrative Code rules 5.25(4), 5.26(1) and 36.1(4)(*c*).

Count II
OBTAINING OR POSSESSING PRESCRIPTION DRUGS WITHOUT LAWFUL AUTHORITY

Respondent is charged with obtaining, possessing, or attempting to obtain or possess prescription drugs without lawful authority in violation of Iowa Code sections 147.55(9) and 155A.6B(5) and 657 Iowa Administrative Code rules 5.26(1) and 36.1(4)(*aj*).

Count III
DIVERSION OF PRESCRIPTION DRUGS

Respondent is charged with diverting a prescription drug from a pharmacy for personal use or distribution in violation of Iowa Code sections 147.55(9) and 155A.6B(5) and 657 Iowa Administrative Code rules 5.26(1) and 36.1(4)(*ak*).

D. FACTUAL CIRCUMSTANCES

1. Respondent worked as a full-time assistant manager and pharmacy support person for HyVee.

2. The pharmacy received reports from customers that tablets were missing from hydrocodone prescriptions.

3. Closed circuit TV footage revealed that Respondent accessed some bags of filled prescriptions.

4. Respondent admitted to taking hydrocodone tablets from filled prescription bags on 10-15 occasions.

E. SETTLEMENT

This matter may be resolved by settlement agreement. The procedural rules governing the Board's settlement process are found at 657 Iowa Administrative Code rule 36.3. If you are interested in pursuing settlement of this matter, please contact Assistant Attorney General Meghan Gavin.

F. PROBABLE CAUSE FINDING

On this the 1st day of September 2015, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.

Chairperson
Iowa Board of Pharmacy
400 SW Eighth Street Suite E
Des Moines, Iowa 50309-4688

cc: Meghan Gavin
Assistant Attorney General
Hoover State Office Building
Des Moines, Iowa 50319

Karen H. Bean
575 Ashton Place NE #7
Cedar Rapids, IA 52402

PROOF OF SERVICE

The undersigned certifies that the foregoing instrument was served upon Respondent to the above cause by:

( ) personal service
(X) certified mail, return receipt requested
Article Number 9171999991703106714900

(X) first class mail
( ) facsimile
( ) other _____

on the 3rd day of September, 2015.

I declare that the statements above are true to the best of my information, knowledge and belief.

Debbie S. Jorgenson

Debbie S. Jorgenson

ADDENDUM O

ORDER TO SHOW CAUSE

DAVID MARCOWITZ, D.O.
CONTROLLED SUBSTANCE REGISTRATION NO. 1305770
CHARITON, IA 50049

BEFORE THE IOWA BOARD OF PHARMACY

Re: Controlled Substance Registration of **DAVID MARCOWITZ, D.O.** Registration No. 1305770 Respondent.	))))))	CASE NO. 2014-171 **ORDER TO SHOW CAUSE**

TO: David Marcowitz, D.O.
1200 N Seventh Street
Chariton, IA 50049

NOTICE:

Pursuant to the provisions of Iowa Code sections 124.304 and 124.305 (2015) and 657 IAC 10.12, you are hereby ordered to show cause why controlled substance registration number 1305770 should not be suspended.

To request a full hearing regarding the suspension of your controlled substance registration, you must file a request for a hearing in writing with the Board within thirty (30) days of service of this Order.

If you do not request a hearing in this matter within thirty (30) days of service of this order, your controlled substance registration will be SUSPENDED.

I. JURISDICTION

Pursuant to Iowa Code chapter 124 (2015) and 657 IAC 10, the Iowa Board of Pharmacy ("Board") has jurisdiction over those who prescribe controlled substances in Iowa. The Board issued David Marcowitz ("Respondent") controlled substance registration number 1305770, subject to the laws of the State of Iowa and the rules of the Board. Controlled substance registration number 1305770 is currently active and expires after January 31, 2016.

II. BASIS FOR ORDER TO SHOW CAUSE

1. Respondent is a licensed physician with the Iowa Board of Medicine.

2. On January 31, 2014, the Department of Financial and Professional Regulation of the State of Illinois approved a Consent Order that suspended his Illinois license to practice medicine and his Illinois controlled substance license for thirty days. The Consent Order provided that Respondent's licenses would be placed on permanent Inactive Status after the period of suspension. Respondent signed the Consent Order on January 2, 2014.

3. On January 22, 2014, Respondent submitted a controlled substance registration renewal to the Board. Respondent answered "no" to the question "has the applicant ever been convicted

of a felony in connection with controlled substances under any State or Federal law or ever surrendered (in lieu of disciplinary action) or had a CSA registration revoked, suspended, or denied?" Respondent did not report the Illinois Consent Agreement to the Board after it was approved on January 31, 2014.

4. On February 6, 2015, the Iowa Board of Medicine filed a Statement of Charges against Respondent, charging him with having a license to practice osteopathic medicine and surgery revoked or suspended, or having other disciplinary action taken by a licensing authority of another state.

5. On June 25, 2015, the Iowa Board of Medicine issued its Findings of Fact, Conclusions of Law, Decision and Order, in Respondent's contested case. The Board indefinitely suspended Respondent's medical license, but stayed the suspension pending successful completion of a mental health evaluation within 60 days, a comprehensive clinical competency evaluation within 90 days, and a professional ethics program within 120 days. The Board issued Respondent a Citation and Warning and ordered him to pay a $3,000 civil penalty. The Board also prohibited him from prescribing, administering, or dispensing controlled substances for the treatment of chronic pain and placed him on probation for five years subject to monitoring.

6. Iowa Code section 124.304(1)"e" and 657 IAC 10.12(1)"e" authorize the Board to suspend, revoke, or restrict a controlled substance registration if the registrant has been disciplined by the registrant's professional licensing board and the discipline revokes, suspends, or modifies the registrant's authority regarding controlled substances.

7. Iowa Code section 124.304(1)"d" and 657 IAC 10.12(1)"d" authorize the Board to suspend, revoke, or restrict a controlled substance registration if the registrant has committed such acts as would render the registrant's registration under section 124.303 inconsistent with the public interest as determined under that section. Under 657 IAC 36.1(4)"k", the Board has the authority to impose discipline on registrants for failing to notify the Board within 30 days after a final decision entered by the licensing authority of another state which decision resulted in a license or registration revocation, suspension, or other disciplinary action.

III. ORDER

Respondent is hereby ordered to show cause why controlled substance registration number 1305770 should not be suspended.

Respondent may request a hearing before the Board in response to this Order by filing a written request with the Board within thirty (30) days of service of this Order. Respondent's written request for a hearing should be directed to Terry Witkowski, Interim Executive Director, Iowa Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. If Respondent submits a timely request for a hearing on the matter, a hearing will be scheduled for the Board's next available hearing date. A separate notice of hearing will be sent to Respondent detailing the date, time, and location of the hearing.

If Respondent does not request a hearing in this matter within thirty (30) days of service of this Order, controlled substance registration number 1305770 will be SUSPENDED.

IT IS SO ORDERED on this 31st day of August, 2015.

Chairperson
Iowa Board of Pharmacy

cc: Laura Steffensmeier
Assistant Attorney General
Hoover Building, 2nd Floor
Des Moines, IA 50319

ADDENDUM P

SETTLEMENT AGREEMENT
AND
FINAL ORDER

ASHLEY HENSON
PHARMACY TECHNICIAN REGISTRATION NO. 8907
CHEROKEE, IOWA

BEFORE THE IOWA BOARD OF PHARMACY

Re: Certified Technician Registration	))	CASE NO. 2015-74
	))	**SETTLEMENT AGREEMENT AND FINAL ORDER**
ASHLEY HENSON, Registration No. 8907, Respondent.	)))	

COME NOW the Iowa Board of Pharmacy ("Board") and Ashley Henson ("Respondent"), and enter into this Settlement Agreement and Final Order ("Agreement") pursuant to Iowa Code sections 17A.10(2) and 272C.3(4) (2015) to settle a licensee disciplinary proceeding currently pending before the Board.

The allegations contained in the Statement of Charges against the Respondent shall be resolved without proceeding to hearing, as the Board and Respondent stipulate as follows:

1. Respondent holds Iowa certified technician registration number 8907, which expired on June 30, 2015.

2. The Board has jurisdiction over the parties and the subject matter of these proceedings.

3. A Statement of Charges was filed against the Respondent on June 23, 2015.

4. Respondent admits to the allegations in the Statement of Charges and acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order.

5. Execution of this Settlement Agreement and Final Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's actions, by freely and voluntarily entering into this Agreement. This Agreement shall constitute the final order of the Board in this case and shall have the force and effect of a disciplinary order entered following a contested case hearing.

6. Respondent is freely and voluntarily entering into this Agreement. Respondent agrees that the State's counsel may present this Agreement to the Board and may have *ex parte* communications with the Board while presenting it.

7. This Agreement shall be part of Respondent's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

8. This Agreement is subject to approval by the Board. If the Board does not approve this Agreement, it shall be of no force or effect on either party, and shall not be admissible for any

RECEIVED
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IOWA BOARD OF PHARMACY

purpose in further proceedings in this matter. If the Board approves this Agreement, it shall be the full and final resolution of this matter.

9. This Agreement, when fully executed, is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapters 22 and 272C.

10. Respondent acknowledges and understands that this Order will be reported to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank, as applicable.

11. This Agreement shall not be binding as to any new complaints received by the Board.

12. The Board's approval of this Agreement shall constitute a FINAL ORDER of the Board.

IT IS THEREFORE ORDERED:

13. Respondent agrees to **VOLUNTARILY SURRENDER** her certified technician registration.

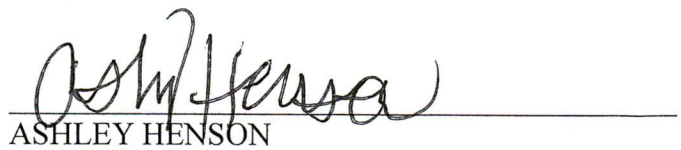
14. This voluntary surrender is considered a revocation of license under Iowa Administrative Code rule 657—36.15 for purposes of reinstatement. Respondent may not request reinstatement for at least one year from the date of this Order.

15. Respondent may request reinstatement of her Iowa certified technician registration by filing an application for reinstatement under Iowa Administrative Code rule 657—36.13. Respondent's registration shall not be reinstated except upon a showing by Respondent that the basis for revocation of her registration no longer exists, and that it is in the public interest for the registration to be reinstated.

16. Respondent agrees not to engage in any aspect of the practice of pharmacy until her registration has been reinstated.

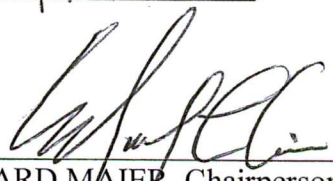
17. Should Respondent violate the terms of this Settlement Agreement and Final Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A (2015) and Iowa Administrative Code chapter 657—36.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 28 day of August, 2015.



ASHLEY HENSON
Respondent

This Combined Statement of Charges, Settlement Agreement, and Final Order is accepted by the Iowa Board of Pharmacy on the 1st day of September, 2015.



EDWARD MAIER, Chairperson
Iowa Board of Pharmacy
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

Copies to:

Meghan Gavin
Assistant Attorney General
Hoover Building, 2nd Floor
Des Moines, IA 50319

ADDENDUM Q

FINDINGS OF FACT, CONCLUSIONS OF LAW, DECISION AND ORDER

SHERRI MARSHALL
PHARMACY TECHNICIAN REGISTRATION NO. 18129
DES MOINES, IOWA

BEFORE THE IOWA BOARD OF PHARMACY

IN THE MATTER OF THE STATEMENT OF CHARGES AGAINST:	CASE NO. 2014-189 DIA NO. 15PHB008
SHERRI MARSHALL Registration No. 18129 RESPONDENT	FINDINGS OF FACT, CONCLUSIONS OF LAW, DECISION AND ORDER

On March 10, 2015, the Iowa Board of Pharmacy (Board) found probable cause to file a Notice of Hearing and Statement of Charges against Sherri Marshall (Respondent), which charged her with three counts:

> Count I: Obtaining or attempting to obtain a prescription drug by forging a prescription, in violation of Iowa Code section 155A.23 and pursuant to Iowa Code sections 147.55(8), 155A.6A(5) and 657 IAC 3.30 and 36.1(4)"j."
>
> Count II: Making a statement tending to deceive, misrepresent, or mislead anyone, or being a party to or an accessory to any fraudulent or deceitful practice or transaction in pharmacy or in the operation or conduct of a pharmacy, in violation of 657 IAC 3.28(1), and pursuant to Iowa Code sections 147.55(3) and (9), 155A.6A(5) and 657 IAC 3.30 and 36.1(4)"c" and "u."
>
> Count III: Engaging in unethical behavior, in violation of 657 IAC 3.28(4), and pursuant to Iowa Code sections 147.55(3) and (9), 155A.6A(5) and 657 IAC 3.30 and 36.1(4)"c" and "u."

The hearing was held on June 23, 2015 at 9:10 a.m. The following members of the Board presided at the hearing: Edward Meier, Chairperson; Edward McKenna; James Miller; Sharon Meyer; Jason Hansel; and LaDonna Gratias. Assistant Attorney General Laura Steffensmeier represented the state. Respondent failed to appear for hearing. The hearing was open to the public, pursuant to Iowa Code section 272C.6(1)(2015), and was recorded by a certified court reporter. Administrative Law Judge Margaret LaMarche assisted the Board in conducting the hearing. After hearing the testimony and examining the exhibits, the Board convened in closed executive session, pursuant to Iowa Code section 21.5(1)(f), to deliberate their decision. The administrative law judge

was instructed to prepare the Findings of Fact, Conclusions of Law, Decision and Order, in conformance with the Board's deliberations.

THE RECORD

The record includes the testimony of Jennifer Tiffany, R.Ph. and State Exhibits 1-17. Protective orders were issued for Exhibits 2, 6, 7, 8, 10, 11, and 13 because they include information that is confidential under Iowa Code section 22.7(2).

FINDINGS OF FACT

1. The Board has issued pharmacy technician registration number 18129 to Respondent, which authorizes her to serve as a pharmacy technician, subject to the laws of the state of Iowa and the rules of the Board. Respondent's pharmacy technician registration is active and will expire on March 31, 2016. (State Exhibits 1, 5)

2. In October and November 2014, Respondent was employed as a pharmacy technician by the Wal-Mart Pharmacy located at SE 14th Street in Des Moines. On November 7, 2014, Wal-Mart notified the Board that Respondent's employment had been terminated based on her involvement with forged prescriptions for hydrocodone/acetaminophen 10/325 mg. Board Compliance Officer Jennifer Tiffany, R.Ph. was assigned to investigate this complaint. (State Exhibits 2, 3, 4; Tiffany testimony).

3. On November 20, 2014, Jennifer Tiffany met with a member of Wal-Mart's Security/Loss Prevention team, who provided documentation from Wal-Mart's investigation and security video footage from the pharmacy. Wal-Mart's investigation was initiated after an individual (JH) contacted the pharmacy on October 9, 2014. JH is subject to a pain management contract that requires him to fill all of his prescriptions at Walgreens. Upon checking the Prescription Monitoring Program (PMP) data base, JH's pain management physician discovered that a prescription in JH's name had been filled at the SE 14th Street Wal-Mart Pharmacy. The prescription was for 240 tablets of hydrocodone/apap 10/325, and it was filled under JH's name on September 25, 2014. (Tiffany testimony; State Exhibits 6, 7)

After JH notified Wal-Mart that he was not aware of this prescription and did not pick it up, a Wal-Mart pharmacist contacted the nurse practitioner who was listed on the prescription as the prescriber. The nurse practitioner confirmed that she did not

authorize the prescription and that it was a forgery. The nurse practitioner signed a statement attesting to that fact. (State Exhibits 6, 7; Tiffany testimony)

JH filed a criminal complaint with the Des Moines Police Department, and Des Moines Police Officer Rahn Bjornson was assigned to investigate the criminal matter. JH told Officer Bjornson that the nurse practitioner whose name was on the prescription worked at the same clinic as his pain management physician, but she did not provide treatment for him. He also told Officer Bjornson that he does not have a prescription for hydrocodone. (State Exhibit 13)

4. Wal-Mart had security video footage from September 25, 2014, which is the date that the forged prescription was transcribed and filled. The video footage shows Respondent transcribing the prescription for JH between 7:30 and 7:50 p.m. and then stapling shut the bag containing the hydrocodone/apap prescription. Respondent should have left the bag open and unsecured to allow counseling by the pharmacist because JH would have been a new customer at the Wal-Mart. Prescription bags are normally hung from a rack behind the register, but the video footage shows Respondent placing the bag with JH's prescription under the counter at the checkout register. The video footage later shows Respondent selling the bag with JH's prescription to a young male, later identified as Respondent's nephew, KL. During the transaction, Respondent reached over the counter and signed the electronic signature capture device for JH's prescription. Additional video footage showed KL leaving the pharmacy and getting into a white SUV that was registered to Adam Patrick, who was reported to be Respondent's boyfriend. (Tiffany testimony; State Exhibits 2, 8, 9)

5. Wal-Mart's security staff showed the video footage from the September 25th transaction to JH and his wife. JH's wife identified the young male who picked up the prescription as KL, who she used to babysit for. JH's wife reported that she knew KL through Respondent, who was a former friend of hers. Officer Bjornson then met with KL, who was then 15 years old, and his mother. KL told Officer Bjornson that he was paid $50 by Adam Patrick to pick up a prescription for "J" on September 25, 2014. KL further stated that Patrick told him that Respondent (his aunt) would be working. KL told Bjornson that Respondent did not ask him any questions when he picked up the prescription and that Respondent signed for the prescription. KL further reported that he repeated the procedure about one week later, but he could not remember the name on the second prescription that he picked up. When KL's mother mentioned the name of JM, KL replied that he thought that was the name on the second prescription. KL's mother reported that JM is a friend of Adam Patrick's who is currently incarcerated. (State Exhibits 2, 13; Tiffany testimony)

6. Two additional hydrocodone prescriptions that were transcribed by Respondent and filled at the SE 14th Street Wal-Mart pharmacy were also identified as fraudulent.

- One prescription, dated September 26, 2014, had purportedly been phoned in by the same nurse practitioner as the September 25th prescription for JH. This prescription was also for 240 tablets of hydrocodone/apap 10/325 and was written for patient EM. The same nurse practitioner was again contacted, and she signed a statement attesting that this prescription was not authorized by her and that it was forged or altered. (Tiffany testimony; State Exhibits 2, 10);
- The other prescription was dated October 1, 2014, was for 300 tablets of hydrocodone/apap 10/325, and was written for patient JM, who was the same person previously identified as a friend of Adam Patrick. Officer Bjornson called the practitioner listed as the authorizing prescriber on this prescription, and the clinic told Bjornson that JM was not one of their patients. Security video footage from October 2, 2014 shows KL picking up the fraudulent prescription for JM from Respondent while she was working. (State Exhibits 2, 11, 12)

7. On October 23, 2014, Officer Bjornson spoke to Respondent by phone and recorded their conversation. Respondent admitted having her nephew KL pick up the prescription for JH. Respondent told Bjornson that she paid KL $20 or $30 and that she planned to kill herself with the pills. Respondent admitted that she knew JM but did not admit involvement with that prescription. (State Exhibits 2, 13)

8. On December 8, 2014, Compliance Officer Jennifer Tiffany sent Respondent a certified letter informing her of the allegations against her related to forgery of prescriptions and theft of controlled substances from the Wal-Mart Pharmacy. Respondent replied by email on December 18, 2014. Respondent wrote that the allegations that she was stealing hydrocodone and forging prescriptions were false. Criminal charges were filed against Respondent and were still pending as of the date of the hearing. (Tiffany testimony; State Exhibits 2, 14, 15)

9. Respondent was personally served with the Notice of Hearing and Statement of Charges by Jennifer Tiffany on May 12, 2015. Respondent failed to appear for hearing. (State Exhibit 17; Tiffany testimony)

CONCLUSIONS OF LAW

Iowa Code section 147.55(2013) provides, in relevant part, that the Board may revoke, suspend, or otherwise discipline a license for any of the following offenses:

> ...
>
> 3. Knowingly making misleading, deceptive, untrue or fraudulent representations in the practice of a profession or engaging in unethical conduct or practice harmful or detrimental to the public. Proof of actual injury need not be established.
>
> ...
>
> 8. Willful or repeated violations of the provisions of this chapter, chapter 272C, or a board's enabling statute.
>
> 9. Other acts or offenses as specified by board rule.

See also 657 IAC 36.1(4)"c" and "u."

Iowa Code section 155A.6A(5)(2013) and 657 IAC 3.30 authorize the board to suspend or revoke the registration of a registered pharmacy technician for any violation of the laws of this state, ... relating to prescription drugs, controlled substances, or nonprescription drugs, or for any violation of this chapter or chapter 124, 124A, 124B, 126, 147, 205, or 272C or any rule of the board.

Count I-Forging Prescriptions

Iowa Code section 155A.23(1)(a)(2013) provides, in relevant part, that a person shall not obtain or attempt to obtain a prescription drug or device by: (1) engaging in fraud, deceit, misrepresentation, or subterfuge; (2) Forging or altering a written, electronic or facsimile prescription or any written, electronic or facsimile order.

In addition, 657 IAC 36.1(4) provides, in relevant part:

> **36.1(4)** *Grounds for discipline.* The board may impose any of the disciplinary sanctions set out in rule 36.1(2) when the board determines that the licensee, registrant, or permittee is guilty of the following acts or offenses:
>
> ...
>
> *j.* Violating a statute or law of this state,...without regard to its designation as either a felony or misdemeanor, which statute or law

> relates to the practice of pharmacy or the distribution of controlled substances, prescription drugs, or nonprescription drugs.
>
> ...

The preponderance of the evidence in this record established that Respondent forged prescriptions for hydrocodone, a controlled substance, and engaged in additional acts of deception and misrepresentation that facilitated the prescriptions to be filled and picked up by persons for whom they were not legitimately prescribed. Respondent engaged in these acts while employed as a pharmacy technician. The evidence collected in the investigations, including but not limited to the security video footage, the statements made by KL and his mother, and Respondent's admissions to the Board's investigator, constitute overwhelming evidence of Respondent's active participation in creating and filling fraudulent prescriptions at the pharmacy where she was employed. Respondent has violated Iowa Code sections147.55(8), 155A.6A(5), 155A.23 and 657 IAC 3.30 and 36.1(4)(j).

Count II-Misrepresentative Deeds

657 IAC 3.28(1) provides that it is unethical conduct for a pharmacy technician to make any statement tending to deceive, misrepresent, or mislead anyone, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in pharmacy or in the operation or conduct of a pharmacy.

The preponderance of the evidence in this record established that Respondent engaged in unethical conduct through misrepresentative deeds when she participated in forging and filling forged hydrocodone prescriptions. Respondent has violated Iowa Code sections 147.55(3), (9), 155A.6A(5) and 657 IAC 3.30 and 36.1(4)"c" and "u."

Count III-Engaging in Unethical Behavior

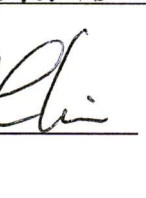
657 IAC 3.28(4) prohibits pharmacy technicians from exhibiting unethical behavior in connection with the technician's pharmacy employment. Unethical behavior includes but is not limited to theft. The preponderance of the evidence in this record established that Respondent engaged in unethical conduct, i.e. theft, when she participated in forging and filling forged hydrocodone prescriptions at the pharmacy where she was employed. Respondent has violated Iowa Code sections 147.55(3), (9), 155A.6A(5) and 657 IAC 3.28(4), 3.30 and 36.1(4)"c" and "u."

DECISION AND ORDER

The very serious nature of Respondent's violations and her failure to appear for hearing justifies the revocation of her registration as a pharmacy technician. IT IS THEREFORE ORDERED that pharmacy technician registration number 18129, issued to Sherri Marshall, is hereby REVOKED. If Respondent seeks reinstatement of her pharmacy technician registration in the future, the burden will be placed on her to show that the basis for the revocation no longer exists and that is in the public interest for her registration to be reinstated. 657 IAC 36.13(4).

IT IS FURTHER ORDERED, pursuant to Iowa Code section 272C.6 and 657 IAC 36.18(2), that Respondent shall pay $75.00 for fees associated with conducting the disciplinary hearing. In addition, the executive director of the Board may bill Respondent for any witness fees and expenses or transcript costs associated with this disciplinary hearing. Respondent shall remit for these expenses within thirty (30) days of receipt of the bill.

Dated this 1st day of September, 2015.



Edward Maier, Chairperson
Iowa Board of Pharmacy

cc: Laura Steffensmeier, Assistant Attorney General
Hoover State Office Building (LOCAL)

A default decision or decision rendered on the merits after a party has failed to appear or participate in a contested case hearing shall become final board action unless within 15 days after the date of notification or mailing of the decision a motion to vacate is filed and served on all parties or unless an appeal of a decision is timely initiated within the time provided by rule 35.26. A motion to vacate must state all facts relied upon by the moving party which establish good cause existed for that party's failure to appear or participate at the contested case proceeding. Each fact so stated shall be substantiated by at least one sworn affidavit of a person with personal knowledge of each such fact, which affidavit(s) shall be attached to the motion. 657 IAC 35.21. The time for further appeal of a decision for which a timely motion to vacate has been filed is stayed pending a decision on the motion to vacate. 657 IAC 35.21(4).

Any aggrieved or adversely affected party may seek judicial review of this decision and order of the board, pursuant to Iowa Code section 17A.19.

ADDENDUM R

IOWA BOARD OF PHARMACY
EXECUTIVE DIRECTOR INTERVIEW QUESTIONS
AND
SCORING SHEET

Iowa Board of Pharmacy
Executive Director Interview Questions

Candidate: _____ Date: **September 2, 2015**

Board Member: _____

I. Working with a Board and staff of diverse personalities with different interests and priorities can be a challenge. In addition, the Board of Pharmacy has numerous constituencies including the people of Iowa; pharmacists, pharmacy owners, and pharmacy staff; legislators and the Governor; other regulatory boards, state, and federal agencies; the Attorney General's office; professional organizations, associations, and societies including IPA, IMS, NABP, and ODCP; consumer groups; and Board staff, to name a few. What basic principles would you use in dealing with these diverse groups? How have you handled similar situations?

_____

II. How would you handle discipline with your staff and peers working for the Board of Pharmacy?

_____

III. What excites you most about this position? What challenges are you looking for in this position? Why should we hire you for this position?

_____

IV. What one word would your co-workers and peers use to best describe you?

_____

V. Provide an example of how you worked with one or more employees or colleagues to improve their skills and abilities.

_____

VI. What do you see as the biggest challenges facing pharmacy in the next five years? How do you see the role of the Board of Pharmacy in addressing these challenges?

_____

VII. How would you deal with someone you knew was 100% wrong about something? How would you handle it?

_____

VIII. What resources do you anticipate being able to draw upon as executive director if circumstances present or issues develop in which you have no experience or procedural knowledge? Where do you turn for assistance or direction?

_____

IX. Many duties or projects can be competently handled by staff members. If you delegate to a member of your staff, how do you determine if the staff member has gone too far with the task or if the task has been satisfactorily completed?

_____

X. Have you contacted the past executive director to discuss this position and the duties and responsibilities of the position? If yes, what were his two best pieces of information or advice to you?

_____

XI. Tell us about a time when you had to cope with strict time demands. How did you cope? What was the result?

_____

XII. What are the active listening techniques you have found to be most effective? Provide a specific example from your past experience to illustrate. Describe the situation, what you did, and how you know you were effective.

_____

XIII. What is the one thing you want to do, investigate, or get clarified on your first day of working for the Board of Pharmacy?

_____

XIV. What do you expect from the Board in this position?

_____

XV. What questions would you ask of Board members if you were interviewing us?

_____

Iowa Board of Pharmacy
Executive Director Interview Questions

Candidate: _____ Date: **September 2, 2015**

Board Member: _____

Total Score:_____ **(***Maximum 105***)**

Managerial Experience • Budgeting, revenue and expenses • Human resources, recruiting, hiring, monitoring, disciplinary • People skills	(20 points maximum)	
Leadership/Team Building Experience	(10 points maximum)	
Pharmacy/ Public Safety Vision	(15 points maximum)	
Organizational Skills	(20 points maximum)	
State Political Process Experience	(10 points maximum)	
Communication Skills	(15 points maximum)	
State Board of Pharmacy Experience	(15 points maximum)	

Additional Comments or Observations:

_____

_____

_____

_____

_____

_____

IOWA BOARD OF PHARMACY

2016 CALENDAR OF BOARD MEETINGS AND CONFERENCES

MONTH	MEETING	DATE(S)	LOCATION
January	**Board Meeting**	January 12-13	Des Moines
January	IPA Legislative Day	January 27	Des Moines
February	Midwest Pharmacy Expo	February 12-14	Des Moines
March	**Board Meeting** ***Alternate***	March 8-9 ***March ??***	Des Moines ***Iowa City***
March	APhA Annual Meeting	March 4-7	Baltimore, MD
May	**Board Meeting**	May 3-4	Des Moines
May	NABP 112th Annual Meeting	May 14-17	San Diego, CA
June	IPA Annual Meeting	June 17-18	West Des Moines
June	**Board Meeting**	June 28-29	Des Moines
August	NABP/AACP Dist. Five 79th Annual Meeting	August 4-6	Lincoln, NE
August	**Board Meeting**	August 30-31	Des Moines
September	CLEAR Annual Conference	September 18-21	New Orleans, LA
November	**Board Meeting**	November 1-2	Des Moines
December	51st ASHP Midyear Clinical Meeting	December 4-6	Las Vegas, NV

nabp
National Association of Boards of Pharmacy
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TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Carmen A. Catizone, Executive Director/Secretary

DATE: October 1, 2015

RE: Nominations for the 2016 Lester E. Hosto Distinguished Service Award, 2016 Fred T. Mahaffey Award, 2016 NABP Honorary President, and the 2016 John F. Atkinson Service Award to be presented at the NABP 112th Annual Meeting

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Nominations are currently being accepted for the following NABP awards: 2016 Lester E. Hosto Distinguished Service Award (DSA), 2016 Fred T. Mahaffey Award, 2016 NABP Honorary President, and the 2016 John F. Atkinson Service Award. The awards presentation will take place at the NABP 112th Annual Meeting, May 14-17, 2016, at the Hilton San Diego Bayfront in San Diego, CA.

Lester E. Hosto DSA

Named in memory of the 1990-1991 NABP President Lester E. Hosto, this award is the highest honor bestowed by the Association. The DSA is awarded in recognition of exemplary service in protecting the public health and significant involvement with NABP. Any individual who meets these criteria may be nominated for the DSA, regardless of his or her member affiliation with NABP.

During the NABP Annual Meeting, the recipient of the DSA is presented with a distinguished plaque and pin acknowledging the Association's recognition of the recipient's meritorious efforts.

Fred T. Mahaffey Award

Named in honor of the late NABP executive director emeritus, the Fred T. Mahaffey Award recognizes a member board of pharmacy that has made substantial contributions to the regulation of the pharmacy profession during the past year. The nominated board's efforts must have contributed to the protection of the public health and welfare through the enforcement of state and federal laws and regulations, and to the advancement of NABP goals and objectives as specified in the Association's Constitution and Bylaws.

Honorary President

Nominees must meet the following criteria:

- service on one or more NABP committees or task forces;
- participation in district and Annual Meetings;
- exemplary services for, or on behalf of, NABP
- strong commitment to NABP, the mission of the Association to protect the public health, and the profession of pharmacy; and
- affiliation, (either current or past,) as a board member or as an administrative officer of an active or associate member board.

John F. Atkinson Service Award

The John F. Atkinson Service Award is awarded in recognition of exemplary service in protecting the public health and should encompass pharmacy law, inspectors, and compliance officers. It is awarded to an individual(s) who has supported the goals and objectives of the Association and the state boards of pharmacy to protect the public health and advanced the need to maintain the safety and integrity of the distribution and dispensing of medications. The extraordinary achievement must have resulted in an accomplishment as exceptional and outstanding as to clearly set the individual apart from his colleagues.

Nominations for these awards must be received at NABP Headquarters no later than December 31, 2015. Letters of nomination, along with a brief biography and current resume or curriculum vitae of the nominee, must include an account explaining why the nominee should be considered for an award.

A nomination form is available on the NABP Web site in the Meetings section, or via the following link: http://www.nabp.net/system/rich/rich_files/rich_files/000/001/131/original/2016-nomination-form-fillable.pdf.

The NABP Executive Committee will review the nominations and select the award recipients. Please submit your nomination to my attention at NABP Headquarters, 1600 Feehanville Dr, Mount Prospect, IL 60056. For more information, please contact Lisa Braddy, executive office supervising coordinator, via e-mail at [redacted] or via phone at [redacted], ext. 4462.

cc: NABP Executive Committee

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TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY,
DEANS – SCHOOLS AND COLLEGES OF PHARMACY

FROM: Carmen A. Catizone, Executive Director/Secretary

DATE: October 8, 2015

RE: MPJE Program Notification

In 2014, the National Association of Boards of Pharmacy® (NABP®) facilitated a review of the Multistate Pharmacy Jurisprudence Examination® (MPJE®) competency statements to ensure that the content areas represented are current and relevant to the application of pharmacy law in practice. The review resulted in modifications and additions to the content areas and these outcomes were included in a national survey of pharmacy regulators earlier this year. The survey yielded information regarding the importance of each of the content areas in practice which in turn produced weights for the MPJE blueprint.

Following the survey, NABP conducted an evaluation of the passing standard for the MPJE. The purpose of the MPJE passing standard meeting is to make a recommendation regarding the level of demonstrable performance that is necessary to pass the examination. To support the validation of a passing (cut) score recommendation and decision, standard setting meetings are held with subject matter experts who understand the purpose of the examination, the content being tested, and characteristics of the examinees. The panel that participated in the MPJE standard setting process was composed of pharmacists from a variety of backgrounds and experiences – board of pharmacy affiliates (executives, members), active practitioners, inspectors/compliance officers, board counsel, and academicians. Collectively, the panel has the requisite expertise encompassing the scope of pharmacy practice and the capacity to recommend a minimum standard for the knowledge and skills necessary for licensure.

NABP is providing the following summary of updates to the MPJE program to provide timely information to the boards of pharmacy participating in the MPJE program and to the schools and colleges of pharmacy. The implementation of the MPJE program changes will be effective April 2016.

- The MPJE will be assembled under the new (updated) competency statements and content area domain allocations (see accompanying attachment).
- The number of examination items will increase from 90 to 120. Of the 120 items, 100 will be used to produce a score for the MPJE and 20 will non-scored or pretest items. The increase in the number of questions will ensure testing across all of the content areas.

- Maximum testing time for the examination will increase from two hours to two and a half hours. The appointment time with the vendor, Pearson VUE, will be three hours to allow for time to read and agree to the confidentially/non-disclosure agreement, tutorial, and post-exam survey. To account for the additional seat time and exam development, the MPJE registration fee will increase from $210 to $250.
- A new passing standard for the MPJE will be implemented on April, 2016; however, the scaled score required to pass will remain at 75. It is typical to see variations in the pass rates after a new standard is in place.

If you have any questions regarding the updates to the MPJE program, please contact Maria Incrocci, competency assessment senior manager at [redacted] or [redacted].

cc: Lucinda Maine, American Association of Colleges of Pharmacy
Peter Vlasses, Accreditation Council for Pharmacy Education
NABP Executive Committee
NABP Advisory Committee on Examinations
NABP MPJE Review Committee
Carmen A. Catizone, Executive Director/Secretary

Multistate Pharmacy Jurisprudence Examination

Competency Statements
(to be implemented April 2016)

Area 1 Pharmacy Practice (83%)

1.1 Legal responsibilities of the pharmacist and other pharmacy personnel

1.1.1 Unique legal responsibilities of the pharmacist-in-charge (or equivalent), pharmacists, interns, and pharmacy owners

Responsibilities for inventory, loss and/or theft of prescription drugs, the destruction/disposal of prescription drugs and the precedence of Local, State, or Federal requirements

1.1.2 Qualifications, scope of duties, and conditions for practice relating to pharmacy technicians and all other non-pharmacist personnel

Personnel ratios, duties, tasks, roles, and functions of non-pharmacist personnel

1.2 Requirements for the acquisition and distribution of pharmaceutical products, including samples

1.2.1 Requirements and record keeping in relation to the ordering, acquiring, and maintenance of all pharmaceutical products and bulk drug substances/excipients

Legitimate suppliers, pedigrees and the maintenance of acquisition records

1.2.2 Requirements for distributing pharmaceutical products and preparations, including the content and maintenance of distribution records

Legal possession of pharmaceutical products (including drug samples), labeling, packaging, repackaging, compounding, and sales to practitioners

1.3 Legal requirements that must be observed in the issuance of a prescription/drug order

1.3.1 Prescription/order requirements for pharmaceutical products and the limitations on their respective therapeutic uses

Products, preparations, their uses and limitations applicable to all prescribed orders for both human and veterinary uses

1.3.2 Scope of authority, scope of practice, and valid registration of all practitioners who are authorized under law to prescribe, dispense, or administer pharmaceutical products, including controlled substances

Federal and State registrations, methadone programs, office-based opioid treatment programs, regulations related to retired or deceased prescribers, Internet prescribing, limits on jurisdictional prescribing

1.3.3 Conditions under which the pharmacist participates in the administration of pharmaceutical products, or in the management of patients' drug therapy

Prescriptive authority, collaborative practice, consulting, counseling, medication administration (including immunization, vaccines), ordering labs, medication therapy management, and disease state management

1.3.4 Requirements for issuing a prescription/order

Content and format for written, telephonic voice transmission, electronic facsimile, computer and Internet, during emergency conditions, and tamper-resistant prescription forms.

1.3.5 Requirements for the issuance of controlled substance prescriptions/orders

Content and format for written, telephonic voice transmission, electronic facsimile, computerized and Internet, during emergency conditions, conditions for changing a prescription, time limits for dispensing initial prescriptions/drug orders, and requirements for multiple Schedule II orders

1.3.6 Limits of a practitioner's authority to authorize refills of a pharmaceutical product, including controlled substances

1.4 Procedures necessary to properly dispense a pharmaceutical product, including controlled substances, pursuant to a prescription/drug order

1.4.1 Responsibilities for determining whether prescriptions/orders were issued for a legitimate medical purpose and within all applicable legal restrictions

Corresponding responsibility, maximum quantities, restricted distribution systems, red flags/automated alerts, controlled substances, valid patient / prescriber relationship, and due diligence to ensure validity of the order

1.4.2 Requirements for the transfer of existing prescription/order information from one pharmacist to another

1.4.3 Conditions under which a prescription/order may be filled or refilled

Emergency fills or refills, partial dispensing of a controlled substance, disaster or emergency protocol, patient identification, requirement for death with dignity, medical marijuana, and conscience /moral circumstances

1.4.4 Conditions under which prospective drug use review is conducted prior to dispensing

Patient specific therapy and requirements for patient specific documentation

1.4.5 Conditions under which product selection is permitted or mandated

Consent of the patient and/or prescriber, passing-on of cost savings, and appropriate documentation

1.4.6 Requirements for the labeling of pharmaceutical products and preparations dispensed pursuant to a prescription/order

Generic and therapeutic equivalency, formulary use, auxiliary labels, patient package inserts, FDA medication guides, and written drug information

1.4.7 Packaging requirements of pharmaceutical products, preparations, and devices to be dispensed pursuant to a prescription/order

Child-resistant and customized patient medication packaging

1.4.8 Conditions under which a pharmaceutical product, preparation, or device may not be dispensed

Adulteration, misbranding, and dating

1.4.9 Requirements for compounding pharmaceutical products

Environmental controls, release checks and testing, beyond use date (BUD), initial and ongoing training

1.4.10 Requirements for emergency kits

Supplying, maintenance, access, security, and inventory

1.4.11 Conditions regarding the return and/or reuse of pharmaceutical products, preparations, bulk drug substances/excipients, and devices

Charitable programs, cancer or other repository programs, previously dispensed, and from ""will call"" areas of pharmacies

1.4.12 Procedures and requirements for systems or processes whereby a non-pharmacist may obtain pharmaceutical products, preparations, bulk drug substances/excipients, and devices

Pyxis (vending), after hour's access, telepharmacies, and secure automated patient drug retrieval centers

1.4.13 Procedures and requirements for establishing and operating central processing and central fill pharmacies

Remote order verification

1.4.14 Requirements for reporting to PMP, accessing information in a PMP and the maintenance of security and confidentiality of information accessed in PMPs

1.4.15 Requirements when informed consent must be obtained from the patient and/or a duty to warn must be executed

Collaborative practice and investigational drug therapy

1.5 Conditions for making an offer to counsel or counseling appropriate patients, including the requirements for documentation

1.5.1 Requirements to counsel or to make an offer to counsel

1.5.2 Required documentation necessary for counseling

1.6 Requirements for the distribution and/or dispensing of non-prescription pharmaceutical products, including controlled substances

1.6.1 Requirements for the labeling of non-prescription pharmaceutical products and devices

1.6.2 Requirements for the packaging and repackaging of non-prescription pharmaceutical products and devices

1.6.3 Requirements for the distribution and/or dispensing of poisons, restricted, non-prescription pharmaceutical products, and other restricted materials or devices

Pseudoephedrine, dextromethorphan, emergency contraception, and behind the counter products as appropriate

1.7 Procedures for keeping records of information related to pharmacy practice, pharmaceutical products and patients, including requirements for protecting patient confidentiality

1.7.1 Requirements pertaining to controlled substance inventories

1.7.2 Content, maintenance, storage, and reporting requirements for records required in the operation of a pharmacy

Prescription filing systems, computer systems and backups, and prescription monitoring programs

1.7.3 Requirements for protecting patient confidentiality and confidential health records

HIPAA requirements and conditions for access and use of information

1.8 Requirements for handling hazardous materials such as described in USP <800>

1.8.1 Requirements for appropriate disposal of hazardous materials

1.8.2 Requirements for training regarding hazardous materials

Reverse distributors, quarantine procedures, comprehensive safety programs, Material Safety Data Sheets

1.8.3 Environmental controls addressing the proper storage, handling, and disposal of hazardous materials

Ventilation controls, personal protective equipment, work practices, and reporting

1.8.4 Methods for the compounding, dispensing and administration of hazardous materials

All hazardous materials including sterile and non-sterile compounding

Area 2 Licensure, Registration, Certification, and Operational Requirements (15%)

2.1 Qualifications, application procedure, necessary examinations, and internship for licensure, registration, or certification of individuals engaged in the storage, distribution, and/or dispensing of pharmaceutical products (prescription and non-prescription)

2.1.1 Requirements for special or restricted licenses, registration, authorization, or certificates

Pharmacists, pharmacist preceptors, pharmacy interns, pharmacy technicians, controlled substance registrants, and under specialty pharmacist licenses (Nuclear, Consultant etc.)

2.1.2 Standards of practice related to the practice of pharmacy

Quality assurance programs (including peer review), changing dosage forms, therapeutic substitution, error reporting, public health reporting requirements (such as notification of potential terrorist event, physical abuse, and treatment for tuberculosis), and issues of conscience and maintaining competency

2.1.3 Requirements for classifications and processes of disciplinary actions that may be taken against a registered, licensed, certified, or permitted individual

2.1.4 Requirements for reporting to, and participating in, programs addressing the inability of an individual licensed, registered, or certified by the Board to engage in the practice of pharmacy with reasonable skill and safety

Impairment caused by the use of alcohol, drugs, chemicals, or other materials, or mental, physical, or psychological conditions

2.2 Requirements and application procedure for the registration, licensure, certification, or permitting of a practice setting or business entity

2.2.1 Requirements for registration, license, certification, or permitting of a practice setting

In-state pharmacies, out-of-state pharmacies, specialty pharmacies, controlled substance registrants, wholesalers, distributors, manufacturers/repackagers, computer services providers, and internet pharmacies

2.2.2 Requirements for an inspection of a licensed, registered, certified, or permitted practice setting

2.2.3 Requirements for the renewal or reinstatement of a license, registration, certificate, or permit of a practice setting

2.2.4 Classifications and processes of disciplinary actions that may be taken against a registered, licensed, certified, or permitted practice setting

2.3 Operational requirements for a registered, licensed, certified, or permitted practice setting

2.3.1 Requirements for the operation of a pharmacy or practice setting that is not directly related to the dispensing of pharmaceutical products

Issues related to space, equipment, advertising and signage, security (including temporary absences of the pharmacist), policies and procedures, libraries and references (including veterinary), and the display of licenses

2.3.2 Requirements for the possession, storage, and handling of pharmaceutical products, preparations, bulk drug substances/excipients, and devices, including controlled substances

Investigational new drugs, repackaged or resold drugs, sample pharmaceuticals, recalls, and outdated pharmaceutical products

2.3.3 Requirements for delivery of pharmaceutical products, preparations, bulk drug substances/excipients, and devices, including controlled substances

Issues related to identification of the person accepting delivery of a drug, use of the mail, contract delivery, use of couriers, use of pharmacy employees, use of kiosks, secure mail boxes, script centers, use of vacuum tubes, and use of drive-up windows

Area 3 General Regulatory Processes (2%)

3.1 Application of regulations

3.1.1 Laws and rules that regulate or affect the manufacture, storage, distribution, and dispensing of pharmaceutical products, preparations, bulk drug substances/excipients, and devices, (prescription and non-prescription), including controlled substances

Food, Drug, and Cosmetic Act(s) and Regulations, the Controlled Substances Act(s) and Regulations, OBRA 90's Title IV Requirements, Practice Acts and Rules, other statutes and regulations, including but not limited to, dispensing of methadone, child-resistant packaging, tamper resistant packaging, drug paraphernalia, drug samples, pharmacist responsibilities in Medicare-certified skilled-nursing facilities, NDC numbers, and schedules of controlled substances

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M E M O R A N D U M

TO: Iowa Board of Pharmacy

FROM: Compliance Officers

SUBJECT: Proposed revisions to USP Chapter 797 for sterile compounding

DATE: October 20, 2015

Proposed revision to USP Chapter 797 for sterile compounding will be published for comment on November 2, 2015 and comments will be accepted until January 31, 2016. Below is a brief summary of the proposed changes.

- Completely reorganizes the chapter and groups like sections together, eliminating redundancies, and clarify requirements. The sections are numbered.
- Replaces the "Low-, Medium-, and High-risk" level terminology with Category 1 and Category 2 risk levels. Category 1 CSPs have a shorter BUD and can be prepared in a segregated compounding area and Category 2 CSPs have a longer BUD and require a cleanroom environment.
- Information specific to hazardous drug handling is removed and replaced with a reference to USP Chapter 800.
- Introduces a new term "in-use time" that designates the time frame in which commercially available products used to prepare CSPs and CSPs must be used after being opened or punctured.
- Guidance is provided for sterility testing on batch sizes less than 40 and refers to a different USP Chapter for batch sizes greater than 40.
- Specifies that the chapter covers compounding for both humans and animals, preparation of proprietary bag and vial systems, and repackaging of commercially available products.
- Personnel qualifications become more strict (including visual observation of hand hygiene / garbing, gloved fingertip sampling, and MFT required quarterly regardless of category; requalification when there has been a 3 month or longer break from compounding).

- Environmental sampling requirements become more strict (including viable airborne particle monitoring and surface sampling at least monthly).
- "Immediate-use" is replaced with "Urgent-use".
- Media-fill testing is simplified to require the most challenging compound the pharmacy makes with microbial growth medium substituted for the ingredients.
- If compounding Category 2 CSPs, the ante-area and buffer areas must be physically separate rooms with doors / walls.
- Cleaning and disinfecting frequencies stay consistent, but allows less frequent cleaning if compounding occurs less frequently; sporicidal agents are required weekly.
- Automatic compounding devices must have "accuracy assessment" each day used with daily record and weekly review of record required.
- Adds requirements for master formulation and compounding records.
- Enhances requirements for visual inspection of each injectable CSP prior to release.
- Records are required to be maintained for at least 3 years after the BUD.

Some potential questions / comments:

- Quarterly personnel monitoring requirements are significantly different; suggest annually for Category 1 and every 6 months for Category 2.
- Segregated compounding area ("SCA") surfaces are required to be smooth, impervious, free from cracks and crevices, etc. but this area is not classified likely because it cannot meet these requirements.
- Cleaning tools are required to be sterile, including for SCA, but SCA is not classified and would not be able to maintain sterility.
- The chapter requires compounders to qualify the vendors it uses and that such "qualification must include an evaluation of the vendor's reputation and reliability". A reputation is completely subjective – who determines what is acceptable?
- The chapter specifically identifies that it covers compounding for animals and has an entire section on APIs; however, current law does not allow compounding for animals from bulk drug substances (although recently released guidance indicates that enforcement action may not be taken, in certain circumstances); how does a compounder reconcile the conflict in law?

BRIEFING

⟨797⟩ Pharmaceutical Compounding—Sterile Preparations, *USP 39* page 626. It is proposed to revise this chapter to improve clarity, respond to stakeholder input, and reflect new science. Major edits to the chapter include:

1. Reorganized existing chapter to group similar topics together, eliminate redundancies, and clarify requirements. Key procedural information is placed in boxes so that it can be easily referenced and followed.
2. Collapsed compounded sterile preparations (CSP) microbial risk categories from three to two and changed terminology. No sterile compounding is inherently "low risk" and preparation of all CSPs must be done carefully. Categories were renamed neutrally as Category 1 and 2 CSPs, which are distinguished primarily by the conditions under which they are made and the time within which they are used. Category 1 CSPs have a shorter beyond use date (BUD) and may be prepared in a segregated compounding area; Category 2 CSPs have a longer BUD and must be prepared in a cleanroom environment.
3. Removed specific information on handling of hazardous drugs and added references to *Hazardous Drugs—Handling in Healthcare Settings* ⟨800⟩.
4. Introduced terminology for "in-use time" to refer to the time before which a conventionally manufactured product used to make a CSP must be used after it has been opened or punctured, or a CSP must be used after it has been opened or punctured.

Additionally, the chapter was revised to add requirements for maintaining master formulation and compounding records, provide guidance on use of isolators, and add guidance for sterility testing of CSP prepared in batch sizes of less than 40.

The proposed chapter is posted online at www.usp.org/usp-nf/notices/general-chapter-797-proposed-revision with line numbers. Please provide the line numbers corresponding to your comments when submitting comments to [redacted].

Additionally, minor editorial changes have been made to update the chapter to current *USP* style.

(CMP: J. Sun.)
Correspondence Number—C163428

⟨797⟩ PHARMACEUTICAL COMPOUNDING—STERILE PREPARATIONS

Change to read:

~~INTRODUCTION~~

~~The objective of this chapter is to describe conditions and practices to prevent harm, including death, to patients that could result from (1) microbial contamination (nonsterility), (2) excessive bacterial endotoxins, (3) variability in the intended strength of correct ingredients that exceeds either monograph limits for official articles (see "official" and "article" in the *General Notices and Requirements*) or 10% for nonofficial articles, (4) unintended chemical and physical contaminants, and (5) ingredients of inappropriate quality in compounded sterile preparations (CSPs). Contaminated CSPs are potentially most hazardous to patients when administered into body cavities, central nervous and vascular systems, eyes, and joints, and when used as baths for live organs and tissues. When CSPs contain excessive bacterial endotoxins (see *Bacterial Endotoxins Test* ⟨85⟩), they are potentially most hazardous to patients when administered into the central nervous system.~~

~~Despite the extensive attention in this chapter to the provision, maintenance, and evaluation of air quality, the avoidance of direct or physical contact contamination is paramount. It is generally acknowledged that direct or physical contact of critical sites of CSPs with contaminants, especially microbial sources, poses the greatest probability of risk to patients. Therefore, compounding personnel must be meticulously conscientious in precluding contact contamination of CSPs both within and outside ISO Class 5 (see *Table 1*) areas.~~

~~To achieve the above five conditions and practices, this chapter provides minimum practice and quality standards for CSPs of drugs and nutrients based on current scientific information and best sterile compounding practices. The use of technologies, techniques, materials, and procedures other than those described in this chapter is not prohibited so long as they have been proven to be equivalent or superior with statistical significance to those described herein. The standards in this chapter do not pertain to the *clinical administration* of CSPs to patients via application, implantation, infusion, inhalation, injection, insertion, instillation, and irrigation, which are the routes of administration. Four specific categories of CSPs are described in this chapter: low-risk level, medium-risk level, and high-risk level, and immediate use. Sterile compounding differs from nonsterile compounding (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩ •—(CN 1-May-2016)) primarily by requiring the maintenance of sterility when compounding exclusively with sterile ingredients and components (i.e., with immediate-use CSPs, low-risk level CSPs, and medium-risk level CSPs) and the achievement of sterility when compounding with nonsterile ingredients and components (i.e., with high-~~

~~risk level CSPs). Some differences between standards for sterile compounding in this chapter and those for nonsterile compounding in *Pharmaceutical Compounding—Nonsterile Preparations* (795) include, but are not limited to, ISO-classified air environments (see *Table 1*); personnel garbing and gloving; personnel training and testing in principles and practices of aseptic manipulations and sterilization; environmental quality specifications and monitoring; and disinfection of gloves and surfaces of ISO Class 5 (see *Table 1*) sources.~~

~~Table 1. ISO Classification of Particulate Matter in Room Air~~ ~~(limits are in particles of 0.5 µm and larger per cubic meter [current ISO] and cubic feet [former Federal Standard No. 209E, FS 209E])~~[*]

~~Class Name~~		~~Particle Count~~	
~~ISO Class~~	~~U.S. FS 209E~~	~~ISO, m^3~~	~~FS 209E, ft^3~~
~~3~~	~~Class 1~~	~~35.2~~	~~1~~
~~4~~	~~Class 10~~	~~352~~	~~10~~
~~5~~	~~Class 100~~	~~3,520~~	~~100~~
~~6~~	~~Class 1,000~~	~~35,200~~	~~1,000~~
~~7~~	~~Class 10,000~~	~~352,000~~	~~10,000~~
~~8~~	~~Class 100,000~~	~~3,520,000~~	~~100,000~~

~~[*] Adapted from former Federal Standard No. 209E, General Services Administration, Washington, DC, 20407 (September 11, 1992) and ISO 14644-1:1999, Cleanrooms and associated controlled environments—Part 1: Classification of air cleanliness. For example, 3,520 particles of 0.5 µm per m^3 or larger (ISO Class 5) is equivalent to 100 particles per ft^3 (Class 100) (1 m^3 = 35.2 ft^3).~~

~~The standards in this chapter are intended to apply to all persons who prepare CSPs and all places where CSPs are prepared (e.g., hospitals and other healthcare institutions, patient treatment clinics, pharmacies, physicians' practice facilities, and other locations and facilities in which CSPs are prepared, stored, and transported). Persons who perform sterile compounding include pharmacists, nurses, pharmacy technicians, and physicians. These terms recognize that most sterile compounding is performed by or under the supervision of pharmacists in pharmacies and also that this chapter applies to all healthcare personnel who prepare, store, and transport CSPs. For the purposes of this chapter, CSPs include any of the following:~~

1. ~~Compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals, including but not limited to the following dosage forms that must be sterile when they are administered to patients: aqueous bronchial and nasal inhalations, baths and soaks for live organs and tissues, injections (e.g., colloidal dispersions, emulsions, solutions, suspensions), irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants.~~
2. ~~Manufactured sterile products that are either prepared strictly according to the instructions appearing in manufacturers' approved labeling (product package inserts) or prepared differently than published in such labeling. [Note—The FDA states that "Compounding does not include mixing, reconstituting, or similar~~

~~acts that are performed in accordance with the directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling" [21 USC 321 (k) and (m)]. However, the FDA-approved labeling (product package insert) rarely describes environmental quality (e.g., ISO Class air designation, exposure durations to non-ISO classified air, personnel garbing and gloving, and other aseptic precautions by which sterile products are to be prepared for administration). Beyond-use exposure and storage dates or times (see *General Notices and Requirements* and *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩) for sterile products that have been either opened or prepared for administration are not specified in all package inserts for all sterile products. Furthermore, when such durations are specified, they may refer to chemical stability and not necessarily to microbiological purity or safety.]~~

~~ORGANIZATION OF THIS CHAPTER~~

~~The sections in this chapter are organized to facilitate the practitioner's understanding of the fundamental accuracy and quality practices for preparing CSPs. They provide a foundation for the development and implementation of essential procedures for the safe preparation of low-risk, medium-risk, and high-risk level CSPs and immediate-use CSPs, which are classified according to the potential for microbial, chemical, and physical contamination. The chapter is divided into the following main sections:~~

- ~~Responsibility of Compounding Personnel~~
- ~~CSP Microbial Contamination Risk Levels~~
- ~~Personnel Training and Evaluation in Aseptic Manipulation Skills~~
- ~~Immediate-Use CSPs~~
- ~~Single-Dose and Multiple-Dose Containers~~
- ~~Hazardous Drugs as CSPs~~
- ~~Radiopharmaceuticals as CSPs~~
- ~~Allergen Extracts as CSPs~~
- ~~Verification of Compounding Accuracy and Sterility~~
- ~~Environmental Quality and Control~~
- ~~Suggested Standard Operating Procedures (SOPs)~~
- ~~Elements of Quality Control~~
- ~~Verification of Automated Compounding Devices (ACDs) for Parenteral Nutrition Compounding~~
- ~~Finished Preparation Release Checks and Tests~~
- ~~Storage and Beyond-Use Dating~~
- ~~Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs~~
- ~~Patient or Caregiver Training~~
- ~~Patient Monitoring and Adverse Events Reporting~~
- ~~Quality Assurance (QA) Program~~
- ~~Abbreviations and Acronyms~~
- ~~Glossary~~
- ~~Appendices I–V~~

~~The requirements and recommendations in this chapter are summarized in *Appendix I*. A list of abbreviations and acronyms is included at the end of the main text, before the *Appendices*.~~

~~All personnel who prepare CSPs shall be responsible for understanding these fundamental practices and precautions, for developing and implementing appropriate procedures, and for continually evaluating these procedures and the quality of final CSPs to prevent harm.~~

~~RESPONSIBILITY OF COMPOUNDING PERSONNEL~~

~~Compounding personnel are responsible for ensuring that CSPs are accurately identified, measured, diluted, and mixed and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed. These performance responsibilities include maintaining appropriate cleanliness conditions and providing labeling and supplementary instructions for the proper clinical administration of CSPs.~~

~~Compounding supervisors shall ensure, through either direct measurement or appropriate information sources, that specific CSPs maintain their labeled strength within monograph limits for *USP* articles, or within 10% if not specified, until their BUDs. All CSPs are prepared in a manner that maintains sterility and minimizes the introduction of particulate matter.~~

~~A written quality assurance procedure includes the following in-process checks that are applied, as appropriate, to specific CSPs: accuracy and precision of measuring and weighing; the requirement for sterility; methods of sterilization and purification; safe limits and ranges for strength of ingredients, bacterial endotoxins, and particulate matter; pH; labeling accuracy and completeness; BUD assignment; and packaging and storage requirements. The dispenser shall, when appropriate and practicable, obtain and evaluate results of testing for identity, strength, purity, and sterility before a CSP is dispensed. Qualified licensed healthcare professionals who supervise compounding and dispensing of CSPs shall ensure that the following objectives are achieved:~~

1. ~~Compounding personnel are adequately skilled, educated, instructed, and trained to correctly perform and document the following activities in their sterile compounding duties:~~
    a. ~~perform antiseptic hand cleansing and disinfection of nonsterile compounding surfaces;~~
    b. ~~select and appropriately don protective garb;~~
    c. ~~maintain or achieve sterility of CSPs in ISO Class 5 (see *Table 1*) PEC devices and protect personnel and compounding environments from contamination by radioactive, cytotoxic, and chemotoxic drugs (see *Hazardous Drugs as CSPs* and *Radiopharmaceuticals as CSPs*);~~
    d. ~~identify, weigh, and measure ingredients; and~~
    e. ~~manipulate sterile products aseptically, sterilize high-risk level CSPs, and label and quality inspect CSPs.~~
2. ~~Ingredients have their correct identity, quality, and purity.~~
3. ~~Opened or partially used packages of ingredients for subsequent use in CSPs are properly stored under restricted access conditions in the compounding facility. Such packages cannot be used when visual inspection detects~~

~~unauthorized breaks in the container, closure, and seal; when the contents do not possess the expected appearance, aroma, and texture; when the contents do not pass identification tests specified by the compounding facility; and when either the BUD or expiration date has been exceeded.~~

4. ~~Water-containing CSPs that are nonsterile during any phase of the compounding procedure are sterilized within 6 hours after completing the preparation in order to minimize the generation of bacterial endotoxins.~~
5. ~~Sterilization methods achieve sterility of CSPs while maintaining the labeled strength of active ingredients and the physical integrity of packaging.~~
6. ~~Measuring, mixing, sterilizing, and purifying devices are clean, appropriately accurate, and effective for their intended use.~~
7. ~~Potential harm from added substances and differences in rate and extent of bioavailability of active ingredients for other than oral route of administration are carefully evaluated before such CSPs are dispensed and administered.~~
8. ~~Packaging selected for CSPs is appropriate to preserve the sterility and strength until the BUD.~~
9. ~~While being used, the compounding environment maintains the sterility or the presterilization purity, whichever is appropriate, of the CSP.~~
10. ~~Labels on CSPs list the names and amounts or concentrations of active ingredients, and the labels or labeling of injections (see *Preservation, Packaging, Storage, and Labeling* in the *General Notices and Requirements*) list the names and amounts or concentrations of all ingredients (see *Labeling* (7)• (CN 1 May 2016)). Before being dispensed or administered, the clarity of solutions is visually confirmed; also, the identity and amounts of ingredients, procedures to prepare and sterilize CSPs, and specific release criteria are reviewed to ensure their accuracy and completeness.~~
11. ~~BUDs are assigned on the basis of direct testing or extrapolation from reliable literature sources and other documentation (see *Stability Criteria and Beyond-Use Dating* under *Pharmaceutical Compounding—Nonsterile Preparations* (795)).~~
12. ~~Procedures for measuring, mixing, dilution, purification, sterilization, packaging, and labeling conform to the correct sequence and quality established for the specified CSP.~~
13. ~~Deficiencies in compounding, labeling, packaging, and quality testing and inspection can be rapidly identified and corrected.~~
14. ~~When time and personnel availability so permit, compounding manipulations and procedures are separated from postcompounding quality inspection and review before CSPs are dispensed.~~

~~This chapter emphasizes the need to maintain high standards for the quality and control of processes, components, and environments and for the skill and knowledge of personnel who prepare CSPs. The rigor of in-process quality control checks and of postcompounding quality inspection and testing increases with the potential hazard of the route of administration. For example, nonsterility, excessive bacterial endotoxin contamination, large errors in strength of correct ingredients, and incorrect ingredients in CSPs are potentially more dangerous to patients when the CSPs are administered~~

~~into the vascular and central nervous systems than when administered by most other routes.~~

~~CSP MICROBIAL CONTAMINATION RISK LEVELS~~

~~The three contamination categories for CSPs described in this section are assigned primarily according to the potential for microbial contamination during the compounding of low risk level CSPs and medium risk level CSPs or the potential for not sterilizing high-risk level CSPs, any of which would subject patients to risk of harm, including death. High-risk level CSPs must be sterilized before being administered to patients. The appropriate risk level—low, medium, or high—is assigned according to the corresponding probability of contaminating a CSP with (1) microbial contamination (e.g., microbial organisms, spores, endotoxins) and (2) chemical and physical contamination (e.g., foreign chemicals, physical matter). Potential sources of contamination include, but are not limited to, solid and liquid matter from compounding personnel and objects; nonsterile components employed and incorporated before terminal sterilization; inappropriate conditions within the restricted compounding environment; prolonged presterilization procedures with aqueous preparations; and nonsterile dosage forms used to compound CSPs.~~

~~The characteristics described below for low , medium , and high-risk level CSPs are intended as a guide to the breadth and depth of care necessary in compounding, but they are neither exhaustive nor prescriptive. The licensed healthcare professionals who supervise compounding are responsible for determining the procedural and environmental quality practices and attributes that are necessary for the risk level they assign to specific CSPs.~~

~~These risk levels apply to the quality of CSPs immediately after the final aseptic mixing or filling or immediately after the final sterilization, unless precluded by the specific characteristics of the preparation. Upon subsequent storage and shipping of freshly finished CSPs, an increase in the risks of chemical degradation of ingredients, contamination from physical damage to packaging, and permeability of plastic and elastomeric packaging is expected. In such cases, compounding personnel are responsible for considering the potential additional risks to the integrity of CSPs when assigning BUDs. The pre-administration storage duration and temperature limits specified in the following subsections apply in the absence of direct sterility testing results that justify different limits for specific CSPs.~~

~~Low Risk Level CSPs~~

~~CSPs compounded under all the following conditions are at a low risk of contamination.~~

~~Low Risk Conditions—~~

1. ~~The CSPs are compounded with aseptic manipulations entirely within ISO Class 5 (see *Table 1*) or better air quality using only sterile ingredients, products, components, and devices.~~
2. ~~The compounding involves only transfer, measuring,and mixing manipulations using not more than three commercially manufactured packages of sterile~~

~~products and not more than two entries into any one sterile container or package (e.g., bag, vial) of sterile product or administration container/device to prepare the CSP.~~

3. ~~Manipulations are limited to aseptically opening ampuls, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing.~~
4. ~~For a low risk level preparation, in the absence of passing a sterility test (see *Sterility Tests* ⟨71⟩), the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 48 hours at controlled room temperature (see *General Notices and Requirements*), for not more than 14 days at a cold temperature (see *General Notices and Requirements*), and for 45 days in solid frozen state between −25° and −10°.~~

~~Examples of Low Risk Compounding~~

1. ~~Single-volume transfers of sterile dosage forms from ampuls, bottles, bags, and vials using sterile syringes with sterile needles, other administration devices, and other sterile containers. The solution content of ampuls should be passed through a sterile filter to remove any particles.~~
2. ~~Simple aseptic measuring and transferring with not more than three packages of manufactured sterile products, including an infusion or diluent solution to compound drug admixtures and nutritional solutions.~~

~~Low Risk Level CSPs with 12 Hour or Less BUD~~ ~~If the PEC is a CAI or CACI that does not meet the requirements described in *Placement of Primary Engineering Controls* or is a laminar airflow workbench (LAFW) or a biological safety cabinet (BSC) that cannot be located within an ISO Class 7 (see *Table 1*) buffer area, then only low-risk level nonhazardous and radiopharmaceutical CSPs pursuant to a physician's order for a specific patient may be prepared, and administration of such CSPs shall commence within 12 hours of preparation or as recommended in the manufacturers' package insert, whichever is less. Low risk level CSPs with a 12 hour or less BUD shall meet all of the following four criteria:~~

1. ~~PECs (LAFWs, BSCs, CAIs, CACIs,) shall be certified and maintain ISO Class 5 (see *Table 1*) as described in *Facility Design and Environmental Controls* for exposure of critical sites and shall be in a segregated compounding area restricted to sterile compounding activities that minimize the risk of CSP contamination.~~
2. ~~The segregated compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites, warehouses, or food preparation. Note that this list is not intended to be all inclusive.~~
3. ~~Personnel shall follow the procedures described in *Personnel Cleansing and Garbing* and *Additional Personnel Requirements* prior to compounding. Sinks~~

should not be located adjacent to the ISO Class 5 (see *Table 1*) PEC. Sinks should be separated from the immediate area of the ISO Class 5 (see *Table 1*) PEC device.

4. The specifications in *Cleaning and Disinfecting the Sterile Compounding Areas, Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures,* and *Viable and Nonviable Environmental Sampling (ES) Testing* shall be followed as described in the chapter.

Compounding personnel must recognize that the absence of an ISO Class 7 (see *Table 1*) buffer area environment in a general uncontrolled environment increases the potential of microbial contamination, and administration durations of microbially contaminated CSPs exceeding a few hours increase the potential for clinically significant microbial colonization, and thus for patient harm, especially in critically ill or immunocompromised patients.

Quality Assurance—Quality assurance practices include, but are not limited to the following:

1. Routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 (see *Table 1*) air quality.
2. Visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments, including eye protection and face masks.
3. Review of all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded.
4. Visual inspection of CSPs to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling.

Media Fill Test Procedure—This test or an equivalent test is performed at least annually by each person authorized to compound in a low risk level environment under conditions that closely simulate the most challenging or stressful conditions encountered during compounding of low risk level CSPs. Once begun, this test is completed without interruption. *Example of test procedure:* within an ISO Class 5 (see *Table 1*) air quality environment, three sets of four 5-mL aliquots of sterile Soybean–Casein Digest Medium (also known as trypticase soy broth or trypticase soy agar [TSA]) are transferred with the same sterile 10-mL syringe and vented needle combination into separate sealed, empty, sterile 30-mL clear vials (i.e., four 5-mL aliquots into each of three 30-mL vials). Sterile adhesive seals are aseptically affixed to the rubber closures on the three filled vials, then the vials are incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature (see *Microbiological Control and Monitoring of Aseptic Processing Environments* ⟨1116⟩). Inspect for microbial growth over 14 days as described in

~~*Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures*.~~

~~Medium Risk Level CSPs~~

~~When CSPs are compounded aseptically under *Low Risk Conditions* and one or more of the following conditions exists, such CSPs are at a medium risk of contamination.~~

~~Medium Risk Conditions~~

1. ~~Multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions.~~
2. ~~The compounding process includes complex aseptic manipulations other than the single volume transfer.~~
3. ~~The compounding process requires unusually long duration, such as that required to complete dissolution or homogeneous mixing.~~
4. ~~For a medium risk preparation, in the absence of passing a sterility test (see *Sterility Tests* ⟨71⟩), the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 30 hours at controlled room temperature (see *General Notices and Requirements*), for not more than 9 days at a cold temperature (see *General Notices and Requirements*), and for 45 days in solid frozen state between −25° and −10°.~~

~~Examples of Medium Risk Compounding~~

1. ~~Compounding of total parenteral nutrition fluids using manual or automated devices during which there are multiple injections, detachments, and attachments of nutrient source products to the device or machine to deliver all nutritional components to a final sterile container.~~
2. ~~Filling of reservoirs of injection and infusion devices with more than three sterile drug products and evacuation of air from those reservoirs before the filled device is dispensed.~~
3. ~~Transfer of volumes from multiple ampuls or vials into one or more final sterile containers.~~

~~Quality Assurance~~ ~~Quality assurance procedures for medium-risk level CSPs include all those for low-risk level CSPs, as well as a more challenging media-fill test passed annually or more frequently.~~

~~Media-Fill Test Procedure~~ ~~This test or an equivalent test is performed at least annually under conditions that closely simulate the most challenging or stressful conditions encountered during compounding. Once begun, this test is completed without interruption. *Example of test procedure:* within an ISO Class 5 (see *Table 1*) air quality environment, six 100-mL aliquots of sterile Soybean–Casein Digest Medium are aseptically transferred by gravity through separate tubing sets into separate evacuated sterile containers. The six containers are then arranged as three pairs, and a sterile 10-~~

~~mL syringe and 18-gauge needle combination is used to exchange two 5-mL aliquots of medium from one container to the other container in the pair. For example, after a 5-mL aliquot from the first container is added to the second container in the pair, the second container is agitated for 10 seconds, then a 5-mL aliquot is removed and returned to the first container in the pair. The first container is then agitated for 10 seconds, and the next 5-mL aliquot is transferred from it back to the second container in the pair. Following the two 5-mL aliquot exchanges in each pair of containers, a 5-mL aliquot of medium from each container is aseptically injected into a sealed, empty, sterile 10-mL clear vial, using a sterile 10-mL syringe and vented needle. Sterile adhesive seals are aseptically affixed to the rubber closures on the three filled vials, then the vials are incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature (see *Microbiological Control and Monitoring of Aseptic Processing Environments* ⟨1116⟩). Inspect for microbial growth over 14 days as described in *Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures*.~~

~~High-Risk Level CSPs~~

~~CSPs compounded under any of the following conditions are either contaminated or at a high risk to become contaminated.~~

~~High-Risk Conditions~~

1. ~~Nonsterile ingredients, including manufactured products not intended for sterile routes of administration (e.g., oral), are incorporated or a nonsterile device is employed before terminal sterilization.~~
2. ~~Any of the following are exposed to air quality worse than ISO Class 5 (see *Table 1*) for more than 1 hour (see *Immediate-Use CSPs*):~~
   - ~~sterile contents of commercially manufactured products,~~
   - ~~CSPs that lack effective antimicrobial preservatives, and~~
   - ~~sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs.~~
3. ~~Compounding personnel are improperly garbed and gloved (see *Personnel Cleansing and Use of Barrier Protective Equipment*).~~
4. ~~Nonsterile water-containing preparations are stored for more than 6 hours before being sterilized.~~
5. ~~It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or compendial specifications in unopened or in opened packages of bulk ingredients (see *Ingredient Selection* under *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).~~

~~For a sterilized high-risk level preparation, in the absence of passing a sterility test, the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 24 hours at controlled room temperature (see *General Notices and Requirements*), for not more than 3 days at a cold temperature (see *General Notices and Requirements*), and for 45 days in solid~~

~~frozen state between −25° and −10°. [Note—Sterility tests for autoclaved CSPs are not required unless they are prepared in batches of more than 25 units.]~~

~~All nonsterile measuring, mixing, and purifying devices are rinsed thoroughly with sterile, pyrogen-free water, and then thoroughly drained or dried immediately before use for high-risk compounding. All high-risk level CSP solutions subjected to terminal sterilization are prefiltered by passing through a filter with a nominal pore size not larger than 1.2 µm preceding or during filling into their final containers to remove particulate matter. Sterilization of high-risk level CSPs by filtration shall be performed with a sterile 0.2 µm or 0.22 µm nominal pore size filter entirely within an ISO Class 5 (see *Table 1*) or superior air quality environment.~~

~~Examples of High Risk Conditions~~—

1. ~~Dissolving nonsterile bulk drug and nutrient powders to make solutions that will be terminally sterilized.~~
2. ~~Exposing the sterile ingredients and components used to prepare and package CSPs to room air quality worse than ISO Class 5 (see *Table 1*) for more than 1 hour (see *Immediate-Use CSPs*).~~
3. ~~Measuring and mixing sterile ingredients in nonsterile devices before sterilization is performed.~~
4. ~~Assuming, without appropriate evidence or direct determination, that packages of bulk ingredients contain at least 95% by weight of their active chemical moiety and have not been contaminated or adulterated between uses.~~

~~Quality Assurance—~~~~Quality assurance procedures for high-risk level CSPs include all those for low-risk level CSPs. In addition, a media-fill test that represents high-risk level compounding is performed semiannually by each person authorized to compound high-risk level CSPs.~~

~~Media Fill Test Procedure for CSPs Sterilized by Filtration~~—~~This test or an equivalent test is performed under conditions that closely simulate the most challenging or stressful conditions encountered when compounding high-risk level CSPs. Once begun, this test is completed without interruption. *Example of test procedure*(in the following sequence):~~

1. ~~Dissolve 3 g of nonsterile commercially available Soybean–Casein Digest Medium in 100 mL of nonbacteriostatic water to make a 3% nonsterile solution.~~
2. ~~Draw 25 mL of the medium into each of three 30-mL sterile syringes. Transfer 5 mL from each syringe into separate sterile 10-mL vials. These vials are the positive controls to generate exponential microbial growth, which is indicated by visible turbidity upon incubation.~~
3. ~~Under aseptic conditions and using aseptic techniques, affix a sterile 0.2 µm or 0.22 µm nominal pore size filter unit and a 20-gauge needle to each syringe. Inject the next 10 mL from each syringe into three separate 10-mL sterile vials. Repeat the process for three more vials. Label all vials, affix sterile adhesive seals to the closure of the nine vials, and incubate them at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of~~

~~media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature (see *Microbiological Control and Monitoring of Aseptic Processing Environments* ⟨1116⟩). Inspect for microbial growth over 14 days as described in *Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures*.~~

~~PERSONNEL TRAINING AND EVALUATION IN ASEPTIC MANIPULATION SKILLS~~

~~Personnel who prepare CSPs shall be trained conscientiously and skillfully by expert personnel and through audio–video instructional sources and professional publications in the theoretical principles and practical skills of aseptic manipulations and in achieving and maintaining ISO Class 5 (see *Table 1*) environmental conditions before they begin to prepare CSPs. Compounding personnel shall perform didactic review and pass written and media-fill testing of aseptic manipulative skills initially, at least annually thereafter for low- and medium-risk level compounding, and semiannually for high-risk level compounding. Compounding personnel who fail written tests or whose media-fill test vials result in gross microbial colonization shall be immediately re-instructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies.~~

~~**Media-Fill Challenge Testing**—The skill of personnel to aseptically prepare CSPs may be evaluated using sterile fluid bacterial culture media-fill verification[4] (i.e., sterile bacterial culture medium transfer via a sterile syringe and needle). Media-fill testing is used to assess the quality of the aseptic skill of compounding personnel. Media-fill tests represent the most challenging or stressful conditions actually encountered by the personnel being evaluated when they prepare particular risk level CSPs and when sterilizing high-risk level CSPs. Media-fill challenge tests that simulate high-risk level compounding are also used to verify the capability of the compounding environment and process to produce a sterile preparation.~~

~~Commercially available sterile fluid culture media, such as Soybean–Casein Digest Medium (see *Sterility Tests* ⟨71⟩), shall be able to promote exponential colonization of bacteria that are most likely to be transmitted to CSPs from the compounding personnel and environment. Media-filled vials are generally incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature (see *Microbiological Control and Monitoring of Aseptic Processing Environments* ⟨1116⟩). Failure is indicated by visible turbidity in the medium on or before 14 days.~~

~~IMMEDIATE-USE CSPS~~

~~The immediate-use provision is intended only for those situations where there is a need for emergency or immediate patient administration of a CSP. Such situations may include cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical therapy where the preparation of the CSP under conditions described for *Low-Risk Level CSPs* subjects the patient to additional risk due to delays in therapy. Immediate-use CSPs are not intended for storage for anticipated needs or~~

~~batch compounding. Preparations that are medium risk level and high risk level CSPs shall not be prepared as immediate-use CSPs.~~

~~Immediate-use CSPs are exempt from the requirements described for *Low Risk Level CSPs* only when all of the following criteria are met:~~

1. ~~The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device. For example, anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs.~~
2. ~~Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour.~~
3. ~~During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces.~~
4. ~~Administration begins not later than 1 hour following the start of the preparation of the CSP.~~
5. ~~Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time.~~
6. ~~If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded.~~

~~Compounding in worse than ISO Class 5 (see *Table 1*) conditions increases the likelihood of microbial contamination, and administration durations of microbially contaminated CSPs exceeding a few hours increase the potential for clinically significant microbial colonization and thus for patient harm, especially in critically ill or immunocompromised patients.~~

~~SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS~~

~~Opened or needle-punctured single-dose containers, such as bags, bottles, syringes, and vials of sterile products and CSPs shall be used within 1 hour if opened in worse than ISO Class 5 (see *Table 1*) air quality (see *Immediate-Use CSPs*), and any remaining contents must be discarded. Single-dose vials exposed to ISO Class 5 (see *Table 1*) or cleaner air may be used up to 6 hours after initial needle puncture. Opened single-dose ampuls shall not be stored for any time period. Multiple-dose containers (e.g., vials) are formulated for removal of portions on multiple occasions because they usually contain antimicrobial preservatives. The BUD after initially entering or opening (e.g., needle-punctured) multiple-dose containers is 28 days (see *Antimicrobial Effectiveness Testing* ⟨51⟩) unless otherwise specified by the manufacturer.~~

~~HAZARDOUS DRUGS AS CSPS~~

~~Although the potential therapeutic benefits of compounded sterile hazardous drug preparations generally outweigh the risks of their adverse effects in ill patients, exposed healthcare workers risk similar adverse effects with no therapeutic benefit. Occupational exposure to hazardous drugs can result in (1) acute effects, such as skin rashes; (2) chronic effects, including adverse reproductive events; and (3) possibly cancer (see Appendix A of NIOSH Publication no. 2004-165).~~

~~Hazardous drugs shall be prepared for administration only under conditions that protect the healthcare workers and other personnel in the preparation and storage areas. Hazardous drugs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure. Many hazardous drugs have sufficient vapor pressures that allow volatilization at room temperature; thus storage is preferably within a containment area such as a negative pressure room. The storage area should have sufficient general exhaust ventilation, at least 12 air changes per hour (ACPH)[2] to dilute and remove any airborne contaminants.~~

~~Hazardous drugs shall be handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparation for administration, and disposal. Hazardous drugs shall be prepared in an ISO Class 5 (see *Table 1*) environment with protective engineering controls in place and following aseptic practices specified for the appropriate contamination risk levels defined in this chapter. Access shall be limited to areas where drugs are stored and prepared to protect persons not involved in drug preparation.~~

~~All hazardous drugs shall be prepared in a BSC[3] or a CACI that meets or exceeds the standards for CACI in this chapter. The ISO Class 5 (see *Table 1*) BSC or CACI shall be placed in an ISO Class 7 (see *Table 1*) area that is physically separated (i.e., a different area from other preparation areas) and optimally has not less than 0.01-inch water column negative pressure to adjacent positive pressure ISO Class 7 (see *Table 1*) or better ante-areas, thus providing inward airflow to contain any airborne drug. A pressure indicator shall be installed that can be readily monitored for correct room pressurization. The BSC and CACI optimally should be 100% vented to the outside air through HEPA filtration.~~

~~If a CACI that meets the requirements of this chapter is used outside of a buffer area, the compounding area shall maintain a minimum negative pressure of 0.01 inch water column and have a minimum of 12 ACPHs.~~

~~When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within the ISO Class 5 (see *Table 1*) environment of a BSC or CACI. The use of a CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable.~~

~~Appropriate personnel protective equipment (PPE) shall be worn when compounding in a BSC or CACI and when using CSTD devices. PPE should include gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, double gloving with~~

~~sterile chemo-type gloves, and compliance with manufacturers' recommendations when using a CACI.~~

~~All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs. This training shall occur prior to preparing or handling hazardous CSPs, and its effectiveness shall be verified by testing specific hazardous drugs preparation techniques. Such verification shall be documented for each person at least annually. This training shall include didactic overview of hazardous drugs, including mutagenic, teratogenic, and carcinogenic properties, and it shall include ongoing training for each new hazardous drug that enters the marketplace. Compounding personnel of reproductive capability shall confirm in writing that they understand the risks of handling hazardous drugs. The training shall include at least the following: (1) safe aseptic manipulation practices; (2) negative pressure techniques when utilizing a BSC or CACI; (3) correct use of CSTD devices; (4) containment, cleanup, and disposal procedures for breakages and spills; and (5) treatment of personnel contact and inhalation exposure.~~

~~NOTE—*Because standards of assay and unacceptable quantities of contamination of each drug have not been established in the literature, the following paragraph is a recommendation only. Future standards will be adopted as these assay methods are developed and proven.*~~

~~In order to ensure containment, especially in operations preparing large volumes of hazardous drugs, environmental sampling to detect uncontained hazardous drugs should be performed routinely (e.g., initially as a benchmark and at least every 6 months or more often as needed to verify containment). This sampling should include surface wipe sampling of the working area of BSCs and CACIs; counter tops where finished preparations are placed; areas adjacent to BSCs and CACIs, including the floor directly under the working area; and patient administration areas. Common marker hazardous drugs that can be assayed include cyclophosphamide, ifosfamide, methotrexate, and fluorouracil. If any measurable contamination (cyclophosphamide levels greater than 1.00 ng per cm^2 have been found to cause human uptake) is found by any of these quality assurance procedures, practitioners shall make the decision to identify, document, and contain the cause of contamination. Such action may include retraining, thorough cleaning (utilizing high pH soap and water), and improving engineering controls. Examples of improving engineering controls are (1) venting BSCs or CACIs 100% to the outside, (2) implementing a CSTD, or (3) re-assessing types of BSCs or CACIs.~~

~~Disposal of all hazardous drug wastes shall comply with all applicable federal and state regulations. All personnel who perform routine custodial waste removal and cleaning activities in storage and preparation areas for hazardous drugs shall be trained in appropriate procedures to protect themselves and prevent contamination.~~

~~RADIOPHARMACEUTICALS AS CSPS~~

~~In the case of production of radiopharmaceuticals for positron emission tomography (PET), general test chapter *Positron Emission Tomography Drugs for Compounding, Investigational, and Research Uses* ⟨823⟩ supersedes this chapter. Upon release of a PET radiopharmaceutical as a finished drug product from a production facility, the~~

further handling, manipulation, or use of the product will be considered compounding, and the content of this section and chapter is applicable.

For the purposes of this chapter, radiopharmaceuticals compounded from sterile components in closed sterile containers and with a volume of 100 mL or less for a single-dose injection or not more than 30 mL taken from a multiple-dose container (see *Packaging and Storage Requirements* (659). (CN 1-May-2016)) shall be designated as, and conform to, the standards for *Low-Risk Level CSPs.*

These radiopharmaceuticals shall be compounded using appropriately shielded vials and syringes in a properly functioning and certified ISO Class 5 (see *Table 1*) PEC located in an ISO Class 8 (see *Table 1*) or cleaner air environment to permit compliance with special handling, shielding, and negative air flow requirements.

Radiopharmaceutical vials designed for multi-use, compounded with technetium-99m, exposed to ISO Class 5 (see *Table 1*) environment, and punctured by needles with no direct contact contamination may be used up to the time indicated by manufacturers' recommendations. Storage and transport of properly shielded vials of radiopharmaceutical CSPs may occur in a limited access ambient environment without a specific ISO class designation.

Technetium-99m/molybdenum-99 generator systems shall be stored and eluted (operated) under conditions recommended by manufacturers and applicable state and federal regulations. Such generator systems shall be eluted in an ISO Class 8 (see *Table 1*) or cleaner air environment to permit special handling, shielding, and air flow requirements. To limit acute and chronic radiation exposure of inspecting personnel to a level that is as low as reasonably achievable (ALARA), direct visual inspection of radiopharmaceutical CSPs containing high concentrations of doses of radioactivity shall be conducted in accordance with ALARA.

Radiopharmaceuticals prepared as *Low-Risk Level CSPs with 12-Hour or Less BUD* shall be prepared in a segregated compounding area. A line of demarcation defining the segregated compounding area shall be established. Materials and garb exposed in a patient care and treatment area shall not cross a line of demarcation into the segregated compounding area.

ALLERGEN EXTRACTS AS CSPS

Allergen extracts as CSPs are single-dose and multiple-dose *intradermal or subcutaneous injections* that are prepared by specially trained physicians and personnel under their direct supervision. Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all *CSP Microbial Contamination Risk Levels* in this chapter only when all of the following criteria are met:

1. The compounding process involves simple transfer via sterile needles and syringes of commercial sterile allergen products and appropriate sterile added substances (e.g., glycerin, phenol in sodium chloride injection).
2. All allergen extracts as CSPs shall contain appropriate substances in effective concentrations to prevent the growth of microorganisms. Nonpreserved allergen extracts shall comply with the appropriate CSP risk level requirements in the chapter.

3. ~~Before beginning compounding activities, personnel perform a thorough hand-cleansing procedure by removing debris from under fingernails using a nail cleaner under running warm water followed by vigorous hand and arm washing to the elbows for at least 30 seconds with either nonantimicrobial or antimicrobial soap and water.~~
4. ~~Compounding personnel don hair covers, facial hair covers, gowns, and face masks.~~
5. ~~Compounding personnel perform antiseptic hand cleansing with an alcohol-based surgical hand scrub with persistent activity.~~
6. ~~Compounding personnel don powder-free sterile gloves that are compatible with sterile 70% isopropyl alcohol (IPA) before beginning compounding manipulations.~~
7. ~~Compounding personnel disinfect their gloves intermittently with sterile 70% IPA when preparing multiple allergen extracts as CSPs.~~
8. ~~Ampul necks and vial stoppers on packages of manufactured sterile ingredients are disinfected by careful wiping with sterile 70% IPA swabs to ensure that the critical sites are wet for at least 10 seconds and allowed to dry before they are used to compound allergen extracts as CSPs.~~
9. ~~The aseptic compounding manipulations minimize direct contact contamination (e.g., from glove fingertips, blood, nasal and oral secretions, shed skin and cosmetics, other nonsterile materials) of critical sites (e.g., needles, opened ampuls, vial stoppers).~~
10. ~~The label of each multiple-dose vial (MDV) of allergen extracts as CSPs lists the name of one specific patient and a BUD and storage temperature range that is assigned based on manufacturers' recommendations or peer-reviewed publications.~~
11. ~~Single-dose allergen extracts as CSPs shall not be stored for subsequent additional use.~~

~~Personnel who compound allergen extracts as CSPs must be aware of greater potential risk of microbial and foreign material contamination when allergen extracts as CSPs are compounded in compliance with the foregoing criteria instead of the more rigorous standards in this chapter for *CSP Microbial Contamination Risk Levels.* Although contaminated allergen extracts as CSPs can pose health risks to patients when they are injected *intradermally or subcutaneously,* these risks are substantially greater if the extract is inadvertently injected *intravenously.*~~

~~VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY~~

~~The compounding procedures and sterilization methods for CSPs correspond to correctly designed and verified written documentation in the compounding facility. Verification requires planned testing, monitoring, and documentation to demonstrate adherence to environmental quality requirements, personnel practices, and procedures critical to achieving and maintaining sterility, accuracy, and purity of finished CSPs. For example, sterility testing (see *Test for Sterility of the Product To Be Examined* under *Sterility Tests* ⟨71⟩) may be applied to specimens of low- and medium-risk level CSPs, and standard self-contained biological indicators (BI) shall be added to nondispensable~~

~~specimens of high-risk level CSPs before terminal sterilization for subsequent evaluation to determine whether the sterilization cycle was adequate (see *Biological Indicators for Sterilization* ⟨1035⟩). Packaged and labeled CSPs shall be visually inspected for physical integrity and expected appearance, including final fill amount. The accuracy of identities, concentrations, amounts, and purities of ingredients in CSPs shall be confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling and certificates of analysis provided by suppliers. When the correct identity, purity, strength, and sterility of ingredients and components of CSPs cannot be confirmed (in cases of, for example, unlabeled syringes, opened ampuls, punctured stoppers of vials and bags, containers of ingredients with incomplete labeling), such ingredients and components shall be discarded immediately.~~

~~Some individual ingredients, such as bulk drug substances, are not labeled with expiration dates when they are stable indefinitely in their commercial packages under their labeled storage conditions. However, despite retaining full chemical stability, such ingredients may gain or lose moisture during storage and use. Changes in moisture content may require testing (see *Loss on Drying* ⟨731⟩) to determine the correct amount to weigh for accurate content of active chemical moieties in CSPs (see *Pharmaceutical Calculations in Prescription Compounding* ⟨1160⟩).~~

~~Although not required, a quantitative stability-indicating chemical assay is recommended to ensure compounding accuracy of CSPs, especially those that contain drug ingredients with a narrow therapeutic plasma concentration range.~~

~~Sterilization Methods~~

~~The licensed healthcare professionals who supervise compounding shall be responsible for determining that the selected sterilization method (see *Methods of Sterilization* under *Sterilization and Sterility Assurance of Compendial Articles* ⟨1211⟩) both sterilizes and maintains the strength, purity, quality, and packaging integrity of CSPs. The selected sterilization process is obtained from experience and appropriate information sources (e.g., see *Sterilization and Sterility Assurance of Compendial Articles* ⟨1211⟩)—and, preferably, verified wherever possible—to achieve sterility in the particular CSPs. General guidelines for matching CSPs and components to appropriate sterilization methods include the following:~~

1. ~~CSPs have been ascertained to remain physically and chemically stable when subjected to the selected sterilization method.~~
2. ~~Glass and metal devices may be covered tightly with aluminum foil, then exposed to dry heat in an oven at a mean temperature of 250° for 30 minutes to achieve sterility and depyrogenation (see *Dry-Heat Sterilization* under *Sterilization and Sterility Assurance of Compendial Articles* ⟨1211⟩ and *Bacterial Endotoxins Test* ⟨85⟩). Such items are either used immediately or stored until use in an environment suitable for compounding *Low-Risk Level CSPs* and *Medium-Risk Level CSPs.*~~
3. ~~Personnel ascertain from appropriate information sources that the sterile microporous membrane filter used to sterilize CSP solutions, during either~~

~~compounding or administration, is chemically and physically compatible with the CSP.~~

~~STERILIZATION OF HIGH-RISK LEVEL CSPS BY FILTRATION~~

~~Commercially available sterile filters shall be approved for human-use applications in sterilizing pharmaceutical fluids. Sterile filters used to sterilize CSPs shall be pyrogen free and have a nominal pore size of 0.2 or 0.22 µm. They shall be certified by the manufacturer to retain at least 10^7 microorganisms of a strain of *Brevundimonas (Pseudomonas) diminuta* on each square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be sterilized (see *High-Risk Conditions* in *High-Risk Level CSPs*).~~

~~The compounding supervisor shall ensure, directly or from appropriate documentation, that the filters are chemically and physically stable at the pressure and temperature conditions to be used, that they have enough capacity to filter the required volumes, and that they will achieve sterility and maintain prefiltration pharmaceutical quality, including strength of ingredients of the specific CSP. The filter dimensions and liquid material to be sterile filtered shall permit the sterilization process to be completed rapidly, without the replacement of the filter during the process. When CSPs are known to contain excessive particulate matter, a prefilter of larger nominal pore size membrane is placed upstream from the sterilizing filter to remove gross particulate contaminants in order to maximize the efficiency of the sterilizing filter.~~

~~Filter units used to sterilize CSPs shall also be subjected to manufacturers' recommended integrity test, such as the bubble point test.~~

~~Compounding personnel shall ascertain that selected filters will achieve sterilization of the particular CSPs being sterilized. Large deviations from usual or expected chemical and physical properties of CSPs (e.g., water-miscible alcohols) may cause undetectable damage to filter integrity and shrinkage of microorganisms to sizes smaller than filter nominal pore size.~~

~~STERILIZATION OF HIGH-RISK LEVEL CSPS BY STEAM~~

~~The process of thermal sterilization employing saturated steam under pressure, or autoclaving, is the preferred method to terminally sterilize aqueous preparations that have been verified to maintain their full chemical and physical stability under the conditions employed (see *Steam Sterilization* under *Sterilization and Sterility Assurance of Compendial Articles* ⟨1211⟩). To achieve sterility, all materials are to be exposed to steam at 121° under a pressure of about 1 atmosphere or 15 psi for the duration verified by testing to achieve sterility of the items, which is usually 20 to 60 minutes for CSPs. An allowance shall be made for the time required for the material to reach 121° before the sterilization exposure duration is timed.~~

~~Not directly exposing items to pressurized steam may result in survival of microbial organisms and spores. Before their sterilization, plastic, glass, and metal devices are tightly wrapped in low particle-shedding paper or fabrics or sealed in envelopes that prevent poststerilization microbial penetration. Immediately before filling ampuls and vials that will be steam sterilized, solutions are passed through a filter having a nominal pore size not larger than 1.2 µm for removal of particulate matter. Sealed containers shall be able to generate steam internally; thus, stoppered and crimped empty vials shall contain a small amount of moisture to generate steam.~~

~~The description of steam sterilization conditions and duration for specific CSPs shall be included in written documentation in the compounding facility. The effectiveness of steam sterilization shall be verified using appropriate BIs of *Bacillus stearothermophilus* (see *Biological Indicators* ⟨1035⟩) and other confirmation methods such as temperature-sensing devices (see *Sterilization and Sterility Assurance of Compendial Articles* ⟨1211⟩ and *Sterility Tests* ⟨71⟩).~~

~~STERILIZATION OF HIGH-RISK LEVEL CSPS BY DRY HEAT~~

~~Dry heat sterilization is usually done as a batch process in an oven designed for sterilization. Heated filtered air shall be evenly distributed throughout the chamber by a blower device. The oven should be equipped with a system for controlling temperature and exposure period. Sterilization by dry heat requires higher temperatures and longer exposure times than does sterilization by steam. Dry heat shall be used only for those materials that cannot be sterilized by steam, when either the moisture would damage the material or the material is impermeable. During sterilization, sufficient space shall be left between materials to allow for good circulation of the hot air. The description of dry heat sterilization conditions and duration for specific CSPs shall be included in written documentation in the compounding facility. The effectiveness of dry heat sterilization shall be verified using appropriate BIs of *Bacillus subtilis* (see *Biological Indicators* ⟨1035⟩) and other confirmation methods such as temperature-sensing devices (see *Sterilization and Sterility Assurance of Compendial Articles* ⟨1211⟩ and *Sterility Tests* ⟨71⟩). [Note—Dry heat sterilization may be performed at a lower temperature than may be effective for depyrogenation] .~~

~~Depyrogenation by Dry Heat~~

~~Dry heat depyrogenation shall be used to render glassware or containers such as vials free from pyrogens as well as viable microbes. A typical cycle would be 30 minutes at 250°. The description of the dry heat depyrogenation cycle and duration for specific load items shall be included in written documentation in the compounding facility. The effectiveness of the dry heat depyrogenation cycle shall be verified using endotoxin challenge vials (ECVs). The bacterial endotoxin test should be performed on the ECVs to verify that the cycle is capable of achieving a 3-log reduction in endotoxin (see *Sterilization and Sterility Assurance of Compendial Articles* ⟨1211⟩ and *Bacterial Endotoxins Test* ⟨85⟩).~~

~~ENVIRONMENTAL QUALITY AND CONTROL~~

~~Achieving and maintaining sterility and overall freedom from contamination of a CSP is dependent on the quality status of the components incorporated, the process utilized, personnel performance, and the environmental conditions under which the process is performed. The standards required for the environmental conditions depend on the amount of exposure of the CSP to the immediate environment anticipated during processing. The quality and control of environmental conditions for each risk level of operation are explained in this section. In addition, operations using nonsterile components require the use of a method of preparation designed to produce a sterile preparation.~~

~~Exposure of Critical Sites~~

~~Maintaining the sterility and cleanliness (i.e., freedom from sterile foreign materials) of critical sites is a primary safeguard for CSPs. Critical sites are locations that include any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampuls, needle hubs) exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination. The risk of, or potential for, critical sites to be contaminated with microorganisms and foreign matter increases with increasing exposed area of the critical sites, the density or concentration of contaminants, and exposure duration to worse than ISO Class 5 (see *Table 1*) air. Examples include an opened ampul or vial stopper on a 10 mL or larger vial or an injection port on a package of intravenous solution having an area larger than the point of a needle or the tip of a syringe.~~

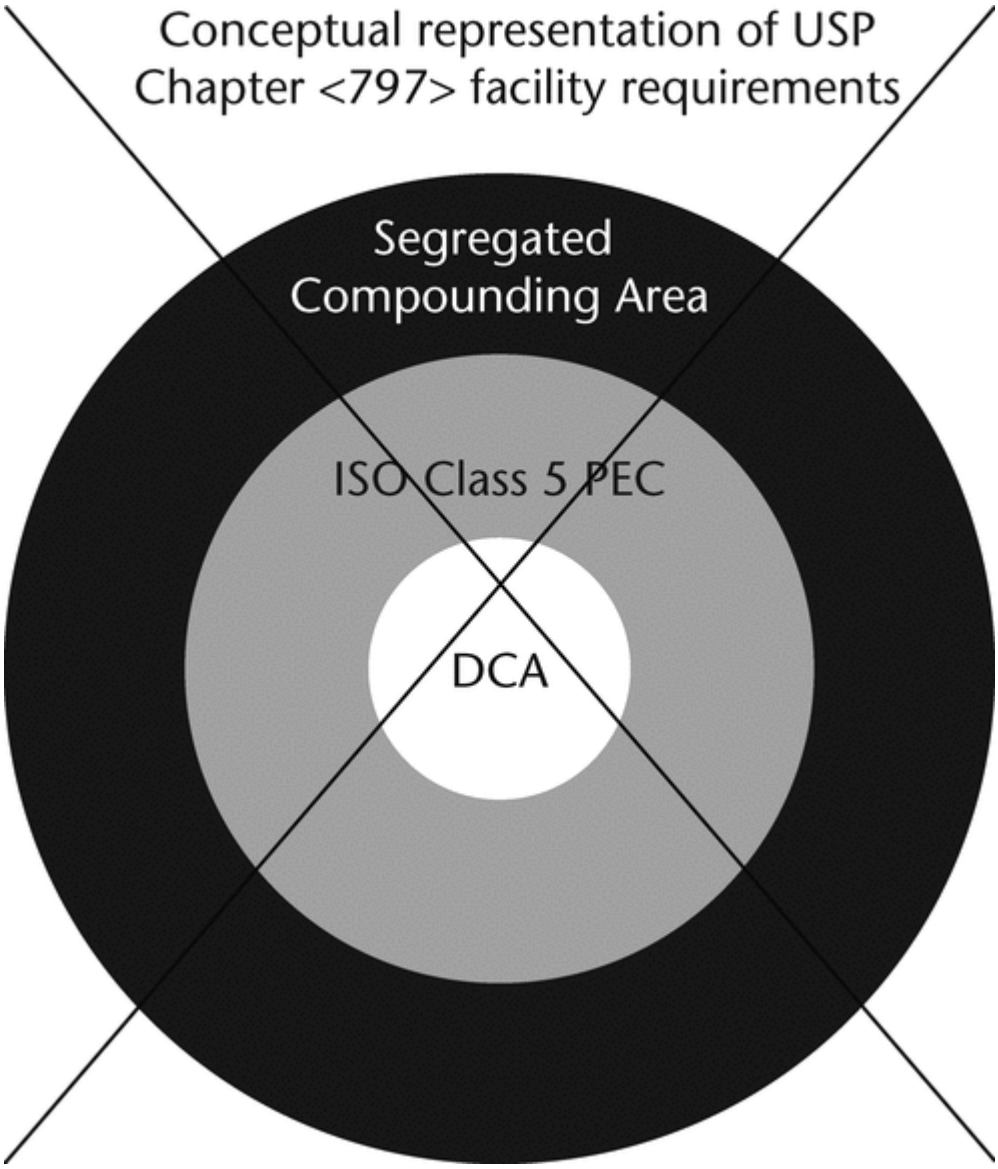
~~The nature of a critical site also affects the risk of contamination. The relatively rough, permeable surface of an elastomeric closure retains microorganisms and other contaminants after swabbing with a sterile 70% IPA pad more readily than does the smoother glass surface of the neck of an ampul. Therefore, the surface disinfection can be expected to be more effective for an ampul.~~

~~Protection of critical sites by precluding physical contact and airborne contamination shall be given the highest priority in sterile compounding practice. Airborne contaminants, especially those generated by sterile compounding personnel, are much more likely to reach critical sites than are contaminants that are adhering to the floor or other surfaces below the work level. Furthermore, large and high-density particles that are generated and introduced by compounding manipulations and personnel have the potential to settle on critical sites even when those critical sites are exposed within ISO Class 5 (see *Table 1*) air.~~

~~ISO Class 5 Air Sources, Buffer Areas, and Ante Areas~~

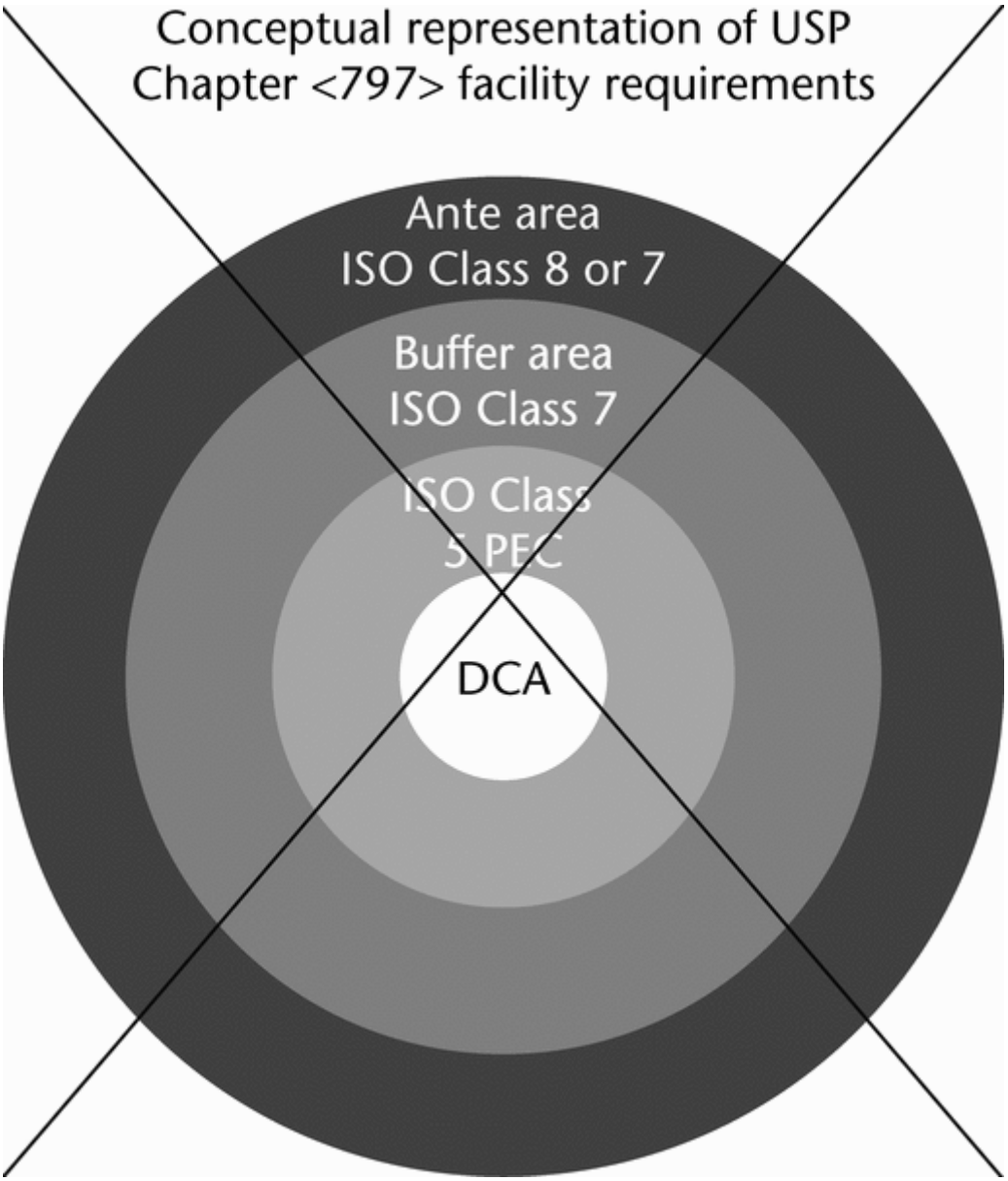
~~The most common sources of ISO Class 5 (see *Table 1*) air quality for exposure of critical sites are horizontal and vertical LAFWs, CAIs, and CACIs. A clean room (see *Microbiological Control and Monitoring of Aseptic Processing Environments* ⟨1116⟩) is a compounding environment that is supplied with HEPA or HEPA filtered air that meets ISO Class 7 (see *Table 1*), the access to which is limited to personnel trained and authorized to perform sterile compounding and facility cleaning. A buffer area is an area that provides at least ISO Class 7 (see *Table 1*) air quality.~~

~~*Figure 1* is a conceptual representation of the placement of an ISO Class 5 (see *Table 1*) PEC in a segregated compounding area used for low risk level CSPs with 12 hour or less BUD. This plan depicts the most critical operation area located within the PEC in a designated area (see definition of *Segregated Compounding Area*) separated from activities not essential to the preparation of CSPs. Placement of devices (e.g., computers, printers) and objects (e.g., carts, cabinets) that are not essential to compounding in the segregated area should be restricted or limited, depending on their effect on air quality in the ISO Class 5 (see *Table 1*) PEC.~~



~~Figure 1. Conceptual representation of the placement of an ISO Class 5 PEC in a segregated compounding area used for low risk level CSPs with 12-hour or less BUD.~~

~~*Figure 2* is a conceptual representation of the arrangement of a facility for preparation of CSPs categorized as low , medium , and high risk level. The quality of the environmental air increases with movement from the outer boundary to the direct compounding area (DCA). Placement of devices in ante-areas and buffer areas is dictated by their effect on the designated environmental quality of atmospheres and surfaces, which shall be verified by monitoring (see *Viable and Nonviable Environmental Sampling (ES) Testing*). It is the responsibility of each compounding facility to ensure that each source of ISO Class 5 (see *Table 1*) environment for exposure of critical sites and sterilization by filtration is properly located, operated, maintained, monitored, and verified.~~



~~Figure 2. Conceptual representation of the arrangement of a facility for preparation of CSPs categorized as low , medium , and high risk level.~~

~~Placement of devices (e.g., computers, printers) and objects (e.g., carts, cabinets) that are not essential to compounding in buffer areas is dictated by their effect on the required environmental quality of air atmospheres and surfaces, which shall be verified by monitoring (see *Viable and Nonviable Environmental Sampling (ES) Testing*). It is the responsibility of each compounding facility to ensure that each source of ISO Class 5 (see *Table 1*) environment for exposure of critical sites and sterilization by filtration is properly located, operated, maintained, monitored, and verified.~~

~~Facility Design and Environmental Controls~~

~~Compounding facilities are physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites. These facilities shall also provide a comfortable and well-lighted working environment, which typically includes a temperature of 20° or cooler, to maintain comfortable conditions for compounding personnel to perform flawlessly when attired in the required aseptic compounding garb. PECs typically include, but are not limited to, LAFWs, BSCs, CAIs, and CACIs, which provide an ISO Class 5 (see *Table 1*) environment for the exposure of critical sites. PECs shall maintain ISO Class 5 (see *Table 1*) or better conditions for 0.5 µm particles (dynamic operating conditions) while compounding CSPs. Secondary engineering controls such as buffer areas and ante-areas generally serve as a core for the location of the PEC. Buffer areas are designed to maintain at least ISO Class 7 (see *Table 1*) conditions for 0.5 µm particles under dynamic conditions and ISO Class 8 (see *Table 1*) conditions for 0.5 µm and larger particles under dynamic conditions for the ante-areas. Airborne contamination control is achieved in the PEC through the use of HEPA filters. The airflow in the PEC shall be unidirectional (laminar flow), and because of the particle collection efficiency of the filter, the "first air" at the face of the filter is, for the purposes of aseptic compounding, free from airborne particulate contamination. HEPA-filtered air shall be supplied in critical areas (ISO Class 5, see *Table 1*) at a velocity sufficient to sweep particles away from the compounding area and maintain unidirectional airflow during operations. Proper design and control prevents turbulence and stagnant air in the critical area. In situ air pattern analysis via smoke studies shall be conducted at the critical area to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions.~~

~~The principles of HEPA-filtered unidirectional airflow in the work environment shall be understood and practiced in the compounding process in order to achieve the desired environmental conditions. Policies and procedures for maintaining and working within the PEC area shall be written and followed. The policies and procedures will be determined by the scope and risk levels of the aseptic compounding activities utilized during the preparation of the CSPs. The CSP work environment is designed to have the cleanest work surfaces (PEC) located in a buffer area. The buffer area shall maintain at least ISO Class 7 (see *Table 1*) conditions for 0.5 µm and larger particles under dynamic operating conditions. The room shall be segregated from surrounding, unclassified spaces to reduce the risk of contaminants being blown, dragged, or otherwise introduced into the filtered unidirectional airflow environment, and this segregation shall be continuously monitored. For rooms providing a physical separation through the use of walls, doors, and pass-throughs, a minimum differential positive pressure of 0.02- to 0.05-inch water column is required. For buffer areas not physically separated from the ante-areas, the principle of displacement airflow shall be employed. This concept utilizes a low pressure differential, high airflow principle. Using displacement airflow typically requires an air velocity of 40 ft per minute or more from the buffer area across the line of demarcation into the ante-area.~~

~~The displacement concept shall not be used for high-risk compounding.[4] The PEC shall be placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation. For example, strong air currents from opened doors, personnel traffic, or air streams from the HVAC systems can disrupt the unidirectional airflow in open-faced workbenches. The operators may also create disruptions in airflow~~

~~by their own movements and by the placement of objects onto the work surface. The PEC shall be placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross-drafts. Room air exchanges are typically expressed as ACPHs. Adequate HEPA-filtered airflow supplied to the buffer area and ante-area is required to maintain cleanliness classification during operational activity through the number of ACPHs. Factors that should be considered when determining air-change requirements include number of personnel working in the room and compounding processes that generate particulates, as well as temperature effects. An ISO Class 7 (see *Table 1*) buffer area and ante-area supplied with HEPA-filtered air shall receive an ACPH of not less than 30. The PEC is a good augmentation to generating air changes in the air supply of an area but cannot be the sole source of HEPA-filtered air. If the area has an ISO Class 5 (see *Table 1*) recirculating device, a minimum of 15 ACPHs through the area supply HEPA filters is adequate, providing the combined ACPH is not less than 30. More air changes may be required, depending on the number of personnel and processes. HEPA-filtered supply air shall be introduced at the ceiling, and returns should be mounted low on the wall, creating a general top-down dilution of area air with HEPA-filtered make-up air. Ceiling-mounted returns are not recommended. All HEPA filters should be efficiency tested using the most penetrating particle size and should be leak tested at the factory and then leak tested again in situ after installation.[5]~~

~~Activities and tasks carried out within the buffer area shall be limited to only those necessary when working within a controlled environment. Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed shall be brought into the area, and they shall be nonpermeable, nonshedding, cleanable, and resistant to disinfectants. Whenever such items are brought into the area, they shall first be cleaned and disinfected. Whenever possible, equipment and other items used in the buffer area shall not be taken out of the area except for calibration, servicing, or other activities associated with the proper maintenance of the item.~~

~~The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area shall be smooth, impervious, free from cracks and crevices, and nonshedding, thereby promoting cleanability and minimizing spaces in which microorganisms and other contaminants may accumulate. The surfaces shall be resistant to damage by disinfectant agents. Junctures of ceilings to walls shall be coved or caulked to avoid cracks and crevices where dirt can accumulate. If ceilings consist of inlaid panels, the panels shall be impregnated with a polymer to render them impervious and hydrophobic, and they shall be caulked around each perimeter to seal them to the support frame. Walls may be constructed of flexible material (e.g., heavy gauge polymer), panels locked together and sealed, or of epoxy-coated gypsum board. Preferably, floors are overlaid with wide sheet vinyl flooring with heat-welded seams and coving to the sidewall. Dust-collecting overhangs, such as ceiling utility pipes, and ledges, such as windowsills, should be avoided. The exterior lens surface of ceiling lighting fixtures should be smooth, mounted flush, and sealed. Any other penetrations through the ceiling or walls shall be sealed. The buffer area shall not contain sources of water (sinks) or floor drains. Work surfaces shall be constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. Carts should be of stainless steel wire, nonporous plastic, or sheet metal~~

~~construction with good quality, cleanable casters to promote mobility. Storage shelving, counters, and cabinets shall be smooth, impervious, free from cracks and crevices, nonshedding, cleanable, and disinfectable; their number, design, and manner of installation shall promote effective cleaning and disinfection.~~

~~Placement of Primary Engineering Controls~~

~~PECs (LAFWs, BSCs, CAIs, and CACIs) shall be located within a restricted access ISO Class 7 (see *Table 1*) buffer area (see *Figure 1*), with the following CAI/CACI exceptions below:~~

- ~~Only authorized personnel and materials required for compounding and cleaning shall be permitted in the buffer area.~~
- ~~Presterilization procedures for high risk level CSPs, such as weighing and mixing, shall be completed in no worse than an ISO Class 8 (see *Table 1*) environment.~~
- ~~PECs shall be located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns.~~

~~CAIs and CACIs shall be placed in an ISO Class 7 (see *Table 1*) buffer area *unless* they meet all of the following conditions:~~

- ~~The isolator shall provide isolation from the room and maintain ISO Class 5 (see *Table 1*) during dynamic operating conditions, including transferring ingredients, components, and devices into and out of the isolator and during preparation of CSPs.~~
- ~~Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site shall maintain ISO Class 5 (see *Table 1*) levels during compounding operations.~~
- ~~Not more than 3520 particles (0.5 µm and larger) per m^3 shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing the transfer.~~[6]

~~It is incumbent on the compounding personnel to obtain documentation from the manufacturer that the CAI/CACI will meet this standard when located in environments where the background particle counts exceed ISO Class 8 (see *Table 1*) for 0.5-µm and larger particles. When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 (see *Table 1*) air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.~~

~~If the PEC is a CAI or CACI that does not meet the requirements above or is a LAFW or BSC that cannot be located within an ISO Class 7 (see *Table 1*) buffer area, then only low risk level nonhazardous and radiopharmaceutical CSPs pursuant to a physician order for a specific patient may be prepared, and administration of the CSP shall commence within 12 hours of preparation or as recommended in the manufacturer's package insert, whichever is less.~~

~~Viable and Nonviable Environmental Sampling (ES) Testing~~

~~The ES program should provide information to staff and leadership to demonstrate that the PEC is maintaining an environment within the compounding area that consistently ensures acceptably low viable and nonviable particle levels. The compounding area includes the ISO Class 5 (see *Table 1*) PEC (LAFWs, BSCs, CAIs, and CACIs), buffer areas, ante-areas, and segregated compounding areas.~~

~~Environmental sampling shall occur as part a comprehensive quality management program and shall occur minimally under any of the following conditions:~~

- ~~as part of the commissioning and certification of new facilities and equipment;~~
- ~~following any servicing of facilities and equipment;~~
- ~~as part of the re-certification of facilities and equipment (i.e., every 6 months);~~
- ~~in response to identified problems with end products or staff technique; or~~
- ~~in response to issues with CSPs, observed compounding personnel work practices, or patient related infections (where the CSP is being considered as a potential source of the infection).~~

~~ENVIRONMENTAL NONVIABLE PARTICLE TESTING PROGRAM~~

~~A program to sample nonviable airborne particles differs from that for viable particles in that it is intended to directly measure the performance of the engineering controls used to create the various levels of air cleanliness, for example, ISO Class 5, 7, or 8 (see *Table 1*).~~

~~**Engineering Control Performance Verification**—PECs (LAFWs, BSCs, CAIs, and CACIs) and secondary engineering controls (buffer and ante-areas) are essential components of the overall contamination control strategy for aseptic compounding. As such, it is imperative that they perform as designed and that the resulting levels of contamination be within acceptable limits. Certification procedures such as those outlined in *Certification Guide for Sterile Compounding Facilities* (CAG-003-2006)[7] shall be performed by a qualified individual no less than every 6 months and whenever the device or room is relocated or altered or major service to the facility is performed.~~

~~**Total Particle Counts**—Certification that each ISO classified area, for example, ISO Class 5, 7, and 8 (see *Table 1*), is within established guidelines shall be performed no less than every 6 months and whenever the LAFW, BSC, CAI, or CACI is relocated or the physical structure of the buffer area or ante-area has been altered. Testing shall be performed by qualified operators using current, state-of-the-art electronic equipment with results of the following:~~

- ~~ISO Class 5: not more than 3520 particles 0.5 µm and larger size per cubic meter of air for any LAFW, BSC, CAI, and CACI;~~
- ~~ISO Class 7: not more than 352,000 particles of 0.5 µm size and larger per cubic meter of air for any buffer area;~~
- ~~ISO Class 8: not more than 3,520,000 particles or 0.5 µm size and larger per cubic meter of air for any ante-area.~~

~~All certification records shall be maintained and reviewed by supervising personnel or other designated employees to ensure that the controlled environments comply with the proper air cleanliness, room pressures, and ACPHs.~~

~~PRESSURE DIFFERENTIAL MONITORING~~

~~A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer area and the ante-area and between the ante-area and the general environment outside the compounding area. The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device. The pressure between the ISO Class 7 (see *Table 1*) and the general pharmacy area shall not be less than 5 Pa (0.02 inch water column). In facilities where low- and medium-risk level CSPs are prepared, differential airflow shall maintain a minimum velocity of 0.2 meters per second (40 feet per minute) between buffer area and ante-area.~~

~~ENVIRONMENTAL VIABLE AIRBORNE PARTICLE TESTING PROGRAM~~

~~The risk of contaminating a CSP prepared under low-risk level and medium-risk level conditions is highly dependent on proper hand hygiene and garbing practices, compounding personnel aseptic technique, and the presence of surface contamination, assuming that all work is performed in a certified and properly functioning ISO Class 5 (see *Table 1*) PEC and secondary engineering controls, ISO Class 7 (see *Table 1*) buffer area, and ISO Class 8 (see *Table 1*) ante-area. High-risk level CSPs pose the greatest threat to patients because compounding personnel are tasked with the requirement of processing nonsterile components and devices in order to achieve sterility.~~

~~A sampling program in conjunction with an observational audit is designed to evaluate the competency of compounding personnel work practices, allowing for the implementation of corrective actions on an ongoing basis (see *Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures*).~~

~~**Sampling Plan**—An appropriate environmental sampling plan shall be developed for airborne viable particles based on a risk assessment of compounding activities performed.~~

~~Selected sampling sites shall include locations within each ISO Class 5 (see *Table 1*) environment and in the ISO Class 7 and 8 (see *Table 1*) areas and in the segregated compounding areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 [see *Table 1*] environment, counters near doors, pass-through boxes). The plan shall include sample location, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels.~~

~~Review of the data generated during a sampling event may detect elevated amounts of airborne microbial bioburden; such changes may be indicative of adverse changes within the environment. It is recommended that compounding personnel refer to *Microbiological Control and Monitoring of Aseptic Processing Environments* (1116) and the CDC's "Guidelines for Environmental Infection Control in Healthcare Facilities, 2003" for more information.~~

~~**Growth Medium**—A general microbiological growth medium such as Soybean–Casein Digest Medium shall be used to support the growth of bacteria. Malt extract agar or some other media that supports the growth of fungi shall be used in high-risk level compounding environments. Media used for surface sampling must be supplemented with additives to neutralize the effects of disinfecting agents (e.g., TSA with lecithin and polysorbate 80).~~

~~**Viable Air Sampling—**Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments (LAFWs, CAIs, clean room or buffer areas, and ante-areas) shall be performed by properly trained individuals for all compounding risk levels.~~

~~Impaction shall be the preferred method of volumetric air sampling. Use of settling plates for qualitative air sampling may not be able to determine adequately the quality of air in the controlled environment. The settling of particles by gravity onto culture plates depends on the particle size and may be influenced by air movement. Consequently, the number of colony forming units (cfu) on a settling plate may not always relate to the concentrations of viable particles in the sampled environment.~~

~~For low-, medium-, and high-risk level compounding, air sampling shall be performed at locations that are prone to contamination during compounding activities and during other activities such as staging, labeling, gowning, and cleaning. Locations shall include zones of air backwash turbulence within LAFW and other areas where air backwash turbulence may enter the compounding area (doorways, in and around ISO Class 5 [see *Table 1*] PEC and environments). Consideration should be given to the overall effect the chosen sampling method will have on the unidirectional airflow within a compounding environment.~~

~~For low-risk level CSPs with 12-hour or less BUD prepared in a PEC (LAFWs, BSCs, CAIs) that maintains an ISO Class 5 (see *Table 1*), air sampling shall be performed at locations inside the ISO Class 5 (see *Table 1*) environment and other areas that are in close proximity to the ISO Class 5 (see *Table 1*) environment during the certification of the PEC.~~

~~**Air Sampling Devices—**There are a number of manufacturers of electronic air sampling equipment. It is important that personnel refer to the manufacturer's recommended procedures when using the equipment to perform volumetric air sampling procedures. The instructions in the manufacturer's user's manual for verification and use of electric air samplers that actively collect volumes of air for evaluation must be followed. A sufficient volume of air (400 to 1000 liters) shall be tested at each location in order to maximize sensitivity. The volumetric air sampling devices need to be serviced and calibrated as recommended by the manufacturer.~~

~~It is recommended that compounding personnel also refer to *Methodology and Instrumentation for Quantitation of Viable Airborne Microorganisms* under *Microbiological Control and Monitoring of Aseptic Processing Environments* (1116), which provides more information on the use of volumetric air samplers and volume of air that should be sampled to detect environmental bioburden excursions.~~

~~**Air Sampling Frequency and Process—**Air sampling shall be performed at least semiannually (i.e., every 6 months) as part of the re-certification of facilities and equipment. If compounding occurs in multiple locations within an institution (e.g., main~~

~~pharmacy, satellites), environmental sampling is required for each individual compounding area. A sufficient volume of air shall be sampled and the manufacturer's guidelines for use of the electronic air sampling equipment followed. Any facility construction or equipment servicing may require that air sampling be performed during these events.~~

~~**Incubation Period**—At the end of the designated sampling or exposure period for air sampling activities, the microbial growth media plates are recovered and their covers secured (e.g., taped), and they are inverted and incubated at a temperature and for a time period conducive to multiplication of microorganisms. TSA should be incubated at 30° to 35° for 48 to 72 hours. Malt extract agar or other suitable fungal media should be incubated at 26° to 30° for 5 to 7 days. The number of discrete colonies of microorganisms are counted and reported as cfu and documented on an environmental sampling form. Counts from air sampling need to be transformed into cfu per cubic meter of air and evaluated for adverse trends.~~

~~**Action Levels, Documentation, and Data Evaluation—**The value of viable microbial sampling of the air in the compounding environment is realized when the data are used to identify and correct an unacceptable situation. Sampling data shall be collected and reviewed on a periodic basis as a means of evaluating the overall control of the compounding environment. If an activity consistently shows elevated levels of microbial growth, competent microbiology personnel shall be consulted.~~

~~Any cfu count that exceeds its respective action level (see *Table 2*) should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location. An investigation into the source of the contamination shall be conducted. Sources could include HVAC systems, damaged HEPA filters, and changes in personnel garbing or work practices. The source of the problem shall be eliminated, the affected area cleaned, and resampling performed.~~

~~Counts of cfu are to be used as an approximate measure of the environmental microbial bioburden. Action levels are determined on the basis of cfu data gathered at each sampling location and trended over time. The numbers in *Table 2* should be used only as guidelines. Regardless of the number of cfu identified in the pharmacy, further corrective actions will be dictated by the identification of microorganisms recovered (at least the genus level) by an appropriate credentialed laboratory of any microbial bioburden captured as a cfu using an impaction air sampler. Highly pathogenic microorganisms (e.g., Gram-negative rods, coagulase positive staphylococcus, molds and yeasts) can be potentially fatal to patients receiving CSPs and must be immediately remedied, regardless of cfu count, with the assistance of a competent microbiologist, infection control professional, or industrial hygienist.~~

~~**Table 2. Recommended Action Levels for Microbial Contamination***~~
~~†(cfu per cubic meter [1000 liters] of air per plate)~~

~~**Classification**~~	~~**Air Sample†**~~
~~ISO Class 5~~	~~> 1~~
~~ISO Class 7~~	~~> 10~~

~~Classification~~	~~Air Sample†~~
~~ISO Class 8 or worse~~	~~> 100~~
~~* Guidance for Industry–Sterile Drug Products Produced by Aseptic Processing–Current Good Manufacturing Practice–US HHS, FDA September 2004.~~	

~~Additional Personnel Requirements~~

~~Food, drinks, and materials exposed in patient care and treatment areas shall not enter ante-areas, buffer areas, or segregated compounding areas where components and ingredients of CSPs are present. When compounding activities require the manipulation of a patient's blood-derived or other biological material (e.g., radiolabeling a patient's or donor's white blood cells), the manipulations shall be clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they shall be controlled by specific SOPs in order to avoid any cross-contamination. Packaged compounding supplies and components, such as needles, syringes, tubing sets, and small- and large-volume parenterals, should be uncartoned and wiped down with a disinfectant that does not leave a residue (e.g., sterile 70% IPA), when possible in an ante-area of ISO Class 8 (see Table 1) air quality, before being passed into the buffer areas. Personnel hand hygiene and garbing procedures are also performed in the ante-area, which may contain a sink that enables hands-free use with a closed system of soap dispensing to minimize the risk of extrinsic contamination. There shall be some demarcation designation that separates the ante-area from the buffer area. Adequate provision for performing antiseptic hand cleansing using an alcohol-based surgical hand scrub with persistent activity followed by the donning of sterile gloves should be provided after entry into the buffer area.~~

~~Cleaning and Disinfecting the Compounding Area~~

~~Environmental contact is a major source of microbial contamination of CSPs. Consequently, scrupulous attention to cleaning and disinfecting the sterile compounding areas is required to minimize this as a source of CSP contamination.~~

~~The cleaning and disinfecting practices and frequencies in this section apply to ISO Class 5 (see Table 1) compounding areas for exposure of critical sites as well as buffer areas, ante-areas, and segregated compounding areas. Compounding personnel are responsible for ensuring that the frequency of cleaning is in accordance with the requirements stated in Table 3 and determining the cleaning and disinfecting products to be used (see *Appendix II*). Any organizational or institutional policies regarding disinfectant selection should be considered by compounding personnel. All cleaning and disinfecting practices and policies for the compounding of CSPs shall be included in written SOPs and shall be followed by all compounding personnel.~~

~~Table 3. Minimum Frequency of Cleaning and Disinfecting Compounding Areas~~

~~Site~~	~~Minimum Frequency~~
~~ISO Class 5 (see Table 1) Primary Engineering Control (e.g., LAFW, BSC, CAI, CACI)~~	~~At the beginning of each shift, before each batch, not longer than 30 minutes following the previous surface disinfection when ongoing compounding activities are occurring, after spills, and when surface contamination is known or~~

~~Site~~	~~Minimum Frequency~~
	~~suspected~~
~~Counters and easily cleanable work surfaces~~	~~Daily~~
~~Floors~~	~~Daily~~
~~Walls~~	~~Monthly~~
~~Ceilings~~	~~Monthly~~
~~Storage shelving~~	~~Monthly~~

~~The selection and use of disinfectants in healthcare facilities is guided by several properties, such as microbicidal activity, inactivation by organic matter, residue, and shelf life (see *Appendix II*). In general, highly toxic disinfectants, such as glutaraldehyde, are not used on housekeeping surfaces (e.g., floors, countertops). Many disinfectants registered by the EPA are one-step disinfectants. This means that the disinfectant has been formulated to be effective in the presence of light to moderate soiling without a pre-cleaning step.~~

~~Surfaces in LAFWs, BSCs, CAIs, and CACIs, which are intimate to the exposure of critical sites, require disinfecting more frequently than do housekeeping surfaces such as walls and ceilings. Disinfecting sterile compounding areas shall occur on a regular basis at the intervals noted in *Table 3* when spills occur, when the surfaces are visibly soiled, and when microbial contamination is known to have been or is suspected of having been introduced into the compounding areas.~~

~~When the surface to be disinfected has heavy soiling, a cleaning step is recommended prior to the application of the disinfectant. Trained compounding personnel are responsible for developing, implementing, and practicing the procedures for cleaning and disinfecting the DCAs written in the SOPs. Cleaning and disinfecting shall occur before compounding is performed. Items shall be removed from all areas to be cleaned, and surfaces shall be cleaned by removing loose material and residue from spills; for example, water soluble solid residues are removed with sterile water (for injection or irrigation) and low-shedding wipes. This shall be followed by wiping with a residue-free disinfecting agent such as sterile 70% IPA, which is allowed to dry before compounding begins.~~

~~Cleaning and disinfecting surfaces in the LAFWs, BSCs, CAIs, and CACIs are the most critical practices before the preparation of CSPs. Consequently, such surfaces shall be cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches.~~

~~Work surfaces in the ISO Class 7 (see *Table 1*) buffer areas and ISO Class 8 (see *Table 1*) ante-areas as well as segregated compounding areas shall be cleaned and disinfected at least daily, and dust and debris shall be removed when necessary from storage sites for compounding ingredients and supplies using a method that does not degrade the ISO Class 7 or 8 (see *Table 1*) air quality (see *Disinfectants and Antiseptics* (1072)).~~

~~Floors in the buffer or clean area, ante area, and segregated compounding area are cleaned by mopping with a cleaning and disinfecting agent once daily at a time when no aseptic operations are in progress. Mopping shall be performed by trained personnel using approved agents and procedures described in the written SOPs. It is incumbent on compounding personnel to ensure that such cleaning is performed properly. In the buffer or clean area, ante area, and segregated compounding area, walls, ceilings, and shelving shall be cleaned and disinfected monthly. Cleaning and disinfecting agents are to be used with careful consideration of compatibilities, effectiveness, and inappropriate or toxic residues (see *Appendix II*). Their schedules of use and methods of application shall be in accordance with written SOPs and followed by custodial or compounding personnel.~~

~~All cleaning materials, such as wipers, sponges, and mops, shall be nonshedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer or clean area, ante area, and segregated compounding areas and shall not be removed from these areas except for disposal. Floor mops may be used in both the buffer or clean area and ante area, but only in that order. Ideally, all cleaning tools are discarded after one use by collection in suitable plastic bags and removed with minimal agitation. If cleaning materials (e.g., mops) are reused, procedures shall be developed (based on manufacturers' recommendations) that ensure that the effectiveness of the cleaning device is maintained and that repeated use does not add to the bioburden of the area being cleaned.~~

~~Supplies and equipment removed from shipping cartons shall be wiped with a suitable disinfecting agent (e.g., sterile 70% IPA) delivered from a spray bottle or other suitable delivery method. After the disinfectant is sprayed or wiped on a surface to be disinfected, the disinfectant shall be allowed to dry, during which time the item shall not be used for compounding purposes.~~

~~Wiping with small sterile 70% IPA swabs that are commercially available in individual foil sealed packages (or a comparable method) is preferred for disinfecting entry points on bags and vials, allowing the IPA to dry before piercing stoppers with sterile needles and breaking necks of ampuls. The surface of the sterile 70% IPA swabs used for disinfecting entry points of sterile packages and devices shall not contact any other object before contacting the surface of the entry point. Sterile 70% IPA wetted gauze pads or other particle-generating material shall not be used to disinfect the sterile entry points of packages and devices.~~

~~When sterile supplies are received in sealed pouches designed to keep them sterile until opening, the sterile supplies may be removed from the covering pouches as the supplies are introduced into the ISO Class 5 (see *Table 1*) PEC (LAFW, BSC, CAI, CACI) without the need to disinfect the individual sterile supply items. No shipping or other external cartons may be taken into the buffer or clean area or segregated compounding area.~~

~~Personnel Cleansing and Garbing~~

~~The careful cleansing of hands and arms and the correct donning of PPE by compounding personnel constitute the first major step in preventing microbial contamination in CSPs. Personnel shall also be thoroughly competent and highly motivated to perform flawless aseptic manipulations with ingredients, devices, and components of CSPs. Squamous cells are normally shed from the human body at a rate~~

~~of 10^6 or more per hour, and those skin particles are laden with microorganisms.[8,9] When individuals are experiencing rashes, sunburn, weeping sores, conjunctivitis, active respiratory infection, as well as when they wear cosmetics, they shed these particles at even higher rates. Particles shed from compounding personnel pose an increased risk of microbial contamination of critical sites of CSPs. Therefore, compounding personnel with such conditions as mentioned above shall be excluded from working in ISO Class 5 (see *Table 1*) and ISO Class 7 (see *Table 1*) compounding areas until their conditions are remedied.~~

~~Before entering the buffer area or segregated compounding area (see *Low-Risk Level CSPs with 12-Hour or Less BUD*), compounding personnel shall remove personal outer garments (e.g., bandannas, coats, hats, jackets, scarves, sweaters, vests); all cosmetics, because they shed flakes and particles; and all hand, wrist, and other visible jewelry or piercings (e.g., earrings, lip or eyebrow piercings) that can interfere with the effectiveness of PPE (e.g., fit of gloves and cuffs of sleeves). The wearing of artificial nails or extenders is prohibited while working in the sterile compounding environment. Natural nails shall be kept neat and trimmed.~~

~~Personnel shall don the following PPE in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. Garbing activities considered the dirtiest include donning of dedicated shoes or shoe covers, head and facial hair covers (e.g., beard covers in addition to face masks), and face masks/eye shields. Eye shields are optional unless working with irritants such as germicidal disinfecting agents or when preparing hazardous drugs.~~

~~After donning dedicated shoes or shoe covers, head and facial hair covers, and face masks, a hand cleansing procedure shall be performed by removing debris from underneath fingernails using a nail cleaner under running warm water followed by vigorous hand washing. Hands and forearms shall be washed to the elbows for at least 30 seconds with soap (either nonantimicrobial or antimicrobial) and water while in the ante area. The use of antimicrobial scrub brushes is not recommended because they can cause skin irritation and skin damage. Hands and forearms to the elbows will be completely dried using either lint-free disposable towels or an electronic hand dryer. After completion of hand washing, a nonshedding gown with sleeves that fit snugly around the wrists and enclosed at the neck is donned. Gowns designated for buffer area use shall be worn, and preferably they should be disposable. If reusable gowns are worn, they should be laundered appropriately for buffer area use.~~

~~Once inside the buffer area or segregated compounding area (see *Low-Risk Level CSPs with 12-Hour or Less BUD*), and prior to donning sterile powder-free gloves, antiseptic hand cleansing shall be performed using a waterless alcohol-based surgical hand scrub with persistent activity[10] following manufacturers' recommendations. Hands are allowed to dry thoroughly before donning sterile gloves.~~

~~Sterile gloves shall be the last item donned before compounding begins. Gloves become contaminated when they contact nonsterile surfaces during compounding activities. Disinfection of contaminated gloved hands may be accomplished by wiping or rubbing sterile 70% IPA to all contact surface areas of the gloves and letting the gloved hands dry thoroughly. Only use gloves that have been tested for compatibility with alcohol disinfection by the manufacturer. Routine application of sterile 70% IPA shall occur throughout the compounding process and whenever nonsterile surfaces (e.g.~~

~~vials, counter tops, chairs, carts) are touched. Gloves on hands shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected. Antiseptic hand cleansing shall be performed as indicated above. Compounding personnel shall be trained and evaluated in the avoidance of touching critical sites.~~

~~When compounding personnel exit the compounding area during a work shift, the exterior gown may be removed and retained in the compounding area if not visibly soiled, to be re-donned during that same work shift only. However, shoe covers, hair and facial hair covers, face masks/eye shields, and gloves shall be replaced with new ones before re-entering the compounding area, and proper hand hygiene shall be performed.~~

~~During high risk compounding activities that precede terminal sterilization, such as weighing and mixing of nonsterile ingredients, compounding personnel shall be garbed and gloved the same as when performing compounding in an ISO Class 5 (see *Table 1*) environment. Properly garbed and gloved compounding personnel who are exposed to air quality that is either known or suspected to be worse than ISO Class 7 (see *Table 1*) shall re-garb PPE along with washing their hands properly, performing antiseptic hand cleansing with a waterless alcohol based surgical hand scrub, and donning sterile gloves upon re-entering the ISO Class 7 (see *Table 1*) buffer area. When CAIs and CACIs are the source of the ISO Class 5 (see *Table 1*) environment, the garbing and gloving requirements for compounding personnel should be as described above, unless the isolator manufacturer can provide written documentation based on validated environmental testing that any component(s) of PPE or personnel cleansing are not required.~~

~~Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures~~

~~Personnel who prepare CSPs shall be trained conscientiously and skillfully by expert personnel and through multimedia instructional sources and professional publications in the theoretical principles and practical skills of garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 (see *Table 1*) environmental conditions, and cleaning and disinfection procedures. This training shall be completed and documented before any compounding personnel begin to prepare CSPs. Compounding personnel shall complete didactic training, pass written competence assessments, undergo skill assessment using observational audit tools, and media-fill testing (see *Appendices III–V*).~~

~~Media-fill testing of aseptic work skills shall be performed initially before beginning to prepare CSPs and at least annually thereafter for low- and medium-risk level compounding and semiannually for high-risk level compounding.~~

~~Compounding personnel who fail written tests or observational audits or whose media-fill test vials have one or more units showing visible microbial contamination shall be re-instructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies. Compounding personnel shall pass all evaluations prior to resuming compounding of sterile preparations. In addition to didactic evaluation and aseptic media fill, compounding personnel must demonstrate proficiency of proper hand hygiene, garbing, and consistent cleaning procedures.~~

~~In the event that cleaning and disinfecting procedures are also performed by other support personnel (e.g., institutional environmental services, housekeeping), thorough~~

~~training of proper hand hygiene, garbing, and cleaning and disinfection procedures shall be done by a qualified aseptic compounding expert. After completion of training, support personnel shall routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert.~~

~~COMPETENCY EVALUATION OF GARBING AND ASEPTIC WORK PRACTICE~~

~~The risk of contaminating a CSP prepared under low-risk level and medium-risk level conditions is highly dependent on proper hand hygiene and garbing practices, compounding personnel aseptic technique, and the presence of surface contamination, assuming that all work is performed in a certified and properly functioning ISO Class 5 (see *Table 1*) PEC and secondary engineering controls, ISO Class 7 (see *Table 1*) buffer area, and ISO Class 8 (see *Table 1*) ante-area. High-risk level CSPs pose the greatest threat to patients because compounding personnel are tasked with the requirement of processing nonsterile components and devices in order to achieve sterility. Compounding personnel shall be evaluated initially prior to beginning compounding CSPs and whenever an aseptic media fill is performed using a form such as the *Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel* (see *Appendix III*) and the personnel glove fingertip sampling procedures indicated below.~~

~~Aseptic Work Practice Assessment and Evaluation via Personnel Glove Fingertip Sampling~~~~—Sampling of compounding personnel glove fingertips shall be performed for all CSP risk level compounding because direct touch contamination is the most likely source of introducing microorganisms into CSPs prepared by humans. Glove fingertip sampling shall be used to evaluate the competency of personnel in performing hand hygiene and garbing procedures in addition to educating compounding personnel on proper work practices, which include frequent and repeated glove disinfection using sterile 70% IPA during actual compounding of CSPs. All personnel shall demonstrate competency in proper hand hygiene and garbing procedures and in aseptic work practices (e.g., disinfection of component surfaces, routine disinfection of gloved hands).~~

~~Sterile contact agar plates shall be used to sample the gloved fingertips of compounding personnel after garbing in order to assess garbing competency and after completing the media fill preparation (without applying sterile 70% IPA) in order to assess the adequacy of aseptic work practices prior to being initially allowed to prepare CSPs for human use and for more experienced personnel to maintain their qualifications to prepare CSPs for human use.~~

~~Garbing And Gloving Competency Evaluation—~~~~Compounding personnel shall be visually observed during the process of performing hand hygiene and garbing procedures (see *Personnel Cleansing and Garbing*under *Personnel Training and Evaluation in Aseptic Manipulation Skills*above). The visual observation shall be documented on a form such as the *Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel* (see *Appendix III*) and maintained to provide a permanent record and long-term assessment of personnel competency.~~

~~**Gloved Fingertip Sampling**~~ ~~All compounding personnel shall successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure (zero cfu) no less than three times before initially being allowed to compound CSPs for human use. Immediately after the compounding employee completes the hand hygiene and garbing procedure (e.g., donning of sterile gloves prior to any disinfection with sterile 70% IPA), the evaluator will collect a gloved fingertip and thumb sample from both hands of the compounding employee onto appropriate agar plates by lightly pressing each fingertip into the agar. The plates will be incubated for the appropriate incubation period and at the appropriate temperature (see *Incubation Period*). After completing the initial gowning and gloving competency evaluation, re-evaluation of all compounding personnel for this competency shall occur at least annually for personnel who compound low- and medium-risk level CSPs and semi-annually for personnel who compound high-risk level CSPs using one or more sample collections during any media-fill test procedure before they are allowed to continue compounding CSPs for human use.~~

~~Immediately prior to sampling, gloves shall not be disinfected with sterile 70% IPA. Disinfecting gloves immediately before sampling will provide false negative results. Plates filled with nutrient agar with neutralizing agents such as lecithin and polysorbate 80 added shall be used when sampling personnel fingertips. Personnel shall "touch" the agar with the fingertips of both hands in separate plates in a manner to create a slight impression in the agar. The sampled gloves shall be immediately discarded and proper hand hygiene performed after sampling. The nutrient agar plates shall be incubated as stated below (see *Incubation Period*). Results should be reported separately as number of cfu per employee per hand (left hand, right hand). The cfu action level for gloved hands will be based on the total number of cfu on both gloves, not per hand.~~

~~**Incubation Period**~~ ~~At the end of the designated sampling period for compounding personnel competency assessment activities (surface or personnel), the agar plates are recovered and covers secured and they are inverted and incubated at a temperature and for a time period conducive to multiplication of microorganisms. TSA with lecithin and polysorbate 80 shall be incubated at 30° to 35° for 48 to 72 hours.~~

~~**Aseptic Manipulation Competency Evaluation**~~ ~~After successful completion of an initial Hand Hygiene and Garbing Competency Evaluation, all compounding personnel shall have their aseptic technique and related practice competency evaluated initially during the *Media-Fill Test Procedure* and subsequent annual or semi-annual *Media-Fill Test Procedures*. Records of these evaluations will be maintained using a form such as the *Sample Form for Assessing Aseptic Technique and Related Practices of Compounding Personnel* (see *Appendix IV*) and maintained to provide a permanent record of and long-term assessment of personnel competency.~~

~~*Media-Fill Test Procedure*~~ ~~The skill of personnel to aseptically prepare CSPs shall be evaluated using sterile fluid bacterial culture media-fill verification, (i.e., sterile bacterial culture medium transfer via a sterile syringe and needle). Media-fill testing is used to assess the quality of the aseptic skill of compounding personnel. Media-fill tests shall represent the most challenging or stressful conditions actually encountered by the personnel being evaluated when they prepare low- and medium-risk level CSPs and when sterilizing high-risk level CSPs. Media-fill challenge tests are also used to verify~~

~~the capability of the compounding environment and processes to produce sterile preparations.~~

~~A commercially available sterile fluid culture media, such as Soybean–Casein Digest Medium (see *Sterility Tests* ⟨71⟩), that is able to promote exponential colonization of bacteria that are most likely to be transmitted to CSPs from the compounding personnel and environment is commonly used. For high-risk level CSPs nonsterile commercially available Soybean–Casein Digest Medium may be used to make a 3% solution. Normal processing steps, including filter sterilization, shall be mimicked. Media-filled vials shall be incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature (see *Microbiological Control and Monitoring of Aseptic Processing Environments* ⟨1116⟩). Failure is indicated by visible turbidity in any one of the media-fill units on or before 14 days. Other methodologies recommended by a competent microbiologist to enhance recovery time and sensitivity to detect microbial contamination may be considered (see *CSP Microbial Contamination Risk Levels* for examples of media-fill procedures).~~

~~SURFACE CLEANING AND DISINFECTION SAMPLING AND ASSESSMENT~~

~~Surface sampling is an important component of the maintenance of a suitable microbially controlled environment for compounding CSPs, especially since transfer of microbial contamination from improperly disinfected work surfaces via inadvertent touch contact by compounding personnel can be a potential source of contamination into CSPs. It is useful for evaluating facility and work surface cleaning and disinfecting procedures and employee competency in work practices such as disinfection of component/vial surface cleaning. Surface sampling shall be performed in all ISO classified areas on a periodic basis. Sampling can be accomplished using contact plates or swabs, and it shall be done at the conclusion of compounding. Locations to be sampled shall be defined in a sample plan or on a form. The size of the plate to be used for each sampled location usually ranges from 24 to 30 cm^2. Contact plates are filled with general solid agar growth medium and neutralizing agents above the rim of the plate, and they are used for sampling regular or flat surfaces. Swabs may be used for sampling irregular surfaces, especially for equipment (see *Microbiological Control and Monitoring of Aseptic Processing Environments* ⟨1116⟩).~~

~~Cleaning and Disinfecting Competency Evaluation—~~~~Compounding personnel and other personnel responsible for cleaning shall be visually observed during the process of performing cleaning and disinfecting procedures, during initial personnel training on cleaning procedures, during changes in cleaning staff, and at the completion of any media-fill test procedure (see *Cleaning and Disinfecting of Compounding Areas*).~~

~~The visual observation shall be documented using a form such as the *Sample Form for Assessing Cleaning and Disinfection Procedures* (see *Appendix V*) and maintained to provide a permanent record and long-term assessment of personnel competency.~~

~~Surface Collection Methods—~~~~To sample surfaces using a contact plate, gently touch the sample area with the agar surface and roll the plate across the surface to be sampled. The contact plate will leave a growth media residue behind; therefore, immediately after sampling with the contact plate, the sampled area shall be thoroughly wiped with a nonshedding wipe soaked in sterile 70% IPA.~~

~~If an area is sampled via the swab method, collection of the sample is processed by using appropriate procedures that will result in the surface location equivalent to that of a contact plate. After swabbing the surface to be sampled, swabs are placed in an appropriate diluent; an aliquot is planted on or in the specified nutrient agar. Results should be reported as cfu per unit of surface area.~~

~~Action Levels, Documentation, and Data Evaluation~~

~~The value of viable microbial monitoring of gloved fingertips and surfaces of components and the compounding environment are realized when the data are used to identify and correct an unacceptable work practice. Sampling data shall be collected and reviewed on a routine basis as a means of evaluating the overall control of the compounding environment. If an activity consistently shows elevated levels of microbial growth, competent microbiology personnel shall be consulted.~~

~~Any cfu count that exceeds its respective action level (see *Table 4*) should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location. An investigation into the source of the contamination shall be conducted. Sources could include HVAC systems, damaged HEPA filters, and changes in personnel garbing or working practices. The source of the problem shall be eliminated, the affected area cleaned, and resampling performed.~~

~~When gloved fingertip sample results exceed action levels after proper incubation, a review of hand hygiene and garbing procedures as well as glove and surface disinfection procedures and work practices shall be performed and documented. Employee training may be required to correct the source of the problem.~~

~~Counts of cfu are to be used as an approximate measure of the environmental microbial bioburden. Action levels are determined on the basis of cfu data gathered at each sampling location and trended over time. The numbers in *Table 4* should be used only as guidelines. Regardless of the number of cfu identified in the compounding facility, further corrective actions will be dictated by the identification of microorganisms recovered (at least the genus level) by an appropriate credentialed laboratory of any microbial bioburden captured as a cfu using an impaction air sampler. Highly pathogenic microorganisms (e.g., Gram negative rods, coagulase positive staphylococcus, molds and yeasts) can be potentially fatal to patients receiving CSPs and shall be immediately remedied, regardless of cfu count, with the assistance of a competent microbiologist, infection control professional, or industrial hygienist.~~

~~Table 4. Recommended Action Levels for Microbial Contamination~~[*]

~~Classification~~	~~Fingertip Sample~~	~~Surface Sample (Contact Plate) (cfu per plate)~~
~~ISO Class 5~~	~~> 3~~	~~> 3~~
~~ISO Class 7~~	~~N/A~~	~~> 5~~
~~ISO Class 8 or worse~~	~~N/A~~	~~> 100~~

[*] ~~Pharmaceutical Inspection Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice for Medicinal Products Annexes PE 009-6, 5 April 2007.~~

~~SUGGESTED STANDARD OPERATING PROCEDURES (SOPS)~~

~~The compounding facility shall have written, properly approved SOPs designed to ensure the quality of the environment in which a CSP is prepared. The following procedures are recommended:~~

1. ~~Access to the buffer area is restricted to qualified personnel with specific responsibilities or assigned tasks in the compounding area.~~
2. ~~All cartoned supplies are decontaminated in the area by removing them from shipping cartons and wiping or spraying them with a nonresidue-generating disinfecting agent while they are being transferred to a clean and properly disinfected cart or other conveyance for introduction into the buffer area. Manufacturers' directions or published data for minimum contact time will be followed. Individual pouched sterile supplies need not be wiped because the pouches can be removed as these sterile supplies are introduced into the buffer area.~~
3. ~~Supplies that are required frequently or otherwise needed close at hand but not necessarily needed for the scheduled operations of the shift are decontaminated and stored on shelving in the ante-area.~~
4. ~~Carts used to bring supplies from the storeroom cannot be rolled beyond the demarcation line in the ante-area, and carts used in the buffer area cannot be rolled outward beyond the demarcation line unless cleaned and disinfected before returning.~~
5. ~~Generally, supplies required for the scheduled operations of the shift are wiped down with an appropriate disinfecting agent and brought into the buffer area, preferably on one or more movable carts. Supplies that are required for back-up or general support of operations may be stored on the designated shelving in the buffer area, but excessive amounts of supplies are to be avoided.~~
6. ~~Nonessential objects that shed particles shall not be brought into the buffer area, including pencils, cardboard cartons, paper towels, and cotton items (e.g., gauze pads).~~
7. ~~Essential paper-related products (e.g., paper syringe overwraps, work records contained in a protective sleeve) shall be wiped down with an appropriate disinfecting agent prior to being brought into the buffer area.~~
8. ~~Traffic flow in and out of the buffer area shall be minimized.~~
9. ~~Personnel preparing to enter the buffer area shall remove all personal outer garments, cosmetics (because they shed flakes and particles), and all hand, wrist, and other visible jewelry or piercings that can interfere with the effectiveness of PPE.~~
10. ~~Personnel entering the ante-area shall don attire as described in *Personnel Cleansing and Garbing* and *Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures*.~~
11. ~~Personnel shall then thoroughly wash hands and forearms to the elbow with soap and water for at least 30 seconds. An air dryer or disposable nonshedding towels are used to dry hands and forearms after washing.~~

12. ~~Personnel entering the buffer area shall perform antiseptic hand cleansing prior to donning sterile gloves using a waterless alcohol-based surgical hand scrub with persistent activity.~~
13. ~~Chewing gum, drinks, candy, or food items shall not be brought into the buffer area or ante-area. Materials exposed in patient care and treatment areas shall never be introduced into areas where components and ingredients for CSPs are present.~~
14. ~~At the beginning of each compounding activity session, and whenever liquids are spilled, the surfaces of the direct compounding environment are first cleaned with USP Purified Water to remove water-soluble residues. Immediately thereafter, the same surfaces are disinfected with a nonresidue-generating agent using a nonlinting wipe.~~
15. ~~Primary engineering controls shall be operated continuously during compounding activity. When the blower is turned off and before other personnel enter to perform compounding activities, only one person shall enter the buffer area for the purposes of turning on the blower (for at least 30 minutes) and disinfecting the work surfaces.~~
16. ~~Traffic in the area of the DCA is minimized and controlled.~~
17. ~~Supplies used in the DCA for the planned procedures are accumulated and then decontaminated by wiping or spraying the outer surface with sterile 70% IPA or removing the outer wrap at the edge of the DCA as the item is introduced into the aseptic work area.~~
18. ~~All supply items are arranged in the DCA so as to reduce clutter and provide maximum efficiency and order for the flow of work.~~
19. ~~After proper introduction into the DCA of supply items required for and limited to the assigned operations, they are so arranged that a clear, uninterrupted path of HEPA filtered air will bathe all critical sites at all times during the planned procedures. That is, no objects may be placed between the first air from HEPA filters and an exposed critical site.~~
20. ~~All procedures are performed in a manner designed to minimize the risk of touch contamination. Gloves are disinfected with adequate frequency with an approved disinfectant such as sterile 70% IPA.~~
21. ~~All rubber stoppers of vials and bottles and the necks of ampuls are disinfected by wiping with sterile 70% IPA and waiting for at least 10 seconds before they are used to prepare CSPs.~~
22. ~~After the preparation of every CSP, the contents of the container are thoroughly mixed and then inspected for the presence of particulate matter, evidence of incompatibility, or other defects.~~
23. ~~After procedures are completed, used syringes, bottles, vials, and other supplies are removed, but with a minimum of exit and re-entry into the DCA so as to minimize the risk of introducing contamination into the aseptic workspace.~~

~~ELEMENTS OF QUALITY CONTROL~~

~~A written description of specific training and performance evaluation program for individuals involved in the use of aseptic techniques for the preparation of sterile~~

~~products shall be developed for each site. This program equips personnel with the appropriate knowledge and trains them in the required skills necessary to perform the assigned tasks. Each person assigned to the aseptic area in the preparation of sterile products shall successfully complete specialized training in aseptic techniques and aseptic area practices prior to preparing CSPs (see *Personnel Training and Evaluation in Aseptic Manipulation Skills* and *Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures*).~~

~~Ingredients and Devices~~

~~Compounding personnel ascertain that ingredients for CSPs are of the correct identity and appropriate quality using the following information: vendor labels, labeling, certificates of analysis, direct chemical analysis, and knowledge of compounding facility storage conditions.~~

~~STERILE INGREDIENTS AND DEVICES~~

~~Commercially available sterile drug products, sterile ready-to-use containers, and devices are examples of sterile components. A written procedure for unit-by-unit physical inspection preparatory to use is followed to ensure that these components are sterile, free from defects, and otherwise suitable for their intended use.~~

~~NONSTERILE INGREDIENTS AND DEVICES~~

~~If any nonsterile components, including containers and ingredients, are used to make a CSP, such CSPs must be high risk. Nonsterile active ingredients and added substances or excipients for CSPs should preferably be official *USP* or *NF* articles. When nonofficial ingredients are used, they shall be accompanied by certificates of analysis from their suppliers to aid compounding personnel in judging the identity, quality, and purity in relation to the intended use in a particular CSP. Physical inspection of a package of ingredients is necessary in order to detect breaks in the container, looseness in the cap or closure, and deviation from the expected appearance, aroma, and texture of the contents.~~

~~Bulk or unformulated drug substances and added substances or excipients shall be stored in tightly closed containers under temperature, humidity, and lighting conditions that are either indicated in official monographs or approved by suppliers. The date of receipt by the compounding facility shall be clearly and indelibly marked on each package of ingredient. After receipt by the compounding facility, packages of ingredients that lack a supplier's expiration date cannot be used after 1 year unless either appropriate inspection or testing indicates that the ingredient has retained its purity and quality for use in CSPs.~~

~~Careful consideration and evaluation of nonsterile ingredient sources is especially warranted when the CSP will be administered into the vascular system, central nervous system, or eyes.~~

~~Upon receipt of each lot of the bulk drug substance or excipient used for CSPs, the individual compounding the preparation performs a visual inspection of the lot for evidence of deterioration, other types of unacceptable quality, and wrong identification. For bulk drug substances or excipients, visual inspection is performed on a routine basis as described in the written protocol.~~

~~Equipment~~

~~It is necessary that equipment, apparatus, and devices used to compound a CSP be consistently capable of operating properly and within acceptable tolerance limits. Written procedures outlining required equipment calibration, annual maintenance, monitoring for proper function, and controlled procedures for use of the equipment and specified time frames for these activities are established and followed. Routine maintenance and frequencies shall be outlined in these SOPs. Results from the equipment calibration, annual maintenance reports, and routine maintenance are kept on file for the lifetime of the equipment. Personnel are prepared through an appropriate combination of specific training and experience to operate or manipulate any piece of equipment, apparatus, or device they may use when preparing CSPs. Training includes gaining the ability to determine whether any item of equipment is operating properly or is malfunctioning.~~

~~VERIFICATION OF AUTOMATED COMPOUNDING DEVICES (ACDs) FOR PARENTERAL NUTRITION COMPOUNDING~~

~~ACDs for the preparation of parenteral nutrition admixtures are widely used by pharmacists in hospitals and other healthcare settings. They are designed to streamline the labor-intensive processes involved in the compounding of these multiple-component formulations by automatically delivering the individual nutritional components in a predetermined sequence under computerized control. Parenteral nutrition admixtures often contain 20 or more individual additives representing as many as 50 or more individual components (e.g., 15 to 20 crystalline amino acids, dextrose monohydrate, and lipids; 10 to 12 electrolyte salts; 5 to 7 trace minerals; and 12 vitamins). Thus, ACDs can provide improved accuracy and precision of the compounding process over the traditional manual compounding methods.~~

~~Accuracy~~

~~The accuracy of an ACD can be determined in various ways to ensure that the correct quantities of nutrients, electrolytes, or other nutritional components are delivered to the final infusion container. Initially, the ACD is tested for its volume and weight accuracy. For volume accuracy, a suitable volume of Sterile Water for Injection, USP, which represents a typical additive volume (e.g., 40 mL for small volume range of 1 to 100 mL, 300 mL for large volume range of 100 to 1000 mL), is programmed into the ACD and delivered to the appropriate volumetric container. The compounding personnel should then consult *Volumetric Apparatus* ⟨31⟩ for appropriate parameters to assess the volumetric performance of the ACD. For gravimetric accuracy, the balance used in conjunction with the ACD is tested using various weight sizes that represent the amounts typically used to deliver the various additives. Compounding personnel should consult •*Balances* ⟨41⟩• (CN 1-May-2016) for acceptable tolerances of the weights used. In addition, the same volume of *Sterile Water for Injection* used to assess volumetric accuracy is then weighed on the balance used in conjunction with the ACD. For example, if 40 mL of water was used in the volumetric assessment, its corresponding weight should be about 40 g (assuming the relative density of water is 1.0). In addition, during the use of the ACD, certain additives, such as potassium chloride (corrected for density differences), can also be tested in the same manner as with an in-process test.~~

~~Finally, additional tests of accuracy may be employed that determine the content of certain ingredients in the final volume of the parenteral nutrition admixture. Generally, pharmacy departments do not have the capability to routinely perform chemical analyses such as analyses of dextrose or electrolyte concentrations. Consequently, hospital or institutional laboratories may be called upon to perform these quality assurance tests. However, the methods in such laboratories are often designed for biological, not pharmaceutical, systems. Thus, their testing procedures shall be verified to meet the *USP* requirements stated in the individual monograph for the component being tested. For example, under *Dextrose Injection*, the following is stated: It contains not less than 95.0% and not more than 105.0% of the labeled amount of $C_6H_{12}O_6 \cdot H_2O$. The hospital or institutional chemistry laboratories must validate their methods to apply to this range and correct for their typical measurement of anhydrous dextrose versus dextrose monohydrate. Similar ranges and issues exist, for example, for injections of calcium gluconate, magnesium sulfate, and potassium chloride. The critical point is the use of *USP* references and possible laboratory procedural differences.~~

~~Precision~~

~~The intermediate precision of the ACD can be determined on the basis of the day-to-day variations in performance of the accuracy measures. Thus, compounding personnel shall keep a daily record of the above-described accuracy assessments and review the results over time. This review shall occur at least at weekly intervals to avoid potentially clinically significant cumulative errors over time. This is especially true for additives with a narrow therapeutic index, such as potassium chloride.~~

~~FINISHED PREPARATION RELEASE CHECKS AND TESTS~~

~~The following quality metrics shall be performed for all CSPs before they are dispensed or administered.~~

~~Inspection of Solution Dosage Forms and Review of Compounding Procedures~~

~~All CSPs that are intended to be solutions shall be visually examined for the presence of particulate matter and not administered or dispensed when such matter is observed. The prescription orders, written compounding procedure, preparation records, and expended materials used to make CSPs at all contamination risk levels are inspected for accuracy of correct identities and amounts of ingredients, aseptic mixing and sterilization, packaging, labeling, and expected physical appearance before they are administered or dispensed.~~

~~PHYSICAL INSPECTION~~

~~Finished CSPs are individually inspected in accordance with written procedures after compounding. If not distributed promptly, these CSPs are individually inspected just prior to leaving the storage area. Those CSPs that are not immediately distributed are stored in an appropriate location as described in the written procedures. Immediately after compounding, and as a condition of release, each CSP unit, where possible, should be inspected against lighted white or black background or both for evidence of visible particulates or other foreign matter. Prerelease inspection also includes container–closure integrity and any other apparent visual defect. CSPs with observed~~

~~defects should be immediately discarded or marked and segregated from acceptable products in a manner that prevents their administration. When CSPs are not distributed promptly after preparation, a predistribution inspection is conducted to ensure that a CSP with defects, such as precipitation, cloudiness, and leakage, which may develop between the time of release and the time of distribution, is not released.~~

~~Compounding Accuracy Checks~~

~~Written procedures for double-checking compounding accuracy shall be followed for every CSP during preparation and immediately prior to release. The double-check system should meet state regulations and include label accuracy and accuracy of the addition of all drug products or ingredients used to prepare the finished product and their volumes or quantities. The used additive containers and, for those additives for which the entire container was not expended, the syringes used to measure the additive should be quarantined with the final products until the final product check is completed. Compounding personnel shall visually confirm that ingredients measured in syringes match the written order being compounded. Preferably, a person other than the compounder can verify that correct volumes of correct ingredients were measured to make each CSP. For example, compounding personnel would pull the syringe plunger back to the volume measured.~~

~~When practical, the accuracy of measurements is confirmed by weighing a volume of the measured fluid, then calculating that volume by dividing the weight by the accurate value of the density, or specific gravity, of the measured fluid. Correct density or specific gravity values programmed in ACDs, which measure by weight using the quotient of the programmed volume divided by the density or specific gravity, shall be confirmed to be accurate before and after delivering volumes of the liquids assigned to each channel or port. These volume accuracy checks and the following additional safety and accuracy checks in this section shall be included in the SOP manual of the CSP facility.~~

~~Sterility Testing~~

~~All high-risk level CSPs that are prepared in groups of more than 25 identical individual single-dose packages (e.g., ampuls, bags, syringes, vials) or in multiple-dose vials (MDVs) for administration to multiple patients or that are exposed longer than 12 hours at 2° to 8° and longer than 6 hours at warmer than 8° before they are sterilized shall meet the sterility test (see *Sterility Tests* ⟨71⟩) before they are dispensed or administered. The *Membrane Filtration* method is the method of choice where feasible (e.g., components are compatible with the membrane). A method not described in the *USP* may be used if verification results demonstrate that the alternative is at least as effective and reliable as the *USP Membrane Filtration* method or the *USP Direct Inoculation of the Culture Medium* method where the *Membrane Filtration* method is not feasible.~~

~~When high-risk level CSPs are dispensed before receiving the results of their sterility tests, there shall be a written procedure requiring daily observation of the incubating test specimens and immediate recall of the dispensed CSPs when there is any evidence of microbial growth in the test specimens. In addition, the patient and the physician of the patient to whom a potentially contaminated CSP was administered are notified of the potential risk. Positive sterility test results should prompt a rapid and systematic investigation of aseptic technique, environmental control, and other sterility assurance~~

~~controls to identify sources of contamination and correct problems in the methods or processes.~~

~~Bacterial Endotoxin (Pyrogen) Testing~~

~~All high-risk level CSPs, except those for inhalation and ophthalmic administration, that are prepared in groups of more than 25 identical individual single-dose packages (e.g., ampuls, bags, syringes, vials) or in MDVs for administration to multiple patients or that are exposed longer than 12 hours at 2° to 8° and longer than 6 hours at warmer than 8° before they are sterilized shall be tested to ensure that they do not contain excessive bacterial endotoxins (see *Bacterial Endotoxins Test* ⟨85⟩ and *Pyrogen Test* ⟨151⟩). In the absence of a bacterial endotoxins limit in the official monograph or other CSP formula source, the CSP shall not exceed the amount of USP Endotoxin Units (per hour per kilogram of body weight or square meters of body surface area) specified in *Bacterial Endotoxins Test* ⟨85⟩ referenced above for the appropriate route of administration.~~

~~Identity and Strength Verification of Ingredients~~

~~Compounding facilities shall have at least the following written procedures for verifying the correct identity and quality of CSPs before they are dispensed and administered:~~

1. ~~That labels of CSPs bear correct names and amounts or concentrations of ingredients, the total volume, the BUD, the appropriate route(s) of administration, the storage conditions, and other information for safe use.~~
2. ~~That there are correct identities, purities, and amounts of ingredients by comparing the original written order with the written compounding record for the CSP.~~
3. ~~That correct fill volumes in CSPs and correct quantities of filled units of the CSPs were obtained. When the strength of finished CSPs cannot be confirmed to be accurate, based on the above three inspections, the CSPs shall be assayed by methods that are specific for the active ingredients.~~

~~STORAGE AND BEYOND-USE DATING~~

~~BUDs for compounded preparations are usually assigned on the basis of professional experience, which should include careful interpretation of appropriate information sources for the same or similar formulations (see *Stability Criteria and Beyond-Use Dating* under *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩). BUDs for CSPs are rarely based on preparation-specific chemical assay results, which are used with the Arrhenius equation to determine expiration dates (see *General Notices and Requirements*) for manufactured products. The majority of CSPs are aqueous solutions in which hydrolysis of dissolved ingredients is the most common chemical degradation reaction. The extent of hydrolysis and other heat-catalyzed degradation reactions at any particular time point in the life of a CSP represents the thermodynamic sum of exposure temperatures and durations. Such lifetime stability exposure is represented in the mean kinetic temperature calculation (see *Pharmaceutical Calculations in Prescription Compounding* ⟨1160⟩). Drug hydrolysis rates increase exponentially with arithmetic~~

~~temperature increase; thus, exposure of a beta-lactam antibiotic solution for 1 day at controlled room temperature (see *General Notices and Requirements*) will have an equivalent effect on the extent of hydrolysis of approximately 3 to 5 days in cold temperatures (see *General Notices and Requirements*).~~

~~Personnel who prepare, dispense, and administer CSPs shall store them strictly in accordance with the conditions stated on the label of ingredient products and finished CSPs. When CSPs are known to have been exposed to temperatures warmer than the warmest labeled limit or to temperatures exceeding 40° (see *General Notices and Requirements*) for more than 4 hours, such CSPs should be discarded unless direct assay data or appropriate documentation confirms their continued stability.~~

~~Determining Beyond-Use Dates~~

~~BUDs and expiration dates are not the same (see *General Notices and Requirements*). Expiration dates for the chemical and physical stability of manufactured sterile products are determined from results of rigorous analytical and performance testing, and they are specific for a particular formulation in its container and at stated exposure conditions of illumination and temperature. When CSPs deviate from conditions in the approved labeling of manufactured products contained in CSPs, compounding personnel may consult the manufacturer of particular products for advice on assigning BUDs based on chemical and physical stability parameters. BUDs for CSPs that are prepared strictly in accordance with manufacturers' product labeling shall be those specified in that labeling or from appropriate literature sources or direct testing. BUDs for CSPs that lack justification from either appropriate literature sources or by direct testing evidence shall be assigned as described in *Stability Criteria and Beyond-Use Dating* under *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩.~~

~~In addition, compounding personnel may refer to applicable publications to obtain relevant stability, compatibility, and degradation information regarding the drug or its congeners. When assigning a beyond-use date, compounding personnel should consult and apply drug-specific and general stability documentation and literature where available, and they should consider the nature of the drug and its degradation mechanism, the container in which it is packaged, the expected storage conditions, and the intended duration of therapy (see *Expiration Date and Beyond-Use Date* under *Labeling* in the *General Notices and Requirements*). Stability information must be carefully interpreted in relation to the actual compounded formulation and conditions for storage and use. Predictions based on other evidence, such as publications, charts, and tables, would result in theoretical BUDs. Theoretically predicted beyond-use dating introduces varying degrees of assumptions and, hence, a likelihood of error or at least inaccuracy. The degree of error or inaccuracy would be dependent on the extent of differences between the CSPs' characteristics (e.g., composition, concentration of ingredients, fill volume, container type and material) and the characteristics of the products from which stability data or information is to be extrapolated. The greater the doubt of the accuracy of theoretically predicted beyond-use dating, the greater the need to determine dating periods experimentally. Theoretically predicted beyond-use dating periods should be carefully considered for CSPs prepared from nonsterile bulk active ingredients having therapeutic activity, especially where these CSPs are expected to be compounded routinely. When CSPs will be distributed to and administered in residential locations other than healthcare facilities, the effect of potentially uncontrolled and~~

~~unmonitored temperature conditions shall be considered when assigning BUDs. It must be ascertained that CSPs will not be exposed to warm temperatures (see *General Notices and Requirements*) unless the compounding facility has evidence to justify stability of CSPs during such exposure.~~

~~It should be recognized that the truly valid evidence of stability for predicting beyond-use dating can be obtained only through product-specific experimental studies. Semiquantitative procedures such as thin-layer chromatography (TLC) may be acceptable for many CSPs. However, quantitative stability-indicating assays such as high-performance liquid chromatographic (HPLC) assays would be more appropriate for certain CSPs. Examples include CSPs with a narrow therapeutic index, where close monitoring or dose titration is required to ensure therapeutic effectiveness and to avoid toxicity; where a theoretically established beyond-use dating period is supported by only marginal evidence; or where a significant margin of safety cannot be verified for the proposed beyond-use dating period. In short, because beyond-use dating periods established from product-specific data acquired from the appropriate instrumental analyses are clearly more reliable than those predicted theoretically, the former approach is strongly urged to support dating periods exceeding 30 days.~~

~~To ensure consistent practices in determining and assigning BUDs, the compounding facility should have written policies and procedures governing the determination of the BUDs for all compounded products. When attempting to predict a theoretical BUD, a compounded or an admixed preparation should be considered as a unique system that has physical and chemical properties and stability characteristics that differ from its components. For example, antioxidant, buffering, or antimicrobial properties of a sterile vial for injection (SVI) might be lost upon its dilution, with the potential of seriously compromising the chemical stability of the SVI's active ingredient or the physical or microbiological stability of the SVI formulation in general. Thus, the properties stabilized in the SVI formulation usually cannot be expected to be carried over to the compounded or admixed preparation. Preparation-specific, experimentally determined stability data evaluation protocols are preferable to published stability information.~~

~~Compounding personnel who assign BUDs to CSPs when lacking direct chemical assay results must critically interpret and evaluate the most appropriate available information sources to determine a conservative and safe BUD. The SOP manual of the compounding facility and each specific CSP formula record shall describe the general basis used to assign the BUD and storage conditions.~~

~~When manufactured MDVs (see *Multiple-Dose Container* under *Preservation, Packaging, Storage,* and *Labeling* in the *General Notices and Requirements*) of sterile ingredients are used in CSPs, the stoppers of the MDVs are inspected for physical integrity and disinfected by wiping with a sterile 70% IPA swab before each penetration with a sterile withdrawal device. When contaminants or abnormal properties are suspected or observed in MDVs, such MDVs shall be discarded. The BUD after initially entering or opening (e.g., needle puncturing) multiple-dose containers is 28 days (see *Antimicrobial Effectiveness Testing* ⟨51⟩) unless otherwise specified by the manufacturer.~~

~~Proprietary Bag and Vial Systems~~

~~The sterility storage and stability beyond-use times for attached and activated (where activated is defined as allowing contact of the previously separate diluent and drug~~

~~contents) container pairs of drug products for intravascular administration (e.g., ADD-Vantage®, Mini Bag Plus®) shall be applied as indicated by the manufacturer. In other words, follow manufacturers' instructions for handling and storing ADD Vantage®, Mini Bag Plus®, Add A Vial®, Add-Ease® products, and any others.~~

~~Monitoring Controlled Storage Areas~~

~~To ensure that product potency is retained through the manufacturer's labeled expiration date, compounding personnel shall monitor the drug storage areas within the compounding facility. Controlled temperature areas in compounding facilities include controlled room temperature, 20° to 25° with mean kinetic temperature 25°; controlled cold temperature, 2° to 8° with mean kinetic temperature 8°; cold temperature, 2° to 8°; freezing temperature, −25° and −10° (see *General Notices and Requirements)* if needed to achieve freezing, and the media specific temperature range for microbial culture media. A controlled temperature area shall be monitored at least once daily and the results documented on a temperature log. Additionally, compounding personnel shall note the storage temperature when placing the product into or removing the product from the storage unit in order to monitor any temperature aberrations. Suitable temperature recording devices may include a calibrated continuous recording device or a National Institute of Standards and Technology (NIST) calibrated thermometer that has adequate accuracy and sensitivity for the intended purpose, and it shall be properly calibrated at suitable intervals. If the compounding facility uses a continuous temperature recording device, compounding personnel shall verify at least once daily that the recording device itself is functioning properly.~~

~~The temperature sensing mechanisms shall be suitably placed in the controlled temperature storage space to reflect accurately its true temperature. In addition, the compounding facility shall adhere to appropriate procedures of all controlled storage spaces to ensure that such spaces are not subject to significantly prolonged temperature fluctuations as may occur, for example, by leaving a refrigerator door open too long.~~

~~MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPS~~

~~This section summarizes the responsibilities of compounding facilities for maintaining quality and control of CSPs that are dispensed and administered within their parent healthcare organizations.~~

~~Compounding personnel shall ensure proper storage and security of CSPs prepared by or dispensed from the compounding facility until either their BUDs are reached or they are administered to patients. In fulfilling this general responsibility, the compounding facility is responsible for the proper packaging, handling, transport, and storage of CSPs prepared by or dispensed from it, including the appropriate education, training, and supervision of compounding personnel assigned to these functions. The compounding facility should assist in the education and training of noncompounding personnel responsible for carrying out any aspect of these functions.~~

~~Establishing, maintaining, and ensuring compliance with comprehensive written policies and procedures encompassing these responsibilities is a further responsibility of the compounding facility. Where noncompounding personnel are assigned tasks~~

~~involving any of these responsibilities, the policies and procedures encompassing those tasks should be developed by compounding supervisors. The quality and control activities related to distribution of CSPs are summarized in the following five subsections. Activities or concerns that should be addressed as the compounding facility fulfills these responsibilities are as follows.~~

~~Packaging, Handling, and Transport~~

~~Inappropriate processes or techniques involved with packaging, handling, and transport can adversely affect quality and package integrity of CSPs. Although compounding personnel routinely perform many of the tasks associated with these functions, some tasks, such as transport, handling, and placement into storage, may be fulfilled by noncompounding personnel who are not under the direct administrative control of the compounding facility. Under these circumstances, appropriate SOPs shall be established by the compounding facility with the involvement of other departments or services whose personnel are responsible for carrying out those CSP-related functions for which the compounding facility has a direct interest. The performance of the noncompounding personnel is monitored for compliance to established policies and procedures.~~

~~The critical requirements that are unique to CSPs and that are necessary to ensure CSP quality and packaging integrity shall be addressed in SOPs. For example, techniques should be specified to prevent the depression of syringe plungers or dislodging of syringe tips during handling and transport. Additionally, disconnection of system components (e.g., where CSPs are dispensed with administration sets attached to them) shall be prevented through the BUD of the CSP. Foam padding or inserts are particularly useful where CSPs are transported by pneumatic tube systems. Regardless of the methods used, the compounding facility must evaluate their effectiveness and the reliability of the intended protection. Evaluation should be continuous—for example, through a surveillance system, including a system of problem reporting to the compounding facility.~~

~~Inappropriate transport and handling can adversely affect the quality of certain CSPs having unique stability concerns. For example, the physical shaking that might occur during pneumatic tube transport or undue exposure to heat or light must be addressed on a preparation-specific basis. Alternative transport modes or special packaging measures might be needed for the proper assurance of quality of these CSPs. The use of tamper-evident closures and seals on CSP ports can add an additional measure of security to ensure product integrity regardless of the transport method used.~~

~~Chemotoxic and other hazardous CSPs require safeguards to maintain the integrity of the CSP and to minimize the exposure potential of these products to the environment and to personnel who may come in contact with them. Transportation by pneumatic tube should be discouraged because of potential breakage and contamination. Special requirements associated with the packaging, transport, and handling of these agents include the prevention of accidental exposures or spills and the training of personnel in the event of an exposure or spill. Examples of special requirements of these agents also include exposure-reducing strategies such as the use of Luer lock syringes and connections, syringe caps, the capping of container ports, sealed plastic bags, impact-resistant containers, and cautionary labeling.~~

~~Use and Storage~~

~~The compounding facility is responsible for ensuring that CSPs in the patient-care setting maintain their quality until administered. The immediate labeling of the CSP container will display prominently and understandably the requirements for proper storage and expiration dating. Delivery and patient-care-setting personnel shall be properly trained to deliver the CSP to the appropriate storage location. Outdated and unused CSPs shall be returned to the compounding facility for disposition.~~

~~SOPs must exist to ensure that storage conditions in the patient-care setting are suitable for the CSP-specific storage requirements. Procedures include daily monitoring and documentation of drug storage refrigerators to ensure temperatures between 2° and 8° and the monthly inspection of all drug storage locations by compounding personnel. Inspections shall confirm compliance with appropriate storage conditions, separation of drugs and food, proper use of MDVs, and the avoidance of using single-dose products as MDVs. CSPs, as well as all other drug products, shall be stored in the patient-care area in such a way as to secure them from unauthorized personnel, visitors, and patients.~~

~~Readying for Administration~~

~~Procedures essential for generally ensuring quality, especially sterility assurance, when readying a CSP for its subsequent administration include proper hand washing, aseptic technique, site care, and change of administration sets. Additional procedures may also be essential for certain CSPs, devices, or techniques. Examples where such special procedures are needed include in-line filtration, the operation of automated infusion control devices, and the replenishment of CSPs into the reservoirs of implantable or portable infusion pumps. When CSPs are likely to be exposed to warmer than 30° for more than 1 hour during their administration to patients, the maintenance of their sterility and stability should be confirmed from either relevant and reliable sources or direct testing.~~

~~Redispensed CSPs~~

~~The compounding facility shall have the sole authority to determine when unopened, returned CSPs may be redispensed. Returned CSPs may be redispensed only when personnel responsible for sterile compounding can ensure that such CSPs are sterile, pure, and stable (contain labeled strength of ingredients). The following may provide such assurance: the CSPs were maintained under continuous refrigeration and protected from light, if required, and no evidence of tampering or any readying for use outside the compounding facility exists. Assignment of new storage times and BUDs that exceed the original dates for returned CSPs is permitted only when there is supporting evidence from sterility testing and quantitative assay of ingredients. Thus, initial preparation and thaw times should be documented and reliable measures should have been taken to prevent and detect tampering. Compliance with all procedures associated with maintaining product quality is essential. The CSPs shall not be redispensed if there is not adequate assurance that preparation quality and packaging integrity (including the connections of devices, where applicable) were continuously maintained between the time the CSPs left and the time they were returned.~~

~~Additionally, CSPs shall not be redispensed if redispensing cannot be supported by the originally assigned BUD.~~

~~Education and Training~~

~~The assurance of CSPs' quality and packaging integrity is highly dependent on the proper adherence of all personnel to the pertinent SOPs. Compounding personnel shall design, implement, and maintain a formal education, training, and competency assessment program that encompasses all the functions and tasks addressed in the foregoing sections and all personnel to whom such functions and tasks are assigned. This program includes the assessment and documentation of procedural breaches, administration mishaps, side effects, allergic reactions, and complications associated with dosage or administration, such as extravasation. This program should be coordinated with the institution's adverse events and incident reporting programs.~~

~~Packing and Transporting CSPs~~

~~The following sections describe how to maintain sterility and stability of CSPs until they are delivered to patient care locations for administration.~~

~~PACKING CSPS FOR TRANSIT~~

~~When CSPs are distributed to locations outside the premises in which they are compounded, compounding personnel select packing containers and materials that are expected to maintain physical integrity, sterility, and stability of CSPs during transit. Packing is selected that simultaneously protects CSPs from damage, leakage, contamination, and degradation, and protects personnel who transport packed CSPs from harm. The SOP manual of the compounding facility specifically describes appropriate packing containers and insulating and stuffing materials, based on information from product specifications, vendors, and experience of compounding personnel. Written instructions that clearly explain how to safely open containers of packed CSPs are provided to patients and other recipients.~~

~~TRANSIT OF CSPS~~

~~Compounding facilities that ship CSPs to locations outside their own premises shall select modes of transport that are expected to deliver properly packed CSPs in undamaged, sterile, and stable condition to recipients.~~

~~Compounding personnel should ascertain that temperatures of CSPs during transit by the selected mode will not exceed the warmest temperature specified on the storage temperature range on CSP labels. It is recommended that compounding personnel communicate directly with the couriers to learn shipping durations and exposure conditions that CSPs may encounter.~~

~~Compounding personnel shall include specific handling and exposure instructions on the exteriors of containers packed with CSPs to be transported and obtain reasonable assurance of compliance therewith from transporters. Compounding personnel shall periodically review the delivery performance of couriers to ascertain that CSPs are being efficiently and properly transported.~~

~~Storage in Locations Outside Compounding Facilities~~

~~Compounding facilities that ship CSPs to patients and other recipients outside their own premises shall ascertain or provide, whichever is appropriate, the following assurances:~~

1. ~~Labels and accessory labeling for CSPs include clearly readable BUDs, storage instructions, and disposal instructions for out-of-date units.~~
2. ~~Each patient or other recipient is able to store the CSPs properly, including the use of a properly functioning refrigerator and freezer if CSPs are labeled for such storage.~~

~~PATIENT OR CAREGIVER TRAINING~~

~~A formal training program is provided as a means to ensure understanding and compliance with the many special and complex responsibilities placed on the patient or caregiver for the storage, handling, and administration of CSPs. The instructional objectives for the training program include all home care responsibilities expected of the patient or caregiver and is specified in terms of patient or caregiver competencies.~~

~~Upon the conclusion of the training program, the patient or caregiver should, correctly and consistently, be able to do the following:~~

1. ~~Describe the therapy involved, including the disease or condition for which the CSPs are prescribed, goals of therapy, expected therapeutic outcome, and potential side effects of the CSPs.~~
2. ~~Inspect all drug products, CSPs, devices, equipment, and supplies on receipt to ensure that proper temperatures were maintained during transport and that goods received show no evidence of deterioration or defects.~~
3. ~~Handle, store, and monitor all drug products, CSPs, and related supplies and equipment in the home, including all special requirements related to same.~~
4. ~~Visually inspect all drug products, CSPs, devices, and other items the patient or caregiver is required to use immediately prior to administration in a manner to ensure that all items are acceptable for use. For example, CSPs must be free from leakage, container cracks, particulates, precipitate, haziness, discoloration, or other deviations from the normal expected appearance, and the immediate packages of sterile devices must be completely sealed, with no evidence of loss of package integrity.~~
5. ~~Check labels immediately prior to administration to ensure the right drug, dose, patient, and time of administration.~~
6. ~~Clean the in-home preparation area, scrub hands, use proper aseptic technique, and manipulate all containers, equipment, apparatus, devices, and supplies used in conjunction with administration.~~
7. ~~Employ all techniques and precautions associated with CSP administration; for example, preparing supplies and equipment, handling of devices, priming the tubing, and discontinuing an infusion.~~
8. ~~Care for catheters, change dressings, and maintain site patency as indicated.~~
9. ~~Monitor for and detect occurrences of therapeutic complications such as infection, phlebitis, electrolyte imbalance, and catheter misplacement.~~

10. ~~Respond immediately to emergency or critical situations such as catheter breakage or displacement, tubing disconnection, clot formation, flow blockage, and equipment malfunction.~~
11. ~~Know when to seek and how to obtain professional emergency services or professional advice.~~
12. ~~Handle, contain, and dispose of wastes, such as needles, syringes, devices, biohazardous spills or residuals, and infectious substances.~~

~~Training programs include a hands-on demonstration and practice with actual items that the patient or caregiver is expected to use, such as CSP containers, devices, and equipment. The patient or caregiver practices aseptic and injection technique under the direct observation of a health professional.~~

~~The compounding facility, in conjunction with nursing or medical personnel, is responsible for ensuring initially and on an ongoing basis that the patient or caregiver understands, has mastered, and is capable of and willing to comply with all of these home care responsibilities. This is achieved through a formal, written assessment program. All specified competencies in the patient or caregiver training program are formally assessed. The patient or caregiver is expected to demonstrate to appropriate healthcare personnel mastery of assigned activities before being allowed to administer CSPs unsupervised by a health professional.~~

~~Printed material such as checklists or instructions provided during training may serve as continuing post training reinforcement of learning or as reminders of specific patient or caregiver responsibilities. Post training verbal counseling can also be used periodically, as appropriate, to reinforce training and to ensure continuing correct and complete fulfillment of responsibilities.~~

~~PATIENT MONITORING AND ADVERSE EVENTS REPORTING~~

~~Compounding facilities shall clinically monitor patients treated with CSPs according to the regulations and guidelines of their respective state healthcare practitioner licensure boards or of accepted standards of practice. Compounding facilities shall provide patients and other recipients of CSPs with a way to address their questions and report any concerns that they may have with CSPs and their administration devices.~~

~~The SOP manuals of compounding facilities shall describe specific instructions for receiving, acknowledging, and dating receipts, and for recording, or filing, and evaluating reports of adverse events and of the quality of preparation claimed to be associated with CSPs. Reports of adverse events with CSPs shall be reviewed promptly and thoroughly by compounding supervisors to correct and prevent future occurrences. Compounding personnel are encouraged to participate in adverse event reporting and product defects programs of the FDA and USP.~~

~~QUALITY ASSURANCE (QA) PROGRAM~~

~~A provider of CSPs shall have in place a formal QA program intended to provide a mechanism for monitoring, evaluating, correcting, and improving the activities and processes described in this chapter. Emphasis in the QA program is placed on maintaining and improving the quality of systems and the provision of patient care. In~~

~~addition, the QA program ensures that any plan aimed at correcting identified problems also includes appropriate follow-up to make certain that effective corrective actions were performed.~~[11]

~~Characteristics of a QA program include the following:~~

1. ~~Formalization in writing;~~
2. ~~Consideration of all aspects of the preparations and dispensing of products as described in this chapter, including environmental testing and verification results;~~
3. ~~Description of specific monitoring and evaluation activities;~~
4. ~~Specification of how results are to be reported and evaluated;~~
5. ~~Identification of appropriate follow-up mechanisms when action limits or thresholds are exceeded; and~~
6. ~~Delineation of the individuals responsible for each aspect of the QA program.~~

~~In developing a specific plan, focus is on establishing objective, measurable indicators for monitoring activities and processes that are deemed high risk, high volume, or problem prone. In general, the selection of indicators and the effectiveness of the overall QA program is reassessed on an annual basis.~~

~~ABBREVIATIONS AND ACRONYMS~~

~~ACD~~	~~automated compounding device~~
~~ACPH~~	~~air changes per hour~~
~~ALARA~~	~~as low as reasonably achievable~~
~~ASHRAE~~	~~American Society of Heating, Refrigerating and Air Conditioning Engineers~~
~~BI~~	~~biological indicator~~
~~BSC~~	~~biological safety cabinet~~
~~BUD~~	~~beyond-use date~~
~~CACI~~	~~compounding aseptic containment isolator~~
~~CAI~~	~~compounding aseptic isolator~~
~~CDC~~	~~Centers for Disease Control and Prevention~~
~~CETA~~	~~Controlled Environment Testing Association~~
~~cfu~~	~~colony-forming unit(s)~~
~~CSP~~	~~compounded sterile preparation~~
~~CSTD~~	~~closed-system vial-transfer device~~
~~DCA~~	~~direct compounding area~~
~~ECV~~	~~endotoxin challenge vial~~
~~EU~~	~~Endotoxin Unit~~

~~FDA~~	~~Food and Drug Administration~~
~~HEPA~~	~~high efficiency particulate air~~
~~HICPAC~~	~~Healthcare Infection Control Practices Advisory Committee~~
~~HVAC~~	~~heating, ventilation, and air conditioning~~
~~IPA~~	~~isopropyl alcohol~~
~~ISO~~	~~International Organization for Standardization~~
~~LAFW~~	~~laminar airflow workbench~~
~~MDVs~~	~~multiple-dose vials~~
~~MMWR~~	~~Morbidity and Mortality Weekly Report~~
~~NIOSH~~	~~National Institute for Occupational Safety and Health~~
~~NIST~~	~~National Institute of Standards and Technology~~
~~PEC~~	~~primary engineering control~~
~~PET~~	~~positron emission tomography~~
~~PPE~~	~~personnel protective equipment~~
~~psi~~	~~pounds per square inch~~
~~QA~~	~~quality assurance~~
~~SOP~~	~~standard operating procedure~~
~~SVI~~	~~sterile vial for injection~~
~~TSA~~	~~trypticase soy agar~~
~~USP~~	~~United States Pharmacopeia~~

~~GLOSSARY~~

~~**Ante Area:**An ISO Class 8 (see *Table 1*) or better area where personnel hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high-particulate-generating activities are performed. It is also a transition area that (1) provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas and (2) reduces the need for the heating, ventilating, and air conditioning (HVAC) control system to respond to large disturbances.[12]~~

~~**Aseptic Processing:**(see *Microbiological Control and Monitoring of Aseptic Processing Environments* (1116)) A mode of processing pharmaceutical and medical products that involves the separate sterilization of the product and of the package (containers–closures or packaging material for medical devices) and the transfer of the product into the container and its closure under at least ISO Class 5 (see *Table 1*) conditions.~~

~~**Beyond-Use Date (BUD):**(see *General Notices and Requirements* and *Pharmaceutical Compounding—Nonsterile Preparations* (795)) For the purpose of this chapter, the date or time after which a CSP shall not be stored or transported. The date is determined from the date or time the preparation is compounded.~~

~~**Biological Safety Cabinet (BSC):**A ventilated cabinet for CSPs, personnel, product, and environmental protection having an open front with inward airflow for personnel protection, downward high-efficiency particulate air (HEPA) filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection.~~

~~**Buffer Area:**An area where the primary engineering control (PEC) is physically located. Activities that occur in this area include the preparation and staging of components and supplies used when compounding CSPs.~~

~~**Clean Room:**(see *Microbiological Control and Monitoring of Aseptic Processing Environments* ⟨1116⟩ and also the definition of *Buffer Area*) A room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class.~~

~~**Compounding Aseptic Containment Isolator (CACI):**A compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.~~

~~**Compounding Aseptic Isolator (CAI):**A form of isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbially retentive filter (HEPA minimum).[13]~~

~~**Critical Area:**An ISO Class 5 (see *Table 1*) environment.~~

~~**Critical Site:**A location that includes any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampuls, needle hubs) exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination. Risk of microbial particulate contamination of the critical site increases with the size of the openings and exposure time.~~

~~**Direct Compounding Area (DCA):**A critical area within the ISO Class 5 (see *Table 1*) primary engineering control (PEC) where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.~~

~~**Disinfectant:**An agent that frees from infection, usually a chemical agent but sometimes a physical one, and that destroys disease-causing pathogens or other harmful microorganisms but may not kill bacterial and fungal spores. It refers to substances applied to inanimate objects.~~

~~**First Air:**The air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.~~

~~**Hazardous Drugs:**Drugs are classified as hazardous if studies in animals or humans indicate that exposures to them have a potential for causing cancer, development or reproductive toxicity, or harm to organs. (See current NIOSH publication.)~~

~~**Labeling:**[see *General Notices and Requirements* and 21 USC 321 (k) and (m)] A term that designates all labels and other written, printed, or graphic matter on an immediate container of an article or preparation or on, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term "label" designates that part of the labeling on the immediate container.~~

~~**Media Fill Test:**(see *Microbiological Control and Monitoring of Aseptic Processing Environments* ⟨1116⟩) A test used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile product without microbial contamination. During this test, a microbiological growth medium such as Soybean–Casein Digest Medium is substituted for the actual drug product to simulate admixture compounding.[1] The issues to consider in the development of a media fill test are media fill procedures, media selection, fill volume, incubation, time and temperature, inspection of filled units, documentation, interpretation of results, and possible corrective actions required.~~

~~**Multiple-Dose Container:**(see *General Notices and Requirements* and ⟨659⟩. (CN 1-May-2016)) A multiple-unit container for articles or preparations intended for parenteral administration only and usually containing antimicrobial preservatives. The beyond-use date (BUD) for an opened or entered (e.g., needle-punctured) multiple-dose container with antimicrobial preservatives is 28 days (see *Antimicrobial Effectiveness Testing* ⟨51⟩), unless otherwise specified by the manufacturer.~~

~~**Negative Pressure Room:**A room that is at a lower pressure than the adjacent spaces and, therefore, the net flow of air is *into* the room.[12]~~

~~**Pharmacy Bulk Package:**(see ⟨659⟩. (CN 1-May-2016)) A container of a sterile preparation for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes. The closure shall be penetrated only one time after constitution with a suitable sterile transfer device or dispensing set, which allows measured dispensing of the contents. The pharmacy bulk package is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area).~~

~~Where a container is offered as a pharmacy bulk package, the label shall (a) state prominently "Pharmacy Bulk Package—Not for Direct Infusion," (b) contain or refer to information on proper techniques to help ensure safe use of the product, and (c) bear a statement limiting the time frame in which the container may be used once it has been entered, provided it is held under the labeled storage conditions.~~

~~**Primary Engineering Control (PEC):**A device or room that provides an ISO Class 5 (see *Table 1*) environment for the exposure of critical sites when compounding CSPs. Such devices include, but may not be limited to, laminar airflow workbenches (LAFWs), biological safety cabinets (BSCs), compounding aseptic isolators (CAIs), and compounding aseptic containment isolators (CACIs).~~

~~**Preparation:**A preparation, or a CSP, that is a sterile drug or nutrient compounded in a licensed pharmacy or other healthcare-related facility pursuant to the order of a licensed prescriber; the article may or may not contain sterile products.~~

~~**Product:**A commercially manufactured sterile drug or nutrient that has been evaluated for safety and efficacy by the FDA. Products are accompanied by full prescribing information, which is commonly known as the FDA-approved manufacturer's labeling or product package insert.~~

~~**Positive Pressure Room:**A room that is at a higher pressure than the adjacent spaces and, therefore, the net airflow is *out of* the room.[12]~~

~~**Single Dose Container:**(see *General Notices and Requirements* and (659). (CN 1-May-2016)) A single-dose container is a single unit container for articles (see *General Notices and Requirements*) or preparations intended for parenteral administration only. It is intended for a single use. A single-dose container is labeled as such. Examples of single-dose containers include prefilled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.~~

~~**Segregated Compounding Area:**A designated space, either a demarcated area or room, that is restricted to preparing low-risk level CSPs with 12-hour or less BUD. Such area shall contain a device that provides unidirectional airflow of ISO Class 5 (see *Table 1*) air quality for preparation of CSPs and shall be void of activities and materials that are extraneous to sterile compounding.~~

~~**Sterilizing Grade Membranes:**Membranes that are documented to retain 100% of a culture of 10^7 microorganisms of a strain of *Brevundimonas (Pseudomonas) diminuta* per square centimeter of membrane surface under a pressure of not less than 30 psi (2.0 bar). Such filter membranes are nominally at 0.22-µm or 0.2-µm nominal pore size, depending on the manufacturer's practice.~~

~~**Sterilization by Filtration:**Passage of a fluid or solution through a sterilizing grade membrane to produce a sterile effluent.~~

~~**Terminal Sterilization:**The application of a lethal process (e.g., steam under pressure or autoclaving) to sealed containers for the purpose of achieving a predetermined sterility assurance level of usually less than 10^{-6}, or a probability of less than one in one million of a nonsterile unit.[13]~~

~~**Unidirectional Flow** (see footnote 3)**:**An airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.~~

~~APPENDICES~~

~~Appendix I. Principal Competencies, Conditions, Practices, and Quality Assurances That Are Required († "shall") and Recommended (‡ "should") in USP Chapter ⟨797⟩~~

~~NOTE—This tabular appendix selectively abstracts and condenses the full text of ⟨797⟩ for rapid reference only. Compounding personnel are responsible for reading, understanding and complying with the full text and all official USP terminology, content, and conditions therein.~~
~~INTRODUCTION~~
~~‡ Chapter purpose is to prevent harm and death to patients treated with CSPs.~~
~~† Chapter pertains to preparation, storage, and transportation, but not administration, of CSPs.~~
~~† Personnel and facilities to which ⟨797⟩ applies; therefore, for whom and which it may be enforced by regulatory and accreditation authorities.~~
~~† Types of preparations designated to be CSPs according to their physical forms, and their sites and routes of administration to patients.~~
~~† Compounding personnel must be meticulously conscientious to preclude contact contamination of CSPs both within and outside ISO Class 5 areas.~~
~~ORGANIZATION~~
~~† All compounding personnel shall be responsible for understanding fundamental practices and precautions within USP ⟨797⟩, for developing and implementing appropriate procedures, and for continually evaluating these procedures and the quality of final CSPs to prevent harm.~~
~~RESPONSIBILITY OF COMPOUNDING PERSONNEL~~
~~† Practices and quality assurances required to prepare, store, and transport CSPs that are sterile, and acceptably accurate, pure, and stable.~~
~~CSP MICROBIAL CONTAMINATION RISK LEVELS~~
~~† Proper training and evaluation of personnel, proper cleansing and garbing of personnel, proper cleaning and disinfecting of compounding work environments, and proper maintenance and monitoring of controlled environmental locations (all of which are detailed in their respective sections).~~
~~Low Risk Level CSPs~~
~~† Aseptic manipulations within an ISO Class 5 environment using three or fewer sterile products and entries into any container.~~
~~† In absence of passing sterility test, store not more than 48 hours at controlled room temperature, 14 days at cold temperature, and 45 days in solid frozen state at −25° to~~

~~−10° or colder.~~
~~† Media-fill test at least annually by compounding personnel.~~
~~**Low Risk Level CSPs with 12 Hour or Less BUD**~~
~~† Fully comply with all four specific criteria.~~
~~‡ Sinks should not be located adjacent to the ISO Class 5 primary engineering control.~~
~~‡ Sinks should be separated from the immediate area of the ISO Class 5 primary engineering control device.~~
~~**Medium Risk Level CSPs**~~
~~† Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs.~~
~~† In absence of passing sterility test, store not more than 30 hours at controlled room temperature, 9 days at cold temperature, and 45 days in solid frozen state at −25° to −10° or colder.~~
~~†Media fill test at least annually by compounding personnel.~~
~~**High Risk Level CSPs**~~
~~† Confirmed presence of nonsterile ingredients and devices, or confirmed or suspected exposure of sterile ingredients for more than one hour to air quality inferior to ISO Class 5 before final sterilization.~~
~~† Sterilization method verified to achieve sterility for the quantity and type of containers.~~
~~† Meet allowable limits for bacterial endotoxins.~~
~~† Maintain acceptable strength and purity of ingredients and integrity of containers after sterilization.~~
~~† In absence of passing sterility test, store not more than 24 hours at controlled room temperature, 3 days at cold temperature, and 45 days in solid frozen state at −25° to −10° or colder.~~
~~† Media fill test at least semiannually by compounding personnel.~~
~~PERSONNEL TRAINING AND EVALUATION IN ASEPTIC MANIPULATIONS SKILLS~~
~~† Pass didactic, practical skill assessment and media fill testing initially, followed by an annual assessment for a low- and medium risk level compounding and semi-annual assessment for high-risk level compounding.~~
~~† Compounding personnel who fail written tests, or whose media fill test vials result in gross microbial colonization, shall be immediately reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies.~~
~~IMMEDIATE-USE CSPs~~
~~† Fully comply with all six specified criteria.~~
~~SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS~~

~~† Beyond-use date 28 days, unless specified otherwise by the manufacturer, for closure sealed multiple-dose containers after initial opening or entry.~~
~~† Beyond-use time of 6 hours, unless specified otherwise by the manufacturer, for closure sealed single-dose containers in ISO Class 5 or cleaner air after initial opening or entry.~~
~~† Beyond-use time of 1 hour for closure sealed single-dose containers after being opened or entered in worse than ISO Class 5 air.~~
~~† Storage of opened single-dose ampuls is not permitted.~~
~~HAZARDOUS DRUGS AS CSPs~~
~~† Appropriate personnel protective equipment.~~
~~† Appropriate primary engineering controls (BSCs and CACIs) are used for concurrent personnel protection and exposure of critical sites.~~
~~† Hazardous drugs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure.~~
~~† At least 0.01 inch water column negative pressure and 12 air changes per hour in non-cleanrooms in which CACIs are located.~~
~~† Hazardous drugs shall be handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparing for administration, and disposal.~~
~~† Hazardous drugs shall be prepared in an ISO Class 5 environment with protective engineering controls in place, and following aseptic practices specified for the appropriate contamination risk levels.~~
~~† Access to drug preparation areas shall be limited to authorized personnel.~~
~~† A pressure indicator shall be installed that can readily monitor room pressurization, which is documented daily.~~
~~† Annual documentation of full training of personnel regarding storage, handling, and disposal of hazardous drugs.~~
~~† When used, a CSTD shall be used in an ISO Class 5 primary engineering control device.~~
~~† At least 0.01 inch water column negative pressure is required for compounding of hazardous drugs.~~
~~‡ Negative-pressure buffer area is not required for low-volume compounding operations when CSTD is used in BSC or CACI.~~
~~† Compounding personnel of reproductive capability shall confirm in writing that they understand the risks of handling hazardous drugs.~~
~~† Disposal of all hazardous drug wastes shall comply with all applicable federal and state regulations.~~
~~‡ Total external exhaust of primary engineering controls.~~
~~‡ Assay of surface wipe samples every 6 months.~~

~~RADIOPHARMACEUTICALS AS CSPs~~
~~† Positron Emission Tomography is according to USP chapter ⟨823⟩.~~
~~† Appropriate primary engineering controls and radioactivity containment and shielding.~~
~~† Radiopharmaceuticals compounded from sterile components, in closed sterile containers, with volume of 100 mL or less for a single-dose injection or not more than 30 mL taken from a multiple-dose container shall be designated as and conform to the standards for low risk level CSPs.~~
~~† Radiopharmaceutical vials, designed for multi-use, compounded with technetium-99m, exposed to ISO Class 5 environment and punctured by needles with no direct contact contamination may be used up to the time indicated by manufacturers' recommendations.~~
~~† Location of primary engineering controls permitted in ISO Class 8 controlled environment.~~
~~† Technetium-99m/Molybdenum-99 generators used according to manufacturer, state, and federal requirements.~~
~~† Radiopharmaceuticals prepared as low risk level CSPs with 12 hour or less BUD shall be prepared in a segregated compounding area.~~
~~† Materials and garb exposed in patient care and treatment area shall not cross a line of demarcation into the segregated compounding area.~~
~~† Technetium-99m/Molybdenum-99 generators must be eluted in ISO Class 8 conditions.~~
~~† Segregated compounding area will be designated with a line of demarcation.~~
~~‡ Storage and transport of properly shielded vials of radiopharmaceutical CSPs may occur in a limited access ambient environment without a specific ISO class designation.~~
~~ALLERGEN EXTRACTS AS CSPs~~
~~† Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels when certain criteria are met.~~
~~VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY~~
~~† Review labels and document correct measurements, aseptic manipulations, and sterilization procedures to confirm correct identity, purity, and strength of ingredients in, and sterility of, CSPs.~~
~~‡ Assay finished CSPs to confirm correct identity and, or, strength of ingredients.~~
~~‡ Sterility test finished CSPs.~~
~~**Sterilization Methods**~~
~~† Verify that methods achieve sterility while maintaining appropriate strength, purity, quality, and packaging integrity.~~
~~‡ Prove effectiveness by USP chapter ⟨71⟩, equivalent, or superior sterility testing.~~

~~Sterilization of High-Risk Level CSPs by Filtration~~
~~† Nominal 0.2-µm pore size sterile membranes that are chemically and physically compatible with the CSP.~~
~~† Complete rapidly without filter replacement.~~
~~† Subject filter to manufacturer's recommended integrity test (e.g., bubble point test) after filtering CSPs.~~
~~Sterilization of High-Risk Level CSPs by Steam~~
~~† Test to verify the mass of containers to be sterilized will be sterile after the selected exposure duration in the particular autoclave.~~
~~† Ensure live steam contacts all ingredients and surfaces to be sterilized.~~
~~† Pass solutions through a 1.2 µm or smaller nominal pore size filter into final containers to remove particulates before sterilization.~~
~~† Heated filtered air shall be evenly distributed throughout the chamber by a blower device.~~
~~† Dry heat shall only be used for those materials that cannot be sterilized by steam, when the moisture would either damage or be impermeable to the materials.~~
~~† Sufficient space shall be left between materials to allow for good circulation of the hot air.~~
~~† The description of dry heat sterilization conditions and duration for specific CSPs shall be included in written documentation in the compounding facility. The effectiveness of dry heat sterilization shall be verified using appropriate biological indicators and other confirmation.~~
~~‡ The oven should be equipped with a system for controlling temperature and exposure period.~~
~~Depyrogenation by Dry Heat~~
~~† Dry heat depyrogenation shall be used to render glassware or containers, such as vials free from pyrogens as well as viable microbes.~~
~~† The description of the dry heat depyrogenation cycle and duration for specific load items shall be included in written documentation in the compounding facility.~~
~~† The effectiveness of the dry heat depyrogenation cycle shall be verified using endotoxin challenge vials (ECVs).~~
~~‡ The bacterial endotoxin test should be performed on the ECVs to verify the cycle is capable of achieving a 3 log reduction in endotoxin.~~
~~ENVIRONMENTAL QUALITY AND CONTROL~~
~~Exposure of Critical Sites~~
~~† ISO Class 5 or better air.~~
~~† Preclude direct contact (e.g., touch and secretions) contamination.~~
~~ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas~~

~~† A buffer area is an area that provides at least ISO Class 7 air quality.~~
~~† New representations of facility layouts.~~
~~† Each compounding facility shall ensure that each source of ISO Class 5 environment for exposure of critical sites and sterilization by filtration is properly located, operated, maintained, monitored, and verified.~~
~~† Devices (e.g., computers and printers) and objects (e.g., carts and cabinets) can be placed in buffer areas and shall be verified by testing or monitoring.~~
~~**Viable and Nonviable Environmental Sampling (ES) Testing**~~
~~† Environmental sampling shall occur as part a comprehensive quality management program and shall occur minimally when several conditions exist.~~
~~‡ The ES program should provide information to staff and leadership to demonstrate that the engineering controls are maintaining an environment within the compounding area that consistently maintains acceptably low viable and nonviable particle levels.~~
~~**Environmental Nonviable Particle Testing Program**~~
~~† Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) shall be performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) shall be used.~~
~~**Total Particle Counts**~~
~~† Certification that each ISO classified area (e.g., ISO Class 5, 7 and 8) is within established guidelines shall be performed no less than every 6 months and whenever the LAFW, BSC, CAI, or CACI is relocated or the physical structure of the buffer room or ante-area has been altered.~~
~~† Testing shall be performed by qualified operators using current, state-of-the-art electronic equipment with results meeting ISO Class 5, 7, or 8 depending on the requirements of the area.~~
~~† All certification records shall be maintained and reviewed by supervising personnel or other designated employee to ensure that the controlled environments comply with the proper air cleanliness, room pressures, and air changes per hour.~~
~~**Pressure Differential Monitoring**~~
~~† A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer area and ante-area, and the ante-area and the general environment outside the compounding area.~~
~~† The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device.~~
~~† The pressure between the ISO Class 7 and general pharmacy area shall not be less than 5 Pa (0.02 inch water column (w.c.)).~~
~~† In facilities where low- and medium-risk level CSPs are prepared, differential airflow~~

~~shall maintain a minimum velocity of 0.2 meter/second (40 fpm) between buffer area and ante-area.~~
~~Environmental Viable Airborne Particle Testing Program—Sampling Plan~~
~~† An appropriate environmental sampling plan shall be developed for airborne viable particles based on a risk assessment of compounding activities performed.~~
~~† Selected sampling sites shall include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the segregated compounding areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes).~~
~~† The plan shall include sample location, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels.~~
~~‡ It is recommended that compounding personnel refer to USP Chapter *Microbiological Control and Monitoring of Aseptic Processing Environments* (1116) and the CDC Guidelines for Environmental Infection Control in Healthcare Facilities 2003 for more information.~~
~~Growth Media~~
~~† A general microbiological growth medium such as Soybean–Casein Digest Medium (also known as trypticase soy broth (TSB) or agar (TSA)) shall be used to support the growth of bacteria.~~
~~† Malt extract agar (MEA) or some other media that supports the growth of fungi shall be used in high-risk level compounding environments.~~
~~† Media used for surface sampling shall be supplemented with additives to neutralize the effects of disinfecting agents (e.g., TSA with lecithin and polysorbate 80).~~
~~Viable Air Sampling~~
~~† Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments shall be performed by properly trained individuals for all compounding risk levels.~~
~~† Impaction shall be the preferred method of volumetric air sampling.~~
~~† For low , medium , and high risk level compounding, air sampling shall be performed at locations that are prone to contamination during compounding activities and during other activities like staging, labeling, gowning, and cleaning.~~
~~† Locations shall include zones of air backwash turbulence within laminar airflow workbench and other areas where air backwash turbulence may enter the compounding area.~~
~~† For low risk level CSPs with 12-hour or less BUD, air sampling shall be performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO class 5 environment, during the certification of the primary engineering control.~~
~~‡ Consideration should be given to the overall effect the chosen sampling method will have on the unidirectional airflow within a compounding environment.~~

~~Air Sampling Devices~~
~~† The instructions in the manufacturer's user manual for verification and use of electric air samplers that actively collect volumes of air for evaluation shall be followed.~~
~~† A sufficient volume of air (400–1000 liters) shall be tested at each location in order to maximize sensitivity.~~
~~‡ It is recommended that compounding personnel also refer to USP Chapter ⟨1116⟩, which can provide more information on the use of volumetric air samplers and volume of air that should be sampled to detect environmental bioburden excursions.~~
~~Air Sampling Frequency and Process~~
~~† Air sampling shall be performed at least semiannually (i.e. every 6 months), as part of the re-certification of facilities and equipment for area where primary engineering controls are located.~~
~~† A sufficient volume of air shall be sampled and the manufacturer's guidelines for use of the electronic air sampling equipment followed.~~
~~‡ Any facility construction or equipment servicing may require the need to perform air sampling during these events.~~
~~Incubation Period~~
~~† The microbial growth media plates used to collect environmental sampling are recovered, covers secured (e.g., taped), inverted, and incubated at a temperature and for a time period conducive to multiplication of microorganisms.~~
~~† The number of discrete colonies of microorganisms shall be counted and reported as colony-forming units (cfu) and documented on an environmental monitoring form. Counts from air monitoring need to be transformed into cfu/cubic meter of air and evaluated for adverse trends.~~
~~‡ TSA should be incubated at 35° ± 2 ° for 2–3 days.~~
~~‡ MEA or other suitable fungal media should be incubated at 28° ± 2 ° for 5–7 days.~~
~~Action Levels, Documentation and Data Evaluation~~
~~† Sampling data shall be collected and reviewed on a periodic basis as a means of evaluating the overall control of the compounding environment.~~
~~† Competent microbiology personnel shall be consulted if an environmental sampling consistently shows elevated levels of microbial growth.~~
~~† An investigation into the source of the environmental contamination shall be conducted.~~
~~‡ Any cfu count that exceeds its respective action level should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location.~~
~~‡ Table titled, Recommended Action Levels for Microbial Contamination should only be used as a guideline~~
~~Facility Design and Environmental Controls~~

~~† Compounding facilities are physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites.~~
~~† Compounding facilities shall provide a comfortable and well-lighted working environment, which typically includes a temperature of 20° or cooler to maintain comfortable conditions for compounding personnel when attired in the required aseptic compounding garb.~~
~~† Primary engineering controls provide unidirectional (i.e., laminar) HEPA air at a velocity sufficient to prevent airborne particles from contacting critical sites.~~
~~† In situ air pattern analysis via smoke studies shall be conducted at the critical area to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions.~~
~~† Policies and procedures for maintaining and working within the primary engineering control area shall be written and followed. The policies and procedures will be determined by the scope and risk levels of the aseptic compounding activities used during the preparation of the CSPs.~~
~~† The principles of HEPA filtered unidirectional airflow in the work environment shall be understood and practiced in the compounding process in order to achieve the desired environmental conditions.~~
~~† Clean rooms for nonhazardous and nonradioactive CSPs are supplied with HEPA that enters from ceilings with return vents low on walls, and that provides not less than 30 air changes per hour.~~
~~† Buffer areas maintain 0.02- to 0.05-inch water column positive pressure, and do not contain sinks or drains.~~
~~† Air velocity from buffer rooms or zones to ante areas is at least 40 feet/minute.~~
~~† The primary engineering controls shall be placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation.~~
~~† The primary engineering controls shall be placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross drafts.~~
~~† HEPA filtered supply air shall be introduced at the ceiling.~~
~~† All HEPA filters shall be efficiency tested using the most penetrating particle size and shall be leak tested at the factory and then leak tested again in situ after installation.~~
~~† Activities and tasks carried out within the buffer area shall be limited to only those necessary when working within a controlled environment.~~
~~† Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed shall be brought into the room.~~
~~† Surfaces and essential furniture in buffer rooms or zones and clean rooms shall be nonporous, smooth, nonshedding, impermeable, cleanable, and resistant to disinfectants.~~
~~† The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area shall be smooth, impervious, free from cracks and crevices, and nonshedding, thereby promoting cleanability, and minimizing spaces in which~~

~~microorganisms and other contaminants may accumulate.~~
~~† The surfaces shall be resistant to damage by disinfectant agents.~~
~~† Junctures of ceilings to walls shall be coved or caulked to avoid cracks and crevices where dirt can accumulate.~~
~~† Ceiling tiles shall be caulked around each perimeter to seal them to the support frame.~~
~~† The exterior lens surface of ceiling lighting fixtures shall be smooth, mounted flush, and sealed.~~
~~† Any other penetrations through the ceiling or walls shall be sealed.~~
~~† The buffer area shall not contain sources of water (sinks) or floor drains. Work surfaces shall be constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected.~~
~~† Carts shall be of stainless steel wire, nonporous plastic, or sheet metal construction with good quality, cleanable casters to promote mobility.~~
~~† Storage shelving, counters, and cabinets shall be smooth, impervious, free from cracks and crevices, nonshedding, cleanable, and disinfectable.~~
~~† Their number, design, and manner of installation the itmes above shall promote effective cleaning and disinfection.~~
~~‡ If ceilings consist of inlaid panels, the panels should be impregnated with a polymer to render them impervious and hydrophobic.~~
~~‡ Dust-collecting overhangs, such as ceiling utility pipes, or ledges, such as windowsills, should be avoided.~~
~~‡ Air returns should be mounted low on the wall creating a general top-down dilution of room air with HEPA-filtered make-up air.~~
~~**Placement of Primary Engineering Controls Within ISO Class 7 Buffer Area**s~~
~~† Primary engineering controls for nonhazardous and nonradioactive CSPs are located in buffer areas, except for CAIs that are proven to maintain ISO Class 5 air when particle counts are sampled 6 to 12 inches upstream of critical site exposure areas during performance of normal inward and outward transfer of materials, and compounding manipulations when such CAIs are located in air quality worse than ISO Class 7.~~
~~† Presterilization procedures for high-risk level CSPs, such as weighing and mixing, shall be completed in no worse than an ISO Class 8 environment.~~
~~† Primary engineering controls shall be located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns.~~
~~† When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.~~
~~† When compounding activities require the manipulation of a patient's blood-derived or other biological material (e.g., radiolabeling a patient's or a donor's white blood cells),~~

~~the manipulations shall be clearly separated from routine material handling procedures and equipment used in CSP preparation activities, and they shall be controlled by specific standard operating procedures in order to avoid any cross-contamination.~~
~~† Food, drinks, and items exposed in patient care areas, and unpacking of bulk supplies and personnel cleansing and garbing are prohibited from buffer areas or rooms.~~
~~† Demarcation designation between buffer areas or rooms and ante-areas.~~
~~† Antiseptic hand cleansing and sterile gloves in buffer areas or rooms.~~
~~‡ Packaged compounding supplies and components, such as needles, syringes, tubing sets, and small- and large-volume parenterals, should be uncartoned and wiped down with a disinfectant that does not leave a residue (e.g., sterile 70% IPA) when possible in an ante-area, of ISO Class 8 air quality, before being passed into the buffer areas.~~
~~Cleaning and Disinfecting the Sterile Compounding Areas~~
~~† Trained personnel write detailed procedures including cleansers, disinfectants, and non-shedding wipe and mop materials.~~
~~† Cleaning and disinfecting surfaces in the LAFWs, BSCs, CAIs, and CACIs shall be cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches.~~
~~† Trained compounding personnel are responsible for developing, implementing, and practicing the procedures for cleaning and disinfecting the DCAs written in the SOPs.~~
~~† Cleaning and disinfecting shall occur before compounding is performed. Items shall be removed from all areas to be cleaned, and surfaces shall be cleaned by removing loose material and residue from spills, e.g., water-soluble solid residues are removed with Sterile Water (for Injection or Irrigation) and low-shedding wipes. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile 70% IPA, which is allowed to dry before compounding begins.~~
~~† Work surfaces in ISO Class 7 and 8 areas and segregated compounding areas are cleaned at least daily.~~
~~† Dust and debris shall be removed when necessary from storage sites for compounding ingredients and supplies, using a method that does not degrade the ISO Class 7 or 8 air quality.~~
~~† Floors in ISO Class 7 and 8 areas are cleaned daily when no compounding occurs.~~
~~† IPA (70% isopropyl alcohol) remains on surfaces to be disinfected for at least 30 seconds before such surfaces are used to prepare CSPs.~~
~~† Emptied shelving, walls, and ceilings in ante-areas are cleaned and disinfected at least monthly.~~
~~† Mopping shall be performed by trained personnel using approved agents and procedures described in the written SOPs.~~
~~† Cleaning and disinfecting agents, their schedules of use and methods of application shall be in accordance with written SOPs and followed by custodial and/or compounding~~

~~personnel.~~
~~† All cleaning materials, such as wipers, sponges, and mops, shall be nonshedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer area, or ante-area, and segregated compounding areas and shall not be removed from these areas except for disposal.~~
~~† If cleaning materials are reused (e.g., mops), procedures shall be developed (based on manufacturer recommendations) that ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned.~~
~~† Supplies and equipment removed from shipping cartons shall be wiped with a suitable disinfecting agent (e.g., sterile 70% IPA) delivered from a spray bottle or other suitable delivery method.~~
~~† After the disinfectant is sprayed or wiped on a surface to be disinfected, the disinfectant shall be allowed to dry, and during this time the item shall not be used for compounding purposes.~~
~~† Sterile 70% IPA wetted gauze pads or other particle-generating material shall not be used to disinfect the sterile entry points of packages and devices.~~
~~**Personnel Cleansing and Garbing**~~
~~† Personnel shall also be thoroughly competent and highly motivated to perform flawless aseptic manipulations with ingredients, devices, and components of CSPs.~~
~~† Personnel with rashes, sunburn, weeping sores, conjunctivitis, active respiratory infection, and cosmetics are prohibited from preparing CSPs.~~
~~† Compounding personnel shall remove personal outer garments; cosmetics; artificial nails; hand, wrist, and body jewelry that can interfere with the fit of gowns and gloves; and visible body piercing above the neck.~~
~~† Order of compounding garb and cleansing in ante-area: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying; non-shedding gown.~~
~~† Order of cleansing and gloving in buffer room or area: hand cleansing with a persistently active alcohol-based product with persistent activity; allow hands to dry; don sterile gloves.~~
~~† Routinely disinfect gloves with sterile 70% IPA after contacting nonsterile objects.~~
~~† Inspect gloves for holes and replace when breaches are detected.~~
~~† Personnel repeat proper procedures after they are exposed to direct contact contamination or worse than ISO Class 8 air.~~
~~† These requirements are exempted only for immediate-use CSPs and CAIs for which manufacturers provide written documentation based on validated testing that such personnel practices are not required to maintain sterility in CSPs.~~
~~**Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures**~~

~~† Personnel who prepare CSPs shall be trained conscientiously and skillfully by expert personnel, multi media instructional sources, and professional publications in the theoretical principles and practical skills of garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 environmental conditions, and cleaning and disinfection procedures.~~
~~† This training shall be completed and documented before any compounding personnel begin to prepare CSPs.~~
~~† Compounding personnel shall complete didactic training, pass written competence assessments, undergo skill assessment using observational audit tools, and media fill testing.~~
~~† Media fill testing of aseptic work skills shall be performed initially before beginning to prepare CSPs and at least annually thereafter for low- and medium-risk level compounding; and semiannually for high-risk level compounding.~~
~~† Compounding personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing visible microbial contamination, shall be reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies.~~
~~† Compounding personnel shall pass all evaluations prior to resuming compounding of sterile preparations.~~
~~† Compounding personnel must demonstrate proficiency of proper hand hygiene, garbing, and consistent cleaning procedures in addition to didactic evaluation and aseptic media fill.~~
~~† Cleaning and disinfecting procedures performed by other support personnel shall be thoroughly trained in proper hand hygiene, and garbing, cleaning, and disinfection procedures by a qualified aseptic compounding expert.~~
~~† Support personnel shall routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert.~~
~~Competency Evaluation of Garbing and Aseptic Work Practices~~
~~† Compounding personnel shall be evaluated initially prior to beginning compounding CSPs and whenever an aseptic media fill is performed using a Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel and the personnel glove fingertip sampling procedures.~~
~~Aseptic Work Practice Assessment and Evaluation via Personnel Glove Fingertip Sampling~~
~~† Monitoring of compounding personnel glove fingertips shall be performed for all CSP risk level compounding.~~
~~† Glove fingertip sampling shall be used to evaluate the competency of personnel in performing hand hygiene and garbing procedures in addition to educating compounding personnel on proper work practices.~~
~~† All personnel shall demonstrate competency in proper hand hygiene and garbing~~

~~procedures in addition to aseptic work practices.~~
~~† Sterile contact agar plates shall be used to sample the gloved fingertips of compounding personnel after garbing to assess garbing competency and after completing the media-fill preparation.~~
~~† Gloves shall not be disinfected with sterile 70% IPA immediately prior to sampling.~~
~~**Garbing and Gloving Competency Evaluation**~~
~~† Compounding personnel shall be visually observed during the process of performing hand hygiene and garbing procedures.~~
~~† The visual observation shall be documented on a Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel and maintained to provide a permanent record of and long-term assessment of personnel competency.~~
~~**Gloved Fingertip Sampling**~~
~~† Immediately after the compounder completes the hand hygiene and garbing procedure, the evaluator shall collect a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates by lightly pressing each finger tip into the agar.~~
~~† The plates shall be incubated for the appropriate incubation period and at the appropriate temperature.~~
~~† All employees shall successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use.~~
~~† After completing the initial gowning and gloving competency evaluation, re-evaluation of all compounding personnel shall occur at least annually for low- and medium-risk level CSPs and semiannually for high-risk level CSPs before being allowed to continue compounding CSPs.~~
~~† Gloves shall not be disinfected with sterile 70% IPA prior to testing.~~
~~† The sampled gloves shall be immediately discarded and proper hand hygiene performed after sampling. The nutrient agar plates shall be incubated as stated below.~~
~~† The cfu action level for gloved hands shall be based on the total number of cfu on both gloves and not per hand.~~
~~‡ Results should be reported separately as number of cfu per employee per hand (left hand, right hand).~~
~~**Incubation Period**~~
~~† At the end of the designated sampling period, the agar plates are recovered, covers secured, inverted and incubated at a temperature and for a time period conducive to multiplication of microorganisms. Trypticase soy agar (TSA) with lecithin and polysorbate 80 shall be incubated at 35°± 2° for 2–3 days.~~
~~**Aseptic Manipulation Competency Evaluation**~~
~~† All compounding personnel shall have their aseptic technique and related practice competency evaluated initially during the media-fill test procedure and subsequent~~

~~annual or semiannual media fill test procedures on the Sample Form for Assessing Aseptic Technique and Related Practices of Compounding Personnel.~~
~~Media Fill Test Procedure~~
~~† The skill of personnel to aseptically prepare CSPs shall be evaluated using sterile fluid bacterial culture media fill verification.~~
~~† Media filled vials shall be incubated within a range of 35° ± 2° for 14 days.~~
~~Surface Cleaning and Disinfection Sampling and Assessment~~
~~† Surface sampling shall be performed in all ISO classified areas on a periodic basis and can be accomplished using contact plates and/or swabs and shall be done at the conclusion of compounding.~~
~~† Locations to be sampled shall be defined in a sample plan or on a form.~~
~~Cleaning and Disinfecting Competency Evaluation~~
~~† Compounding personnel and other personnel responsible for cleaning shall be visually observed during the process of performing cleaning and disinfecting procedures during initial personnel training on cleaning procedures, changes in cleaning staff and at the completion of any Media Fill Test Procedure.~~
~~† Visual observation shall be documented on a Sample Form for Assessing Cleaning and Disinfection Procedures and maintained to provide a permanent record of, and long-term assessment of, personnel competency.~~
~~Surface Collection Methods~~
~~† Immediately after sampling a surface with the contact plate, the sampled area shall be thoroughly wiped with a non-shedding wipe soaked in sterile 70% IPA.~~
~~‡ Results should be reported as cfu per unit of surface area.~~
~~Action Levels, Documentation, and Data Evaluation~~
~~† Environmental sampling data shall be collected and reviewed on a routine basis as a means of evaluating the overall control of the compounding environment.~~
~~† If an activity consistently shows elevated levels of microbial growth, competent microbiology personnel shall be consulted.~~
~~† An investigation into the source of the contamination shall be conducted.~~
~~† When gloved fingertip sample results exceeds action levels after proper incubation, a review of hand hygiene and garbing procedures as well as glove and surface disinfection procedures and work practices shall be performed and documented.~~
~~‡ Any cfu count that exceeds its respective action level should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location.~~
~~SUGGESTED STANDARD OPERATING PROCEDURES~~
~~† All facilities are required to have these, and they must include at least the items enumerated in this section.~~
~~FINISHED PREPARATION RELEASE CHECKS AND TESTS~~

~~Inspection of Solution Dosage Forms and Review of Compounding Procedures~~
~~† Review procedures and documents to ensure sterility, purity, correct identities and amounts of ingredients, and stability.~~
~~† Visually inspect for abnormal particulate matter and color, and intact containers and seals.~~
~~Sterility Testing~~
~~† High-risk level CSPs prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8° before being sterilized.~~
~~Bacterial Endotoxin (Pyrogen) Testing~~
~~† High-risk level CSPs, excluding those for inhalation and ophthalmic administration, prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8°, before being sterilized.~~
~~Identity and Strength Verification of Ingredients~~
~~† Written procedures to verify correct identity, quality, amounts, and purities of ingredients used in CSPs.~~
~~† Written procedures to ensure labels of CSPs contain correct names and amounts or concentrations of ingredients, total volumes, beyond-use dates, storage conditions, and route(s) of administration.~~
~~STORAGE AND BEYOND-USE DATING~~
~~Determining Beyond-Use Dates~~
~~† Use the general criteria in USP ⟨795⟩ in the absence of direct stability-indicating assays or authoritative literature that supports longer durations.~~
~~MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs~~
~~† Written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity, and strength of CSPs.~~
~~Redispensed CSPs~~
~~† When sterility, and acceptable purity, strength, and quality can be ensured.~~
~~† Assignment of sterility storage times and stability beyond-use dates that occur later than those of originally dispensed CSPs must be based on results of sterility testing and quantitative assay of ingredients.~~
~~Packaging and Transporting CSPs~~
~~† Packaging maintains physical integrity, sterility, stability, and purity of CSPs.~~
~~† Modes of transport that maintain appropriate temperatures and prevent damage to CSPs.~~
~~PATIENT OR CAREGIVER TRAINING~~
~~† Multiple-component formal training program to ensure patients and caregivers~~

understand the proper storage, handling, use, and disposal of CSPs.
PATIENT MONITORING AND ADVERSE EVENTS REPORTING
† Written standard procedures describe means for patients to ask questions and report concerns and adverse events with CSPs, and for compounding supervisors to correct and prevent future problems.
‡ Adverse events and defects with CSPs reported to FDA's MedWatch and USP's MEDMARX programs.
GLOSSARY
† Twenty-eight terms are defined and integral to complying with USP ⟨797⟩.

Appendix II. Common Disinfectants Used in Health Care for Inanimate Surfaces and Noncritical Devices, and Their Microbial Activity and Properties[1]

Chemical Category of Disinfectant							
		Isopropyl alcohol	**Accelerated hydrogen peroxide**	**Quaternary Ammonium (e.g., dodecyl dimethyl ammonium chloride)**	**Phenolics**	**Chlorine (e.g., sodium hypochlorite)**	**Iodophors (e.g., povidone-iodine)**
Concentration Used		**60–95%**	**0.5%**[3]	**0.4–1.6% aq**	**0.4–1.6% aq**	**100–5000 ppm**	**30–50 ppm**
Microbial Inactivation[2]	Bacteria	+	+	+	+	+	+
	Lipophilic viruses	+	+	+	+	+	+
	Hydrophilic viruses	±	+	±	±	+	±
	M.tuberculosis	+	+	±	+	+	±
	Mycotic agents (fungi)	+	+	+	+	+	±
	Bacterial Spores	–	–	–	–	+	–
Important Chemical & Physical Properties	Shelf life >1 week	+	+	+	+	+	+
	Corrosive or deleterious effects	±	–	–	–	±	±
	Non-evaporable	–	–	+	+	–	+

Chemical Category of Disinfectant							
		Isopropyl alcohol	Accelerated hydrogen peroxide	Quaternary Ammonium (e.g., dodecyl dimethyl ammonium chloride)	Phenolics	Chlorine (e.g., sodium hypochlorite)	Iodophors (e.g., povidone-iodine)
Concentration Used		60–95%	0.5%[3]	0.4–1.6% aq	0.4–1.6% aq	100–5000 ppm	30–50 ppm
	residue						
	Inactivated by organic matter	+	±	+	±	+	+
	Skin irritant	±	−	+	+	+	±
	Eye irritant	+	−	+	+	+	+
	Respiratory irritant	−	−	−	−	+	−
	Systemic toxicity	+	−	+	+	+	+

Key to abbreviation and symbols: aq = diluted with water; ppm = parts per million; + = yes; − = no; ± = variable results.

[1] Modified from World Health Organization, Laboratory Bio Safety Manual 1983 and Rutala WA, "Antisepsis, disinfection and sterilization in the hospital and related institutions," *Manual of Clinical Microbiology,* American Society for Microbiology, Washington, DC, 1995, pages 227-245.

[2] Inactivation of the most common microorganisms (i.e., bacteria) occurs with a contact time of ≤1 minute; inactivation of spores requires longer contact times (e.g., 5-10 minutes for 5,000 ppm chlorine solution against *C. difficile spores). Reference: Perez J, Springthorpe VS, Sattar SA, "Activity of selected oxidizing microbicides against the spores of Clostridium difficile: Relevance to environmental control," American Journal of Infection Control, August 2005, pages 320-325.*

[3] *Accelerated* hydrogen peroxide is a new generation of hydrogen peroxide-based germicides in which the potency and performance of the active ingredient have been enhanced and accelerated through the use of appropriate acids and detergents.

Appendix III. Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel

Printed name and position/title of person assessed:	
Name of facility or location:	

Hand Hygiene and Garbing Practices: The qualified evaluator will check each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.*

	~~Presents in a clean appropriate attire and manner.~~
	~~Wears no cosmetics or jewelry (watches, rings, earrings, etc. piercing jewelry included) upon entry into ante-areas.~~
	~~Brings no food or drinks into or stored in the ante-areas or buffer areas.~~
	~~Is aware of the line of demarcation separating clean and dirty sides and observes required activities.~~
	~~Dons shoe covers or designated clean-area shoes one at a time, placing the covered or designated shoe on clean side of the line of demarcation, as appropriate.~~
	~~Dons beard cover if necessary.~~
	~~Dons head cover assuring that all hair is covered.~~
	~~Dons face mask to cover bridge of nose down to include chin.~~
	~~Performs hand hygiene procedure by wetting hands and forearms and washing using soap and warm water for at least 30 seconds.~~
	~~Dries hands and forearms using lint-free towel or hand dryer.~~
	~~Selects the appropriate sized gown examining for any holes, tears, or other defects.~~
	~~Dons gown and ensures full closure.~~
	~~Disinfects hands again using a waterless alcohol-based surgical hand scrub with persistent activity and allows hands to dry thoroughly before donning sterile gloves.~~
	~~Dons appropriate sized sterile gloves ensuring that there is a tight fit with no excess glove material at the fingertips.~~
	~~Examines gloves ensuring that there are no defects, holes, or tears.~~
	~~While engaging in sterile compounding activities, routinely disinfects gloves with sterile 70% IPA prior to work in the direct compounding area (DCA) and after touching items or surfaces that may contaminate gloves.~~

	~~Removes PPE on the clean side of the ante-area.~~
	~~Removes gloves and performs hand hygiene.~~
	~~Removes gown and discards it, or hangs it on hook if it is to be reused within the same work day.~~
	~~Removes and discards mask, head cover, and beard cover (if used).~~
	~~Removes shoe covers or shoes one at a time, ensuring that uncovered foot is placed on the dirty side of the line of demarcation and performs hand hygiene again. (Removes and discards shoe covers every time the compounding area is exited).~~

~~***The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking check marks, N/A, or N/O) and shown and informed of specific corrections.**~~		
~~Signature of Person Assessed~~	~~Printed Name~~	~~Date~~
~~Signature of Qualified Evaluator~~	~~Printed Name~~	~~Date~~

~~Appendix IV. Sample Form for Assessing Aseptic Technique and Related Practices of Compounding Personnel~~

~~Printed name and position/title of person assessed:~~	
~~Name of facility or location:~~	

~~**Aseptic Technique, Safety, and Quality Assurance Practices:** The qualified evaluator checks each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.*~~	
	~~Completes the Hand Hygiene and Garbing Competency Assessment Form.~~
	~~Performs proper hand hygiene, garbing, and gloving procedures according to SOPs.~~
	~~Disinfects ISO Class 5 device surfaces~~

	~~with an appropriate agent.~~
	~~Disinfects components/vials with an appropriate agent prior to placing into ISO Class 5 work area.~~
	~~Introduces only essential materials in a proper arrangement in the ISO Class 5 work area.~~
	~~Does not interrupt, impede, or divert flow of first-air to critical sites.~~
	~~Ensures syringes, needles, and tubing remain in their individual packaging and are only opened in ISO Class 5 work area.~~
	~~Performs manipulations only in the appropriate DCA of the ISO Class 5 device.~~
	~~Does not expose critical sites to contact contamination or worse than ISO Class 5 air.~~
	~~Disinfects stoppers, injection ports, and ampul necks by wiping with sterile 70% IPA and allows sufficient time to dry.~~
	~~Affixes needles to syringes without contact contamination.~~
	~~Punctures vial stoppers and spikes infusion ports without contact contamination.~~
	~~Labels preparation(s) correctly.~~
	~~Disinfects sterile gloves routinely by wiping with sterile 70% IPA during prolonged compounding manipulations.~~
	~~Cleans, sets up, and calibrates automated compounding device (e.g., "TPN compounder") according to manufacturer's instructions.~~
	~~Disposes of sharps and waste according to institutional policy or recognized guidelines.~~
~~***The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking check marks, N/A, or N/O) and shown and informed of specific corrections.**~~	

~~Signature of Person Assessed~~	~~Printed Name~~	~~Date~~
~~Signature of Qualified Evaluator~~	~~Printed Name~~	~~Date~~

~~Appendix V. Sample Form for Assessing Cleaning and Disinfection Procedures~~

~~Printed name and position/title of person assessed:~~	
~~Name of facility or location:~~	

~~Cleaning and Disinfection Practices:~~ ~~The qualified evaluator will check each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.*~~

~~Daily Tasks:~~	
	~~Prepares correct concentration of disinfectant solution according to manufacturer's instructions.~~
	~~Uses appropriately labeled container for the type of surface to be cleaned (floor, wall, production bins, etc.).~~
	~~Documents disinfectant solution preparation.~~
	~~Follows garbing procedures when performing any cleaning activities.~~
	~~At the beginning of each shift, cleans all ISO Class 5 devices prior to compounding in the following order: walls, IV bar, automated compounders, and work surface.~~
	~~Uses a lint free wipe soaked with sterile 70% IPA or other approved disinfectant solution and allows to dry completely.~~
	~~Removes all compounder components and cleans all ISO Class 5 areas as stated above at the end of each shift.~~
	~~Cleans all counters and easily cleanable work surfaces.~~
	~~Mops floors, using the mop labeled “floors,” starting at the wall opposite the room entry door; mops floor surface in even strokes toward the operator. Moves~~

	~~carts as needed to clean entire floor surface. Use of a microfiber cleaning system is an acceptable alternative to mops.~~
	~~In the ante-area, cleans sink and all contact surfaces; cleans floor with a disinfectant solution or uses microfiber cleaning system.~~
~~Monthly Tasks:~~	
	~~Performs monthly cleaning on a designated day. Prepares a disinfectant solution as stated in daily tasks that is appropriate for the surfaces to be cleaned.~~
	~~Cleans buffer area and ante-area ceiling, walls, and storage shelving with a disinfectant solution and a mop or uses a microfiber cleaning system.~~
	~~Once ISO Class 5 area is clean, cleans compounding room ceiling, followed by walls and ending with the floor. Uses appropriate labeled mops or microfiber cleaning system.~~
	~~Cleans all buffer area totes and storage shelves by removing contents and using a germicidal detergent soaked lint free wipe, cleans the inside surfaces of the tote and then the entire exterior surfaces of the tote. Allows totes to dry. Prior to replacing contents into tote, wipes tote with sterile 70% IPA to remove disinfectant residue. Uses new wipe as needed.~~
	~~Cleans all buffer area carts by removing contents and using germicidal detergent soaked lint free wipe, cleans all carts starting with the top shelf and top of post, working down to wheels. Cleans the under side of shelves in a similar manner. Uses a new wipe for each cart. Allows to dry. Wipes carts with sterile 70% IPA wetted lint free wipe to remove any disinfectant residue. Uses new wipe as needed.~~
	~~Cleans buffer area chairs, the interior and exterior of trash bins, and storage bins using disinfectant solution soaked lint free wipe.~~
	~~Documents all cleaning activities as to who performed such activities with date and time noted.~~
~~*The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking check marks, N/A, or N/O) and shown and informed of specific~~	

~~**corrections.**~~		
~~Signature of Person Assessed~~	~~Printed Name~~	~~Date~~
~~Signature of Qualified Evaluator~~	~~Printed Name~~	~~Date~~

▲1. INTRODUCTION AND SCOPE

This chapter describes the minimum practices and quality standards to be followed when preparing compounded sterile human and animal drugs (compounded sterile preparations, or CSPs). These practices and standards must be used to prevent harm, including death, to human and animal patients that could result from 1) microbial contamination (nonsterility), 2) excessive bacterial endotoxins, 3) variability from the intended strength of correct ingredients, 4) chemical and physical contaminants, and/or 5) use of ingredients of inappropriate quality.

1.1 Scope

CSP AFFECTED

The requirements and standards described in this chapter must be used to ensure the sterility of any CSP. Although the list below is not exhaustive, the following must be sterile:

- Injections
- Aqueous bronchial inhalations
- Baths and soaks for live organs and tissues
- Irrigations for internal body cavities (i.e., any space that does not freely communicate with the environment outside of the body)
- Ophthalmics
- Implants

For the compounding of hazardous drugs, see *Hazardous Drugs—Handling in Healthcare Settings* ⟨800⟩.

PERSONNEL AND SETTINGS AFFECTED

This chapter applies to all persons who prepare CSPs (e.g., pharmacists, pharmacy technicians, physicians, veterinarians, and nurses) at all places where CSPs are prepared (e.g., hospitals and other healthcare institutions, patient treatment sites, infusion facilities, pharmacies, and physicians' or veterinarians' practice sites).

The compounding organization's leadership and all employees involved in preparing, storing, and transporting CSPs are responsible for 1) ensuring that the applicable practices and quality standards in this chapter are continually and consistently applied to their operations, and 2) proactively identifying and remedying potential problems within their operations.

SPECIFIC PRACTICES

Administration of medications: This chapter is not intended to address administration of sterile medications. Administration of sterile medications should be performed in accordance with the Centers for Disease Control and Prevention's Safe Injection Practices[1] and the manufacturer's or compounder's labeling of the sterile medication.

Proprietary bag and vial systems: Docking and activation of proprietary bag and vial systems (e.g., ADD-Vantage®, Mini Bag Plus®, addEASE®) strictly in accordance

with the manufacturer's instructions for immediate administration to an individual patient is not considered compounding. However, aseptic technique must be followed when attaching the proprietary bag and vial system.

Docking of the proprietary bag and vial systems for future activation and administration is considered compounding and must be performed in accordance with this chapter, with the exception of *12. Establishing Beyond-Use Dates and In-Use Times*. Beyond-use dates (BUDs) for proprietary bag and vial systems must be assigned in accordance with the manufacturer's instructions provided in product labeling.

Reconstitution or dilution: Reconstituting or diluting a conventionally manufactured sterile product with no intervening steps strictly in accordance with the manufacturer's labeling for administration to an individual patient is not considered compounding. However, aseptic technique must be followed during preparation, and procedures must be in place to minimize the potential for contact with nonsterile surfaces and introduction of particulate matter or biological fluids.

Any other reconstitution or dilution of a conventionally manufactured sterile product is considered compounding and must be performed in accordance with this chapter.

Repackaging: Repackaging of a conventionally manufactured sterile product from its original primary container into another primary container must be performed in accordance with the requirements in this chapter for CSPs, including assignment of BUDs and in-use times as described in *12. Establishing Beyond-Use Dates and In-Use Times*.

1.2 Factors Affecting the Risks Associated with CSPs

CSPs can be compounded using only sterile starting ingredients or using some or all nonsterile starting ingredients. If all of the components used to compound a drug are sterile to begin with, the sterility of the components must be maintained during compounding to produce a sterile compounded preparation. If one or more of the starting components being used to compound is not sterile, the sterility of the compounded preparation must be achieved through a sterilization process, such as terminal sterilization in the final sealed container or sterile filtration, and then maintained through subsequent manipulations of the preparation. When compounding with nonsterile starting ingredients, the quality of the components and the effectiveness of the sterilization step are particularly critical to achieving a sterile preparation. In all cases, failure to achieve and/or maintain sterility of CSPs can lead to serious harm, including death. Personnel engaged in compounding and handling CSPs must strictly adhere to the standards in this chapter throughout the compounding process and until the preparation reaches the intended patient(s).

The risks to the sterility associated with a particular CSP depend on a number of factors, including the following:

- Batch size
- Complexity of the compounding process (e.g., number of manipulations involved; whether starting with nonsterile or sterile components)

- Inherent nature of the drug being compounded (e.g., whether the drug is susceptible to microbial growth; whether the preparation will be preservative free)
- Complexity of the compounding operation (e.g., multiple people in the cleanroom at the same time; multiple CSPs being prepared at the same time; activity in the surrounding areas)
- Length of time between the start of compounding (including making a stock solution) and administration of the drug to the patient

Ultimately, the risk to the population of patients is lower if the compounding is done for an individual patient as compared to when the compounding is done in a batch for multiple patients. When applying the standards in this chapter, the risks of a particular compounding operation must be considered, and steps commensurate with these risks must be taken to ensure a quality CSP.

1.3 Risk Categories

Consistent with this risk-based approach, this chapter distinguishes between two categories of CSPs, Category 1 and Category 2, primarily by the conditions under which they are made and the time within which they will be used. Category 1 CSPs are those assigned a maximum BUD of 12 hours or less at controlled room temperature or 24 hours or less if refrigerated if made in accordance with all of the applicable standards for Category 1 CSPs in this chapter. Category 2 CSPs are those that may be assigned a BUD of greater than 12 hours at room temperature or greater than 24 hours if refrigerated (see *12. Establishing Beyond-Use Dates and In-Use Times*) if made in accordance with all of the applicable standards for Category 2 CSPs in this chapter. See *Table 1* for a summary comparison of the minimum requirements in this chapter for Category 1 and 2 CSPs.

This chapter describes minimum requirements that apply to compounding of all CSPs, and also to repackaging of sterile products. If a compounder does not meet all of the Category 2 requirements, the CSP or repackaged sterile product will be considered a Category 1, and the shorter BUD applicable to Category 1 CSPs must be assigned. The minimum requirements not specifically described as applicable to Category 1 or Category 2, such as minimum training and competency testing and personal hygiene for personnel, are applicable to compounding of all CSPs and repackaging of sterile products.

Table 1. Summary Comparison of Minimum Requirements for Category 1 and Category 2 CSPs[a]

	Category 1 CSPs	Category 2 CSPs
Personnel Qualifications		
Visual observation of hand hygiene and garbing	Quarterly	Quarterly
Gloved fingertip sampling	Quarterly	Quarterly

	Category 1 CSPs	Category 2 CSPs
Media fill testing	Quarterly	Quarterly
Personal Protective Equipment		
See *Table 2*.		
Buildings and Facilities		
Primary engineering control (PEC)	Not required to be placed in a classified area	Required to be placed in a classified area
Recertification	Every 6 months	Every 6 months
Environmental Monitoring		
Nonviable airborne monitoring	Every 6 months	Every 6 months
Viable airborne monitoring	Monthly	Monthly
Surface sampling	Monthly	Monthly
Release Testing		
Physical inspection	Required	Required
Sterility testing	Not required	Based on assigned BUD
Endotoxin testing	Not required	Required if prepared from nonsterile ingredient(s)[b]
BUD		
BUD assignment	≤12 hours at controlled room temperature or ≤24 hours if refrigerated	>12 hours at controlled room temperature or >24 hours if refrigerated

[a] This table summarizes the requirements that apply specifically to Category 1 and Category 2 CSPs. There are numerous requirements in the chapter that are not summarized in this table because they apply to all CSPs, regardless of whether they are Category 1 or Category 2.
[b] See exemptions in *10.3 Bacterial Endotoxins Testing*.

1.4 Urgent-Use CSPs

A CSP may be prepared in worse than International Organization for Standardization (ISO) Class 5 air quality (see *4.1 Protection from Airborne Contaminants*) in rare circumstances when a CSP is needed urgently (e.g., cardiopulmonary resuscitation) for a single patient, and preparation of the CSP under conditions described for Category 1 or Category 2 would subject the patient to additional risk due to delays in therapy. In these circumstances, the compounding procedure must be a continuous process not to exceed 1 hour, and administration of the CSP must begin immediately upon completion of preparation of the CSP. Aseptic technique must be followed during preparation, and procedures must be in place to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other CSPs.

1.5 Roadmap through Chapter

The chapter is organized as follows:

1. Introduction and Scope
2. Personnel Qualifications—Training, Evaluation, and Requalification
3. Personal Hygiene and Personal Protective Equipment
4. Buildings and Facilities
5. Environmental Monitoring
6. Cleaning and Disinfecting Compounding Areas
7. Equipment and Components
8. Sterilization and Depyrogenation
9. SOPs and Master Formulation and Compounding Records
10. Release Testing
11. Labeling
12. Establishing Beyond-Use Dates and In-Use Times
13. Quality Assurance and Quality Control
14. CSP Storage, Handling, Packaging, and Transport
15. Complaint Handling and Adverse Event Reporting
16. Documentation
17. Radiopharmaceuticals as CSPs
Glossary
Appendices
Appendix 1. Acronyms
Appendix 2. Common Disinfectants Used in Health Care for Inanimate Surfaces and Noncritical Devices, and Their Microbial Activity and Properties

2. PERSONNEL QUALIFICATIONS—TRAINING, EVALUATION, AND REQUALIFICATION

Because the failure of compounding personnel to follow procedures and adhere to quality standards poses the greatest risk of CSP contamination, all personnel involved in the preparation and handling of CSPs must be trained and qualified and must undergo annual refresher training and requalification in appropriate sterile compounding standards and practices. Training, qualification, and requalification of personnel must be documented.

Each compounding facility must develop a written training program that describes the required training, the frequency of training, and the process for evaluating the performance of individuals involved in sterile compounding. This program should equip personnel with the appropriate knowledge and train them in the required skills necessary to perform their assigned tasks. This section describes the minimum qualifications for personnel preparing and handling CSPs, including the training, evaluation, and requalification of such personnel.

Separate from the formal competency testing and requalification described in this section, supervisors of compounding personnel should observe compounding activities on a daily basis and take immediate corrective action if deficient practices are observed.

2.1 Demonstrating Proficiency in Core Competencies

Before beginning to prepare CSPs, personnel must complete training and be able to demonstrate proficiency in the theoretical principles and hands-on skills of sterile manipulations and in achieving and maintaining appropriate environmental conditions. Successful completion must be demonstrated through written testing and hands-on demonstration of skills. Proficiency must be demonstrated in at least the following core competencies:

- Hand hygiene and garbing
- Cleaning and disinfection
- Measuring and mixing
- Aseptic manipulation
- Proper cleanroom behavior
- Methods of sterilization and depyrogenation, if applicable
- Use of equipment
- Documentation of the compounding process (e.g., master formulation and compounding records)
- Understanding the direction of the HEPA-filtered unidirectional airflow within the ISO Class 5 area
- Proper use of PECs
- The potential impact of personnel activities such as moving materials into and out of the compounding area

The following sections describe in detail the competency testing that must be conducted initially for all sterile compounding personnel in garbing and hand hygiene and aseptic manipulation, and the requirements for retraining and requalification.

2.2 Competency Testing in Garbing and Hand Hygiene

Gloved fingertip/thumb sampling is important because direct touch contamination is the most likely source of microorganisms. Gloved fingertip sampling evaluates a compounding person's competency in correctly performing hand hygiene and garbing (see *Box 2-1*). All persons performing compounding must successfully complete an initial competency evaluation, including visual observation and gloved fingertip/thumb sampling [zero colony-forming units (CFUs)] no fewer than three times before being allowed to compound CSPs, to demonstrate that they can perform the procedure consistently. After the initial competency evaluation, compounding personnel must successfully complete gloved fingertip/thumb sampling quarterly (no more than a total of three CFUs). Each fingertip/thumb evaluation must occur after separate, full hand hygiene and garbing procedures.

Compounding personnel must be visually observed by competent personnel while performing hand hygiene and garbing procedures (see *3. Personal Hygiene and Personal Protective Equipment*). The visual audit must be documented and the documentation maintained to provide a permanent record and long-term assessment of personnel competency.

Sampling must be performed on sterile gloves inside of an ISO Class 5 PEC. If conducting gloved fingertip/thumb sampling in a Restricted Access Barrier System (RABS) [e.g., Compounding Aseptic Isolator (CAI) or Compounding Aseptic Containment Isolator (CACI)] or an isolator, samples must be taken from the sterile

gloves placed over the gauntlet gloves. In addition, gloved fingertip/thumb sampling must be performed after completing the media-fill preparation without applying sterile alcohol or any other agent that could interfere with the ability of the gloved fingertip test to assess the adequacy of aseptic work practices.

Box 2-1 Gloved Fingertip Sampling and Testing Procedures

- Use two plates filled with nutrient agar containing neutralizing agents (e.g., lecithin and polysorbate 80) in a size range of 24- to 30-cm^2 in size.
- Do NOT disinfect gloves with sterile 70% isopropyl alcohol (IPA) or any other disinfectant immediately before touching the agar plate because this could cause a false-negative result.
- Collect a gloved fingertip and thumb sample from both hands by lightly pressing each fingertip into the agar. Use a separate plate for each hand.
- Re-cover the agar plates without further contact with agar. Label the plates with a personnel identifier, right or left hand, date, and time.
- Immediately discard the gloves after sampling.
- Invert the plates and incubate them at a temperature and for a time period conducive to multiplication of microorganisms (e.g., 20°–35° for 5 days).
- Record the number of CFU per hand (left hand, right hand).
- Determine whether the CFU action level for gloved hands (i.e., zero CFU initially or three CFU thereafter) is exceeded by counting the total number of CFUs on both gloves, not per hand.

2.3 Competency Testing in Aseptic Manipulation

After successful completion of the initial hand hygiene and garbing competency evaluation, all sterile compounding personnel must have their sterile technique and related practices evaluated during a media-fill test (see *Box 2-2*). Evaluation results must be documented and the documentation maintained to provide a permanent record and long-term assessment of personnel competency.

Box 2-2 Media-Fill Testing Procedures

- When performing these testing procedures, use the most difficult and challenging compounding procedures and processing conditions encountered by the person during a work shift (e.g., the most manipulations, most complex flow of materials, longest time to compound), replacing all the components used in the CSPs with microbial growth medium.
- Include all normal processing steps and incorporate worst-case conditions, including sterilizing filtration if used.
- Do not interrupt the test once it has begun, unless the normal work day involves interruptions.
- If all of the starting components are sterile to begin with, transfer sterile fluid microbial culture medium, such as sterile soybean-casein digest, into the same types of container–closure systems commonly used at the facility to evaluate a person's skill at aseptically processing CSPs into finished dosage forms.
- If some of the starting components are nonsterile to begin with, use a nonsterile commercially available medium, such as soybean-casein digest powder, to make a 3% solution. Prepare the nonsterile culture medium according to the manufacturer's instructions and manipulate it in a manner that reflects nonsterile-to-sterile compounding activities.
- Incubate media-filled vials at 20°–35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, incubate the filled containers for at least 7 days at the lower temperature (20°–25°) followed by 7 days at 30°–35°. Failure is indicated by visible turbidity or other visual manifestations of growth in the medium in one or more container–closure unit(s) on or before 14 days. Investigate media-fill failures to determine possible causes (e.g., sterilizing filter failure). Document and discuss investigational findings with personnel before any re-testing.
- If using a purchased pre-prepared microbial growth medium, either verify that the growth medium is growth promoting, or obtain a certificate of analysis (COA) from the supplier of the growth medium to ensure that it will support the growth of microorganisms.
- If using a microbial growth medium prepared in-house, the growth promotion capability of the medium must be demonstrated and documented (see *Sterility Tests* ⟨71⟩).
- Always store microbial growth media in accordance with manufacturer instructions and use them before their expiration date.

2.4 Reevaluation, Retraining, and Requalification

REQUALIFICATION AFTER FAILURE

Persons who fail written tests; visual observation of hand hygiene, garbing, and aseptic technique; gloved fingertip/thumb sampling; or media-fill tests must undergo immediate requalification through additional training by competent compounding personnel. Personnel who fail visual observation of hand hygiene, garbing, and aseptic technique; gloved fingertip/thumb sampling; or media-fill tests must pass three

successive reevaluations in the deficient area before they can resume compounding of sterile preparations.

REFRESHER TRAINING PROGRAM

Compounding personnel must successfully complete annual refresher training in the core competencies listed in *2.1 Demonstrating Proficiency in Core Competencies*. Successful completion must be demonstrated through written testing and hands-on demonstration of skills.

TIMING OF REEVALUATION AND REQUALIFICATION

- Visual observation—Compounding personnel must be visually observed while performing hand hygiene and garbing procedures initially and then at least quarterly.
- Gloved fingertip sampling—Compounding personnel must perform fingertip/thumb sampling three times initially and then quarterly to confirm their competency and work practices. Fingertip sampling conducted as part of a routine media-fill test can be counted in fulfilling these reevaluation requirements.
- Media-fill testing—After initial qualification, conduct media-fill tests of all personnel engaged in compounding CSPs at least quarterly to evaluate aseptic technique and requalify them.
- Cleaning and disinfecting—Retrain and requalify personnel in cleaning and disinfecting compounding areas after a change in cleaning and disinfecting procedures.
- After a pause in compounding—Personnel who have not compounded CSPs in more than 3 months must be requalified in all core competencies before resuming compounding duties.

If compounding is done less frequently than the frequencies specified above (e.g., quarterly), personnel reevaluation and requalification must occur before each compounding session begins.

3. PERSONAL HYGIENE AND PERSONAL PROTECTIVE EQUIPMENT

Because personnel preparing CSPs are the most likely cause of CSP contamination, compounding personnel must maintain proper personal hygiene and use personal protective equipment (PPE).

Personnel suffering from rashes, sunburn, oozing tattoos or sores, conjunctivitis, active respiratory infection, or other active communicable disease must be excluded from working in compounding areas until their conditions are resolved.

3.1 Personnel Preparation

Compounding personnel must take appropriate steps to prevent microbial contamination of CSPs. Squamous cells are normally shed from the human body at a rate of 10^6 or more per hour, and those skin particles are laden with microorganisms.[2,3] Before entering a designated compounding area, compounding staff must remove any

items that are not easily cleanable and that are not necessary for compounding. For example, personnel must:

- Remove personal outer garments (e.g., bandanas, coats, hats, jackets, scarves, sweaters, and vests)
- Remove all cosmetics because they shed flakes and particles
- Remove all hand, wrist, and other exposed jewelry or piercings (e.g., rings, watches, bracelets, earrings, and lip or eyebrow rings) that can interfere with the effectiveness of PPE (e.g., fit of gloves, cuffs of sleeves, and eye protection). Cover any jewelry that cannot be removed (e.g., surgically implanted jewelry)
- Remove ear buds, headphones, and cell phones, or other similar devices
- Keep natural nails clean and neatly trimmed to minimize particle shedding and avoid glove punctures. Nail polish, artificial nails, and extenders must be removed.

3.2 Hand Hygiene

Hand hygiene is required before initiating any compounding activities and when re-entering the ante-area after a break in compounding activity. After donning shoe covers, head and facial hair covers, and face masks, hand hygiene must be conducted (see *Box 3-1*). Hands must be washed with unscented soap and water. Alcohol hand sanitizers alone are not sufficient. Do not combine antimicrobial soaps and handrubs with alcohol-based products because of potential adverse dermatologic reactions. Brushes are not recommended for hand hygiene because of the potential for skin irritation and increased bacterial shedding. Dry hands and forearms with either low-lint disposable towels or wipes. After hands are washed and dried, perform hand antisepsis using a suitable alcohol-based handrub with sustained antimicrobial activity immediately before donning sterile gloves. Follow the manufacturer's instructions for application times, and apply the product to dry hands only. [NOTE—Soap must not be added to a partially empty soap dispenser. This practice of "topping off" dispensers can lead to bacterial contamination of soap.]

Box 3-1 Hand Hygiene Procedures

- Remove debris from underneath fingernails, if present, using a nail cleaner under warm running water.
- Wash hands and forearms up to the elbows with unscented soap and water for at least 30 seconds.
- Dry hands and forearms to the elbows completely with low-lint disposable towels or wipes.
- Immediately prior to donning sterile gloves, apply a suitable alcohol-based handrub with sustained antimicrobial activity, following the manufacturer's instructions for application times, and use a sufficient amount of product to keep the hands wet for the duration of the application time.
- Allow hands to dry thoroughly before donning sterile gloves.

3.3. Garb and Glove Requirements

The garb and glove requirements for CSPs depend on the category of CSP and type of PEC used. *Table 2* summarizes the minimum garb and glove requirements for CSPs.

Table 2. Minimum Garb and Glove Requirements

CSP Category	PEC type	Minimum Requirement
Category 1	Any	• Non-cotton, low-lint, disposable gown or coveralls • Low-lint, disposable covers for shoes • Low-lint, disposable covers for head and facial hair that cover the ears and forehead • Sterile gloves and sterile sleeves[a]
Category 2	Laminar airflow system (LAFS) and biological safety cabinet (BSC)	• Non-cotton, low-lint, disposable gowns or coveralls • Low-lint, disposable covers for shoes • Low-lint, disposable covers for head and facial hair that cover the ears and forehead • Mask • Sterile gloves and sterile sleeves[a] • Eye shield is optional
Category 2	RABS (CAI or CACI) or isolator	• Non-cotton, low-lint, disposable gowns or coveralls • Low-lint, disposable covers for shoes and hair • Sterile gloves

[a] If a sterile gown is used, the use of sterile sleeves is optional.

Personnel intending to enter a buffer area or segregated compounding area must put on protective clothing. Protective clothing must be put on in an order that eliminates the greatest risk of contamination. As noted previously, put on shoe covers, head and facial hair covers, face masks, and gown, before completing hand cleansing procedures and then put on sterile gloves and sterile sleeves (if used). If sterile gowns are used, put on sterile gloves and gowns after hand cleansing procedures. Garbing and degarbing should not occur in the ante-area at the same time.

GOWNS

Visibly soiled gowns must be changed immediately. Gowns and other garbing items must be segregated and stored before use in an enclosure to prevent contamination (e.g., away from sinks to avoid splashing). Coveralls and sterile gowns must not be reused.

GLOVES

Gloves must be sterile and powder free. Use only gloves that have been tested by the manufacturer for compatibility with alcohol disinfection. Before putting on gloves, perform hand hygiene as described in *Box 3-1*. Hands must be completely dry before putting on sterile gloves. Unless donning a sterile gown, sterile gloves must be the last item put on before handling anything in the buffer or segregated compounding area and before compounding begins in the PEC. If donning a sterile gown, put on the gloves first, then the sterile gown.

Routine application of sterile 70% IPA to gloves must occur throughout the compounding process and whenever nonsterile surfaces (e.g., vials, counter tops, chairs, carts) are touched. Contaminated gloved hands can be disinfected by rubbing sterile 70% IPA solution onto all contact surface areas of the gloves and letting the gloved hands dry thoroughly.

Gloves on hands and gauntlet sleeves on RABS and isolators must be inspected routinely by the personnel using them for holes, punctures, or tears and must be replaced immediately if such defects are detected. Sterile gloves must be placed over the gauntlet gloves of the RABS and isolators.

EXITING AND REENTERING COMPOUNDING AREAS

When compounding personnel exit the buffer or segregated compounding area during a work shift, a nonsterile gown can be removed and retained in the ante or segregated compounding area if not visibly soiled, to be re-donned during that same work shift only. Coveralls and sterile gowns may not be reused and must be replaced with new ones. Shoe covers, hair and facial hair covers, face masks, head covering, gloves, and sleeves may not be reused and must be replaced with new ones. Goggles must be either sterilized or disinfected with sterile 70% IPA before each use. Hand hygiene must be performed before resuming sterile compounding.

COMPOUNDING HAZARDOUS DRUGS

For PPE requirements when handling hazardous drugs, refer to ⟨800⟩.

4. BUILDINGS AND FACILITIES

Buildings and facilities in which compounding will be taking place must be designed, built, outfitted, and maintained properly to prevent airborne contamination of CSPs. Areas related to compounding operations in such facilities (i.e., ante-area, buffer area, segregated compounding area, and PEC) must be separated from areas not directly related to compounding and must be appropriately controlled to achieve and maintain required air quality classification levels (see *Table 3*), depending on the nature of the operation being performed in the specific area.

A facility's design must ensure that the movement of personnel, equipment, and components into and out of the compounding area does not disrupt air quality in the area or create a route of contamination. The number of operations being performed, the number of personnel in the compounding area (and in adjacent areas), and the complexity of the compounding procedures are critical factors that determine whether a facility will be able to maintain control of environmental conditions. All of these factors must be taken into account when designing and outfitting a facility in which sterile compounding will be performed.

This section describes applicable air quality standards and the appropriate design of buildings and facilities intended for the preparation of CSPs. It describes in detail the materials to be used and the steps to be taken in designing facilities to ensure suitable conditions. This section also discusses the environmental controls that must be in place to ensure achievement and maintenance of sterility for CSPs.

4.1 Protection from Airborne Contaminants

Buildings and facilities used in compounding must be designed to prevent airborne contamination of the area in which sterile compounding occurs. Without proper design and controls, airborne contaminants are likely to reach the area where compounding occurs, increasing the risk that CSPs will be exposed to microbial contamination.

APPLICABLE AIR QUALITY STANDARDS

The internationally accepted standards for air quality in controlled environments are described in *Table 3* and referenced throughout this chapter.

Table 3. ISO Classification of Particulate Matter in Room Air

ISO Class	Particle Count[a]/m^3
3	35.2
4	352
5	3,520
6	35,200
7	352,000
8	3,520,000

[a] Limits for number of particles ≥0.5 µm measured under typical operating conditions.

DESIGN REQUIREMENTS TO MAINTAIN AIR QUALITY

For compounding Category 1 or 2 CSPs, buildings and facilities intended for compounding CSPs must be designed so that air quality increases with movement through separate operational areas to the PEC. Separate areas of operation must be appropriately controlled, depending on the necessary level of air quality. Classified areas in which the air quality is controlled include ante-areas, buffer areas, and PECs.

- Ante-areas must meet at least ISO Class 8 standards. Typically, personnel hand hygiene and garbing procedures, staging of components, order entry, CSP handling, and other activities that potentially generate high levels of particulates are performed in this area. Ante-areas are also transition areas to ensure that proper air pressure relationships are maintained between designated areas.
- A buffer area must provide at least ISO Class 7 air quality. Activities in this area must be especially carefully controlled to avoid affecting the air quality in the area where CSP preparation occurs.
- Areas intended for CSP preparation must meet ISO Class 5 standards. ISO Class 5 standards are achieved through use of a PEC, such as a LAFS, BSC, CAI, CACI, or isolator.

A PEC used for compounding may be placed in an unclassified, segregated compounding area (see below) if only Category 1 CSPs are compounded in the PEC.

4.2 Facility Design and Environmental Controls

In addition to minimizing airborne contamination and protecting CSPs, compounding facilities must be designed and controlled to provide a well-lit and comfortable working environment, with appropriate temperature and humidity for compounding personnel wearing the required garb. The room must be maintained at a temperature of 20° or cooler and a humidity below 60% at all times. Temperature and humidity must be controlled through an efficient heating, ventilation, and air conditioning (HVAC) system rather than through use of humidifiers and dehumidifiers, which can contain standing water that can contribute to microbial contamination.

It is the responsibility of compounding facility management to ensure that each operational area related to CSP preparation meets the ISO-classified air quality standard appropriate for the activities to be conducted there and, specifically, that the ISO Class 5 areas are optimally located, operated, maintained, monitored, and verified to have appropriate air quality.

DESIGN OF A COMPOUNDING FACILITY

A compounding facility generally consists of separate, designated operational clean areas, including an ante-area, a buffer area, and a PEC, or a segregated compounding area containing a PEC where CSPs are prepared. See *Placement and Use of Primary Engineering Controls* for the requirements for a segregated compounding area. The ante-area must be separated from the surrounding, unclassified sections of the building to reduce the risk of contaminants being blown, dragged, tracked, or otherwise introduced into the high-efficiency particulate air (HEPA)–filtered clean environment. This separation must be continuously maintained and monitored (see *5. Environmental Monitoring*). When compounding Category 2 CSPs, the ISO Class 8 ante-area and the ISO Class 7 buffer area must be separate rooms, with walls and doors between them and controls to prevent the flow of lower-quality air into the more controlled areas.

The PEC must be located in the buffer area or the segregated compounding area so as to avoid conditions that could adversely affect their separate operations. For example, strong air currents from opened doors, personnel traffic, or air streams from the HVAC system(s) can disrupt the unidirectional airflow of an open-faced PEC such as a laminar airflow workbench (LAFW). Compounding personnel can also create disruptions in airflow by their own movements adjacent to the PEC, their manipulations within the PEC, and by placing objects onto work surfaces within the PEC. Access of personnel to controlled areas must be limited. For example, only authorized personnel and materials required for compounding and cleaning should be permitted in the buffer area.

Due to the interdependence of the various rooms or areas that make up a compounding facility, it is essential to carefully define and control the dynamic interactions permitted between areas and rooms. When designing doors, consider door closures, door surfaces, and the swing of the door, all of which can affect airflow.

Airlocks and interlocking doors can be used to facilitate better control of air balance between a higher classified area and an area of lesser air quality (e.g., between the buffer area and ante-area), or between a classified area and an unclassified area (e.g.,

between the ante-area and an uncontrolled area such as a hallway). If a pass-through is used, it must only be opened one door at a time; both doors must never be opened at the same time.

It is critical to adequately control materials (e.g., supplies, equipment, and utensils) as they move from lesser to higher classified areas to prevent the influx of contaminants. For this reason, when designing a facility, consider the movement of materials.

When designing the facility, consider whether all materials used can be easily cleaned. Avoid using door seals and sweeps that are difficult to clean. Hands-free access doors are preferred. Do not use tacky mats in ISO-classified areas.

THE CSP PROCESSING ENVIRONMENT

All CSPs must be prepared in a PEC, which provides an ISO Class 5 environment (with the exception of Urgent-Use CSPs, see *1.4 Urgent-Use CSPs*). The compounding environment must continuously meet ISO Class 5 or better conditions for 0.5-µm particles and must exclude microbial contamination during compounding of CSPs (typical operating conditions).

HEPA filters and unidirectional (laminar) airflow are used to maintain the appropriate airborne particulate classification of the area. Unidirectional airflow must be maintained in the PEC at all times. HEPA-filtered air must be supplied to the PEC at a velocity sufficient to sweep particles away from critical sites and maintain unidirectional airflow during operations. Proper design and control prevents turbulence and creation of eddies or stagnant air in the PEC.

Air must be introduced through HEPA filters located at the ceiling of the buffer area containing the PEC, and returns should be mounted low on the wall, creating a general top-down dilution of area air through HEPA-filtered air.

PLACEMENT AND USE OF PRIMARY ENGINEERING CONTROLS

Proper placement of the PEC is critical to ensuring an ISO Class 5 environment for compounding CSPs.

LAFS: Provides an ISO Class 5 or better environment for sterile compounding. A LAFS provides smooth, unidirectional HEPA-filtered airflow that is designed to prevent contamination of a sterile compounding environment. The LAFS can consist of either a LAFW or a HEPA filter alone creating an ISO Class 5 zone within an ISO Class 7 room, as long as unidirectional airflow is maintained.

The LAFS must be located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns. If used to prepare only Category 1 CSPs, the ISO Class 5 environment can be obtained by placing a LAFW in a segregated compounding area. If used to prepare Category 2 CSPs, the LAFS must be located within a restricted access buffer area with an ISO Class 7 or better air quality.

BSC: A ventilated cabinet with an open front and inward and downward HEPA-filtered airflow and HEPA-filtered exhaust. A BSC must be located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns. A BSC used to prepare only Category 1 CSPs can be placed in an unclassified area. If used to prepare Category 2 CSPs, the BSC must be located within a restricted access buffer area with an ISO Class 7 or better air quality. If a BSC is used to prepare hazardous drugs, see ⟨800⟩.

RABS: Can include a CAI or a CACI, and can be used to provide an ISO Class 5 environment for preparing CSPs (see *Microbiological Control and Monitoring of Aseptic Processing Environments* ⟨1116⟩). A RABS is different from an isolator (see description of isolators below). In a RABS, glove ports are used to provide physical separation between the surrounding area and the aseptic manipulations. If used to prepare Category 2 CSPs, the area surrounding the RABS must meet ISO Class 7 or better air quality.

All transport ports on the RABS must be closed during compounding. When a RABS is used, the recovery time after opening to achieve ISO Class 5 air quality must be documented, and internal procedures must be developed to ensure that adequate recovery time is allowed after opening and closing the RABS, both before and during compounding operations.

Isolator: Provides isolation from the surrounding area and maintains ISO Class 5 air quality during typical operating conditions. The following standards must be met to qualify as an isolator:

- High-integrity transfer ports are used to move supplies, ingredients, components, and devices into and out of the isolator.
- The isolator is decontaminated using a generator that distributes a sporicidal chemical agent throughout the isolator chamber.
- The isolator maintains constant overpressure of at least 0.05-inch water column.
- The manufacturer has provided documentation that the isolator will continuously meet ISO Class 5 conditions, including during material transfer.

If ISO Class 5 classification is achieved using an isolator that meets the requirements above, the isolator can be located in an ISO Class 8 area and used to prepare Category 2 CSPs. In addition, when using an isolator, some functions, such as hand washing, can be done in the ISO Class 8 area. Water sources such as sinks and drains must be located at least 1 meter from the isolator. If the isolator does not meet the requirements above, it is considered a RABS that must be located within at least an ISO Class 7 area to prepare Category 2 CSPs, or within a segregated compounding area to prepare Category 1 CSPs.

Segregated Compounding Areas: In some situations, a PEC may be located within an unclassified area, without a buffer or ante-area. This type of design is called a segregated compounding area. Category 2 CSPs must never be compounded in segregated compounding areas; only Category 1 CSPs can be compounded in facilities with such designs. It is critical to locate a segregated compounding area away from unsealed windows, doors that connect to the outdoors, and significant traffic flow. A segregated compounding area must not be located adjacent to construction sites, warehouses, food preparation areas, or other environmental control challenges. The impact of activities that will be conducted around or adjacent to the segregated compounding area must be considered carefully when designing such an area, and the perimeter of the segregated compounding area must be defined.

ACTIVITIES IN RELATION TO THE PEC

The facility where CSPs are prepared must be designed so that activities such as hand hygiene and gowning will not adversely affect the ability of the PEC to function as designed. In facilities with ante-areas and buffer areas, the sink used for hand hygiene must not be placed in the buffer area. The sink should be placed in the ante-area to allow for hand washing before entering the buffer area. In a segregated compounding area, the sink must be located at least 1 meter from the PEC.

AIR-EXCHANGE REQUIREMENTS

For facilities designed with ante-areas and buffer areas, adequate HEPA-filtered airflow to the buffer and ante-areas is required to maintain the appropriate cleanliness classification during compounding activities. Airflow adequacy is measured in terms of the number of air changes per hour (ACPH). Factors that should be considered when determining appropriate air-exchange requirements for an area include the maximum number of personnel permitted to work in the area, the number of particulates that may be generated from activities and processes in the area, and the effects of temperature.

An ISO Class 7 buffer or ante-area supplied with HEPA-filtered air must measure an ACPH of not less than 30, and the ACPH may need to be higher to maintain the classification, depending on the factors previously described. The ACPH of 30 can include recirculated HEPA-filtered air, but at least half (a minimum of 15 ACPH) must be HEPA-filtered fresh air.

If an isolator that meets the specifications described above is used to achieve ISO Class 5 air quality, air exchange requirements in the room where the isolator is located can be reduced to 15 ACPH.

ESTABLISHING AND MAINTAINING PRESSURE DIFFERENTIALS

To prevent the flow of poorer quality air from one area to another area of higher air quality classification, except when a segregated compounding area is used, a minimum differential positive pressure of 0.02-inch water column is required to separate each ISO-classified area. The pressure differential between the ISO Class 7 area and the general pharmacy area must not be less than 0.02-inch water column.

A pressure gauge or velocity meter must be used to monitor the pressure differential or airflow between the ante-area and buffer area and between the ante-area and the general environment outside the classified areas. The results must be reviewed and documented on a log at least daily or by a continuous recording device.

4.3 Constructing Areas to Achieve Easily Cleanable Conditions

The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in a classified area or in a segregated compounding area must be smooth, impervious, free from cracks and crevices, and non-shedding, thereby promoting cleanability and minimizing spaces in which microorganisms and other contaminants can accumulate. Surfaces must be resistant to damage by disinfectants. Junctures between the ceiling and the walls must be coved or sealed to eliminate cracks and crevices where dirt can accumulate. If ceilings consist of inlaid panels, the panels must be impregnated with a polymer to render them impervious and hydrophobic, and they must be sealed.

Walls must be constructed of durable material (e.g., heavy-gauge polymer). Panels must be locked together and sealed. If gypsum board is used, it must be epoxy-coated. Floors must be overlaid with wide sheet vinyl flooring with heat-welded seams and coving to the sidewall. Classified areas and segregated compounding areas must not

contain dust-collecting overhangs, such as utility pipes, or ledges, such as windowsills. The exterior lens surface of ceiling light fixtures must be smooth, mounted flush, and sealed. Any other penetrations through the ceiling or walls must be sealed. The buffer area or area inside the perimeter of a segregated compounding area cannot contain water sources (e.g., sinks) or floor drains.

Work surfaces must be constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they can be easily cleaned and disinfected.

4.4 Placement and Movement of Materials

Only furniture, storage shelving, counters, cabinets, supplies, and other materials necessary for performing compounding activities are permitted in buffer or segregated compounding areas. Any objects located in buffer or segregated compounding areas must be smooth, impervious, free from cracks and crevices, non-shedding, and easily cleaned and disinfected. Their number, design, and manner of installation must promote effective cleaning and disinfecting. Certain items are not permitted in buffer areas. These include, but are not limited to, coarse cardboard, external shipping containers, and nonessential paper (e.g., paper towels and tissues).

Carts used to transport components or equipment into classified areas must be constructed from stainless steel, nonporous plastic, or sheet metal, with good quality, cleanable casters to promote mobility and ensure ease of disinfection.

Certain devices (e.g., computers) and objects (e.g., carts and cabinets) essential to compounding can be located in the segregated compounding area, but must be located at an appropriate distance from the PEC so that they have no detrimental effects on the air quality inside the PEC. The appropriate distance must be determined by considering the surrounding environment and the activities conducted in it.

Before being brought into a buffer area or segregated compounding area, objects must be cleaned and disinfected. Equipment and other items used in a buffer area or a segregated compounding area should not be removed except for calibration, servicing, or other activities associated with proper maintenance. If removed, these items must be cleaned and disinfected before they are returned to the buffer area or segregated compounding area.

4.5 Certification and Recertification of Facilities

Before a facility is used to compound either Category 1 or Category 2 CSPs, it must be certified by an independent, qualified individual as meeting its design and air quality specifications (see *Table 3*). It is important to place special emphasis on certifying the ISO Class 5 areas. During certification of ISO Class 5 areas, air sampling must be performed inside the PEC and the surrounding ISO-classified areas. Routine staff activity during compounding-related processes must be simulated during certification.

Certification of the PEC must include:

- **Airflow Testing** to determine acceptability of the air velocity and volume, the air exchange rate, and room pressure cascade to ensure that air consistently flows from clean to dirty areas, and that the appropriate quality of air is maintained under typical operating conditions.

- **HEPA Filter Integrity Testing** using the most penetrating particle size. HEPA filters must be leak tested at the factory and then leak tested again after installation and as part of recertification.
- **Total Particle Counts Testing** under typical operating conditions by qualified operators using current, state-of-the-art electronic equipment.
- **Smoke Studies** for each PEC under full operational processing conditions to demonstrate unidirectional airflow and sweeping action over and away from the product(s).

Certification of other ISO-classified areas must include:

- **Airflow Testing** to determine acceptability of the air velocity and volume, the air exchange rate, and room pressure cascade to ensure that air consistently flows from clean to dirty areas and that the appropriate quality of air is maintained under typical operating conditions.

Classified areas must be recertified if there are changes to the area such as redesign, construction, or replacement or relocation of the PEC, or alteration in the configuration of the room that could affect airflow or air quality. Recertification must be done at least every 6 months.

All certification and recertification records must be reviewed by supervising personnel or other designated employees to ensure that the controlled environments comply with the proper standards and records must be maintained in accordance with the requirements in *16. Documentation*.

4.6 Design and Construction of Facilities for Compounding with Hazardous Drugs

For design of facilities in which compounding with hazardous drugs will occur, see ⟨800⟩.

5. ENVIRONMENTAL MONITORING

An effective environmental monitoring program provides meaningful information on the quality of the compounding environment and any environmental trends in surrounding areas. In addition, an effective environmental monitoring program will identify potential routes of contamination, allowing for implementation of corrections to prevent CSP contamination. Sterile compounding facilities must develop and implement written environmental monitoring procedures (see *9. SOPs and Master Formulation and Compounding Records*). All environmental sampling and results must be documented, and records must be maintained in accordance with the requirements in *16. Documentation*.

5.1 General Monitoring Requirements

Sterile compounding facilities must be qualified initially using environmental air and surface sampling as described below to establish a baseline level of environmental quality. After initial qualification, the environment in which sterile compounding activities are performed must be monitored regularly to ensure that the environment remains suitable for sterile compounding.

Environmental monitoring involves the collection and review of environmental samples from various air and surface locations to detect airborne and surface contaminants. Data from sampling are then used to assess airborne nonviable particulate and microbial contamination risks, potential routes of contamination, and the adequacy of disinfection procedures. Data collected from environmental sampling must be reviewed regularly to detect elevated levels of microbial bioburden, elevated levels of nonviable particulates, or other adverse changes within the environment.

Data from air and surface sampling must be reviewed in conjunction with personnel data to assess the state of environmental control and to identify CSP contamination risks. Prompt corrective action in response to any adverse data is essential to maintain the necessary environmental quality for CSP preparation. Data must also be reviewed following corrective actions to confirm that the actions taken have been effective in achieving the required air and surface quality levels (see *Table 3* and *Table 5*).

Routine environmental sampling during compounding operations must be conducted to confirm that the environmental quality in ISO-classified areas is maintained. Sampling also must be performed in any of the following circumstances.

- As part of the certification of new facilities and equipment
- As part of recertification, following any servicing of facilities or equipment (see *4. Buildings and Facilities*)
- In response to identified problems (e.g., sterility failures; a complaint of patient infection when the CSP is considered to be a potential source of the infection)
- In response to identified trends (e.g., repeated positive fingertip sampling results or failed media fill simulations; repeated observations of air or surface contamination)

The sampling program must include: 1) nonviable airborne particulate sampling; 2) viable airborne particulate sampling; and 3) surface sampling, including but not limited to equipment, work surfaces, and room surfaces.

To obtain an environmental sample that is representative of the full operating conditions at the facility, environmental air sampling (both viable and nonviable) must be conducted during periods of typical activity (i.e., when compounding is occurring). However, the sampling program must be designed and conducted in a manner that minimizes the chance that the sampling itself will contribute to contamination of the CSP, the operator, or the environment.

The sampling program must be developed based on an understanding of risk factors, including but not limited to criticality of the environment sampled, number and types of activities conducted in the room being monitored, maximum number of personnel that may be working in the room at one time, and how the CSPs will be exposed to the immediate environment during compounding. The sampling program must contain a listing of the sample locations, procedures for collecting samples, frequency of sampling, size of sample (e.g., surface area, volume of air), time of day sampled in relation to activities in the compounding area, and levels that will trigger corrective action. Sampling timing and locations should be carefully selected based on their relationship to the operation performed in the area. Sampling locations, frequencies, and timing must be clearly described in a facility's established Standard Operating

Procedure (SOP). It is important to sample locations posing the most contamination risk to the CSP (i.e., the PEC), and sampling locations should be selected that are likely to be representative of the conditions throughout the area.

Graphic presentation of the results collected over a period of time can be useful in identifying trends, or for indicating that a significant change has occurred, even when the results fall within the specified limits.

It is important that personnel be trained in the proper operation of the air sampling equipment used to ensure reproducible sampling. All air sampling devices must be serviced and calibrated at appropriate intervals (i.e., as recommended by the manufacturer).

5.2 Monitoring Air Quality for Nonviable Airborne Particles

Because maintaining appropriate air quality is essential to the overall contamination prevention strategy for sterile compounding, it is imperative that all engineering control equipment function as designed and that the levels of airborne particles remain within acceptable limits during compounding operations (see *Table 3*). A monitoring program for nonviable airborne particles must be developed and implemented to measure the performance of the engineering controls that are being used to provide the specified levels of air cleanliness (e.g., in the PEC and ISO Class 7 and 8 areas).

AIR SAMPLING TIMING AND LOCATIONS

Air sampling sites must be selected in all classified areas. Measurements of air cleanliness must be taken in each PEC, at locations where there is greatest risk to the exposed CSPs, containers, and closures. Measurements of air cleanliness in other classified areas, including the buffer area and ante-area, should be taken at representative locations that reflect the quality of air in the area. When conducting sampling of the PEC, care should be taken to avoid disturbing the unidirectional airflow.

Total particle counts of all ISO-classified areas must be conducted during typical operations every 6 months.

DATA EVALUATION AND ACTION LEVELS

If levels measured during the nonviable air sampling program exceed the criteria in *Table 3* for the appropriate ISO classification levels of the area sampled when measured under typical operating conditions, an investigation of the cause must be conducted and corrective action must be taken to prevent future deviations. When nonviable air sampling results for an ISO Class 5 PEC exceed the criteria in *Table 3*, all compounding activities must cease in that PEC and a corrective action plan must be implemented immediately. When nonviable air sampling results for ISO Class 7 or 8 areas exceed the criteria in *Table 3*, a corrective action plan must be implemented immediately. In such a case, if compounding is continued, the BUDs for any CSPs compounded must not exceed the BUDs for Category 1 CSPs until the area is successfully recertified. Some examples of corrective action include a procedural improvement, such as enhanced disinfection; a process or facility improvement; or HEPA filter replacement or repair. The extent of the investigation should be consistent with the type of excursion, and should include an evaluation of trends.

5.3 Monitoring Air Quality for Viable Airborne Particles

An environmental sampling program for viable airborne particles must be developed and implemented to assess microbiological air quality in all classified areas. The goals of an environmental sampling program are to determine whether contamination is present at unacceptable levels and to assess whether proper personnel practices are being followed and proper environmental conditions maintained.

AIR SAMPLING TIMING AND LOCATIONS

Air sampling sites must be selected in all classified areas. When conducting sampling of the PEC, care should be taken to avoid disturbing unidirectional airflow. See *Box 5-1* for active air sampling procedures. Active air sampling of all ISO-classified areas must be conducted during typical operating conditions at least monthly. Active air sampling is required in each ISO-classified area (e.g., PEC and ISO Class 7 and 8 areas). A general microbiological growth medium that supports the growth of bacteria and fungi, such as trypticase soy agar (TSA) or soybean-casein digest medium, must be used. Samples must be incubated at 20°–25° for 5–7 days and then at 30°–35° for 2–3 additional days. A microbiological incubator that is monitored to maintain the required temperature must be used to incubate the samples. The microbiological incubator must be placed in a location outside of a cleanroom or segregated compounding area. All sampling activities must be performed by properly trained individuals.

Box 5-1 Active Air Sampling Procedures for Viable Airborne Monitoring

- Decontaminate sampling equipment according to the manufacturer's instructions and handle aseptically.
- When media are brought into an ISO-classified area, wipe the wrapping with sterile 70% IPA using a low-lint sterile wipe before removing the media from their packaging.
- Examine media used to collect samples for damage or contamination, and handle in an aseptic manner. Discard contaminated or damaged media and conduct an investigation to determine the cause of the damage or contamination. If a damaged sampling device or packaging is identified (e.g., cracks or foreign bodies on the media surface, or discoloration), examine the entire lot of devices from that vendor to determine whether other devices are damaged or contaminated.
- Using an active air sampling device, test at least 1 cubic meter or 1,000 liters of air from each area sampled.
- At the end of the designated sampling, retrieve the medium and cover it to protect it from external contamination. Protect media from physical damage and keep at appropriate temperatures during transport to the incubator.
- Invert the media plates and incubate the medium at 20°–25° for 5–7 days and then at 30°–35° for 2–3 additional days.
- Examine the media plates for growth daily during normal business hours and record the total number of discrete colonies of microorganisms as CFU per cubic meter of air on an environmental sampling form based on sample type, sample location, and sample date.

DATA EVALUATION AND ACTION LEVELS

767 Evaluate counts against the action levels in *Table 4*, and examine counts in relation to
768 previous data to identify adverse results or trends. If levels measured during the viable
769 air sampling program reach or exceed the levels in *Table 4*, corrective actions must be
770 taken, including repeat air sampling. If a CFU count is identified below the action levels
771 in *Table 4*, primary screening and characterization must be performed (see *Microbial*
772 *Characterization, Identification, and Strain Typing* ⟨1113⟩). Highly pathogenic
773 microorganisms (e.g., gram-negative rods, coagulase positive staphylococcus, molds
774 and yeasts) are potentially fatal to patients receiving CSPs and must be immediately
775 remedied through cleaning and disinfection, regardless of CFU count. If levels
776 measured during viable air sampling exceed the levels in *Table 4*, the genus must be
777 identified, and when possible, identify the species of any microorganism recovered, with
778 the assistance of a credentialed microbiology laboratory.

779 **Table 4. Action Levels for Viable Airborne Particle Air Sampling[a]**

ISO Class	Air Sampling Action Levels (CFU/m³)[b]
5	≥1
7	≥10
8	≥100

[a] Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice–US Dept of Health and Human Services, Food and Drug Administration, (FDA) September 2004.
[b] All action levels must be based on sampling in the vicinity of exposed materials/articles during compounding operations.

780 **5.4 Sampling Surfaces for Contamination**

781 Surface sampling is an important component of the maintenance of a suitably
782 controlled environment for compounding CSPs, especially because transfer of microbial
783 contamination from improperly disinfected work surfaces via inadvertent touch contact
784 by compounding personnel is a potential source of contamination of CSPs. Surface
785 sampling is useful for evaluating facility and work surface cleaning and disinfecting
786 procedures, and employee competency in work practices such as cleaning and
787 disinfection of component/vial surfaces.
788 Surface sampling for microbial contamination must be performed in all ISO-classified
789 areas. All sampling sites and procedures must be described in the facility's SOP.

790 SAMPLING TIMING AND LOCATIONS

791 When conducted, surface sampling must be performed at the conclusion of
792 compounding activities, but before the area has been cleaned and disinfected. Media
793 used for surface sampling must be supplemented with additives to neutralize the effects
794 of any residual disinfecting agents (e.g., TSA with lecithin and polysorbate 80).
795 Multiple locations must be sampled at least monthly within each ISO-classified area,
796 including the following (see ⟨1116⟩):

797 - The interior of the PEC and equipment contained in it

- Staging or work areas near the PEC
- Frequently touched surfaces
- Pass-through chambers

SAMPLING PROCEDURES

Contact sampling devices (e.g., plates, paddles, or slides) containing microbial growth media must be used for sampling flat surfaces. Sterile swabs wetted with sterile water can be used when sampling irregular surfaces and difficult-to-reach locations in classified areas, such as crevices, corners, and spaces between surfaces.

Surface sampling devices must contain general microbial growth media (e.g., soybean casein digest media) supplemented with neutralizing additives (e.g., lecithin and polysorbate 80). Use a surface sampling device (e.g., plates, paddles, or slides) in the size range of 24- to 36-cm^2. Contact sampling devices must be certified by the manufacturer to meet growth promotion tests in *Microbial Enumeration Tests* ⟨61⟩. Contact plates must have a raised convex surface. Plates must be stored according to the manufacturer's recommendation. See *Box 5-2* for the procedures for conducting surface sampling with contact sampling devices. Follow the manufacturer's instructions for using sampling swabs.

Box 5-2 Using Devices for Flat Surface Sampling

- Examine media used to collect samples for damage or contamination and handle in an aseptic manner. Discard contaminated or damaged media and conduct an investigation to determine the cause of the damage or contamination. If a damaged sampling device or packaging is identified (e.g., cracks or foreign bodies on the media surface, or discoloration), examine the entire lot of devices from that vendor to determine whether other devices are damaged or contaminated.
- If using commercially prepared devices, wipe the wrapping with sterile 70% IPA using a low-lint sterile cloth before removing the devices from their packaging.
- Remove the cover from the contact sampling device and firmly press the media surface onto the surface to be sampled. The contact sampling device will leave a residue of growth medium on the sample site. After sampling, use a low-lint sterile wipe to thoroughly clean the sampled area with sterile water and disinfect with sterile 70% IPA.
- After exposure, cover each contact sampling device to protect it from further contamination.
- Invert the plates and incubate the contact sampling devices at 20°–25° for 5–7 days and then at 30°–35° for 2–3 additional days.
- Examine the sampling devices for growth daily during normal business hours, and record the observed count at each time point. At the final time point, record the total number of discrete colonies of microorganisms (CFU/sample) on the environmental sampling record based on sample type, sample location and sample date.

DATA EVALUATION AND ACTION LEVELS

If levels measured during surface sampling exceed the criteria in *Table 5*, an investigation of the cause must be conducted and corrective action must be taken to prevent future deviations. When surface sampling results for an ISO Class 5 PEC exceed the criteria in *Table 5*, all compounding activities must cease in that PEC. When surface sampling results for ISO Class 7 or 8 areas exceed the criteria in *Table 5*, a corrective action plan must be implemented immediately. In such a case, if compounding is continued, the BUDs for any CSPs compounded must not exceed the BUDs for Category 1 CSPs until the surfaces are retested and the results fall below action levels in *Table 5*. Some examples of corrective action include a procedural, facility, or equipment improvement. The extent of the investigation should be consistent with the type of excursion and should include an evaluation of trends.

Table 5. Action Levels for Surface Sampling

ISO Class	Work Surfaces Sampled Using Contact Plates (CFU/plate)[a]	Work Surfaces Sampled Using Swabs (CFU/25 cm^2 or per sample)[a]	Non-work Surfaces Sampled Using Contact Plates (CFU/plate)[b]	Non-work Surfaces Sampled Using Swabs (CFU/25 cm^2 or per sample)[b]
5	>3	>3	N/A[c]	N/A[c]
7	>5	>5	>10	>10
8	>25	>25	>50	>50

[a] Work surfaces are those surfaces that are in direct contact with materials used in compounding. These action levels are based on the expectation that materials will be disinfected before introduction to an ISO Class 5 area.
[b] Non-work surfaces are those surfaces that do not come into direct contact with materials used in compounding.
[c] All surfaces within the ISO Class 5 area are considered work surfaces.

6. CLEANING AND DISINFECTING COMPOUNDING AREAS

Surfaces in compounding areas are a major source of microbial contamination of CSPs. Therefore, scrupulous attention must be paid to cleaning and disinfection. Cleaning and disinfecting the surfaces in sterile compounding areas must occur on a regular basis at the intervals noted in *Table 6*. Cleaning and disinfection must be repeated when spills occur; when surfaces, floors, and walls are visibly soiled; and when microbial contamination is known to have been, or is suspected of having been, introduced into the compounding areas.

If compounding is done less frequently than the cleaning frequencies specified below (e.g., once a week or once a month), cleaning must occur before each compounding session begins, instead of according to the frequencies described in *Table 6*.

Table 6. Minimum Frequency for Cleaning and Disinfecting Surfaces in Classified and Segregated Compounding Areas

Site	Minimum Frequency

Site	Minimum Frequency
PEC (except for an isolator)	At the beginning and end of each shift; before each batch; no longer than 30 minutes following the previous surface disinfection when ongoing compounding activities are occurring; after spills; and when surface contamination is known or suspected
Isolator (as defined in *4. Buildings and Facilities*)	Clean the isolator each time it is opened; decontaminate the isolator once it is closed after each time it has been opened, or after each cleaning cycle, if cleaning occurs without opening
Work surfaces outside the PEC (e.g., buffer area and/or segregated compounding area)	Daily
Floors	Daily
Walls	Monthly
Ceilings	Monthly
Storage shelving	Monthly

6.1 Disinfectants

Cleaning and disinfection agents must be selected and used with careful consideration of compatibilities, effectiveness, and inappropriate or toxic residues (see *Appendix 2* and *Disinfectants and Antiseptics ⟨1072⟩*). The selection and use of disinfectants must be guided by microbicidal activity, inactivation by organic matter, residue, and shelf life. Sporicidal agents must be used at least weekly to clean all ISO-classified and segregated compounding areas (see *Disinfectants and Antiseptics ⟨1072⟩, Classification of Disinfectants, Table 2, General Classification of Antiseptics, Disinfectants, and Sporicidal Agents*).

The frequency, methods, and locations of disinfection agent use must be established in written SOPs, in accordance with the manufacturer's instructions, and followed by environmental services (i.e., custodial) or compounding personnel.

6.2 Cleaning Tools

All cleaning tools (e.g., wipes, sponges, and mop heads) must be sterile and low-lint, preferably composed of synthetic microfibers and dedicated for use in buffer or ante-areas or segregated compounding areas. All cleaning tools must be cleaned and re-sterilized after each use. They must be discarded after an appropriate amount of time, to be determined based on the condition of the materials. Disposal must involve collecting them in suitable plastic bags and removing them from classified and segregated compounding areas, with minimal agitation so as not to disperse contaminants into the air.

6.3 Cleaning and Disinfecting Floors, Ceilings, Walls, and Shelving

865 Floors in all ISO-classified and segregated compounding areas should be cleaned by
866 mopping with a cleaning and disinfection agent once daily at a time when no aseptic
867 operations are in progress. Mopping should be in the direction of clean to dirty areas.
868 Mopping must be performed by trained personnel using approved agents and
869 procedures, which must be described in written SOPs. In all ISO-classified and
870 segregated compounding areas, the walls, ceilings, and shelving must be cleaned and
871 disinfected monthly.

872 **6.4 Cleaning and Disinfecting Work Surfaces**

873 For both Category 1 and Category 2 CSPs, cleaning and disinfecting work surfaces in
874 the PEC are the most critical steps before preparing CSPs. These surfaces must be
875 cleaned and disinfected more frequently than other surfaces such as walls and ceilings.
876 With the exception of isolators (as defined in *4. Buildings and Facilities*), all surfaces in
877 the PEC must be cleaned at the beginning and end of each work shift; no longer than
878 30 minutes following the previous surface disinfection when ongoing compounding
879 activities are occurring; when there are spills; and when surface contamination is known
880 or suspected from procedural breaches. Additionally, surfaces in the PEC in direct
881 contact with materials used in compounding must be cleaned before starting each batch
882 of CSPs. When using an isolator, cleaning must be done when the isolator is opened.
883 Decontaminate the isolator once it is closed after each time it has been opened, or after
884 each cleaning cycle, if cleaning occurs without opening. See *Box 6-1* for a summary of
885 procedures for cleaning and disinfecting visibly soiled areas in the PEC.

886 **Box 6-1 Procedures for Cleaning and Disinfecting Visibly Soiled Areas in the PEC**

- Remove all items on the surface and remove loose material and residue from spills using a suitable cleaning agent.
- Use sterile water for injection or irrigation and sterile low-lint wipes to remove water-soluble solid residues.
- Wipe the affected area with a disinfectant (e.g., sterile 70% IPA).
- Allow the surface to dry before beginning compounding.

887 Work surfaces in the buffer, ante, and segregated compounding areas must be
888 cleaned and disinfected at least daily, and storage sites for compounding ingredients
889 and supplies must remain free from dust and debris. This must be achieved using a
890 method that does not diminish the ISO Class 7 or 8 air quality.

891 **6.5 Cleaning and Disinfecting Compounding Supplies**

892 No shipping or other external cartons are allowed into the buffer or ante-areas or
893 segregated compounding areas. Before compounding supplies are introduced into
894 buffer areas, they must be wiped with a suitable disinfectant (e.g., sterile 70% IPA) that
895 is delivered from a spray bottle or other suitable delivery method. After the disinfectant
896 is sprayed or wiped on the surface to be disinfected, the disinfectant must be allowed to
897 dry, during which time the item cannot be used.

898 **6.6 Disinfecting Critical Sites**

899 Critical sites (e.g., vial stoppers, ampul necks, and intravenous bag septums) must be
900 disinfected by wiping them with sterile 70% IPA swabs that are commercially available

in individual foil-sealed packages (or a comparable method). The IPA must be allowed to dry before piercing stoppers with sterile needles or breaking the necks of ampuls. The sterile 70% IPA swabs used for disinfecting critical sites and devices must not contact any other object before contacting the critical site.

7. EQUIPMENT AND COMPONENTS

7.1 Equipment

The equipment used for compounding CSPs must be of appropriate design and adequate size. The equipment also must be of suitable composition such that the surfaces that contact components are not reactive, additive, or sorptive, and therefore, will not affect or alter the purity of the CSP. Equipment in direct contact with the CSP and container–closure system must be sterilized and depyrogenated using methods appropriate for the equipment and container–closure system (see *8. Sterilization and Depyrogenation*, and *Sterilization and Sterility Assurance of Compendial Articles ⟨1211⟩, Methods of Sterilization*).

Equipment must be suitably located to facilitate sterile compounding operations. It must be consistently capable of operating properly and within acceptable tolerance limits. Compounding personnel must establish, maintain, and follow written procedures for the calibration, maintenance, and use of the equipment, as well as monitoring it for proper function. Personnel must also maintain results from equipment calibration, annual maintenance reports, and other routine maintenance records in accordance with the requirements in *16. Documentation*.

Automated compounding devices (ACDs) are designed to streamline the labor-intensive processes involved in the compounding of multiple-ingredient preparations (e.g., parenteral nutrition) by automatically delivering the individual ingredients in a predetermined sequence under computerized control. ACDs can improve the accuracy and precision of the compounding process, compared with manual compounding methods.

When using ACDs, compounding personnel must conduct an accuracy assessment of the ACD each day it is used to compound CSPs. The volume and weight accuracy of the ACD must be determined, based on manufacturer recommendations, to ensure that the correct quantities of ingredients are delivered to the final container. The precision of the ACD can be monitored based on an assessment of day-to-day variations in its accuracy measures. Compounding personnel must keep a daily record of the accuracy measures and must review the results at least weekly to identify trends over time.

7.2 Components

Compounding personnel must establish, maintain, and follow written procedures for the selection and inventory control of all CSP components, including all ingredients (i.e., bulk active pharmaceutical ingredients (APIs) and inactive ingredients), containers, and closures. These written procedures must be followed for all components, from receipt to consumption.

COMPONENT SELECTION

Compounders must use qualified vendors. A vendor is qualified when there is evidence to support its ability to supply a material that consistently meets all quality specifications. Qualification must include an evaluation of the vendor's reputation and reliability.

Ingredients that are the subject of a *USP* or *NF* monograph must be used when available. APIs used in compounding must be manufactured by an FDA-registered facility. Each API must be accompanied by a valid COA that includes the specifications and test results and shows that the API meets the monograph, if one exists, and any additional specifications required to appropriately compound the CSP. Other bulk ingredients should be accompanied by a valid COA that shows that the ingredient meets the monograph, if one exists, and any additional specifications for the ingredient.

When ingredients other than APIs cannot be obtained from an FDA-registered facility, compounders must use professional judgment in selecting an acceptable and reliable source. When ingredients are obtained from an unregistered facility, the compounder must establish the identity, strength, purity, and quality of the ingredients obtained from that supplier by reasonable means. These means may include checking each lot of the component when received, or periodically verifying quality by testing a sample of components obtained from that supplier to determine whether the COAs for ingredients sourced from that supplier accurately reflect the characteristics of the ingredients.

When components of compendial quality are not obtainable, components of high quality such as those that are chemically pure, analytical reagent grade, or American Chemical Society (ACS)–certified may be used. However, these components should be used cautiously because the standards for analytical reagents or ACS–grade materials do not consider whether the presence of any impurity raises human or animal safety concerns.

Careful consideration and evaluation of nonsterile ingredient sources is especially warranted when the CSP will be administered into the vascular system, central nervous system, or eyes.

Each lot of commercially available sterile, depyrogenated containers and container–closure systems must be accompanied by a COA or other documentation showing conformance with established specifications.

COMPONENT RECEIPT

Upon receipt of each lot of a component, a visual inspection must be performed to ensure that the ingredient appears to be what it is represented to be; the lot must also be examined for evidence of deterioration and other aspects of unacceptable quality. Facility personnel must verify the labeling and condition of the component [e.g., whether the outer packaging is damaged and whether temperature-sensing indicators show that the component has been exposed to excessive temperature(s)].

Analytical results in the vendor-supplied COA for each lot of incoming ingredient must be inspected against the compounding facility's current specification sheet to ensure that the acceptance criteria are met. If there is a compendial monograph for any ingredient received, facility personnel must verify that the COA for the ingredient demonstrates that the ingredient has met the acceptance criteria of all specified monograph tests for that lot and includes the test results.

Any ingredients found to be of unacceptable quality must be promptly rejected, clearly labeled as rejected, and segregated to prevent their use before appropriate disposal.

Any other lots of that ingredient from that vendor must be examined to determine whether other lots have the same defect.

The date of receipt by the compounding facility must be clearly and indelibly marked on each ingredient package, except for finished dosage forms obtained from FDA-registered manufacturers. For each ingredient, information including receipt date, quantity received, supplier's name, lot number, expiration date, and results of any in-house or third-party testing performed must be recorded. Compounding personnel must keep a written record of each shipment of components received, in accordance with the recordkeeping requirements described in *16. Documentation*.

COMPONENT EVALUATION BEFORE USE

Before use, all components must be re-inspected. Ingredient packages must be inspected to detect container breaks, looseness of the cap or closure, and deviation from the expected appearance, aroma, and texture of the contents that might have occurred during storage. Sterile container–closures and sterile devices must be visually inspected to ensure that they are free from defects that could compromise sterility, and are otherwise suitable for their intended use.

Compounding personnel must ascertain before use that ingredients for CSPs are of the correct identity and appropriate quality and have been stored under appropriate conditions. The following information should be used to make this determination: prescription or medication order, compounding record, master formulation record (if used), vendor labels and COAs, product labeling, and knowledge of the compounding facility storage conditions and practices.

If the correct identity, purity, strength, and sterility of ingredients and other components intended for preparation of CSPs cannot be confirmed (e.g., containers of ingredients with incomplete labeling, unlabeled syringes, opened ampuls, punctured vial stoppers, flexible intravenous bags), they must be promptly rejected, clearly labeled as rejected, and segregated to prevent their use before appropriate disposal.

COMPONENT HANDLING AND STORAGE

All components must be handled and stored in a manner that prevents contamination, mix-ups, and deterioration. Ingredients must be stored in tightly closed containers under temperature, humidity, and lighting conditions consistent with those indicated in official monographs or specified by the suppliers/manufacturer. Moisture-sensitive ingredients must be stored in tight, well-closed containers.

Packages of ingredients that lack a vendor's expiration date must not be used after 1 year from receipt by the compounding facility, unless appropriate inspection and testing indicates that the ingredient has retained its purity and quality for use in CSPs.

For information on handling and storage of hazardous drugs, see ⟨800⟩.

8. STERILIZATION AND DEPYROGENATION

Each CSP must be sterile and pyrogen-free before release. When selecting the sterilization method for each CSP, personnel must take into consideration the nature of the components, its physical and chemical properties, and the intended container–closure system. The sterilization method used must sterilize the CSP while maintaining its physical and chemical stability (i.e., appropriate strength, purity, quality), and the

packaging integrity of the CSP. Utensils and materials in direct contact with the components, the CSP, and the container–closure system must be sterilized and depyrogenated using appropriate methods (see *Sterilization of Compendial Articles* ⟨1229⟩). If sterilization and depyrogenation of container–closure systems is performed on site, the efficacy of each process must be established and documented, and the process must be shown to be reproducible. CSPs that are terminally sterilized are expected to use a process that achieves a sterility assurance level (SAL) of 10^{-6}. An SAL of 10^{-6} is equivalent to a probability that 1 unit in a million is nonsterile. Generally, an SAL value cannot be applied to CSPs that are aseptically filled into a sterile container following sterilization.

The following must be considered when selecting an appropriate sterilization method:

- Terminal sterilization (e.g., dry heat, steam, or irradiation) is the preferred method, unless the specific CSP or container–closure system cannot tolerate terminal sterilization.
- Filtration is not an option if compounding a suspension when the suspended particles are removed by the filter being used, which could affect the strength of the CSP.
- Dry heat is not an option if a CSP component is labile when exposed to the temperatures used.
- Steam sterilization is not an option if moisture, pressure, or the temperatures used would degrade the CSP.

A description of the sterilization and depyrogenation process, including the temperature, pressure (if applicable), duration, and permissible load conditions for each cycle, must be included in the facility's written SOPs (see *9. SOPS and Master Formulation and Compounding Records*.)

In addition, the SOPs must include a schedule and method for establishing and periodically verifying the effectiveness of the sterilization and depyrogenation methods selected, as well as the method for maintaining and cleaning the sterilizers and depyrogenation equipment.

The following sections provide general guidance on specific sterilization methods.

8.1 Sterilization by Filtration

See *Sterilizing Filtration of Liquids* ⟨1229.4⟩. Commercially available sterile filters must be certified by the manufacturer as suitable for pharmaceutical use when used to sterilize CSPs. Sterilizing filters must be sterile and pyrogen-free and have a nominal pore size of 0.2 or 0.22 µm. They must be certified by the manufacturer to retain at least 10^7 microorganisms of a strain of *Brevundimonas diminuta* per square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be filtered (i.e., pressure, flow rate, and volume filtered).

The person responsible for selecting the sterilization method must ascertain from appropriate information sources that the sterilizing-grade membrane filter selected is chemically and physically compatible with the specific formulation of the CSP. For example, CSPs containing water-miscible alcohols may cause undetectable damage to filter integrity and shrinkage of microorganisms to sizes smaller than the filter's nominal pore size.

The responsible person must ensure, directly or from appropriate documentation from the supplier, that the filters 1) are chemically and physically stable at the pressure and temperature conditions that will be used; 2) have enough capacity to filter the required volumes; and 3) will yield a sterile filtrate while maintaining pre-filtration pharmaceutical quality, including strength of ingredients of the specific CSP. The filter dimensions and the preparation to be sterilized by filtration should permit the sterilization process to be completed without the need for replacement of the filter during the process. When CSPs are known to contain excessive particulate matter, to maximize the efficiency of the final sterilizing filtration, a pre-filtration step should be performed using a filter of larger nominal pore size, or a separate filter of larger nominal pore size should be placed upstream of (i.e., prior to) the sterilizing filter to remove gross particulate contaminants before the CSP is passed through the sterilizing grade filter. Excessive particulate matter requiring a prefiltration step also could be a signal of an inappropriate formulation, and therefore the formulation and the process should be assessed to ensure that they are appropriate; if necessary, they should be modified. Filter units used to sterilize CSPs must be subjected to the manufacturers' recommended post–use integrity test, such as a bubble point test.

8.2 Sterilization by Steam Heat

See *Steam Sterilization by Direct Contact* ⟨1229.1⟩. The process of thermal sterilization using saturated steam under pressure (i.e., autoclaving) is the preferred method for terminal sterilization of aqueous preparations in their final, sealed container–closure system. Steam heat sterilization is not an option if moisture, pressure, or the temperatures used would degrade the CSP. Steam heat sterilization is also used to sterilize many components (e.g., elastomeric closures) and some types of equipment. To achieve sterility, all materials must be directly exposed to steam under adequate pressure for the length of time necessary, as determined by use of appropriate biological indicators, to render the items sterile (i.e., kill any microorganisms, including bacterial spores that might be present).This is usually between 20 and 60 minutes at 121° saturated steam under a pressure of 15 psi. The duration of the exposure period must include sufficient time for the CSP or other items to reach the sterilizing temperature. The CSP and other items must remain at the sterilizing temperature for the duration of the sterilization period. The sterilization cycle should be designed to achieve a SAL of 10^{-6}.

CSPs must be placed in suitable trays to allow steam to reach the CSPs without entrapment of air. Flat, stainless steel trays with low sides or ventilated bottoms will permit steam contact. When preparing plastic, glass, and metal devices or other items for steam sterilization, the items must be wrapped in low-lint protective fabric or paper or sealed in envelopes that will permit steam penetration and prevent post sterilization microbial contamination. Immediately before filling ampuls and vials that will be steam sterilized, solutions must be passed through a filter having a nominal pore size of not larger than 1.2 µm for removal of particulate matter.

Sealed containers must be able to generate steam internally. Stoppered and crimped empty vials must contain a small amount of moisture to generate steam. Deep containers, such as beakers and graduated cylinders, should be placed on their sides to prevent air entrapment, or should have a small amount of water placed in them when steam sterilized. Porous materials and those items with occluded pathways (e.g.,

tubing) should only be sterilized by steam if the autoclave chamber has suitable cycles for dry goods, such as a pre-vacuum process to remove air before steam is sent into the chamber. Elastomeric closures and many other dry goods will need a drying cycle after steam exposure to remove condensed or absorbed moisture.

The effectiveness of steam sterilization must be established and verified with each sterilization run or load by using appropriate biological indicators, such as spores of *Geobacillus stearothermophilus*, ATCC 12980, ATCC 7953 or equivalent (see *Biological Indicators for Sterilization* ⟨1035⟩), and other confirmation methods such as physicochemical indicators and integrators (see *Sterilization—Chemical and Physicochemical Indicators and Integrators* ⟨1209⟩).

The steam supplied must be free of contaminants and generated using clean water. The seals on the doors of autoclave chambers should be examined visually every day they are used for cracks or other damage, and the seal surfaces should be kept clean. A data recorder or chart must be used to monitor each cycle and to examine for cycle irregularities (e.g., deviations in temperature or pressure).

Because the temperatures used to achieve sterilization by steam heat are lower than those used to achieve depyrogenation, materials in direct contact with the CSP (e.g., the container–closure system) must first undergo a depyrogenation process (e.g., dry heat or rinsing with pyrogen-free water) before being sterilized using steam heat, unless the materials used are certified to be pyrogen-free (see *Depyrogenation* ⟨1228⟩).

8.3 Sterilization by Dry Heat

See *Dry Heat Sterilization* ⟨1229.8⟩. Dry heat can be used only for those items that cannot be sterilized by steam or other means, when either the moisture would damage the material or the wrapping material is impermeable. Sterilization by dry heat requires higher temperatures and longer exposure times than sterilization by steam. The duration of the exposure period must include sufficient time for the CSP or other items to reach the sterilizing temperature. The CSP and other items must remain at the sterilizing temperature for the duration of the sterilization period.

Dry heat sterilization is usually done in an oven designed for sterilization at a temperature of 160° or higher, although sterilization processes at lower temperatures have been developed and validated. If lower temperatures are used, they must be shown to achieve effective sterilization (see *Dry Heat Sterilization* ⟨1229.8⟩, *Validation of Dry Heat Sterilization, Biological Indicators*).

Heated air must be evenly distributed throughout the chamber, which is typically done by an air blower. The oven must be equipped with temperature controls and a timer. During sterilization, sufficient space must be left between materials to allow for good circulation of the hot air. A data recorder or chart must be used to monitor each cycle and the data must be reviewed to identify cycle irregularities (e.g., deviations in temperature or exposure time).

The effectiveness of the dry heat sterilization method must be established and verified with each sterilization run or load using appropriate biological indicators such as spores of *Bacillus atrophaeus*, ATCC 9372, (see ⟨1035⟩) and other confirmation methods (e.g., temperature-sensing devices).

Because the temperatures used to achieve sterilization by dry heat are lower than those used to achieve depyrogenation, materials in direct contact with the CSP (e.g.,

the container–closure system) must first undergo a depyrogenation process (e.g., dry heat or rinsing with pyrogen-free water) before being sterilized using dry heat, unless the materials used are certified to be pyrogen-free (see ⟨1228⟩).

8.4 Depyrogenation by Dry Heat

See ⟨1228⟩. Dry heat depyrogenation must be used to render glassware and other thermostable containers pyrogen-free. Depyrogenation processes typically operate at a range of temperatures from approximately 170° up to about 400°, depending on the exposure time. For example, a typical cycle would hold the items at 250° for 30 minutes. The duration of the exposure period must include sufficient time for the items to reach the depyrogenation temperature. The items must remain at the depyrogenation temperature for the duration of the depyrogenation period.

The effectiveness of the dry heat depyrogenation cycle must be established and verified annually using endotoxin challenge vials (ECVs) to demonstrate that the cycle is capable of achieving a ≥3-log reduction in endotoxins (see *Bacterial Endotoxins Test* ⟨85⟩).

9. SOPS AND MASTER FORMULATION AND COMPOUNDING RECORDS

Every compounding facility must establish and follow written SOPs for sterile compounding. The SOPs must ensure that the entire compounding operation is well designed, functions as designed, and will yield CSPs that are safe for administration to patients. The compounding process for CSPs must be described in SOPs.

A Master Formulation Record is required when CSPs are prepared in a batch for multiple patients or when CSPs are prepared from nonsterile ingredients. A Master Formulation Record documents the ingredients, specific procedures, equipment to be used, and testing required for each CSP. A Compounding Record is required for every CSP prepared and requires documentation by all individuals involved in the actual preparation of the CSP.

9.1 Creating and Following SOPs

Facilities preparing CSPs must develop SOPs on all aspects of the compounding operation. All personnel who conduct or oversee compounding activities must be trained in the SOPs and are responsible for ensuring that they are followed. All compounding personnel must:

- Be able to immediately recognize potential problems, deviations, or errors associated with preparing a CSP (e.g., related to equipment, facilities, materials, personnel, compounding process, or testing) that could potentially result in contamination or other adverse impact on CSP quality
- Report any problems, deviations, or errors to the compounding supervisor or designee, who must take corrective actions

Compounding supervisors must ensure that SOPs are appropriate and are fully implemented, which includes ensuring that staff demonstrate consistency and competency in performing every procedure that relates to their job function.

1209 Compounding supervisors must also ensure that appropriate follow-up occurs if
1210 problems, deviations, or errors are identified.

1211 **9.2 Creating Master Formulation Records**

1212 A Master Formulation Record must be created for CSPs prepared in a batch for
1213 multiple patients or for CSPs prepared from nonsterile ingredients. Any changes or
1214 alterations to the Master Formulation Record must be performed only by authorized
1215 personnel and must be documented. *Box 9-1* lists the information that must be included
1216 in a Master Formulation Record.

1217 **Box 9-1 Master Formulation Record**

A Master Formulation Record must include at least the following information:

- Name, strength, and dosage form of the CSP
- Physical description of the final preparation
- Identities and amounts of all ingredients and appropriate container–closure systems
- Complete instructions for preparing the CSP, including equipment, supplies, and a description of the compounding steps
- BUD and storage requirements
- Quality control procedures (e.g., pH, filter integrity, and visual inspection)
- Sterilization method, if applicable (e.g., filter, steam, or dry heat)
- Any other information needed to describe the operation and ensure its repeatability (e.g., adjusting pH and tonicity and temperature)

1218 **9.3 Creating Compounding Records**

1219 A Compounding Record must be created by the compounder preparing the CSP to
1220 document the compounding process. The Compounding Record or inventory control
1221 system must permit traceability of all ingredients. The Master Formulation Record (when
1222 used) can be used as the basis for preparing the Compounding Record. For example, a
1223 copy of the Master Formulation Record can be made that contains spaces for recording
1224 the information needed to complete the Compounding Record. It is critical that the
1225 Compounding Record document in detail any deviations from the process outlined in
1226 the Master Formulation Record and any problems or errors experienced during the
1227 compounding of the CSP. *Box 9-2* lists the information that must be included in a
1228 Compounding Record.
1229 Each Compounding Record must be reviewed and approved before the CSP is
1230 released (signature or initials and date).

1231 **Box 9-2 Compounding Records**

Compounding Records must include at least the following information:

- Name, strength, and dosage form of the CSP
- Master Formulation Record reference for the preparation, when used
- Date and time of preparation of the CSP
- Assigned internal identification number (e.g., prescription or lot number)
- Signature or initials of individuals involved in each step (e.g., technician or pharmacist)
- Name, vendor or manufacturer, lot number, and expiration date of each ingredient and container–closure system
- Weight or measurement of each ingredient
- Documentation of the calculations made to determine and verify quantities and/or concentrations of components, if appropriate
- Documentation of quality control procedures in accordance with the SOP (e.g., filter integrity, pH, and visual inspection)
- Any deviations from the Master Formulation Record, if used, and any problems or errors experienced during the compounding of the CSP
- Total quantity compounded
- Assigned BUD
- Duplicate container label if prepared in a batch

10. RELEASE TESTING

At the completion of compounding, before release and dispensing, the CSP must be inspected as described below to determine whether the physical appearance of the CSP is as it should be and to confirm that the CSP and its labeling match the prescription or medication order.

The physical inspection described in *10.1 Physical Inspection of CSP* must be performed on all CSPs before they are released. In addition, sterility and bacterial endotoxin testing must be performed in some cases (see *12. Establishing Beyond-Use Dates and In-Use Times*), as described in *10.2 Sterility Testing* and *10.3 Bacterial Endotoxins Testing*. All checks and inspections, and any other tests or checks necessary to ensure the quality of the CSP (e.g., assays), must be included in the facility's SOP (see *9. SOPS and Master Formulation and Compounding Records*). Additional quality assurance and quality control activities are discussed in *13. Quality Assurance and Quality Control*.

10.1 Physical Inspection of CSP

After compounding, and as a condition of release, each individual CSP unit must be inspected to identify any apparent physical defect. Each individual injectable CSP unit must be inspected against a lighted white background and a black background for evidence of visible particulates or other foreign matter, or discoloration. Some CSPs also must be visually checked for certain characteristics (e.g., emulsions must be checked for phase separation). Pre-release inspection also must include a visual inspection of container–closure integrity (e.g., checking for leakage, cracks in the

container, or improper seals). CSPs with observed defects must be immediately discarded, or marked and segregated from acceptable units in a manner that prevents them from being released or dispensed.

When a CSP will not be released or dispensed promptly after preparation, a pre-release inspection must be conducted immediately before it is released or dispensed to make sure that the CSP does not exhibit any defects, such as precipitation, cloudiness, or leakage, which may develop during storage. A CSP with such defects must be immediately discarded, or marked and segregated from acceptable units in a manner that prevents it from being released or dispensed.

10.2 Sterility Testing

Category 1 CSP BUDs apply regardless of whether sterility testing is conducted (see *Table 7*). If a Category 2 CSP is assigned a BUD that requires sterility testing (see *Table 8*), the testing must be performed in a manner consistent with ⟨71⟩, with the exception, in some cases, of the batch sizes specified in *Sterility Tests* ⟨71⟩*, Table 3. Minimum Number of Articles to be Tested in Relation to the Number of Articles in the Batch*. If the number of units of CSPs to be prepared in a single batch is less than the number of units needed for testing, additional units may be required to be compounded to be able to conduct sterility testing. For batch sizes of 1–39 units, each sterility test must be performed using a number of units equal to 10% of the batch size, rounded up to the next whole number. For batch sizes of 40 or more units, the sample sizes specified in *Sterility Tests* ⟨71⟩*, Table 3* must be used.

When the CSP formulation permits, the Membrane Filtration method is the method of choice for sterility testing. The preferred alternative is the Direct Inoculation of the Culture Medium method; both methods are described in ⟨71⟩.

If sterility testing will be conducted, ideally the results should be obtained before dispensing to patient(s). If it is anticipated that there will be situations in which there may be an urgent need to dispense a CSP before the results of the sterility testing are known, a written procedure (SOP) must be developed and followed; this SOP must describe how these situations will be handled. In addition, this SOP must require frequent observation of the incubating test specimen and must require immediate recall of the dispensed CSP (if possible) or immediate notification of the patient's prescriber, if any evidence of microbial growth is found during the test.

Positive sterility test results must prompt a rapid and systematic investigation into the causes of the sterility failure, including identification of the contaminating organism (at least to the genus level) and any aspects of the facility, process, or personnel that may have contributed to the sterility failure. The source of the contamination, if identified, must be corrected, and the facility should determine whether the conditions causing the sterility failure affect other CSPS. The investigation and resulting corrective actions must be documented.

10.3 Bacterial Endotoxins Testing

All Category 2 CSPs made from one or more nonsterile ingredients, except those for inhalation and topical ophthalmic administration, must be tested to ensure that they do not contain excessive bacterial endotoxins (see ⟨85⟩ and *Pyrogen Test* ⟨151⟩). A CSP does not need to be tested for bacterial endotoxins if the COA for the nonsterile ingredient lists the endotoxins burden, or if the compounding facility has predetermined

the endotoxins burden of the nonsterile ingredient and found it acceptable, and the material is stored under cool and dry conditions.

In the absence of a bacterial endotoxins limit in an official monograph or other CSP formula source, the CSP must not exceed the endotoxins limit calculated as described in ⟨85⟩ for the appropriate route of administration.

11. LABELING

CSPs must be labeled with adequate, legible identifying information to prevent errors during storage, dispensing, and use. The term labeling designates all labels and other written, printed, or graphic matter on an article's immediate container or on, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term label designates that part of the labeling on the immediate container. See *Labeling ⟨7⟩, Labels and Labeling for Products and Other Categories, Compounded Preparations*.

The label must, at a minimum, display prominently and understandably the following information:

- Assigned internal identification number (e.g., prescription or lot number)
- Brand and/or generic name(s), or active ingredient(s) and amounts or concentrations
- Dosage form
- Total amount, if it is not obvious from the container
- Storage conditions
- BUD and when appropriate, an in-use time (see *12. Establishing Beyond-Use Dates and In-Use Times*)
- Whether it is a single-dose or multiple-dose container
- Indication that the preparation is compounded

The labeling must, at a minimum, display prominently and understandably the following information:

1. Patient name, or for animal drugs, owner’s name and species of patient
2. Route of administration, if known
3. Any special handling instructions
4. Any warning statements that are applicable
5. Name, address, and contact information of the compounder if the CSP is to be sent outside of the facility in which it was compounded

Labeling operations must be controlled to prevent labeling errors and CSP mix-ups. A final check must be conducted to verify that the correct and complete label has been affixed to the finished CSP. All labels must also comply with applicable state laws and regulations.

12. ESTABLISHING BEYOND-USE DATES AND IN-USE TIMES

Each CSP label must state the date beyond which the preparation cannot be used and must be discarded. A CSP may also be labeled with an in-use time within which it must be used after it has been opened or punctured. A number of critical parameters must be considered before establishing these dates. It is also important to understand the various terms that are used in discussion of these dates.

12.1 Terminology

A number of terms are used to describe the time period during which a drug is considered to retain its desired characteristics so that it can be safely administered to a patient to achieve the desired therapeutic effect.

The expiration date identifies the time during which a conventionally manufactured drug product may be expected to maintain its labeled identity, strength, quality, and purity, provided it is kept under the labeled storage conditions. The expiration date limits the time during which a conventionally manufactured product may be dispensed or used. Expiration dates are determined based on product-specific studies that evaluate the specific formulation of a drug product in the specific container in which it is to be stored and under the conditions to which it could be exposed. Temperature, humidity, and light are some of the factors that can affect whether and how much a product degrades over time. An expiration date is determined by taking representative samples from batches and placing them in storage under controlled conditions and then testing them at scheduled intervals to determine whether they meet specifications throughout their labeled shelf lives. When an expiration date is stated only in terms of the month and the year, it is a representation that the intended expiration date is the last day of the stated month.

A BUD is included on the label of each CSP to indicate the date or date and hour after which the CSP must not be used, because its required quality characteristics (e.g., sterility, strength, purity) cannot be ensured. The term expiration date is not appropriate for CSPs, because the types of full stability studies conducted by manufacturers to establish expiration dates for conventionally manufactured products are not typically performed for CSPs. BUDs for CSPs are calculated in terms of hours or days.

An in-use time refers to the time before which a conventionally manufactured product or a CSP must be used after it has been opened or needle punctured (e.g., after a container closure of a vial has been penetrated).

12.2 Critical Parameters to Be Considered in Establishing a BUD

Time is a critical factor in establishing a BUD. The more time that passes between the compounding of a CSP and its administration to a patient, the greater the risk of harm to the patient if the stability or sterility of the CSP has been compromised. With respect to sterility, this is especially the case if microbial contamination is present from the outset. BUDs for CSPs should be established conservatively to ensure that the drug maintains its required characteristics until administration to reduce the risk to patients of receiving a contaminated or degraded preparation. Both sterility and stability considerations must be taken into account when establishing a BUD.

STERILITY CONSIDERATIONS

1382 Microbial contamination of a CSP poses a significant risk to patients, and if the CSP is
1383 contaminated during preparation, the risk increases the longer the time the CSP is
1384 stored before administration.
1385 When establishing a BUD for a CSP, it is critical that compounding personnel carefully
1386 consider all of the possible ways that the sterility of the CSP could be compromised
1387 over time. The following factors related to sterility must be carefully considered:

1388 • Whether the CSP will be tested for sterility, and the results will be known, before
1389 the CSP is released or dispensed
1390 • Whether the CSP will be terminally sterilized in its final container (provided the
1391 drug and its container–closure can withstand the terminal sterilization process)
1392 (see *8. Sterilization and Depyrogenation*)
1393 • Whether the CSP contains a preservative, or is inherently susceptible to
1394 microbial survival or growth, if contaminated
1395 • Whether the container–closure system and sealing method will ensure the
1396 integrity of the CSP until administration to the patient

1397 STABILITY CONSIDERATIONS

1398 Over time, active ingredient(s) in a CSP may degrade, reducing the strength of the
1399 preparation and/or producing harmful impurities. Additionally, the container–closure
1400 system may degrade, which can lead to several potential deleterious effects, such as: 1)
1401 reducing the integrity of the CSP; 2) leaching of harmful chemicals into the preparation
1402 from the container–closure system; and/or 3) absorption of the active ingredient onto
1403 the container, thereby reducing potency. When establishing a BUD for a CSP, it is
1404 critical that compounding personnel carefully consider all of the possible ways that the
1405 physical or chemical characteristics of the CSP could change over time. The following
1406 issues must be carefully considered:

1407 • The chemical and physical stability properties of the drug and/or its formulation
1408 (i.e., if the drug and its formulation are known to degrade over time and/or
1409 under certain storage conditions)
1410 • The compatibility of the container–closure system with the finished preparation
1411 (e.g., consider leachables, interactions, and storage conditions of the
1412 components)

1413 In addition:

1414 • If the CSP includes components from conventionally manufactured product(s),
1415 the BUD of the CSP must not exceed the shortest remaining expiration date of
1416 any of the starting components.
1417 • If the CSP includes components from other compounded preparations, the BUD
1418 of the final CSP must not exceed the shortest remaining BUD of any of the
1419 starting CSP components.

1420 **12.3 Establishing a BUD for a CSP**

BUDs for CSPs must be established in accordance with *Table 7* for Category 1 CSPs and *Table 8* for Category 2 CSPs. The BUDs specified in the tables indicate the hours or days after the CSP is prepared and beyond which the CSP cannot be used. The BUD is determined from the time the CSP is compounded. One day is equivalent to 24 hours.

The BUDs in *Table 7* and *Table 8* for CSPs are based on the risk of microbial contamination, not the physical or chemical stability of the CSP, and involve the following assumptions:

1. The CSP and its components can remain chemically and physically stable for the BUD period
2. None of the factors identified in *12.2 Critical Parameters to Be Considered in Establishing a BUD*, would require a shorter BUD

If there is any indication, based on the factors described in *12.2. Critical Parameters to be Considered in Establishing a BUD*, that the particular CSP formulation will not remain chemically or physically stable for the specified period, a shorter BUD must be assigned based on the time period during which the CSP is expected to remain chemically and physically stable.

Table 8 establishes the longest permitted BUDs for Category 2 CSPs, based the following variables:

METHOD OF ACHIEVING STERILITY

Because terminal sterilization using a verified method provides reasonable assurance that a CSP will be sterile, *Table 8* allows longer BUDs for CSPs that are terminally sterilized and not sterility tested than for aseptically prepared CSPs that are not sterility tested. Not all CSPs can be terminally sterilized, and if the CSP is aseptically prepared (e.g., using only sterile products or sterilized by filtration), the shorter BUDs in *Table 8* for aseptically prepared CSPs that are not sterility tested must not be exceeded.

STARTING COMPONENTS

An aseptically prepared CSP compounded from one or more nonsterile starting component has a higher risk of microbial contamination than an aseptically prepared CSP compounded only from sterile starting components. *Table 8* allows for longer BUDs for CSPs aseptically prepared from only sterile starting components.

WHETHER THE CSP WILL BE STERILITY TESTED AND THE RESULTS KNOWN BEFORE THE DRUG IS RELEASED OR DISPENSED

Sterility testing (see *10.2 Sterility Testing*) before releasing or dispensing a CSP can provide additional assurance of the absence of contamination. When the results of sterility testing are known before dispensing, a longer BUD is permitted in *Table 8*. If sterility testing is not performed, a shorter BUD is required in *Table 8*.

If a sterility test is performed and there is an urgent need to dispense the CSP before sterility test results become available, a CSP can be dispensed to a patient before the end of the sterility testing period if:

- The prescriber specifically requests dispensing before completion of the sterility test, and the request is documented

- The patient and the prescriber are notified of any microbial growth during the sterility testing. The species of microbial contaminant is reported to the prescriber to ensure appropriate medical therapy following exposure to a contaminated CSP

PRESENCE OF A PRESERVATIVE

Although a preservative must not be considered a substitute for good aseptic practices, preservatives can be added to multiple-dose CSPs because they may inhibit the growth of microorganisms for short periods of time. If a CSP contains a preservative whose effectiveness for the length of the BUD has been verified based on antimicrobial effectiveness testing (see *Antimicrobial Effectiveness Testing* ⟨51⟩), the BUD in *Table 8* for a CSP containing a preservative can be assigned. Shorter BUDs are required for preservative-free CSPs, as compared to CSPs that contain a verified preservative.

The particular CSP formulation must pass antimicrobial effectiveness testing in accordance with ⟨51⟩ at the completion of the sterility test (if conducted) or at the time of preparation (if sterility testing is not performed). The test must be completed and the results obtained on the specific formulation before any of the CSP is released or dispensed. The test needs to be conducted only once on each formulation in the particular container–closure system in which it will be stored or released/dispensed.

STORAGE CONDITIONS

The specified conditions under which a CSP will be stored are important in determining an appropriate BUD. Storage in a refrigerator or in a freezer (see *Packaging and Storage Requirements* ⟨659⟩) has been shown to slow the growth of microorganisms. Therefore, *Tables 7* and *8* allow for longer BUDs for CSPs stored in colder conditions than when stored at controlled room temperature.

Storage under frozen conditions places the container–closure under physical stress, and the degree of stress may depend on the formulation and other factors. Therefore, if a Category 2 CSP is to be stored in a freezer, the integrity of the CSP in the particular container–closure system in which it will be stored must have been demonstrated for 45 days at frozen storage. A container–closure integrity test needs to be conducted only once on each formulation and fill volume in the particular container–closure system in which it will be stored or released/dispensed. Once the CSP is thawed, the CSP must not be re-frozen.

It must be recognized that CSPs may be stored under different storage conditions before they are used (e.g., they may first be frozen, and then thawed in the refrigerator, and finally kept at controlled room temperature before administration). The storage time of a CSP must not exceed the original BUD placed on the CSP for its labeled storage conditions, and BUDs are not additive. For example, a CSP cannot be stored for 4 days at controlled room temperature, then 7 days refrigerated, and then 45 days in a freezer, for a total of 56 days. Once a CSP is stored under a condition that would require a shorter BUD (i.e., controlled room temperature), the CSP must be used within the shorter timeframe for that storage condition (in this example, 4 days).

Table 7. BUDs for Category 1 CSPs[a]

	Storage Conditions

	Storage Conditions	
	Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)
BUD	≤12 hours	≤24 hours

[a] The BUDs specified in the table indicate the hours after the Category 1 CSP is prepared beyond which the CSP cannot be used. The BUD is determined from the time the CSP is compounded.

1504 **Table 8. BUDs for Category 2 CSPs[a]**

	Preparation Characteristics			Storage Conditions		
	Method of Achieving Sterility	**Sterility Testing Performed**	**Preservative Added**	**Controlled Room Temperature (20°–25°)**	**Refrigerator (2°–8°)**	**Freezer (–25° to –10°)[b]**
BUD	Aseptically prepared CSPs	No	No	Prepared from one or more nonsterile starting component 4 days	Prepared from one or more nonsterile starting component 7 days	Prepared from one or more nonsterile starting component 45 days
				Prepared from only sterile starting components 6 days	Prepared from only sterile starting components 9 days	Prepared from only sterile starting components 45 days
			Yes[c]	28 days	42 days	45 days
		Yes	No	28 days	42 days	45 days
			Yes[d]	42 days	42 days	45 days
	Terminally Sterilized CSPs	No	No	14 days	28 days	45 days
			Yes[c]	28 days	42 days	45 days
		Yes	No	28 days	42 days	45 days
			Yes[d]	42 days	42 days	45 days

[a] The BUDs specified in the table indicate the days after the Category 2 CSP is prepared beyond which the CSP cannot be used. The BUD is determined from the time the CSP is compounded. One day is equivalent to 24 hours.

[b] The integrity of the container–closure system with the particular CSP in it must have been demonstrated for 45 days at frozen storage. The container–closure integrity test needs to be conducted only once on each formulation in the particular container–closure system in which it will be stored or released/dispensed.

[c] The particular CSP formulation must pass antimicrobial effectiveness testing in accordance with ⟨51⟩ at the time of preparation. The test must be completed and the results obtained on the specific formulation before any of the CSP is dispensed. The test needs to be conducted only once on each formulation in the

	Preparation Characteristics			Storage Conditions		
	Method of Achieving Sterility	Sterility Testing Performed	Preservative Added	Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)	Freezer (–25° to –10°)[b]

particular container–closure system in which it will be stored or released/dispensed.

[d] The particular CSP formulation must pass antimicrobial effectiveness testing in accordance with ⟨51⟩ at the completion of sterility test (i.e., 14 days after preparation). The test must be completed and the results obtained on the specific formulation before any of the CSP is dispensed. The test needs to be conducted only once on each formulation in the particular container–closure system in which it will be stored or released/dispensed.

12.4 Establishing In-Use Times

The in-use time is the time before which a conventionally manufactured product or a CSP must be used after it has been opened or needle-punctured. The in-use time assigned cannot exceed the expiration date of the conventionally manufactured product or the BUD of a CSP. The in-use time may be dependent on the type of product or CSP and the environment where the manipulations occur (e.g., ISO Class 5, or worse than ISO Class 5). *Table 9* specifies the in-use times for conventionally manufactured products and CSPs that are opened, stored, and used for sterile compounding in ISO Class 5 or better air quality. *Table 10* specifies the in-use times for conventionally manufactured products and CSPs that are opened and/or stored in worse than ISO Class 5 air quality.

Table 9. In-Use Times for Conventionally Manufactured Products and CSPs Opened, Stored, and Used for Sterile Compounding in ISO Class 5 or Better Air Quality

Components	In-Use Time
Conventionally Manufactured Sterile Product	
Ampuls	Use *immediately* after opening and passing through a sterile particulate filter
Pharmacy Bulk Package	As specified by the manufacturer
Single-dose container (e.g., bag, bottle, syringe, or vial)	6 hours
Multiple-dose container	28 days, unless otherwise specified by the manufacturer
CSP	
Compounded single-dose container	6 hours
Compounded stock solutions	6 hours
Compounded multiple-dose container[a]	28 days, unless otherwise specified by the original compounder

[a] The particular CSP formulation must pass antimicrobial effectiveness testing in accordance with ⟨51⟩ at

Components	In-Use Time
Conventionally Manufactured Sterile Product	
the completion of the sterility test (if conducted) or at the time of preparation (if sterility testing is not performed). The test must be completed and the results obtained on the specific formulation before any of the CSP is released or dispensed. The test needs to be conducted only once on each formulation in the particular container–closure system in which it will be stored or released/dispensed.	

1519 **Table 10. In-Use Times for Conventionally Manufactured Products and CSPs**
1520 **Opened and/or Stored in Worse than ISO Class 5 Air[a]**

Components	In-Use Time
Conventionally Manufactured Sterile Product	
Ampuls	Use *immediately* after opening and passing through a sterile particulate filter
Pharmacy Bulk Package	Not applicable. Contents of pharmacy bulk packages must be used only in an ISO Class 5 or better environment.
Single-dose container (e.g., bag, bottle, syringe, vial)	Use for a single patient within the time specified by the manufacturer, or by the end of the case or procedure, whichever comes first. Discard remainder.
Multiple-dose container	28 days, unless otherwise specified by the manufacturer
CSP	
Compounded single-dose container	Use for a single patient immediately. Discard remainder.
Compounded multiple-dose container[b]	28 days, unless otherwise specified by the original compounder

[a] Compounding or repackaging must not occur in worse than ISO Class 5 air.
[b] The particular CSP formulation must pass antimicrobial effectiveness testing in accordance with ⟨51⟩ at the completion of the sterility test (if conducted) or at the time of preparation (if sterility testing is not performed). The test must be completed and the results obtained on the specific formulation before any of the CSP is released or dispensed. The test needs to be conducted only once on each formulation in the particular container–closure system in which it will be stored or released/dispensed.

1521
1522 **13. QUALITY ASSURANCE AND QUALITY CONTROL**

1523 A quality assurance (QA) and quality control (QC) program is necessary to ensure that
1524 consistently high-quality CSPs are prepared. QA is a set of written processes that, at a
1525 minimum, verifies, monitors, and reviews the adequacy of the compounding process.
1526 QC is the observation of techniques and activities that demonstrate that requirements
1527 are met.
1528 Each facility must have a formal, written QA and QC program that establishes a
1529 system of adherence to procedures, prevention and detection of errors and other quality
1530 problems, and appropriate corrective actions when needed. A facility's QA program
1531 must be formally established and documented in SOPs that ensure that all aspects of

1532 the preparation of CSPs are conducted in accordance with this chapter and applicable
1533 federal, state, and local laws and regulations.
1534 The QA program must, at a minimum, address the following functions:

1535 - Personnel qualifications and training:
1536 - Periodically review personnel files for each employee to determine
1537 whether personnel continue to meet basic qualifications, are obtaining
1538 required training, and are getting qualified and requalified in
1539 accordance with the specified frequencies (e.g., gloved fingertip/thumb
1540 sampling)
1541 - Assess staff performance, including aseptic techniques, cleanroom
1542 behavior, and other critical activities (e.g., media-fill testing)
1543 - Component selection and handling:
1544 - Carefully select, and ensure ongoing qualification of suppliers and
1545 service providers (e.g., chemical vendors and external testing
1546 laboratories)
1547 - Select ingredients that are the subject of a *USP* or *NF* monograph and
1548 that are manufactured at an FDA-registered facility, when available
1549 - Inspect incoming components against their COAs to ensure that they
1550 meet their specifications
1551 - Quarantine, properly dispose of, and investigate components that do
1552 not meet their specifications
1553 - Design and maintenance of the building, facility, and equipment:
1554 - Review the adequacy of the design of the building, facility, and
1555 equipment; when changes are made, assess their effects to make sure
1556 they do not adversely affect the operation (e.g., certification)
1557 - Ensure that facilities and equipment used in compounding are installed,
1558 operated, and maintained properly per appropriate and pre-established
1559 specifications
1560 - Detect adverse trends in environmental monitoring data to take
1561 preventive action and corrective action
1562 - Compounding process:
1563 - Approve Master Formulation Records (when used), or any changes to
1564 them, before they are implemented
1565 - Review Compounding Records for accuracy, completeness, and
1566 conformance to established specifications
1567 - Review final labeling against prescription or medication orders
1568 - Ensure that all errors, process problems, or deviations from procedures
1569 are documented
1570 - Investigate any error, deviation, out-of-specification result, or complaint,
1571 and implement, oversee, and document appropriate corrective action to
1572 prevent recurrence
1573 - Final CSP release:
1574 - Assess the final CSP before release (e.g., physical inspection, sterility
1575 testing, and analytical testing)

    - Review internal or external testing programs (if used) for conformance with applicable standards (e.g., sterility testing and endotoxin testing)
- Documentation:
    - Establish SOPs and assess conformance to SOPs
    - Establish and assess conformance with document control and records management procedures
    - Establish, maintain, and follow written procedures for handling all written and oral complaints regarding a CSP

The roles and duties of personnel responsible for each aspect of the QA program must be described in the SOPs. Designated personnel responsible for the QA program must have adequate training, experience, responsibility, and authority to perform these duties.

The overall QA program must be assessed annually.

14. CSP STORAGE, HANDLING, PACKAGING, AND TRANSPORT

Appropriate processes or techniques for storing, handling, packaging, and transporting CSPs must be in place and must also be outlined in SOPs. Personnel who will be storing, handling, packaging, and transporting CSPs within the facility must be properly trained in accordance with the relevant SOPs.

14.1 Storing CSPs within the Compounding Facility

To help ensure that CSP quality is retained while the CSP is stored at the compounding facility, compounding personnel must monitor conditions in the drug storage areas. A controlled temperature area must be checked at least once daily to determine whether the temperature remains within the appropriate range, and the results must be documented on a temperature log. If the compounding facility uses a continuous temperature recording device, compounding personnel must verify at least once daily that the recording device is functioning properly. In addition, the compounding facility must adhere to appropriate procedures for all controlled temperature areas to ensure that such spaces are not subject to prolonged temperature fluctuations (e.g., by leaving a refrigerator door open too long).

When it is known that a CSP has been exposed to temperatures that exceed storage temperature limits, (i.e., temperatures warmer than the warmest labeled limit or temperatures exceeding 40° for more than 4 hours), the CSP should be discarded.

14.2 Handling of CSPs

CSPs must be handled properly while in the compounding facility to maintain CSP quality and packaging integrity. For example, techniques should be in place to prevent the depression of syringe plungers or dislodging of syringe tips. Additionally, disconnection of system components (e.g., where CSPs are dispensed with administration sets attached to them) must be prevented throughout the BUD or until administration of the CSP.

14.3 Packaging of CSPs

Compounding personnel must select and use packaging materials that will maintain the physical integrity, sterility, and stability of the CSPs. Packaging materials must protect CSPs from damage, leakage, contamination, degradation, and adsorption, while simultaneously protecting transport personnel from harm. The facility must have written SOPs that describe appropriate shipping containers and insulating and stuffing materials based on the product specifications, information from vendors, and knowledge of the mode of transport. For example, when CSPs are transported within the facility through pneumatic tube systems, foam padding or inserts may be useful for preventing breakage and spills. Compounding personnel must continuously monitor the effectiveness and reliability of the packaging materials.

Alternative modes of transport and/or special packaging may be needed to protect the quality of CSPs. The use of tamper-evident closures and seals on CSP ports can provide an additional measure of security that can help ensure product integrity, regardless of the transport method used. If the CSP is sensitive to light, light-resistant packaging materials must be used. In some cases, the CSP should be packaged in a special container (e.g., a cooler) to protect it from temperature fluctuations.

14.4 Transporting CSPs

Compounding personnel must select modes of transport that are expected to deliver properly packed CSPs in an undamaged, sterile, and stable condition. Inappropriate handling and transport can adversely affect the quality of CSPs in general, particularly certain CSPs with unique stability concerns. For example, the physical shaking that might occur during pneumatic tube transport, or undue exposure to heat or light, must be considered and addressed on a preparation-specific basis. Compounding personnel must include specific handling instructions on the exteriors of containers that are used to transport CSPs.

14.5 Handling of Hazardous Drugs

For information on the storage, packaging, handling, and transport of hazardous drugs, see ⟨800⟩.

15. COMPLAINT HANDLING AND ADVERSE EVENT REPORTING

Compounding facilities must provide patients and other CSP recipients with a way to submit questions and report any concerns or complaints they may have regarding a CSP. SOPs must be developed, implemented, and followed for the receipt, acknowledgment, and handling of all complaints about the quality and labeling of, or possible adverse reactions to, a specific CSP.

15.1 Complaint Handling

A qualified individual must review all complaints to determine whether the complaint indicates a potential quality problem with the CSP. If so, a thorough investigation into the cause of the problem must be initiated and completed promptly. The investigation must consider whether the quality problem extends to other batches of the same CSP, or to other CSPs that could have been affected. Corrective action, if necessary, must be implemented immediately for all potentially affected CSPs. When warranted, consider whether to initiate a recall of potentially affected CSPs and whether to cease sterile

compounding operations until all underlying problems have been identified and corrected.

A written record of each complaint must be kept, regardless of the source (e.g., e-mail, telephone, mail). The record must contain the name of the complainant, the date the complaint was received, the nature of the complaint, and the response to the complaint. In addition, to the extent that the information is known, the following should be recorded: the name and strength of the CSP, the prescription or medication order number, and the lot number, if one is assigned. The record must also include the findings of any investigation and any follow-up. Complaint records must be easily retrievable for review and evaluation for possible trends and must be retained in accordance with the recordkeeping requirements in *16. Documentation*. A CSP that is returned in connection with a complaint must be quarantined until it is destroyed after completion of the investigation and in accordance with applicable federal, state, and local laws and regulations.

15.2 Adverse Event Reporting

Reports of potential adverse events involving a CSP must be reviewed promptly and thoroughly by compounding personnel. The reports must be handled in accordance with the procedures for handling complaints as described in section *15.1 Complaint Handling*, as well as the record retention requirements described in *16. Documentation*. Relevant healthcare professionals and patients must be informed as appropriate. If required, adverse events must be reported in accordance with applicable state and local laws and regulations. In addition, serious or unexpected adverse events associated with a CSP should be reported to the FDA through the MedWatch program for human drugs and Form FDA 1932a for animal drugs.

16. DOCUMENTATION

All facilities where CSPs are prepared must have and maintain written documentation to demonstrate compliance with this chapter, including all SOPs, Master Formulation Records (when used), Compounding Records, laboratory and equipment records, prescriptions or medication orders, and all information related to complaints.

All records must be legible and stored in a manner that prevents their deterioration and/or loss. Records can be kept electronically. Records must be maintained either at the facility or at another location that is readily accessible within a reasonable period of time.

All records specific to the compounding of a particular CSP (e.g., Master Formulation Record, Compounding Record, and testing results) must be kept for at least 3 years after the BUD of the CSP, or as required by state laws and regulations, whichever is longer. Facility design and initial qualification records must be kept as long as the facility is in operation. All other records must be kept for at least 3 years, or as required by state laws and regulations, whichever is longer. Examples include records related to personnel training and qualification, equipment maintenance and calibration, receipt of components, environmental monitoring, complaints, and quality assurance.

Recordkeeping must also comply with all applicable federal laws and regulations.

17. RADIOPHARMACEUTICALS AS CSPS

Radiopharmaceuticals are associated with risks of radiation exposure to healthcare practitioners and unintentional radiation exposure to patients. Compounding of radiopharmaceuticals must comply with applicable federal, state, and local laws and regulations such as those from the Nuclear Regulatory Commission (NRC), FDA, and State Boards of Pharmacy.

Unless done in strict conformance with the manufacturer's package insert, any further use or handling and manipulation of conventionally manufactured radiopharmaceutical product is considered compounding and must follow the standards in this chapter and applicable federal, state, and local laws and regulations. Radiation exposures must be kept as low as reasonably achievable (the ALARA principle). Therefore, appropriate shielding must be used to help minimize radiation exposure. Additional equipment needed for radiation control when compounding may include, but is not limited to:

- Radiation detectors
- Static and handheld monitors
- Handheld monitors
- Lead (or other appropriate) shielding
- Shielded waste cans
- Non-shedding absorbent mats
- L-Blocks
- Tongs
- Syringe, vial, and elution shields
- Syringe re-cappers
- Final unit dose containment shielding
- Dose calibrators
- Dippers and dipper lifts

Radioisotope generator systems (e.g., Tc-99m/Mo-99, Rb-82/Sr-82, Ga-68/Ge-68) must be stored and eluted (operated) under conditions recommended by the manufacturer and applicable state and federal regulations. The generators must be eluted in an ISO Class 8 or cleaner air environment that allows special generator shielding, airflow requirements, and the use of lifting devices (e.g., cranes and/or wenches) due to the weight of the generator and shielding. Radioisotope generators producing radioisotopes with a half-life of 15 minutes or less (e.g., Rb-82/Sr-82) can be eluted in accordance with the manufacturer's instructions at the point of care (e.g., at the bedside or in the patient care area). Visual inspection of radiopharmaceutical CSPs containing high concentrations of radioactivity (e.g., for color and absence of particulate material) must be performed in accordance with ALARA principles to limit acute and chronic radiation exposure of the inspecting personnel.

All compounding personnel must be properly gowned and garbed as described in *3. Personal Hygiene and Personal Protective Equipment*. However, personnel compounding radiopharmaceuticals are permitted to use personal radiation dosimeters. Personal radiation dosimeters can be film, thermoluminescent, or electronic. Whole-body badge radiation dosimeters must be worn underneath the gown, whereas

ring/wrist badges that measure the dose at the extremities must be worn under gloves. If personnel are going from a cleanroom to a patient care area, all PPE must be changed before leaving one area and entering the other.

When compounding activities require the manipulation of a patient's blood-derived or other biological material (e.g., radiolabeling of white blood cells), the manipulation must be performed in a separate, dedicated ISO Class 7 area that contains a PEC. All blood manipulations in the radiolabeling process, except for the centrifuge steps, must be performed inside the dedicated PEC. Dedicated equipment must be used for all blood manipulations. Strict SOPs must be developed and implemented to minimize the risk of patient-to-patient cross-contamination.

Some radiopharmaceutical preparations (e.g., volatile or gaseous preparations such as iodine or xenon) may require pressurization configurations that are different from those described in *4. Buildings and Facilities*. In these cases, the facility must comply with applicable federal, state, and local laws and regulations.

Nonradioactive compounds may be compounded in the same compounding area in which radioactive compounds have been prepared, provided the following takes place:

- The ISO Class 5 area is decontaminated and monitored for radioactivity above background levels.
- The dose calibrator is left inside the PEC.
- The PEC is operated in accordance with all the standards in this chapter when nonradioactive CSPs are being prepared.

GLOSSARY

Airlock: A space with interlocked doors, constructed to maintain air pressure control when items move between two adjoining areas (generally with different air cleanliness standards). The intent of an airlock is to prevent ingress of particulate matter and microbial contamination from a lesser-controlled area.

Ante-area: An ISO Class 8 or cleaner area where personnel hand hygiene and garbing procedures and other activities that generate high particulate levels are performed. The ante-area is the transition area between the unclassified area of the facility and the buffer area. [NOTE–The ante-area is sometimes referred to as an ante-room when solid doors and walls are present.]

Aseptic processing or preparation: A process by which separate, sterile components (e.g., drugs, containers, or closures) are brought together under conditions that maintain their sterility. The components can either be purchased as sterile or, when starting with nonsterile components, can be separately sterilized prior to combining (e.g., by membrane filtration, autoclave).

Batch: More than one unit of CSP prepared in a single process and intended to have uniform characteristics and quality, within specified limits.

Beyond-use date (BUD): The date or time after which a CSP cannot be used and must be discarded. The date or time is determined from the date or time when the preparation was compounded.

1788 **Biological safety cabinet (BSC):** A ventilated cabinet with unidirectional HEPA-
1789 filtered airflow and HEPA-filtered exhaust to protect the worker from hazardous drugs. A
1790 BSC used to prepare a CSP must be capable of providing an ISO Class 5 environment
1791 for preparation of the CSP.

1792 **Buffer area:** An ISO Class 7 (or ISO Class 8 if using an isolator) or cleaner area
1793 where the PEC that generates and maintains an ISO Class 5 environment is physically
1794 located.

1795 **Category 1 CSP:** A CSP assigned a BUD of 12 hours or less at controlled room
1796 temperature or 24 hours or less refrigerated.

1797 **Category 2 CSP:** A CSP assigned a BUD of greater than 12 hours at controlled room
1798 temperature or greater than 24 hours refrigerated that is compounded in accordance
1799 with all applicable standards for Category 2 CSPs in this chapter.

1800 **Certificate of analysis (COA):** A report from the supplier of a component, container,
1801 or closure that accompanies the supplier's material and contains the specifications and
1802 results of all analyses and a description of the material.

1803 **Classified space:** A space that maintains an air cleanliness classification based on
1804 the International Organization for Standardization (see also definition for ISO Class).

1805 **Cleanroom:** An ISO-classified room in which the concentration of airborne particles is
1806 controlled to meet a specified airborne-particulate cleanliness class to prevent particle
1807 and microbial contamination of CSPs.

1808 **Compounded sterile preparation (CSP):** A preparation intended to be sterile that is
1809 created by combining, diluting, pooling, or otherwise altering a drug product or bulk drug
1810 substance. A product produced by reconstituting a conventionally manufactured product
1811 for an individual patient strictly in accordance with the directions contained in the
1812 approved labeling provided by the product manufacturer is not considered a CSP for the
1813 purposes of this chapter.

1814 **Compounding aseptic containment isolator (CACI):** A type of RABS that uses
1815 HEPA filtration to provide an ISO Class 5 clean air environment designed for the
1816 compounding of sterile hazardous drugs.

1817 **Compounding aseptic isolator (CAI):** A type of RABS that uses HEPA filtration to
1818 provide an ISO Class 5 clean air environment designed for compounding of sterile non-
1819 hazardous drugs.

1820 **Compounded stock solution:** A compounded solution to be used in the preparation
1821 of multiple units of a finished CSP.

1822 **Container–closure system:** The sum of packaging components that together
1823 contain and protect the dosage form. This includes primary packaging components and
1824 secondary packaging components, if the latter are intended to provide additional
1825 protection.

1826 **Conventionally manufactured product:** A pharmaceutical dosage form, usually the
1827 subject of an FDA-approved application, and manufactured under current good

manufacturing practice conditions. Conventionally manufactured products are not compounded preparations.

Critical site: A location that includes any component or fluid pathway surfaces (e.g., vial septa, injection ports, and beakers) or openings (e.g., opened ampuls and needle hubs) that are exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination.

Direct compounding area: A critical area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.

Disinfectant: A chemical agent used on inanimate surfaces and objects to destroy fungi, viruses, and bacteria, but not necessarily their spores.

Expiration date: Date placed on a conventionally manufactured product to limit the time during which it can be used.

Filter integrity test: A test (e.g., bubble point test) of the integrity of a sterilizing grade filter performed after the filtration process to detect whether the integrity of the filter has been compromised.

First air: The air exiting the HEPA filter in a unidirectional air stream.

Hazardous drug: Any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low dose in humans or animals, genotoxicity, or new drugs that mimic existing hazardous drugs in structure or toxicity.

In-use time: The time before which a conventionally manufactured product or a CSP must be used after it has been opened or needle punctured (e.g., after a container closure of a vial has been penetrated).

ISO Class: An air quality classification from the International Organization for Standardization.

Isolator: An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer.

Label: A display of written, printed, or graphic matter on the immediate container of any article.

Labeling: All labels and other written, printed, or graphic matter that are 1) on any article or any of its containers or wrappers, or 2) accompanying such an article.

Laminar airflow system (LAFS): A device or zone within a buffer area that provides an ISO Class 5 or better environment for sterile compounding. The system provides a unidirectional HEPA-filtered airflow.

Laminar airflow workbench (LAFW): A device that is a type of LAFS that provides an ISO Class 5 or better environment for sterile compounding. The device provides a unidirectional HEPA-filtered airflow.

1867 **Media fill test:** A simulation used to qualify processes and personnel engaged in
1868 sterile compounding to ensure that the processes and personnel are able to produce
1869 sterile CSPs without microbial contamination.

1870 **Microbial contamination:** The presence of microorganisms in, or on, an item.

1871 **Multiple-dose container:** A container of sterile medication for parenteral
1872 administration (e.g., injection or infusion) that is designed to contain more than one
1873 dose of the medication. A multiple-dose container is usually required to meet the
1874 antimicrobial effectiveness testing criteria. See *Container Content for Injections* ⟨697⟩,
1875 *Determination of Volume of Injection in Containers, Multi-Dose Containers*.

1876 **Pass-through:** An enclosure with seals on interlocking doors that are positioned
1877 between two spaces for the purpose of minimizing particulate transfer while moving
1878 materials from one space to another.

1879 **Pharmacy bulk package:** A conventionally manufactured sterile product for
1880 parenteral use that contains many single doses intended for use in a pharmacy
1881 admixture program. A pharmacy bulk package may either be used to prepare
1882 admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile
1883 syringes.

1884 **Positive-pressure room:** A room that is maintained at higher pressure than the
1885 adjacent spaces, and therefore the net airflow is out of the room.

1886 **Primary engineering control (PEC):** A device or zone that provides an ISO Class 5
1887 environment for sterile compounding.

1888 **Preservative:** A substance added to inhibit microbial growth or to prevent
1889 decomposition or undesirable chemical changes.

1890 **Pyrogen:** A substance that induces a febrile reaction in a patient.

1891 **Pyrogen-free:** A substance lacking sufficient endotoxins or other fever-inducing
1892 contamination to induce a febrile or pyrogenic response.

1893 **Quality assurance (QA):** A system of procedures, activities, and oversight that
1894 ensures that operational and quality standards are consistently met.

1895 **Quality control (QC):** The sampling, testing, and documentation of results that, taken
1896 together, ensure that specifications have been met before release of the preparation.

1897 **Reconstitution:** The process of adding a diluent to a powdered medication to
1898 prepare a sterile solution or suspension.

1899 **Release testing:** Testing performed to ensure that a preparation meets appropriate
1900 quality characteristics.

1901 **Repackaging:** The act of removing a conventionally manufactured sterile product
1902 from its original primary container and placing it into another primary container, usually
1903 of smaller size.

1904 **Responsible person:** The individual accountable for an activity.

Restricted access barrier system (RABS): An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. Examples of RABS include CAIs and CACIs.

Segregated compounding area: A designated, unclassified space, area, or room that contains a PEC and is suitable for preparation of Category 1 CSPs only.

Single-dose containers: A container of sterile medication for parenteral administration (e.g., injection or infusion) that is designed for use with a single patient as a single injection/infusion. A single-dose container usually does not contain a preservative.

Specification: The tests, analytical methods, and acceptance criteria to which a drug substance, drug product, CSP, component, container–closure system, equipment, or other material used in drug preparation must conform to be considered acceptable for its intended use.

Stability: The extent to which a CSP retains physical and chemical properties and characteristics within specified limits throughout its BUD.

Sterility: The freedom from viable microorganisms.

Sterility testing: A documented and established laboratory procedure for detecting viable microbial contamination in a sample or preparation.

Sterilizing-grade membranes: Filter membranes that are documented to retain 100% of a culture of 10^7 microorganisms of a strain of *Brevundimonas diminuta* per cm^2 of membrane surface under a pressure of not less than 30 psi. Such filter membranes are nominally 0.22-µm or 0.2-µm pore size.

Sterilization by filtration: Passage of a gas or liquid through a sterilizing-grade membrane to consistently yield filtrates that are sterile.

Terminal sterilization: The application of a lethal process (e.g., dry heat, steam, irradiation) to sealed containers for the purpose of achieving a predetermined SAL of greater than 10^{-6} or a probability of less than one in one million of a nonsterile unit.

Unclassified space: A space not required to meet any air cleanliness classification based on the International Organization for Standardization (ISO).

Unidirectional airflow: Air within a PEC moving in a single direction in a uniform manner and at sufficient speed to reproducibly sweep particles away from the direct compounding area or testing area.

Verification: Confirmation that a method, process, or system will perform as expected under the conditions of actual use.

APPENDICES

Appendix 1. Acronyms

1944

ACD	Automated compounding device
ACPH	Air changes per hour
ALARA	As low as reasonably achievable
API	Active pharmaceutical ingredient
BSC	Biological safety cabinet
BUD	Beyond-use date
CACI	Compounding aseptic containment isolator
CAI	Compounding aseptic isolator
CFU	Colony-forming units
COA	Certificate of analysis
CSP	Compounded sterile preparation
ECV	Endotoxin challenge vial
FDA	Food and Drug Administration
HEPA	High-efficiency particulate air
HVAC	Heating, ventilation, and air conditioning
IPA	Isopropyl alcohol
ISO	International Organization for Standardization
LAFS	Laminar airflow system
LAFW	Laminar airflow workbench
NRC	Nuclear Regulatory Commission
PEC	Primary engineering control
PPE	Personal protective equipment
QA	Quality assurance
QC	Quality control
RABS	Restricted access barrier system
SAL	Sterility assurance level
SOP	Standard operating procedure
TSA	Trypticase soy agar

1945 **Appendix 2. Common Disinfectants Used in Health Care for Inanimate Surfaces**
1946 **and Noncritical Devices, and Their Microbial Activity and Properties**[a]
1947

Chemical Category of Disinfectant

		Isopropyl Alcohol	Accelerated Hydrogen Peroxide	Quaternary Ammonium (e.g., dodecyl dimethyl ammonium chloride)	Phenolics	Chlorine (e.g., sodium hypochlorite)	Iodophors (e.g., povidone–iodine)
Concentration Used		60%–95%	0.5%[b]	0.4%–1.6% aq	0.4%–1.6% aq	100–5000 ppm	30–50 ppm
Microbial Inactivation[c]	Bacteria	+	+	+	+	+	+
	Lipophilic viruses	+	+	+	+	+	+
	Hydrophilic viruses	±	+	±	±	+	±
	M. tuberculosis	+	+	±	+	+	±
	Mycotic agents (fungi)	+	+	+	+	+	±
	Bacterial spores	–	–	–	–	+	–
Important Chemical and Physical Properties	Shelf life >1 week	+	+	+	+	+	+
	Corrosive or deleterious effects	±	–	–	–	±	±
	Non-evaporable residue	–	–	+	+	–	+
	Inactivated by organic matter	+	±	+	±	+	+
	Skin irritant	±	–	+	+	+	±
	Eye irritant	+	–	+	+	+	+
	Respiratory irritant	–	–	–	–	+	–
	Systemic toxicity	+	–	+	+	+	+

Key to abbreviation and symbols: aq = diluted with water; ppm = parts per million; + = yes; – = no; ± = variable results.

Chemical Category of Disinfectant							
		Isopropyl Alcohol	Accelerated Hydrogen Peroxide	Quaternary Ammonium (e.g., dodecyl dimethyl ammonium chloride)	Phenolics	Chlorine (e.g., sodium hypochlorite)	Iodophors (e.g., povidone–iodine)

[a] Modified from World Health Organization, Laboratory Bio Safety Manual 1983 and Rutala WA. Antisepsis, disinfection and sterilization in the hospital and related institutions. *Man Clin Microbiol*. Washington D.C.: American Society for Microbiology;1995, 227–245.

[b] Accelerated hydrogen peroxide is a new generation of hydrogen peroxide–based germicides in which the potency and performance of the active ingredient have been enhanced and accelerated through the use of appropriate acids and detergents.

[c] Inactivation of the most common microorganisms (i.e., bacteria) occurs with a contact time of ≤1 minute; inactivation of spores requires longer contact times (e.g., 5–10 minutes for 5,000 ppm chlorine solution against *C. difficile* spores). Perez J, Springthorpe VS, Sattar SA. Activity of selected oxidizing microbicides against the spores of *Clostridium difficile*: relevance to environmental control. *Am J Infect Con*. 2005;33(6):320–325.

▲*USP40*

SWS WORKFLOW VALIDATION

XML Attribute	XML Value	SWS Attribute	SWS Value	Notes
corres-id	*missing*			XML inconsistent with SWS
corres-id	*missing*			XML inconsistent with SWS
corres-id	*missing*			XML inconsistent with SWS
corres-id	*missing*			XML inconsistent with SWS
corres-id	*missing*			XML inconsistent with SWS
corres-id	*missing*			XML inconsistent with SWS
corres-id	*missing*			XML inconsistent with SWS

~~[1] U.S. Food and Drug Administration, Guidance for Industry, *Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice,* September 2004.~~

~~[2] Guidelines for Environmental Infection Control in Health-Care Facilities, Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC), MMWR, vol. 52, no. RR-10, June 6, 2003, figure 3, pg. 12.~~

~~[3] NSF/ANSI 49.~~

~~[4] ISO 14644-4:2001 Cleanrooms and associated controlled environments—Design, construction, and start up, *Case Postale 56,* CH-1211 Geneve 20, Switzerland, tel. +41-22-749-01-11.~~

[5] ~~By definition (IEST RP CC 001.4), HEPA filters are a minimum of 99.97% efficient when tested using 0.3 µm thermally generated particles and a photometer or rated at their most penetrating particle size using a particle counter.~~

[6] ~~Sample procedures are detailed in CETA Applications Guide CAG 002 2006 section 2.09.~~

[7] ~~Controlled Environment Testing Association, 1500 Sunday Drive, Ste. 102, Raleigh, NC 27607; www.CETAinternational.org.~~

[8] ~~Agalloco J, Akers JE. Aseptic Processing: A Vision of the Future. *Pharmaceutical Technology*, 2005. Aseptic Processing supplement, s16.~~

[9] ~~Eaton T. Microbial Risk Assessment for Aseptically Prepared Products. *Am Pharm Rev*. 2005; 8 (5, Sep/Oct): 46–51.~~

[10] ~~*Guideline for Hand Hygiene in Health care Settings,* MMWR, October 25, 2002, vol. 51, No. RR-16 available on the Internet at *http://www.cdc.gov/handhygiene/*.~~

[11] ~~The use of additional resources, such as the Accreditation Manual for Home Care from the Joint Commission on Accreditation of Healthcare Organizations, may prove helpful in the development of a QA plan.~~

[12] ~~See *American Society of Heating, Refrigerating and Air Conditioning Engineers, Inc. (ASHRAE), Laboratory Design Guide*.~~

[13] ~~*CETA Applications Guide for the Use of Compounding Isolators in Compounding Sterile Preparations in Healthcare Facilities,* CAG 001 2005, Controlled Environment Testing Association (CETA), November 8, 2005.~~

▲[1] Centers for Disease Control and Prevention and the Safe Injection Practices Coalition, One & Only Campaign, http://www.oneandonlycampaign.org/safe_injection_practices.▲ *USP40*

▲[2] Agalloco J, Akers JE. Aseptic processing: a vision of the future. *Pharm Technol*. 2005; Aseptic Processing supplement, s16.▲ *USP40*

▲[3] Eaton T. Microbial risk assessment for aseptically prepared products. *Am Pharm Rev*. 2005;8(5):46–51.▲ *USP40*

From: Funk, Andrew [IBPE]
To: Jorgenson, Debbie [IBPE]
Subject: FW: Calif Legislature pass bill requiring multilingual medication instructions / fyi Mark Bowden
Date: Monday, September 14, 2015 11:26:34 AM

Hi Debbie,

Can you include this as an informational item on the next Board meeting's agenda?

Thanks,

Andrew Funk, RPh
Compliance Officer, Iowa Board of Pharmacy
Office: (515) 281-5944
Cell: [redacted]
Fax: [redacted]
Andrew.Funk@Iowa.gov

From: Bowden, Mark [IBM]
Sent: Monday, September 14, 2015 7:42 AM
To: Witkowski, Terry [IBPE]; Funk, Andrew [IBPE]; Woolery, Dale [ODCP]; Nebel, Kent [IBM]; Olds, John [IBM]
Subject: Calif Legislature pass bill requiring multilingual medication instructions / fyi Mark Bowden

Calif. Legislature passes bill requiring multilingual medication instructions

BY BARBARA FEDER OSTROV | KAISER HEALTH NEWS | MEDCITYNEWS.COM | SEPTEMBER 12, 2015

California's pharmacists would be required to provide prescription drug labels or medication instructions in five languages besides English under a bill passed unanimously Thursday by California lawmakers.

The bill, AB 1073, will be sent to Gov. Jerry Brown for his signature and would take effect Jan. 1 if signed into law. Upon request from patients or their caregivers, pharmacists would need to provide medication instructions in Spanish, Tagalog, Chinese, Vietnamese or Korean, the most common languages in California after English. The instructions could be on prescription labels or in patient handouts.

The measure would make California the second state in the nation, after New York, to require pharmacists to provide non-English materials for patients to take home. New York's law only applies to pharmacy chains with eight or more stores, while

California's applies to all pharmacies regardless of size.

"We're hoping this improves medical adherence and saves lives," said Sarah de Guia, executive director of the California Pan-Ethnic Health Network, which supported the bill. The legislation will make it easier for non-English and limited-English speakers to take their medications correctly, she said.

An estimated 6.8 million Californians – nearly 20 percent of the state's residents – are considered to have limited English skills, according to the U.S. Census.

The California Board of Pharmacy, which supported the bill, already requires pharmacists to offer free interpreting services for non-English speakers, upon request at the pharmacy counter. Some California pharmacies already provide translated prescription labels and medication instructions, but they aren't required to by law.

Other pharmacies, from "mom-and-pop" stores serving ethnic communities to large drugstore chains, go further to serve the state's diverse population. CVS, which operates 865 pharmacies in California, provides medication instructions in 15 languages in addition to English when customers request them. The company also provides telephone translation in more than 150 languages, said company spokesman Mike DeAngelis.

A California Pharmacists Association spokeswoman declined to comment on the bill Thursday.

The current prescription translation bill faced no opposition, but similar bills in previous years had stalled over pharmacists' fears of liability if prescription labels or medication instruction handouts weren't correctly translated. This time, pharmacists will have more flexibility and oversight in developing the translated information for their customers, said Virginia Herold, executive officer of the California Board of Pharmacy.

"Pharmacy services are an integral part of health care and language skills should never be an impediment to equal access," said California Assemblyman Phil Ting (D-San Francisco), who sponsored the bill. "California is the most linguistically diverse state in the nation. By ensuring that all patients understand their medications, we will save lives and improve healthcare for millions of people."

A state law passed in 2007 required the California Board of Pharmacy to develop more patient-friendly prescription labels. The board subsequently provided translations in five languages for common medication instructions, such as "take one pill at night." But pharmacists didn't have to use them, and many didn't.

There's little current data on how many California pharmacies offer prescription labels or medication instructions in languages other than English. A California Board of Pharmacy survey found that about 70 percent of pharmacies offered some translations, but their accuracy could not be determined.

A 2009 study of pharmacies in four states (not including California) found that 43 percent of pharmacies reported medication translations were available in at least one language other than English, but 21 percent reported limited availability and 35 percent cited no availability.

Herold said the Board of Pharmacy will urge pharmacists to place the medication instructions directly on the prescription bottle label, where they can't be lost, although that's not mandated by the current bill.

“Nobody got everything they wanted (in the bill), but we think we’re moving in the right direction, compared to where we were five years ago,” Herold said.

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$750,000 settlement points to the need for strong HIPAA policies

Posted by: klee34

H PAA, HIPAA audits, HIPAA compliance HIPAA data breach HIPAA enforcement, H PAA healthcare data

Many have talked about how H PAA audits have yet to materialize. But for some providers, H PAA-related investigations are very much a reality. Take the story of Cancer Care Group Inc., located in Indiana, which provides a cautionary tale of what could happen if a covered entity does not do everything in its power to ensure HIPAA compliance.

On September 2, the U.S. Department of Health and Human Service's Office for Civil Rights (OCR) reported that it agreed to settle potential violations of HIPAA with the Cancer Care Group for a sizeable $750,000. Not only will the Cancer Care Group have to pay up, but it also had to agree to a three-year corrective action plan that OCR will monitor.

Here's what happened (and it's something that is, unfortunately, a fairly common occurrence and easy mistake to make): On August 29, 2012, the OCR was notified by the Cancer Care Group that there was a breach of unsecured electronic PHI due to a laptop bag being stolen from an employee's car. The bag contained the employee's computer and unencrypted back-up media that contained the names, addresses, dates of birth, Social Security numbers, insurance information and clinical information of approximately 55,000 current and former Cancer Care patients, according to the government. OCR said the Cancer Care Group did not have a written policy to routinely remove back-up media from devices that left the clinics, which contributed to the breach.

Although the H PAA audits have been delayed several times — and at the beginning of this year OCR Director Jocelyn Samuels couldn't give a definitive timeline for the audits — the government can still investigate alleged violations, even if they're self-reported by an organization. However, a 2014 survey by NueMD — a seller of cloud-based medical practice software — of more than 1,000 healthcare providers and administrators found that most doctors are unprepared with only 32% of respondents indicating they knew about the HIPAA audits at all.

In an article about the Cancer Care Group settlement, the *National Law Review* urges covered entities and business associates "to ensure that risk assessments and policies are up to date, are well documented, and provide for adequate safeguards for the nature and scope of the business involved."

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Denver area pharmacy draws penalty for HIPAA privacy violation

Settlement with OCR highlights need to meet HIPAA obligations

August 10, 2015
By Ned Milenkovich, PharmD, JD

Ned Milenkovich

The Department of Health and Human Services' Office of Civil Rights (OCR) has announced a settlement with a Denver-area pharmacy in a case that centered on violation of HIPAA requirements through disposal of medical records in an unsecure manner.

See also: A HIPAA violation, a $1.8 million verdict, and three takeaways

In 2012, a local Denver news station notified the OCR that records had been found in open containers on the pharmacy's premises. OCR opened an investigation and discovered intact medical records containing protected health information for more than 1,600 of the pharmacy's patients. The investigation revealed that the pharmacy had failed to safeguard the protected health information of its patients, failed to implement written HIPAA policies, and failed to provide staff with training on its HIPAA policies and procedures.

National privacy standards

All three violations committed by the Denver pharmacy show failure to comply with HIPAA's Privacy Rule, which establishes national standards to protect individuals' medical records and other personal health information. The rule requires safeguards to protect the privacy of personal information and sets limits and conditions on the uses and disclosures that may be made of such information without patient authorization.

See also: Omnibus Guidelines expected to brings changes to 340B program

Although the HIPAA Privacy Rule does not specify how covered entities must dispose of paper documents, it explains that facilities "must review their own circumstances to determine what steps are reasonable to safeguard protected health information through disposal, and develop and implement policies and procedures to carry out those steps."

The settlement

In addition to the $125,000 fine, the pharmacy is required to adopt a corrective plan that will include the development of a comprehensive HIPAA policies and procedures manual. The procedures are required to include HIPAA training for all pharmacy employees. Each employee

must then certify to having received the training, and the pharmacy must review the method and content of the training on an annual basis.

While announcing the settlement, OCR took the opportunity to reiterate the importance of secure disposal of paper medical records.

“Regardless of size, organizations cannot abandon protected health information or dispose of it in dumpsters or other containers that are accessible by the public or other unauthorized persons,” said OCR director Jocelyn Samuels. “Even in our increasingly electronic world, it is critical that policies and procedures be in place for secure disposal of patient information, whether that information is in electronic or paper form.”

Disposal methods

According to the OCR, examples of proper methods of disposal include:

- Shredding, burning, pulping, or pulverizing protected health information in paper records so that the information is rendered essentially unreadable, indecipherable, and otherwise cannot be reconstructed before it is placed in a dumpster or other trash receptacle.
- Maintaining protected health information in opaque bags in a secure area and using a disposal vendor as a business associate to pick up and shred or otherwise destroy the information.
- In justifiable cases, based on the size and type of covered entity, and the nature of the protected health information, depositing it in locked dumpsters that are accessible only by authorized persons, such as appropriate refuse workers.

Reminder to pharmacies

This recent OCR HIPAA enforcement action should serve as a reminder to pharmacies that are determined to be healthcare providers transacting electronically and that would therefore fall under the classification of a HIPAA “covered entity.” These pharmacies, like other HIPAA covered entities, are coming under increasing scrutiny by OCR, and to the extent necessary, they are being disciplined through monetary fines as well as required to undertake remedial corrective action to protect patient identifiable health information.

From: Jim Miller
To: Witkowski, Terry [IBPE]
Cc: Funk, Andrew [IBPE]; Jorgenson, Debbie [IBPE]
Subject: Re: FW: NPM site feedback regarding PTCB 2020 requirement
Date: Thursday, September 17, 2015 1:41:10 PM

Yes, I think this is valuable input and the discussion regarding technician training and certification will be something the bop needs to stay on top of. Thanks
Jim

On Wed, Sep 16, 2015 at 3:12 PM, Witkowski, Terry [IBPE] <Terry.Witkowski@iowa.gov> wrote:

> Jim,
>
> Is this something you want distributed to the Board at the November meeting?
>
> **Therese (Terry) Witkowski**
>
> **Executive Officer**
>
> **Iowa Board of Pharmacy**
>
> **terry.witkowski@iowa.gov**
>
> **515-281-6676**
>
> *The Iowa Board of Pharmacy promotes, preserves, and protects the public health, safety, and welfare through the effective regulation of the practice of pharmacy and the licensing of pharmacies, pharmacists, and others engaged in the sale, delivery, or distribution of prescription drugs and devices. Iowa Code § 155A.2(1).*
>
> ---
>
> **From:** Megan Myers [mailto:[redacted]]
> **Sent:** Wednesday, September 16, 2015 3:08 PM
> **To:** Jim Miller
> **Cc:** Anthony Pudlo; Witkowski, Terry [IBPE]
> **Subject:** NPM site feedback regarding PTCB 2020 requirement

Dear Jim,

I had an opportunity through conference calls and a meeting last week to seek input from both pharmacists and technicians at New Practice Model sites regarding the proposed requirement for technicians to complete an accredited program in order to be eligible for the PTCB certification exam.

Attached are a compilation of comments. My impression from the group is overall this requirement is not supported as is – but if PTCB is able to demonstrate proof of program quality and if completing a program could help develop more career opportunities/expanded roles for technicians (aka a career ladder) then there might be more support for this requirement.

Please let me know if there is anything you would like clarified, or want any additional feedback from the group.

Sincerely,

Megan

Megan Myers

New Practice Model Project Manager

Iowa Pharmacy Association

Phone: 515-270-0713

Fax: 515-270-2979

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The NPM group recognizes a need for technician education but does not support required graduation from an accredited ASHP program for several reasons:

Feedback from Pharmacists:

1) There is a concern about the quality of the programs currently in place – pass rates for PTCB are still low even when prospective technicians graduate from a program. Pharmacists do not believe the quality is there and have seen more success with training technicians themselves. Having access to a quality program in the area is also a concern. Sites can't support a program that can't prove its value. There needs to be data to support program quality. If a program does become required, it should be affordable.

2) This requirement may set the bar too high for entry level technician positions. Education through an accredited program may be beneficial for some of the expanding roles for technicians (TCT, telepharmacy, etc…) but it is not necessary for the traditional entry level functions (Rx entry/cashier/filling). The roles and responsibilities of the technician in the pharmacy must be considered. PTCB exam is intended to be a minimal competency exam and should mirror the responsibilities for entry level duties in various practice settings.

3) Most entry level technicians do not intend to make pharmacy a career path. It's often a stepping stone to other careers in health care. The growth potential to make being a pharmacy technician a career path needs to be considered.

4) This requirement may make it even more difficult to attract and retain technicians. Sites are already having difficulty finding qualified technicians and this requirement may make the shortage even worse.

5) Training needs to be site specific. It would be better if pharmacists could set up internships at the local level where technicians in training could earn CE towards certification requirements.

Additionally: ND has a similar requirement. Problems observed even when the company covers tuition cost of program participation are as follows:

1) Successful completion rate of the program is relatively low.

2) This has resulted in a decreasing number of technicians entering the workforce which has created a bidding war to hire technicians.

3) Due to the bidding war, technician salaries have increased to double what is found in other markets, but their job responsibilities have not changed.

4) This requirement has created a barrier to entry level positions.

An alternative approach may be to incorporate employee training into the pharmacy curriculum so pharmacists are better prepared to train employees.

Sites have seen technicians struggle with the PTCB exam in the last year or so and have noticed the dip in pass-rates.

Feedback from currently certified pharmacy technicians:

1) This requirement would have been a barrier to several of the technicians on our conference call. They consider the cost (avg. cost of $2,500) to be a significant barrier. The time needed to invest in a program would have also been barrier as many of them were looking for a job at the moment and needed the income.
2) Right now technicians see little opportunity for promotion or climbing a career ladder. Therefore the return on investment for paying for formal education is minuscule.

3) The technicians stated that hands on learning/on-the-job training is more effective for their current role than formal education. Formal education would be a reasonable expectation for expanded pharmacy roles such as tech-check-tech but should not be a requirement for certification.
4) Technicians recognize the potential benefit of having more competent help at the entry-level position through structured technician training including having a realistic expectation of the stressful high-paced environment. This could potentially help decrease turnover from new hires leaving a job due to stress. But there was also a concern that making it a requirement would decrease the already scarce applicant pool.

IPRN Welcomes Amanda Latta as Monitor

DES MOINES, IOWA, September 18, 2015 - The Iowa Pharmacy Recovery Network (IPRN) has hired Amanda Latta, PharmD, as the organization's monitor. She will oversee the day-to-day operations of the state's monitoring and advocacy peer-review program that assists impaired pharmacy professionals in Iowa.

Latta is a 2002 graduate of the University of Iowa College of Pharmacy and worked as a staff pharmacist at Walgreens from 2002 to 2011. During that time, she also served as adjunct faculty at the Drake University College of Pharmacy and Health Sciences and was a preceptor at the Patient Care Center in Des Moines, Iowa. In June 2015, she attended the American Pharmacists Association (APhA) Institute on Alcoholism and Drug Dependencies (formerly the Utah School) and began serving as an IPRN advocate for two clients earlier in 2015.

"Amanda brings compassion, enthusiasm, a wealth of ideas, and joy to this position," said Kate Gainer, CEO of the Iowa Pharmacy Association, the organization that administers the program.

Among her duties as monitor, Latta will develop treatment plans for clients and track their progress, assist IPRN advocates with client reporting, provide reports to the Iowa Board of Pharmacy, and monitor IPRN's 24-hour hotline. She will also work to increase the program's exposure and educate pharmacists, students, pharmacy technicians and employers about the services provided by IPRN to help pharmacy professionals suffering from the disease of addiction.

***

About the Iowa Pharmacy Recovery Network
The Iowa Pharmacy Recovery Network is a monitoring and advocacy peer-review program administered by the Iowa Pharmacy Association for the purpose of assisting impaired pharmacists, pharmacy students, and pharmacy technicians, whose dependency and or disability is potentially threatening to professional performance and public safety. If you suspect impairment, contact IPRN at 1-877-890-IPRN (4776) or [redacted].

About the Iowa Pharmacy Association
The Iowa Pharmacy Association is the state society representing the profession of pharmacy in Iowa, united for the purpose of promoting safe and effective medication use to improve the health of patients. Since 1880, the Iowa Pharmacy Association is organized to preserve and advance the interests of the profession and to serve the professional needs of all pharmacists, student pharmacists, and pharmacy technicians.

8515 Douglas Ave, Suite 16 • Des Moines, IA 50322 • 515.270.0713 • Fax: 515.270.2979
Website: www.iarx.org • E-mail [redacted]

Iowa Pharmacy Recovery Network

Quarter	3rd	3rd	3rd	3rd	3rd	3rd	3rd	3rd	3rd	3rd					
Member # and Initials	1R	2R	3R	4R	5R	6R	7R	8R	9R	10R					
Profession	RPh	RPh	RPh	RPh	RPh	RPh	RPh	RPh	RPh	RPh					
Licensure/Certification Status/OIG	robation-OIG	Probation	Probation	Active	Probation	Suspension	Suspension	Suspension	Probation	Active					
IPRN Contract	12/19/2010	10/24/2012	10/24/2012	11/30/2012	1/15/2013	9/16/2014	11/5/2014	12/2/2014	6/11/2015	Pending					
Contract Completion Date	12/19/2015	10/24/2017	10/24/2017	11/30/2017	1/15/2018	9/16/2019	11/5/2019	12/2/2019	6/11/2020	Pending					
IPRN Status	Active	Active	Active	Active	Active	Active	Active	Active	Active	Pending					
Advocate Initials	TP	TP	CP	JR	CP	ES	ES	ES	AL	BA					
Professional Work Status	a pharmacist	Working	Working	Not working	Working	Not working	Not working	Not working	Working	Not Working					
UA Ordered	NA	Ordered	Ordered	NA	Ordered	NA	NA	NA	Ordered	NA					
Monthly Report Received	Y	Y	Y	Y	Y	Y		Y	Y	NA					
	Y	Y	Y	Y	Y	Y	Y	Y	Y	NA					
	Y	Y	Y	Y	Y	Y	Pending	Y	Y	NA					
(1) Monthly Client Meetings	Y	Y	Y	NA	Y	Y	Y	Y	Y	Y					
	Excused	Y	Excused		Excused	Y	Y	Y	Excused	Y					
	Excused, willi	Y	Excused		Y	Y	Y	Y	Excused	Y					
Number of Contacts this Quarter	10	11	2	3	20	6	9	8	8	20					
Date of Last Contact	10/4/2015	10/4/2015	10/4/2015	10/1/2015	10/3/2015	9/30/2015	9/28/2015	9/30/2015	10/4/2015	9/22/2015					
Contacts (phone, in person, email)	Person, Email	person. Email	Person, Email	Email	In Person, Email, Text		, mostly texts	Person Email	Person, Email	erson/19Email					
Contract Compliance	3	3	3	2	3	3	3	3	3	NA					
12 Step Attendance	3	3	3	NA	NA	3	Very Good!!3	3	3	3					
Attitude Towards Recovery	3	3	3		3	3	3	3	3	3					
Attitude Towards Family	3	3	3		3	3	3	2	3	3					
Attitude Towards Employment	3	3	3		3	cy position; enjoys working		NA	3	3					
Participation in Treatment	3	3	NA	NA	NA	NA	NA	NA	NA	3					
Quarter Goals Met	3	3	3		3	3	3	3	3	3					
Overall Recovery	3	3	3		3	3	3	3	3	3					
Additional Comments for the Board	of Pharmacy	same time. Only requirement is monthly report.			rk and family.	ly engaged in 12 Step work.		with advocate	ent meetings.	n of his case.					
Quarter	3rd	3rd													
Member # and Initials	11R	12T													
Profession	RPh	ch in Training													
Licensure/Certification Status/OIG	Suspension	Probation													
IPRN Contract	9/11/2015	6/29/2015													
Contract Completion Date	9/11/2020	6/29/2020													
IPRN Status	Active	Active													
Advocate Initials	AL	JK													
Professional Work Status	Not Working	Working													
UA Ordered	NA	Ordered													
Monthly Report Received	NA	Y													
	NA	Y													
	Y	Y													
(1) Monthly Client Meetings	Y	Excused													
	Y	Excused													
	Y	Excused													
Number of Contacts this Quarter	25	4/wk average													
Date of Last Contact	10/4/2015	9/30/2015													

Iowa Pharmacy Recovery Network

Contacts (phone, in person, email)	person, email	Person													
Contract Compliance	2	3													
12 Step Attendance	2	3													
Attitude Towards Recovery	3	3													
Attitude Towards Family	3	3													
Attitude Towards Employment	3	3													
Participation in Treatment	NA	3													
Quarter Goals Met	2	3													
Overall Recovery	3	3													
Additional Comments for the Boar	the program.	ent employee													
Key:															
1 = Poor															
2 = Acceptable															
3 = Excellent															
NA = Not Applicable															

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October 14, 2015

Andrew Funk, Executive Director
Iowa Board of Pharmacy Examiners
400 SW Eighth Street, Suite E
Des Moines, IA 50309-4688

Re: Hy-Vee Pharmacy Fulfillment Center's 2015 Q2 Error Report

Dear Mr. Funk

Hy-Vee Pharmacy Fulfillment Center (IA License #1472) respectfully submits our Third Quarter 2015 Error Report, for dates ranging from July 1, 2015, through September 30, 2015. All prescriptions dispensed through our Automatic Distribution Dispensing System (ADDS) from the Hy-Vee Pharmacy Fulfillment Center are monitored through the Pharmacy Quality Commitment Program and are reflected in the error report.
During the third quarter of 2015, the Hy-Vee Pharmacy Fulfillment Center dispensed 1,536,711 prescriptions utilizing our ADDS to our retail Hy-Vee pharmacies in seven states. During this third quarter period, we had 576 errors associated with ADDS, resulting in an error-free percentage of 99.9% for prescriptions dispensed through ADDS. Of the 576 errors, 1 prescription reached the patient and no patients were harmed as a result of the errors. The error reaching a patient was the result of a miscount by the Parata robot.

Summary

Number of Prescriptions dispensed through ADDS	1,536,711
Number of Errors associated with ADDS	576
Error Free Percentage	99.9%
Number of Errors Reaching the Patient	1
Percentage of Errors Reaching the Patient	0.0001%
Number of Patients harmed as a result of errors	0

Categories of Errors

The ten distinct categories of errors are listed below, along with the number of errors in each category.

Category	Number of Errors	Percentage of Prescriptions
Incorrect Drug	0	0.00%
Incorrect Quantity	243	0.0154%
Incorrect Dose	0	0%
Incorrect Dosage Form	0	0%
Incorrect Directions	0	0%
Incorrect Patient Name	0	0%

Hy-Vee, Inc.
5820 Westown Parkway, West Des Moines, Iowa 50266
Phone: (515) 267-2800

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Other Incorrect Label Information	0	0%
Computer Order Entry	0	0%
Incorrect Safety Cap	205	0.0133%
Other Errors	128	0.0083%

Please see the attached reports for a detailed description of each error, the category, and corrective action adopted by the Hy-Vee Pharmacy Fulfillment Center.

Quantity Errors

Quantity errors are caused by the calibration of the scale or the air pressure in our ADDS. The Hy-Vee Pharmacy Fulfillment Center continues to monitor particular NDC's that are miscounted or damaged by the ADDS. We adjust the calibration of our scales and air pressure in our ADDS with respect to the applicable drug to optimize the settings and reduce the incidence of incorrect quantities or broken tablets and capsules. We are exploring changing manufacturers for the NDC's that consistently are damaged or miscount.

Incorrect Safety Caps

The process for providing non-safety caps is a manual process. We continue to work daily with our packing team to ensure that they do not forget to include the snap caps for patients requesting a snap cap. The computer screen places a large red message on the screen, alerting the packer to add the snap caps before sealing the bag.

Other Errors

Errors, such as the barcode cutting off on the prescription label, capping issues, or bag seals, are the result of our mechanical process for automatically filling prescriptions. We respond to these errors immediately and continue to adjust and refine our mechanical systems. For example, adjustments are made to the automated capper machines to ensure that the caps are securely put on the prescription vials.

Errors related to Replenishment and Inventory

We experienced 25 errors with replenishment and 9 with inventory in the 3rd quarter. We reviewed the importance of removing all foil and cotton with the replenishment staff. We determined that the inventory errors were the result of an employee placing the product in the wrong location on the shelf. The inventory team has been instructed and trained to use the scan technology and pay better attention when placing product on the shelf. Our quality system immediately caught all of these errors at the replenishment stations.

Quality Training

The Hy-Vee Pharmacy Fulfillment Center Director and Pharmacy Manager are consistently looking at all reported errors and addressing and training staff immediately when an error is identified. We are constantly refining our procedures and equipment to ensure that our level of quality is never compromised.

All registered pharmacy employees working at the Hy-Vee Pharmacy Fulfillment Center have completed the Quality Assurance training. We are committed to continual monitoring and improvement of our quality at the Hy-Vee Pharmacy Fulfillment Center.

Respectfully submitted,
Hy-Vee, Inc.

Hy-Vee, Inc.
5820 Westown Parkway, West Des Moines, Iowa 50266
Phone: (515) 267-2800

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Helen E. Eddy, R.Ph., MBA
AVP, Pharmacy Services

Hy-Vee, Inc.
5820 Westown Parkway, West Des Moines, Iowa 50266
Phone: (515) 267-2800

Incorrect Drug

Store#	DateReported	Reached Patient	QRE Type	Desc	Prescription	Dispensed	Reason for Error	Corrective Action
Subtotal = 0	Percentage of Total Scripts(1,536,711) = 0.00%	Reached Patient = 0	Number of prescriptions through automation 1,536,711					

Month Totals

July= 501,822

August= 510,937

September= 523,952

Incorrect Quantity

Store#	DateReported	Reached Patient	QRE Type	Desc	Prescription	Dispensed	Reason for Error	Corrective Action
4016	7/1/2015	N	Incorrect quantity	pv2 broken 85/90	Baclofen		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/2/2015	N	Incorrect quantity	PV2 broken tab 125/135	Captopril		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/6/2015	N	Incorrect quantity	Rx was short #60			Item was incorrectly checked by a pharmacist at exceptions station after failing weight check.	Pharmacists were instructed to double check quantity before approving any item that fails weight check.
4016	7/6/2015	N	Incorrect quantity	pv2 broken 179/180	Furosemide		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/6/2015	N	Incorrect quantity	pv2 broken 29/30	folic acid		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/6/2015	N	Incorrect quantity	pv1 broken 26/30	Buspirone		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/7/2015	N	Incorrect quantity	PV2 - BORKEN TAB 29/30	FOLIC ACID	FOLIC ACID	Mechanical Error	Adjust Cell Pressure/Settings
4016	7/7/2015	N	Incorrect quantity	RX was 1 tablet short			Mechanical Error	Adjust Cell Pressure/Settings
4016	7/8/2015	N	Incorrect quantity	Broken tablets in vial of rx			Mechanical Error	Adjust Cell Pressure/Settings
4016	7/8/2015	N	Incorrect quantity	pv1 broken 89/90	Pramipexole		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/9/2015	N	Incorrect quantity	pv2 - broken tabs 177/180	Captopril	Captopril	Mechanical Error	Adjust Cell Pressure/Settings
4016	7/9/2015	N	Incorrect quantity	pv2- broken tab 29/30	ferrous sulfate	ferrous sulfate	Mechanical Error	Adjust Cell Pressure/Settings
4016	7/10/2015	N	Incorrect quantity	PV - broken tabs 85/90	Buspirone	Busprirone	Mechanical Error	Adjust Cell Pressure/Settings
4016	7/12/2015	N	Incorrect quantity	pv1 broken 29/30	Lisinopril		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/12/2015	N	Incorrect quantity	pv1 broken 59/60	Lialda		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/12/2015	N	Incorrect quantity	pv2 broken 29/30	Lisinopril		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/13/2015	N	Incorrect quantity	6 broken tablets out of 180	Buspirone		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/13/2015	N	Incorrect quantity	pv1 - broken tab 269/270	np thyroid	np thyroid	Mechanical Error	Adjust Cell Pressure/Settings
4016	7/13/2015	N	Incorrect quantity	pv1 - broken tabs 88/90	Chlorothiazide	Chlorothiazide	Mechanical Error	Adjust Cell Pressure/Settings
4016	7/13/2015	N	Incorrect quantity	pv1 - broken tab 29/30	Estradiol	Estradiol	Mechanical Error	Adjust Cell Pressure/Settings
4016	7/13/2015	N	Incorrect quantity	pv2 - broken tab 92/93	aripiprazole	aripiprazole	Mechanical Error	Adjust Cell Pressure/Settings
4016	7/13/2015	N	Incorrect quantity	pv2- broken tab 84/90	Clonidine	Clonidine	Mechanical Error	Adjust Cell Pressure/Settings
4016	7/13/2015	N	Incorrect quantity	pv2 - broken tab 88/90	folic acid	folic acid	Mechanical Error	Adjust Cell Pressure/Settings
4016	7/14/2015	N	Incorrect quantity	pv2 - broken tab 179/180	carvedilol	carvedilol	Mechanical Error	Adjust Cell Pressure/Settings
4016	7/14/2015	N	Incorrect quantity	pv2 - broken tabs 88/90	folic acid	folic acid	Mechanical Error	Adjust Cell Pressure/Settings
4016	7/14/2015	N	Incorrect quantity	pv1 - short count 29/30	vit b12	vit b12	Mechanical Error	Adjust Cell Pressure/Settings
4016	7/14/2015	N	Incorrect quantity	pv1 - broken tab 59/60	buspirione	Buspirone	Mechanical Error	Adjust Cell Pressure/Settings
4016	7/14/2015	N	Incorrect quantity	pv1 - short count 116/120	Hyoscyamine	Hyoscyamine	Mechanical Error	Adjust Cell Pressure/Settings
4016	7/16/2015	N	Incorrect quantity	pv2 broken tabs 88/90	Furosemide	Furosemide	Mechanical Error	Adjust Cell Pressure/Settings
4016	7/16/2015	N	Incorrect quantity	pv2 - broken tabs 177/180	Furosemide	Furosemide	Mechanical Error	Adjust Cell Pressure/Settings
4016	7/16/2015	N	Incorrect quantity	pv2 - broken tab 179/180	Minoxidil	Minoxidil	Mechanical Error	Adjust Cell Pressure/Settings
4016	7/16/2015	N	Incorrect quantity	pv2 - broken tabs 357/360	carvedilol	carvedilol	Mechanical Error	Adjust Cell Pressure/Settings
4016	7/17/2015	N	Incorrect quantity	PV1. Broken tablets	Buspirone		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/17/2015	N	Incorrect quantity	PV2. broken tablets 29/30	Sodium Bicarbonate		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/20/2015	N	Incorrect quantity	pv2 broken	Metformin		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/20/2015	N	Incorrect quantity	pv2 broken 79/90	Abilify		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/20/2015	N	Incorrect quantity	pv2 broken 29/30	janumet xr		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/20/2015	N	Incorrect quantity	pv2 broken 39/40	Apriso		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/20/2015	N	Incorrect quantity	pv2 broken 120/120	Meclizine		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/20/2015	N	Incorrect quantity	pv2 broken 5/6	Abilify		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/20/2015	N	Incorrect quantity	pv2 broken 26/30	Abilify		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/20/2015	N	Incorrect quantity	pv2 broken 89/90	Abilify		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/20/2015	N	Incorrect quantity	pv2 broken 29/30	Abilify		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/20/2015	N	Incorrect quantity	pv2 broken 26/30	Abilify		Mechanical Error	Adjust Cell Pressure/Settings

4016	7/20/2015	N	Other (explain in pharmacy notes if necessary)	6 broken tablets	Abilify		Mechanical Error	Pressure on dispensing cell was lowered
4016	7/21/2015	N	Incorrect quantity	PV2: broken tab 59/60	Levetiracetam	Levetiracetam	Mechanical Error	Adjust Cell Pressure/Settings
4016	7/21/2015	N	Incorrect quantity	Broken tablets qty was not right because of broken tabs.			Mechanical Error	Adjust Cell Pressure/Settings
4016	7/21/2015	N	Incorrect quantity	5 broken tablets in vial	Buspirone		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/21/2015	N	Incorrect quantity	Rx was short 1 tablet			Mechanical Error	Adjust Cell Pressure/Settings
4016	7/22/2015	N	Incorrect quantity	pv2 broken 28/30	Lisinopril		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/22/2015	N	Incorrect quantity	pv1 broken 30/31	Estradiol		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/22/2015	N	Incorrect quantity	pv1 broken 89/90	Digox.		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/22/2015	N	Incorrect quantity	pv1 broken 58/60	Clonidine		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/23/2015	N	Incorrect quantity	pv1 man count long count 90/30	tolterodine ER		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/24/2015	N	Incorrect quantity	broken tablets - 118/120	Clonidine		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/25/2015	N	Incorrect quantity	over 91/90	felbamate		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/25/2015	N	Incorrect quantity	short 58/60	buspirone		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/25/2015	N	Incorrect quantity	broken tablet 29/30	lisinopril		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/26/2015	N	Incorrect quantity	PV 2 - Broken 61/60	Nortriptyline		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/27/2015	N	Incorrect quantity	PV 1 - broken tablet	Lisinopril		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/28/2015	N	Other (explain in pharmacy notes if necessary)	Store received empty vial			Item was incorrectly checked by a pharmacist at exceptions station after failing weight check.	Pharmacists were instructed to double check quantity before approving any item that fails weight check.
4016	7/28/2015	N	Incorrect quantity	PV 2 - broken tablets 179/180	Furosemide		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/28/2015	N	Incorrect quantity	PV 2 - broken tablets 176/180	furosemide		Mechanical Error	Adjust Cell Pressure/Settings
4016	7/28/2015	N	Incorrect quantity	Rx was short 1 tablet			Mechanical Error	Adjust Cell Pressure/Settings
4016	7/29/2015	N	Incorrect quantity	PV1 - broken 57/60	Cetirizine	Cetirizine	Mechanical Error	Adjust Cell Pressure/Settings
4016	7/29/2015	N	Incorrect quantity	PV1 - broken 59/60	Clonidine	Clonidine	Mechanical Error	Adjust Cell Pressure/Settings
4016	7/29/2015	N	Incorrect quantity	PV1 - broken 89/90	Glyburide	Glyburide	Mechanical Error	Adjust Cell Pressure/Settings
4016	7/30/2015	N	Incorrect quantity	PV 1 - Broken tablet 59/60	Chlorzoxazone			
4016	8/1/2015	N	Incorrect quantity	pv- broken 44/45	desmopressin	desmopressin	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/1/2015	N	Incorrect quantity	pv - broken 30/30	Abilify	Abilify	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/1/2015	N	Incorrect quantity	pv - broken 39/40	desmopressin	desmopressin	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/1/2015	N	Incorrect quantity	pv - broken 119/120	Estradiol	Estraderm	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/1/2015	N	Incorrect quantity	pv - short 89/90	carb-levod er	carbidopa/levodpa	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/2/2015	N	Incorrect quantity	pv1 - short 59/90	carbidopa/levodopa	carbidopa/levod	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/2/2015	N	Incorrect quantity	pv1 - broken tab 29/30	Simvastatin	Simvastatin	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/3/2015	N	Incorrect quantity	pv - broken tab 58/60	Cetirizine	Cetirizine	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/3/2015	N	Incorrect quantity	pv - broken tab 29/30	Cetirizine	Cetirizine	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/3/2015	N	Incorrect quantity	pv- broken tab 28/30	Cetirizine	Cetirizine	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/3/2015	N	Incorrect quantity	pv - broken tab 28/30	Cetirizine	Cetirizine	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/3/2015	N	Incorrect quantity	pv - broken tab 28/30	Cetirizine	Cetirizine	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/3/2015	N	Incorrect quantity	pv- brken tabs 85/90	Cetirizine	Cetirizine	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/3/2015	N	Incorrect quantity	pv- short 29/30	tolterodine	tolterodine	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/3/2015	N	Incorrect quantity	pv - broken 117/120	Cetirizine	Cetirizine	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/4/2015	N	Incorrect quantity	pv1 - broken tab 29/30	Simvastatin	Simvastatin	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/4/2015	N	Incorrect quantity	broken tablet at PV 90/90	Simvastatin	Simvastatin	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/4/2015	N	Incorrect quantity	Rx was 1 tablet long			Mechanical Error	Adjust Cell Pressure/Settings
4016	8/4/2015	N	Incorrect quantity	Rx had broken tablets no not a full #30 in vial			Mechanical Error	Adjust Cell Pressure/Settings
4016	8/5/2015	N	Incorrect quantity	over count 30/15	trifluperazine	trifluperazine	Mechanical Error	Adjust Cell Pressure/Settings

4016	8/5/2015	N	Incorrect quantity	broken tablet from manual count 29/30	Synthroid	Synthroid	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/5/2015	N	Incorrect quantity	short count from man count 30/90	Citalopraam	Citalopraam	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/6/2015	N	Incorrect quantity	short count 59/60	carbidopa/levodopa er		Mechanical Error	Adjust Cell Pressure/Settings
4016	8/7/2015	N	Incorrect quantity	broken tablet 59/60	Estradiol	Estradiol	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/7/2015	N	Incorrect quantity	PV1: 29/30 broken tab	Lisinopril	Lisinopril	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/7/2015	N	Incorrect quantity	PV1: 29/30 broken tab	Lisinopril	Lisinopril	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/7/2015	N	Incorrect quantity	Rx was short because of broken tablets			Mechanical Error	Adjust Cell Pressure/Settings
4016	8/10/2015	N	Incorrect quantity	pv2 broken 526/540	Sodium Bicarbonate		Mechanical Error	Adjust Cell Pressure/Settings
4016	8/10/2015	N	Incorrect quantity	pv2 broken 178/180	lisinopril 20/12.5		Mechanical Error	Adjust Cell Pressure/Settings
4016	8/10/2015	N	Incorrect quantity	pv2 broken 59/60	Furosemide		Mechanical Error	Adjust Cell Pressure/Settings
4016	8/10/2015	Y	Incorrect quantity	Rx was 1 tablet short			Mechanical Error	Adjust Cell Pressure/Settings
4016	8/12/2015	N	Incorrect quantity	pv2 broken 89/90	Furosemide		Mechanical Error	Adjust Cell Pressure/Settings
4016	8/13/2015	N	Incorrect quantity	pv2 broken 88/90	Sodium Bicarbonate		Mechanical Error	Adjust Cell Pressure/Settings
4016	8/13/2015	N	Incorrect quantity	pv2 broken 86/90	Sodium Bicarbonate		Mechanical Error	Adjust Cell Pressure/Settings
4016	8/13/2015	N	Incorrect quantity	pv2 broken 178/180	Clonidine		Mechanical Error	Adjust Cell Pressure/Settings
4016	8/13/2015	N	Incorrect quantity	pv2 broken 87/90	Buspirone		Mechanical Error	Adjust Cell Pressure/Settings
4016	8/13/2015	N	Incorrect quantity	pv1 broken 89/90	Losartan		Mechanical Error	Adjust Cell Pressure/Settings
4016	8/13/2015	N	Incorrect quantity	pv1 broken 59/60	Omeprazole		Mechanical Error	Adjust Cell Pressure/Settings
4016	8/13/2015	N	Incorrect quantity	Rx had broken tablets in vial			Mechanical Error	Adjust Cell Pressure/Settings
4016	8/14/2015	N	Incorrect quantity	PV1: broken tabs	Clonidine	Clonidine	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/14/2015	N	Incorrect quantity	PV1: broken tabs	Clonidine	Clonidine	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/14/2015	N	Incorrect quantity	PV1: broken tab 29/30	Abilify	Abilify	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/14/2015	N	Incorrect quantity	PV1: broken tabs	Clonidine	Clonidine	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/14/2015	N	Incorrect quantity	PV1: broken tabs	Clonidine	Clonidine	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/14/2015	N	Incorrect quantity	PV1: broken tabs	Clonidine	Clonidine	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/14/2015	N	Incorrect quantity	PV1: broken tabs	Clonidine	Clonidine	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/14/2015	N	Incorrect quantity	PV1: 29/30 broken	Clonidine	Clonidine	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/14/2015	N	Incorrect quantity	PV1: broken 59/60	Clonidine	Clonidine	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/14/2015	N	Incorrect quantity	PV1: broken 89/90	Clonidine	Clonidine	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/14/2015	N	Incorrect quantity	PV2: broken 29/30	losartan/hctz	losartan/hctz	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/15/2015	N	Incorrect quantity	PV2- broken tablets (filled 22/23)	venlafaxine	venlafaxine	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/15/2015	N	Incorrect quantity	PV1- broken tablets (filled 58/60)	Clonidine	Clonidine	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/15/2015	N	Incorrect quantity	PV1- broken tablets (filled 267/270)	Clonidine	Clonidine	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/15/2015	N	Incorrect quantity	PV1- broken tablets (filled 89/90)	Clonidine	Clonidine	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/15/2015	N	Incorrect quantity	PV1- broken tablets (filled 88/90)	Clonidine	Clonidine	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/16/2015	N	Incorrect quantity	PV1- broken tablets (filled 29/30)	Clonidine	Clonidine	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/16/2015	N	Incorrect quantity	PV1- broken tablets (filled 29/30)	Clonidine	Clonidine	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/16/2015	N	Incorrect quantity	PV1- broken tablets (filled 29/30)	Clonidine	Clonidine	Mechanical Error	Adjust Cell Pressure/Settings

4016	8/16/2015	N	Incorrect quantity	PV1- broken tablets (filled 29/30)	Clonidine	Clonidine	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/16/2015	N	Incorrect quantity	PV1- broken tablets (filled 58/60)	Clonidine	Clonidine	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/17/2015	N	Incorrect quantity	broken tablets at PV 87/90	np thyroid	np thyroid	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/17/2015	N	Incorrect quantity	5 broken tablets out of 60 at PV	Clonidine	Clonidine	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/18/2015	N	Incorrect quantity	broken tablets at PV 29/30	Losartan	Losartan	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/18/2015	N	Incorrect quantity	broken tablets at PV 61/90	Sodium Bicarbonate	Sodium Bicarbonate	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/18/2015	N	Incorrect quantity	broken tablet at PV	Vytorin	Vytorin	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/18/2015	N	Incorrect quantity	broken tablet at PV	Clonidine	Clonidine	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/20/2015	N	Incorrect quantity	broken tablets at PV 178/180	carvedilol	carvedilol	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/20/2015	N	Incorrect quantity	broken tablets at PV 59/60	Pramipexole	Pramipexole	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/21/2015	N	Incorrect quantity	broken tablets at PV 59/60	Naproxen	Naproxen	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/21/2015	N	Incorrect quantity	broken tablets at PV 130/135	Sodium Bicarbonate	Sodium Bicarbonate	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/21/2015	N	Incorrect quantity	broken tablets at PV 27/30	np thyroid	np thyroid	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/21/2015	N	Incorrect quantity	broken tablets at PV 89/90	losartan/hctz	losartan/hctz	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/24/2015	N	Incorrect quantity	broken tablets at pv 29/30	hctz	hctz	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/24/2015	N	Incorrect quantity	broken tablets at pv 29/30	Furosemide	Furosemide	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/24/2015	N	Incorrect quantity	broken tablets at pv 88/90	Losartan	Losartan	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/24/2015	N	Incorrect quantity	broken tablets at pv 89/60	Verapamil	Verapamil	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/24/2015	N	Incorrect quantity	broken cap at PV 89/90	Diltiazem	Diltiazem	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/24/2015	N	Incorrect quantity	broken cap at PV 89/90	Apriso	Apriso	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/25/2015	N	Incorrect quantity	PV2- broken tablets (filled 175/180)	Sotalol	Sotalol	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/25/2015	N	Incorrect quantity	PV2- broken tablets (filled 29/30)	Losartan	Losartan	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/25/2015	N	Incorrect quantity	PV2- broken tablets (filled 89/90)	Losartan	Losartan	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/25/2015	N	Incorrect quantity	PV2- broken tablets (filled 119/120)	Metformin	Metformin	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/25/2015	N	Incorrect quantity	PV2- overfill and broken tablets (filled 32/30)	Guanfacine	Guanfacine	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/25/2015	N	Incorrect quantity	PV2- broken tablets (filled 114/120)	Sodium Bicarbonate	Sodium Bicarbonate	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/25/2015	N	Incorrect quantity	PV2- broken tablets (filled 29/30)	Sodium Bicarbonate	Sodium Bicarbonate	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/26/2015	N	Incorrect quantity	PV2- broken tablets (filled 87/90)	Furosemide	Furosemide	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/26/2015	N	Incorrect quantity	PV2- broken tablets (filled 88/90)	lisinopril/Hctz	Lisinopril/Hctz	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/26/2015	N	Incorrect quantity	PV2- broken tablets (filled 29/30)	Chlorthalidone	Chlorthalidone	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/26/2015	N	Incorrect quantity	PV2- broken tablets (filled 27/30)	Chlorthalidone	Chlorthalidone	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/26/2015	N	Incorrect quantity	PV2- broken tablets (filled 14/15)	Chlorthalidone	Chlorthalidone	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/26/2015	N	Incorrect quantity	PV2- broken tablets (filled 29/30)	carvedilol	carvedilol	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/26/2015	N	Incorrect quantity	PV2- broken tablets (filled 59/60)	Metformin	Metformin	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/26/2015	N	Incorrect quantity	PV2- broken tablets (filled 29/30)	Loratadine	Loratadine	Mechanical Error	Adjust Cell Pressure/Settings

4016	8/26/2015	N	Incorrect quantity	PV2- broken tablets (filled 29/30)	Lisinopril/Hctz	Lisinopril/Hctz	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/26/2015	N	Incorrect quantity	PV2- broken tablets (filled 29/30)	Lisinopril/Hctz	Lisinopril/Hctz	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/27/2015	N	Incorrect quantity	PV2- broken tablets (filled 87/90)	Sodium Bicarbonate	Sodium Bicarbonate	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/27/2015	N	Incorrect quantity	PV2- broken tablets (filled 43/45)	Furosemide	Furosemide	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/27/2015	N	Incorrect quantity	PV2- broken tablets (filled 56/60)	carvedilol	carvedilol	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/27/2015	N	Other (explain in pharmacy notes if necessary)	PV2- one open capsule in vial	Apriso	Apriso	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/28/2015	N	Incorrect quantity	PV2 - broken 89/90	Azilect	Azilect	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/28/2015	N	Incorrect quantity	PV2 - broken 59/60	Sodium Bicarbonate	Sodium Bicarbonate	Mechanical Error	Adjust Cell Pressure/Settings
4016	8/31/2015	N	Incorrect quantity	short 1 tablet			Mechanical Error	Adjust Cell Pressure/Settings
4016	9/3/2015	N	Incorrect quantity	PV1 - short 12/13	vitamin D		Mechanical Error	Adjust Cell Pressure/Settings
4016	9/3/2015	N	Other (explain in pharmacy notes if necessary)	PV1 - one broken 89/90	duloxetine		Mechanical Error	Adjust Cell Pressure/Settings
4016	9/3/2015	N	Incorrect quantity	PV2 - broken 59/60	primidone		Mechanical Error	Adjust Cell Pressure/Settings
4016	9/3/2015	N	Incorrect quantity	PV2 - broken 58/60	primidone		Mechanical Error	Adjust Cell Pressure/Settings
4016	9/3/2015	N	Incorrect quantity	PV2 - broken 50/30	Lisinopril/hctz		Mechanical Error	Adjust Cell Pressure/Settings
4016	9/3/2015	N	Incorrect quantity	PV2 - broken 59/60	buspirone		Mechanical Error	Adjust Cell Pressure/Settings
4016	9/3/2015	N	Incorrect quantity	PV2 - paper in vial	citalopram		Mechanical Error	Adjust Cell Pressure/Settings
4016	9/4/2015	N	Other (explain in pharmacy notes if necessary)	AI- cap cracked	bupropion hcl er xl		Mechanical Error	Adjust Cell Pressure/Settings
4016	9/4/2015	N	Incorrect quantity	PV1 - broken 119/120	buspirone		Mechanical Error	Adjust Cell Pressure/Settings
4016	9/4/2015	N	Incorrect quantity	PV1 - broken cap 59/60	venlafaxine er		Mechanical Error	Adjust Cell Pressure/Settings
4016	9/4/2015	N	Incorrect quantity	PV1 - 175/180 tablets spilled onto line	enalapril		Mechanical Error	Adjust Cell Pressure/Settings
4016	9/4/2015	N	Incorrect quantity	PV1 - broken cap 119/120	Mexiletine		Mechanical Error	Adjust Cell Pressure/Settings
4016	9/5/2015	N	Incorrect drug	REP B - bisoprolol 5mg was put away with the lisinopril hctz 20/12.5 - caught by replenisher	bisoprolol		Mechanical Error	Adjust Cell Pressure/Settings
4016	9/7/2015	N	Incorrect quantity	pv1- broken 89/90	Losartan	Losartan	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/7/2015	N	Incorrect quantity	pv1 - broken 89/90	duloxetine	duloxetine	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/7/2015	N	Incorrect quantity	pv1 - broken 59/60	duloxetine	duloxetine	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/8/2015	N	Incorrect quantity	pv1 - broken 59/60	Metformin	Metformin	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/8/2015	N	Incorrect quantity	pv1 - 7 broken tabs of 180	Clonidine	Clonidine	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/9/2015	N	Incorrect quantity	pv1 - 1 long 15/14	paricalcitol	paricalcitol	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/10/2015	N	Incorrect quantity	pv1 - broken 59/60	Clonidine	Clonidine	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/10/2015	N	Incorrect quantity	pv -44/45	divalproex	divalproex	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/11/2015	N	Incorrect quantity	Broken 44/45	Buspirone		Mechanical Error	Adjust Cell Pressure/Settings
4016	9/11/2015	N	Incorrect quantity	broken43/45	Buspirone		Mechanical Error	Adjust Cell Pressure/Settings
4016	9/11/2015	N	Incorrect quantity	pv1 - broken 89/90	Metoclopramide	Metoclopramide	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/11/2015	N	Incorrect quantity	pv1 - short 59/6	galanamine	Galantamine	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/13/2015	N	Incorrect quantity	pv2 - broken 29/30	chorthalidone	Chlorthalidone	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/13/2015	N	Incorrect quantity	pv2 - broken 59/60	Primidone	Primidone	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/13/2015	N	Incorrect quantity	pv2 - broken 28/30	Clonidine	Clonidine	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/13/2015	N	Incorrect quantity	pv1- broken 29/30	Simvastatin	Simvastatin	Mechanical Error	Adjust Cell Pressure/Settings

4016	9/13/2015	N	Incorrect quantity	pv1 - broken 38/45	np thyroid	np thyroid	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/13/2015	N	Incorrect quantity	pv1 - broken 44/45	Simvastatin	Simvastatin	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/13/2015	N	Incorrect quantity	pv1 - broken 58/60	enalapril/hctz	enalapril/hctz	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/13/2015	N	Incorrect quantity	auto bagger C - broken cap	pantoprazole	pantoprazole	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/15/2015	N	Incorrect quantity	pv1- broken tabs 57/60	Chlorthalidone	Chlorthalidone	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/15/2015	N	Incorrect quantity	pv1- broken 119/120	Clonidine	Clonidine	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/15/2015	N	Incorrect quantity	pv1 -broken 59/60	polyiron 150 forte	polyiron 150 forte	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/15/2015	N	Incorrect quantity	pv1 - broken 29/30	venlafaxine er	venlafaxine er	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/15/2015	N	Incorrect quantity	pv1 - 16/15 man ct	Bystolic	Bystolic	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/16/2015	N	Incorrect quantity	pv2 - broken 178/180	Clonidine	Clonidine	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/16/2015	N	Incorrect quantity	pv2- broken 60/60	metformin er	metformin er	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/16/2015	N	Incorrect quantity	pv2- broken 175/180	lisinopril/hctz	lisinopril/hctz	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/16/2015	N	Incorrect quantity	pv2 - broken 87/90	Chlorthalidone	Chlorthalidone	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/17/2015	N	Incorrect quantity	pv2 broken 44/45	Furosemide		Mechanical Error	Adjust Cell Pressure/Settings
4016	9/18/2015	N	Incorrect quantity	PV2 - broken tab 59/60	Lithium Carbonate	Lithium Carbonate	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/18/2015	N	Incorrect quantity	PV2 - Broken 28/30	Chlorthalidone	Chlorthalidone	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/18/2015	N	Incorrect quantity	PV2 - broken 79/90	Chlorthalidone	Chlorthalidone	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/18/2015	N	Incorrect quantity	PV1 - broken 116/120	Metoclopramide	Metoclopramide	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/18/2015	N	Incorrect quantity	PV1 - long 26/20	Doxycycline	Doxycycline	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/18/2015	N	Incorrect quantity	PV1 - short 57/60	Neomycin	Neomycin	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/21/2015	N	Incorrect quantity	PV2 - broken tab 40/45	Chlorthalidone	Chlorthalidone	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/21/2015	N	Incorrect quantity	PV2 - broken tab 28/30	Chlorthalidone	Chlorthalidone	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/21/2015	N	Incorrect quantity	PV2 - broken tab 58/60	Megestrol	Megestrol	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/21/2015	N	Incorrect quantity	PV1- broken tablets (filled 44-45)	Spironolactone	Spironolactone	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/21/2015	N	Incorrect quantity	PV1- broken tablets (filled 29/30)	irbesartan	irbesartan	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/21/2015	N	Incorrect quantity	PV1- broken tablet (filled 179/180)	Metoprolol	Metoprolol	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/21/2015	N	Incorrect quantity	PV1- broken tablet (filled 89/90)	Hydralazine	Hydralazine	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/22/2015	N	Incorrect quantity	PV1- broken tablets (filled 84-90)	Chlorthalidone	Chlorthalidone	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/22/2015	N	Incorrect quantity	PV1- broken tablets (filled 29/30)	Losartan	Losartan	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/23/2015	N	Incorrect quantity	PV1- broken tablets (filled 131/135)	Carbidopa-levodopa ER	Carbidopa-levodopa ER	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/24/2015	N	Incorrect quantity	PV2- broken tablet (filled 59/60)	Diflunisal	Diflunisal	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/24/2015	N	Incorrect quantity	PV1- undercount due to 16 dram vial (unlabeled) inside the 40 dram vial (filled 50/90)	Prenatal Rx 1	Prenatal Rx 1	Mechanical Error	16 dram vial was mistakenly placed into 40 dram vial labeler and was caught inside a 40 dram vial. Maintenance staff was notified.
4016	9/25/2015	N	Incorrect quantity	PV1 - broken 89/90	atorvastatin	atorvastatin	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/25/2015	N	Incorrect quantity	PV1 - broken 28/30	estropipate	estropipate	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/28/2015	N	Incorrect quantity	PV2- Broken cap 29/30	Vitamin D		Mechanical Error	Adjust Cell Pressure/Settings
4016	9/28/2015	N	Incorrect quantity	Pv2--broken tab 88/90	Losartan		Mechanical Error	Adjust Cell Pressure/Settings
4016	9/28/2015	N	Incorrect quantity	pv1--broken tab 59/60	Metformin		Mechanical Error	Adjust Cell Pressure/Settings
4016	9/28/2015	N	Incorrect quantity	pv1--broken tab 89/90	Methimazole		Mechanical Error	Adjust Cell Pressure/Settings
4016	9/29/2015	N	Incorrect quantity	PV1: broken 29/30	np thyroid	np thyroid	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/29/2015	N	Incorrect quantity	PV1: broken 53/60	Clonidine	Clonidine	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/29/2015	N	Incorrect quantity	PV1: broken 29/30	Omeprazole	Omeprazole	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/29/2015	N	Incorrect quantity	PV1: short 29/30	Urocit-K	Urocit-K	Mechanical Error	Adjust Cell Pressure/Settings
4016	9/29/2015	N	Incorrect quantity	pv2- broken tablet 99/100	losartan/hctz		Mechanical Error	Adjust Cell Pressure/Settings

4016	9/30/2015	N	Incorrect quantity	pv2 - broken tablet 29/30	candesartan/hctz		Mechanical Error	Adjust Cell Pressure/Settings
Subtotal = 243	Percentage of Total Scripts(1,536,711) = 0.0154%	Reached Patient = 1	Number of prescriptions through automation 1,536,711					

Incorrect Safety Cap

Store#	DateReported	Reached Patient	QRE Type	Desc	Prescription	Dispensed	Reason for Error	Corrective Action
4016	7/1/2015	N	Incorrect safety cap	auto H forgot snap cap	potassium er		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/1/2015	N	Incorrect safety cap	auto H forgot snap cap	potassium er		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/2/2015	N	Incorrect safety cap	auto B forgot snap cap	Benicar		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/6/2015	N	Incorrect safety cap	no snap cap	Hydralazine	Hydralazine	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/7/2015	N	Incorrect safety cap	man pack - cap chipped	Acetaminophen	Acetaminophen	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/7/2015	N	Incorrect safety cap	man pack - chipped cap	Viagra	Viagra	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/7/2015	N	Incorrect safety cap	no snap cap	dexilant	dexilant	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/7/2015	N	Incorrect safety cap	autobagger forgot snap cap	Glipizide		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/7/2015	N	Incorrect safety cap	autobagger forgot snap cap	Trazodone		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/7/2015	N	Incorrect safety cap	autobagger D forgot snap cap	Simvastatin		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/9/2015	N	Incorrect safety cap	multi-pack AI - forgot snap cap	gabapentin	gabapentin	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/9/2015	N	Incorrect safety cap	multi-pack AI - forgot snap cap	levothyroxine	levothyroxine	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/9/2015	N	Incorrect safety cap	autobagger H forgot snap cap	metoprolol tartrate		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.

4016	7/9/2015	N	Incorrect safety cap	autobagger forgot snap cap	Atenolol		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/9/2015	N	Incorrect safety cap	autobagger forgot snap cap	Atenolol		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/10/2015	N	Incorrect safety cap	autobagger forgot snap cap	metoprolol tartrate		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/10/2015	N	Incorrect safety cap	autobagger forgot snap cap	Sucralfate		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/10/2015	N	Incorrect safety cap	autobagger forgot snap cap	Crestor		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/11/2015	N	Incorrect safety cap	AI - forgot snap cap	Furosemide	Furosemide	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/11/2015	N	Incorrect safety cap	autobagger no snap cap	isosorbide mononitrate		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/12/2015	N	Incorrect safety cap	autobagger I forgot snap cap	lamotrigine		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/16/2015	N	Incorrect safety cap	snap cap autobagger C	amlodipine		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/16/2015	N	Incorrect safety cap	auto A forgot snap cap	chlorathalidone		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/20/2015	N	Incorrect safety cap	auto F forgot snap cap	Lisinopril		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/20/2015	N	Incorrect safety cap	auto F forgot snap cap	levothyroxine		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/20/2015	N	Incorrect safety cap	auto A forgot snap cap	Atenolol		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.

4016	7/20/2015	N	Incorrect safety cap	auto A forgot snap cap	atorvastatin		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/21/2015	N	Incorrect safety cap	No non safty cap in bag			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/26/2015	N	Incorrect safety cap	Single autobagger #5 - Forgot snap caps			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/26/2015	N	Incorrect safety cap	single autobagger #5 - forgot snap caps			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/26/2015	N	Incorrect safety cap	single autobagger #5 - forgot snap caps			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/26/2015	N	Incorrect safety cap	single autobagger #4 - forgot snap caps	Metformin		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/28/2015	N	Incorrect safety cap	rx did not have a non safty cap in bag			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/29/2015	N	Incorrect safety cap	Autobagger D - Forgot snap caps (corrected)	??		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/30/2015	N	Incorrect safety cap	Packing - Forgot snap caps	Metformin		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/30/2015	N	Incorrect safety cap	Packing - Forgot snap caps	Potassium Chloride		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/30/2015	N	Incorrect safety cap	Packing - Forgot snap caps	Potassium Chloride		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/30/2015	N	Incorrect safety cap	Packing - Forgot snap caps	pantoprazole		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/30/2015	N	Incorrect safety cap	Packing - Forgot snap caps	levothyroxine		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.

4016	7/30/2015	N	Incorrect safety cap	Packing - Forgot snap caps	isosorbide mono		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/30/2015	N	Incorrect safety cap	Packing - Forgot snap caps	cyclobenzaprine		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/30/2015	N	Incorrect safety cap	Packing - Forgot snap caps	atorvastatin		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/30/2015	N	Incorrect safety cap	Single Pack #5 - No snap caps	Citalopram		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/31/2015	N	Incorrect safety cap	Single Pack #1 - No snap caps	Potassium Chloride		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/31/2015	N	Incorrect safety cap	Multi-pack #2 - forgot snap caps	carvedilol		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/31/2015	N	Incorrect safety cap	Multi-pack #2 - forgot snap caps	Amlodipine		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/7/2015	N	Other (explain in pharmacy notes if necessary)	MAN PACK - FORGOT SAFETY CAP	Trazodone	Trazodone	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/22/2015	N	Other (explain in pharmacy notes if necessary)	Autobag: forgot snap cap	hctz	hctz	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/22/2015	N	Other (explain in pharmacy notes if necessary)	Autobag: forgot snap cap	fenofibric acid	fenofibric acid	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/23/2015	N	Other (explain in pharmacy notes if necessary)	Autobag G: forgot snap cap	meloxicam	meloxicam	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/23/2015	N	Other (explain in pharmacy notes if necessary)	Multi-pack #2: forgot snap cap	Enalapril	Enalapril	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/23/2015	N	Other (explain in pharmacy notes if necessary)	Autobag H: forgot snap cap	Naproxen	Naproxen	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.

4016	7/23/2015	N	Other (explain in pharmacy notes if necessary)	Autobag A: no snap cap	gabapentin	gabapentin	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/24/2015	N	Other (explain in pharmacy notes if necessary)	Autobag H: forgot snap cap	meloxicam	meloxicam	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/24/2015	N	Other (explain in pharmacy notes if necessary)	Autobag: forgot snap cap	atorvastatin	atorvastatin	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/24/2015	N	Other (explain in pharmacy notes if necessary)	Autobag: forgot snap cap	Citalopram	Citalopram	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/21/2015	N	Other (explain in pharmacy notes if necessary)	Autobagger: forgot snap cap	Amlodipine	Amlodipine	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/21/2015	N	Other (explain in pharmacy notes if necessary)	Autobagger: forgot snap cap	Amiodarone	Amiodarone	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/22/2015	N	Other (explain in pharmacy notes if necessary)	Autobag H: no snap cap	gabapentin	gabapentin	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/22/2015	N	Other (explain in pharmacy notes if necessary)	Autobag F:no snap cap	levothyroxine	levothyroxine	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/22/2015	N	Other (explain in pharmacy notes if necessary)	Autobag H: no snap cap	levothyroxine	levothyroxine	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/22/2015	N	Other (explain in pharmacy notes if necessary)	Multi-pack #3: forgot snap cap	kombiglyze XR	kombiglyze XR	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/15/2015	N	Other (explain in pharmacy notes if necessary)	forgot cap autobagger D			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/17/2015	N	Other (explain in pharmacy notes if necessary)	Autobagger D: forgot snap cap (corrected)	Lisinopril	Lisinopril	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/18/2015	N	Other (explain in pharmacy notes if necessary)	Autobagger: forgot snap cap	Enalapril	Enalapril	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.

4016	7/21/2015	N	Other (explain in pharmacy notes if necessary)	Autobagger: no snap cap	Trazodone	Trazodone	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/13/2015	N	Other (explain in pharmacy notes if necessary)	snap cap autobagger D	duloxetine		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	7/13/2015	N	Other (explain in pharmacy notes if necessary)	snap cap autobagger D	atorvastatin		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/1/2015	N	Incorrect safety cap	AI- missing snap cap	Warfarin		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/1/2015	N	Incorrect safety cap	AI- missing snap cap	spironolactone		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/1/2015	N	Incorrect safety cap	AI- missing snap cap	metoprolol er		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/3/2015	N	Incorrect safety cap	AI- missing snap cap	Potassium Chloride		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/3/2015	N	Incorrect safety cap	AI- missing snap cap	lisinopril		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/3/2015	N	Incorrect safety cap	man pack 5 - missing snap cap			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/3/2015	N	Incorrect safety cap	area not noted	fenofibrate		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/3/2015	N	Incorrect safety cap	multi autobagger 4 - no lid	fenofibrate		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/5/2015	N	Incorrect safety cap	AI- missing snap cap	lisinopril		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/5/2015	N	Incorrect safety cap	multi pack H - no snap cap	Potassium Chloride		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.

4016	8/5/2015	N	Incorrect safety cap	multi pack H - no snap cap	levothyroxine		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/6/2015	N	Incorrect safety cap	No non child proof lid in bag			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/8/2015	N	Incorrect safety cap	no non safety caps in bag			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/10/2015	N	Incorrect safety cap	autobagger forgot snap cap	mirtazepine		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/12/2015	N	Incorrect safety cap	autobagger F no snap cap	glimepiride		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/12/2015	N	Incorrect safety cap	autobagger H no snap cap	Lisinopril		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/12/2015	N	Incorrect safety cap	autobagger H forgot snap cap	divalproex		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/12/2015	N	Incorrect safety cap	autobagger H forgot snap cap	Lisinopril		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/12/2015	N	Incorrect safety cap	autobagger E forgot snap cap	Lisinopril		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/13/2015	N	Incorrect safety cap	no non safety caps in bag			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/14/2015	N	Incorrect safety cap	autobagger I- forgot snap caps in rx bag	Lisinopril	Lisinopril	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/14/2015	N	Incorrect safety cap	autobagger I- forgot snap caps in rx bag	Amlodipine	Amlodipine	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/14/2015	N	Incorrect safety cap	autobagger E- forgot snap caps in rx bag	Omeprazole	Omeprazole	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.

4016	8/14/2015	N	Incorrect safety cap	autobagger H- forgot snap caps in rx bag	Cetirizine	Cetirizine	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/14/2015	N	Incorrect safety cap	autobagger H- forgot snap caps in rx bag	Citalopram	Citalopram	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/14/2015	N	Incorrect safety cap	autobagger H- forgot snap caps in rx bag	meloxicam	meloxicam	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/14/2015	N	Incorrect safety cap	autobagger H- forgot snap caps in rx bag	Simvastatin	Simvastatin	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/15/2015	N	Incorrect safety cap	autobagger- forgot snap caps in rx bag	tamsulosin	tamsulosin	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/15/2015	N	Incorrect safety cap	autobagger- forgot snap caps in rx bag	Lisinopril	Lisinopril	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/16/2015	N	Incorrect safety cap	autobagger - forgot snap caps in rx bag	Omeprazole	Omeprazole	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/16/2015	N	Incorrect safety cap	autobagger G- forgot snap caps in rx bag	Amlodipine	Amlodipine	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/19/2015	N	Incorrect safety cap	auto A no snap cap	Bupropion		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/19/2015	N	Incorrect safety cap	auto A no snap caps	Potassium		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/19/2015	N	Incorrect safety cap	auto D no snap cap	Zetia		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/19/2015	N	Incorrect safety cap	auto E no snap cap	Lisinopril		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/19/2015	N	Incorrect safety cap	auto F no snap cap	Amlodipine		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.

4016	8/19/2015	N	Incorrect safety cap	auto G forgot snap cap	tamsulosin		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/19/2015	N	Incorrect safety cap	auto I no snap cap	Simvastatin		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/19/2015	N	Incorrect safety cap	auto I no snap cap	venlafaxine		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/21/2015	N	Incorrect safety cap	rx's did not have a non-safety cap with them from central fill			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/21/2015	N	Incorrect safety cap	No non safety cap like requested in bag from CF			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/26/2015	N	Incorrect safety cap	autobagger D- forgot snap cap in rx bag	Metoprolol	Metoprolol	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/27/2015	N	Incorrect safety cap	autobagger C- forgot snap cap in rx bag	Methotrexate	Methotrexate	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/27/2015	N	Incorrect safety cap	autobagger E- forgot snap cap in rx bag	Metoprolol	Metoprolol	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/27/2015	N	Incorrect safety cap	autobagger E- forgot snap cap in rx bag	Omeprazole	Omeprazole	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/27/2015	N	Incorrect safety cap	autobagger E- forgot snap cap in rx bag	Metformin	Metformin	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/27/2015	N	Incorrect safety cap	autobagger E- forgot snap cap in rx bag	Detrol	Detrol	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/27/2015	N	Incorrect safety cap	autobagger E- forgot snap cap in rx bag	Simvastatin	Simvastatin	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/27/2015	N	Incorrect safety cap	autobagger E- forgot snap cap in rx bag	atorvastatin	atorvastatin	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.

4016	8/27/2015	N	Incorrect safety cap	autobagger E- forgot snap cap in rx bag	Jantoven	Jantoven	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/27/2015	N	Incorrect safety cap	autobagger E- forgot snap cap in rx bag	Atenolol	Atenolol	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/28/2015	N	Incorrect safety cap	Auto Bagger A - forgot snap cap			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/28/2015	N	Incorrect safety cap	AB A - Forgot snap cap			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/28/2015	N	Incorrect safety cap	AB A - Forgot snap cap			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/31/2015	N	Incorrect safety cap	no non safety cap in bag			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/5/2015	N	Other (explain in pharmacy notes if necessary)	forgot to include snap cap at autobagger	lisinopril/hctz	lisinopril/hctz	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/5/2015	N	Other (explain in pharmacy notes if necessary)	forgot to include snap cap at autobagger	Toviaz	Toviaz	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/5/2015	N	Other (explain in pharmacy notes if necessary)	forgot to include snap cap at autobagger	Methotrexate	Methotrexate	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/5/2015	N	Other (explain in pharmacy notes if necessary)	forgot to include snap cap at autobagger	Atenolol	Atenolol	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/21/2015	N	Other (explain in pharmacy notes if necessary)	forgot to include snap cap	pioglitazone	pioglitazone	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/21/2015	N	Other (explain in pharmacy notes if necessary)	forgot to include snap cap	Glipizide	Glipizide	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/21/2015	N	Other (explain in pharmacy notes if necessary)	forgot to include snap caps at multi-auto 2	Simvastatin	Simvastatin	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.

4016	8/21/2015	N	Other (explain in pharmacy notes if necessary)	forgot to include snap caps at multi-auto 2	glimepiride	glimepiride	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/24/2015	N	Other (explain in pharmacy notes if necessary)	forgot to include snap cap at auto E			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/29/2015	N	Other (explain in pharmacy notes if necessary)	forgot snap cap			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/29/2015	N	Other (explain in pharmacy notes if necessary)	Forgot snap cap			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/29/2015	N	Other (explain in pharmacy notes if necessary)	forgot snap cap			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/31/2015	N	Other (explain in pharmacy notes if necessary)	forgot to put snap cap in bag			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/20/2015	N	Other (explain in pharmacy notes if necessary)	forgot to include snap cap at autobagger	Atenolol	Atenolol	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/8/2015	N	Other (explain in pharmacy notes if necessary)	Autobagger D: forgot snap cap	Atenolol	Atenolol	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/20/2015	N	Other (explain in pharmacy notes if necessary)	forgot to include snap cap in packing	Citalopram	Citalopram	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/13/2015	N	Other (explain in pharmacy notes if necessary)	Autobagger E: forgot cap (corrected)	Lisinopril	Lisinopril	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/17/2015	N	Other (explain in pharmacy notes if necessary)	forgot snap cap at autobagger			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/17/2015	N	Other (explain in pharmacy notes if necessary)	forgot snap cap at autobagger			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/17/2015	N	Other (explain in pharmacy notes if necessary)	forgot snap cap at autobagger			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.

4016	8/18/2015	N	Other (explain in pharmacy notes if necessary)	forgot snap cap at autobagger	Omeprazole	Omeprazole	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	8/18/2015	N	Other (explain in pharmacy notes if necessary)	forgot snap cap at autobagger			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/1/2015	N	Other (explain in pharmacy notes if necessary)	Forgot safety cap			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/1/2015	N	Incorrect safety cap	Forgot to put in snap cap			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/2/2015	N	Incorrect safety cap	forgot snap cap			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/2/2015	N	Incorrect safety cap	forgot snap cap			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/2/2015	N	Incorrect safety cap	forgot snap cap			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/3/2015	N	Other (explain in pharmacy notes if necessary)	forgot snap cap when bagging			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/3/2015	N	Other (explain in pharmacy notes if necessary)	forgot snap cap when packing			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/3/2015	N	Incorrect safety cap	forgot snap cap			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/3/2015	N	Incorrect safety cap	forgot snap cap			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/3/2015	N	Incorrect safety cap	forgot snap cap when packing			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/4/2015	N	Incorrect safety cap	AG- missing snapcap			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.

4016	9/4/2015	N	Incorrect safety cap	AG- missing snapcap			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/4/2015	N	Incorrect safety cap	AG -missing snap cap			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/4/2015	N	Incorrect safety cap	AG - missing snapcap			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/5/2015	N	Other (explain in pharmacy notes if necessary)	AG - no snap cap	naproxen		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/5/2015	N	Other (explain in pharmacy notes if necessary)	AG - no snap cap	lisinopril		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/7/2015	N	Other (explain in pharmacy notes if necessary)	auto-bagger - no snap cap	Omeprazole	Omeprazole	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/7/2015	N	Other (explain in pharmacy notes if necessary)	auto-bagger forgot snap cap	Naproxen	Naproxen	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/9/2015	N	Incorrect safety cap	forgot snap cap	atorvastatin	atrovastatin	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/9/2015	N	Incorrect safety cap	no cap	Clonidine	Clonidine	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/9/2015	N	Incorrect safety cap	no snap caps	Metformin	Metformin	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/9/2015	N	Incorrect safety cap	no snap cap	atorvastatin	atorvastatin	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/9/2015	N	Incorrect safety cap	no snap cap	Sertraline	Sertraline	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/16/2015	N	Incorrect safety cap	AD - forgot snap cap	?	?	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.

4016	9/16/2015	N	Incorrect safety cap	AD - forgot snap cap	?	?	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/30/2015	N	Incorrect safety cap	forgot cap - autobagger A			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/29/2015	N	Other (explain in pharmacy notes if necessary)	Autobagger: forgot snap cap	montelukast	montelukast	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/29/2015	N	Other (explain in pharmacy notes if necessary)	Autobagger: forgot snap cap	glimepiride	glimepiride	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/29/2015	N	Other (explain in pharmacy notes if necessary)	Autobagger: forgot snap cap	Furosemide	Furosemide	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/29/2015	N	Other (explain in pharmacy notes if necessary)	Autobagger: forgot snap cap	duloxetine	duloxetine	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/29/2015	N	Other (explain in pharmacy notes if necessary)	Autobagger: forgot snap cap	Triamterene-HCTZ	Triamterene-HCTZ	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/25/2015	N	Incorrect safety cap	Autobagger A- forgot snap caps in rx bag	Lisinopril	Lisinopril	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/25/2015	N	Incorrect safety cap	Autobagger A- forgot snap cap in rx bag	Seroquel	Seroquel	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/25/2015	N	Incorrect safety cap	snap cap	pioglitazone	pioglitazone	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/25/2015	N	Incorrect safety cap	no snap cap	Warfarin	Warfarin	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/22/2015	N	Incorrect safety cap	snap cap			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/22/2015	N	Incorrect safety cap	snap cap			Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.

4016	9/22/2015	N	Incorrect safety cap	snap cap	atorvastatin	atorvastatin	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/15/2015	N	Incorrect safety cap	AG- no snap cap	?	?	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/15/2015	N	Incorrect safety cap	AG - no snap cap	?	?	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/17/2015	N	Incorrect safety cap	auto AB no snap cap	Lisinopril		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/17/2015	N	Incorrect safety cap	auto AB no snap cap	atorvastatin		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/17/2015	N	Incorrect safety cap	auto AB no snap cap	Sertraline		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/17/2015	N	Incorrect safety cap	auto AB no snap cap	Lisinopril		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/17/2015	N	Incorrect safety cap	auto D no snap cap	Furosemide		Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/18/2015	N	Incorrect safety cap	forgot snap cap	Furosemide	Furosemide	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/18/2015	N	Incorrect safety cap	AC - snap cap	olanzapine	olanzapine	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/21/2015	N	Incorrect safety cap	no snap cap	Omeprazole	Omeprazole	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/21/2015	N	Incorrect safety cap	snap cap	atorvastatin	atorvastatin	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/21/2015	N	Incorrect safety cap	snap cap	Hydrochlorothiazide	Hydrochlorothiazide	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.

4016	9/21/2015	N	Incorrect safety cap	snap cap	Metoprolol	Metoprolol	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/21/2015	N	Incorrect safety cap	snap cap	Furosemide	Furosemide	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/21/2015	N	Incorrect safety cap	snap cap	cyclobenzaprine	cyclobenzaprine	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/21/2015	N	Incorrect safety cap	snap cap	Furosemide	Furosemide	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/23/2015	N	Incorrect safety cap	no snap cap	Lisinopril	Lisinopril	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/23/2015	N	Incorrect safety cap	snap cap	Omeprazole	Omeprazole	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/23/2015	N	Incorrect safety cap	snap cap	Amlodipine	Amlodipine	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/24/2015	N	Incorrect safety cap	no snap cap	donepezil	donepezil	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/8/2015	N	Other (explain in pharmacy notes if necessary)	auto bagger - missing snap cap	Furosemide	Furosemide	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
4016	9/12/2015	N	Other (explain in pharmacy notes if necessary)	AUTO-BAGGER - MISSING SNAP CAPS	Sucralfate	Sucralfate	Human Error: The PSP did not recognize the safety caps addition on their screen.	This has been addressed at Quality Assurance meetings and staff meeting to remind all PSP/techs/RPH.
Subtotal = 205	Percentage of Total Scripts(1,536,711) = 0.0133%	Reached Patient = 0	Number of prescriptions through automation 1,536,711					

Other-Paperwork								
Store#	DateReported	Reached Patient	QRE Type	Desc	Prescription	Dispensed	Reason for Error	Corrective Action
4016	7/30/2015	N	Other (explain in pharmacy notes if necessary)	Rx was 1 monograph short			Printer Jam was not cleared immediately	Packer was instructed to clear paper jam immediately before continuing to pack orders or monograph receipts may not be fully printed
4016	7/29/2015	N	Other (explain in pharmacy notes if necessary)	Order of 4 was missing 2 our of 4 monograph			Printer Jam was not cleared immediately	Packer was instructed to clear paper jam immediately before continuing to pack orders or monograph receipts may not be fully printed
4016	8/5/2015	N	Other (explain in pharmacy notes if necessary)	extra mono for another pt in pt bag.			Printer Jam was not cleared immediately	Packer was instructed to clear paper jam immediately before continuing to pack orders or monograph receipts may not be fully printed
4016	8/21/2015	N	Other (explain in pharmacy notes if necessary)	Another pt monograph was in a bag for a different store			Printer Jam was not cleared immediately	Packer was instructed to clear paper jam immediately before continuing to pack orders or monograph receipts may not be fully printed
Subtotal = 4	Percentage of Total Scripts(1,536,711) = 0.0003%	Reached Patient = 0	Number of prescriptions through automation 1,536,711					

Other-Caps

Store#	DateReported	Reached Patient	QRE Type	Desc	Prescription	Dispensed	Reason for Error	Corrective Action
4016	7/27/2015	N	Other (explain in pharmacy notes if necessary)	chipped cap at man pack #1	Losartan	Losartan	Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	7/28/2015	N	Other (explain in pharmacy notes if necessary)	Single Pack #1 - Bad seal on cap	Naproxen		Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	7/29/2015	N	Other (explain in pharmacy notes if necessary)	Packing - cracked lid	??		Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	7/30/2015	N	Other (explain in pharmacy notes if necessary)	Packing - No cap	candesartan		Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	7/30/2015	N	Other (explain in pharmacy notes if necessary)	Packing - Loose cap	Fluoxetine		Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	7/22/2015	N	Other (explain in pharmacy notes if necessary)	Multi-pack #3: no cap	isosorbide mono dr	isosorbide mono dr	Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	7/19/2015	N	Other (explain in pharmacy notes if necessary)	Autobagger: damaged cap	Furosemide	Furosemide	Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	7/21/2015	N	Other (explain in pharmacy notes if necessary)	Autobagger: chipped cap	Diltiazem	Diltiazem	Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	7/21/2015	N	Other (explain in pharmacy notes if necessary)	Autobagger: chipped cap	atorvastatin	atorvastatin	Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	7/22/2015	N	Other (explain in pharmacy notes if necessary)	Autobag: chipped cap	Pravastatin	Pravastatin	Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	7/21/2015	N	Other (explain in pharmacy notes if necessary)	Autobagger D: broken cap	Ranitidine	Ranitidine	Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	7/1/2015	N	Other (explain in pharmacy notes if necessary)	auto H broken lid on vial	triamterene/hydrochlorothiazide		Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	7/7/2015	N	Other (explain in pharmacy notes if necessary)	man pack - cap not secure	Ibuprofen	Ibuprofen	Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	7/8/2015	N	Other (explain in pharmacy notes if necessary)	cracked lid found at autobagger H	Lisinopril		Mechanical Error	Gears in Automated capper were replaced to rectify this issue

4016	7/10/2015	N	Other (explain in pharmacy notes if necessary)	autobagger chipped cap on vial	Metformin		Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	7/10/2015	N	Other (explain in pharmacy notes if necessary)	autobagger chipped cap on vial	Crestor		Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	7/10/2015	N	Other (explain in pharmacy notes if necessary)	Autobagger: chipped cap	atorvastatin	atorvastatin	Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	7/13/2015	N	Other (explain in pharmacy notes if necessary)	bottle cap was chipped autobagger D	venlafaxine		Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	7/13/2015	N	Other (explain in pharmacy notes if necessary)	vial cap was chipper autobagger D	loratadine		Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	7/13/2015	N	Other (explain in pharmacy notes if necessary)	Packing. Cap cracked on vial	Bupropion		Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	7/16/2015	N	Other (explain in pharmacy notes if necessary)	Packing. Cap not secure on vial.	Omeprazole		Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	7/16/2015	N	Other (explain in pharmacy notes if necessary)	Packing. Cap chipped on vial.	isosorbide mononitrate		Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	7/17/2015	N	Other (explain in pharmacy notes if necessary)	Autobagger: cap loose	atorvastatin	atorvastatin	Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	7/20/2015	N	Other (explain in pharmacy notes if necessary)	Autobagger C: no lid	Sertraline	Sertraline	Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	8/5/2015	N	Other (explain in pharmacy notes if necessary)	cap not on completely in packing	tamsulosin	tamsulosin	Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	8/5/2015	N	Other (explain in pharmacy notes if necessary)	cap not on completely in packing	Dilantin	Dilantin	Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	8/5/2015	N	Other (explain in pharmacy notes if necessary)	chipped cap in packing	bisoprolol/hctz	bisoprolol/hctz	Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	8/8/2015	N	Other (explain in pharmacy notes if necessary)	Autobagger: chipped cap	gabapentin	gabapentin	Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	8/20/2015	N	Other (explain in pharmacy notes if necessary)	no cap on vial in packing	Bupropion	Bupropion	Mechanical Error	Gears in Automated capper were replaced to rectify this issue

4016	8/25/2015	N	Other (explain in pharmacy notes if necessary)	autobagger C- cracked vial lid (had to replace)	Escitalopram	Escitalopram	Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	8/11/2015	N	Other (explain in pharmacy notes if necessary)	autobagger vial came without cap	Fluoxetine		Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	8/10/2015	N	Other (explain in pharmacy notes if necessary)	autobagger loose cap	Potassium		Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	8/16/2015	N	Other (explain in pharmacy notes if necessary)	autobagger I- cap broken on rx vial	Citalopram	Citalopram	Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	9/2/2015	N	Other (explain in pharmacy notes if necessary)	cap was loose on vial			Mechanical Error	Gears in Automated capper were replaced to rectify this issue
4016	9/11/2015	N	Other (explain in pharmacy notes if necessary)	AUTO BAGGER I - CAP LOOSE	Ibu	Ibu	Mechanical Error	Gears in Automated capper were replaced to rectify this issue
Subtotal = 35	Percentage of Total Scripts(1,536,711) = 0.0023%	Reached Patient = 0	Number of prescriptions through automation 1,536,711					

Other-Bags

Store#	DateReported	Reached Patient	QRE Type	Desc	Prescription	Dispensed	Reason For Error	Corrective Action
4016	7/13/2015	N	Other (explain in pharmacy notes if necessary)	bag not sealed autobagger D	LOsartan		Mechanical Error	Autobagger was serviced
4016	8/30/2015	N	Other (explain in pharmacy notes if necessary)	bad seal bag wasn't seal all the way			Mechanical Error	Autobagger was serviced
4016	9/24/2015	N	Other (explain in pharmacy notes if necessary)	bag did not seal	Amlodipine	Amlodipine	Mechanical Error	Autobagger was serviced
Subtotal =3	Percentage of Total Scripts(1,536,711) = 0.0002%	Reached Patient = 0	Number of prescriptions through automation 1,536,711					

Other-Caps

Store#	DateReported	Reached Patient	QRE Type	Desc	Prescription	Dispensed	Reason for Error	Corrective Action
4016	7/8/2015	N	Other (explain in pharmacy notes if necessary)	autobagger label coming off vial	Metformin		Mechanical Error	Tear in label caused by capper not gripping vial firmly while capping. Capper was serviced to fix this issue
4016	7/1/2015	N	Other (explain in pharmacy notes if necessary)	autobagger c no bar code on vial	Losartan		Mechanical Error	Tear in label caused by capper not gripping vial firmly while capping. Capper was serviced to fix this issue
4016	7/8/2015	N	Other (explain in pharmacy notes if necessary)	autobagger label coming off vial	Metformin		Mechanical Error	Tear in label caused by capper not gripping vial firmly while capping. Capper was serviced to fix this issue
4016	7/10/2015	N	Other (explain in pharmacy notes if necessary)	autobagger label misprint found on vial	Simvastatin		Mechanical Error	Tear in label caused by capper not gripping vial firmly while capping. Capper was serviced to fix this issue
4016	7/17/2015	N	Other (explain in pharmacy notes if necessary)	Autobagger: puck ruined label	mycophenolate mofetil	mycophenolate mofetil	Mechanical Error	Tear in label caused by capper not gripping vial firmly while capping. Capper was serviced to fix this issue
4016	8/3/2015	N	Other (explain in pharmacy notes if necessary)	multi autobagger 4 - no barcode on label	amlodipine	amlodipine	Mechanical Error	Tear in label caused by capper not gripping vial firmly while capping. Capper was serviced to fix this issue
4016	8/27/2015	N	Other (explain in pharmacy notes if necessary)	Autobagger I- black line through rx label (had to reprint label)	Simvastatin	Simvastatin	Mechanical Error	Tear in label caused by capper not gripping vial firmly while capping. Capper was serviced to fix this issue
4016	8/27/2015	N	Other (explain in pharmacy notes if necessary)	autobagger I- black lines through rx label (had to reprint label)	levothyroxine	levothyroxine	Mechanical Error	Tear in label caused by capper not gripping vial firmly while capping. Capper was serviced to fix this issue
4016	8/31/2015	N	Other (explain in pharmacy notes if necessary)	Bad writing on the label			Mechanical Error	Tear in label caused by capper not gripping vial firmly while capping. Capper was serviced to fix this issue
4016	8/14/2015	N	Other (explain in pharmacy notes if necessary)	autobagger H- label printed wrong on rx vial (had to reprint label)	Simvastatin	Simvastatin	Labeled vial was manual dropped incorrectly into a puck married for another drug. The drug filled correct but the wrong label was on the vial.	Staff was notified of error. Retrained on proper technique when adjusting vial labelers.
4016	8/13/2015	N	Other (explain in pharmacy notes if necessary)	Autobagger A: no barcode	venlafaxine	venlafaxine	Mechanical Error	Tear in label caused by capper not gripping vial firmly while capping. Capper was serviced to fix this issue
4016	9/29/2015	N	Other (explain in pharmacy notes if necessary)	Autobagger: spot torn on barcode	Premarin	Premarin	Mechanical Error	Tear in label caused by capper not gripping vial firmly while capping. Capper was serviced to fix this issue

4016	9/2/2015	N	Other (explain in pharmacy notes if necessary)	vial labeler put wrong label over top of correct label - caught in packing	cyclobenzaprine		Labeled vial was manual dropped incorrectly into a puck married for another drug. The drug filled correct but the wrong label was on the vial.	Staff was notified of error. Retrained on proper technique when adjusting vial labelers.
Subtotal = 13	Percentage of Total Scripts(1,536,711) = 0.0008%	Reached Patient = 0	Number of prescriptions through automation 1,536,711					

Other-Packaging

Store#	DateReported	Reached Patient	QRE Type	Desc	Prescription	Dispensed	Reason for Error	Corrective Action
4016	7/29/2015	N	Other (explain in pharmacy notes if necessary)	When package got to pharmacy the vial was broken inside the bag			Item was caught between sorter trays and broken	New Sorter Trays have been crafted an attached to the sorter belt
4016	7/27/2015	N	Other (explain in pharmacy notes if necessary)	When order got to pharmacy the vial was broken and tablets were all over inside the bag.			Item was caught between sorter trays and broken	New Sorter Trays have been crafted an attached to the sorter belt
4016	7/22/2015	N	Other (explain in pharmacy notes if necessary)	Rx for different store got into another pt/store bag. The tech found when hang up the bag.			Additional vial was placed in bag without being scanned	Instructed packer that all items placed into a bag must be successfully scanned first.
4016	7/21/2015	N	Other (explain in pharmacy notes if necessary)	another stores rx was pack into a package for a different store and pt.			Additional vial was placed in bag without being scanned	Instructed packer that all items placed into a bag must be successfully scanned first.
4016	8/20/2015	N	Other (explain in pharmacy notes if necessary)	6 different stores had the wrong rx in the bag because of an auto bagger error. No rx's reached a pt. We have spoke to the packer on this error.			Mechanical Error, Human Error	Packer was counseled on what may have caused the error. The machine was tested to try to repeat the error and the issue was reported to the software company
4016	8/16/2015	N	Other (explain in pharmacy notes if necessary)	inside pt bag was two drugs that were not for pt. Pharmacy found before sending bag with pt.			Mechanical Error, Human Error	Packer was counseled on what may have caused the error. The machine was tested to try to repeat the error and the issue was reported to the software company
Subtotal = 7	Percentage of Total Scripts(1,536,711) = 0.0005%	Reached Patient = 0	Number of prescriptions through automation 1,536,711					

Other - Replenishment

Store#	DateReported	Reached Patient	QRE Type	Desc	Prescription	Dispensed	Reason for Error	Corrective Action
4016	7/8/2015	N	Incorrect drug	replenishment A #1 nifedical XL 30 mg tablet found in cell for terazosin 2 capsule.	Terazosin	Nifedical XL	Human Error	All drug was not correctly cleared from cycle count container on previous fill
4016	7/9/2015	N	Incorrect drug	olr B - found tablet of metformin 500mg during cycle count of lisinopril/hctz 20/25.	lisinopril/hctz	Metformin	Human Error	All drug was not correctly cleared from cycle count container on previous fill
4016	7/23/2015	N	Other (explain in pharmacy notes if necessary)	Replenishment B: dessicant in cell	nabumetone	nabumetone	Human Error	Technician was notified that desicant was left in cell
4016	7/24/2015	N	Other (explain in pharmacy notes if necessary)	Replenishment B: 2 dessicants found in cell 152E	divalproex	divalproex	Human Error	Technician was notified that desicant was left in cell
4016	7/17/2015	N	Other (explain in pharmacy notes if necessary)	Replenishment A. desicant found in cell during cycly count.	divalproex er		Human Error	Technician was notified that desicant was left in cell
4016	7/11/2015	N	Other (explain in pharmacy notes if necessary)	olr B - 2 desicants in cell	Metformin	Metformin	Human Error	Technician was notified that desicant was left in cell
4016	7/19/2015	N	Other (explain in pharmacy notes if necessary)	OLP A: dessicant in cell	Gemfibrozil	Gemfibrozil	Human Error	Technician was notified that desicant was left in cell
4016	7/19/2015	N	Other (explain in pharmacy notes if necessary)	OLP A: Simvastatin 40mg cell placed on Simvastatin 20mg shelf; discovered by runner.	Simvastatin	Simvastatin	Human Error	Item moved from backstock shelf to primary fill shelf incorrectly. Technician was notified of mistake. Bottles look Similar
4016	7/10/2015	N	Other (explain in pharmacy notes if necessary)	OLR B - dessicant in cell	divalproex	Divalproex	Human Error	Technician was notified that desicant was left in cell
4016	7/2/2015	N	Incorrect quantity	pv1 desicant found in UBER cell	Gemfibrozil		Human Error	Technician was notified that desicant was left in cell
4016	8/24/2015	N	Other (explain in pharmacy notes if necessary)	Replenishment B- dessicant found in cell	Metformin	Metformin	Human Error	Technician was notified that desicant was left in cell
4016	8/20/2015	N	Other (explain in pharmacy notes if necessary)	there were two tablets left in Kirby container from previous pharmacist			Human Error	Pharmacist was notified that tablets were left in Kirby
4016	8/5/2015	N	Other (explain in pharmacy notes if necessary)	replenishment a - desicant pillow pouch found in cell	atorvastatin		Human Error	Technician was notified that desicant was left in cell
4016	8/12/2015	N	Other (explain in pharmacy notes if necessary)	replenishment A- tech found dessicant in cell	atorvastatin	atorvastatin	Human Error	Technician was notified that desicant was left in cell
4016	8/19/2015	N	Other (explain in pharmacy notes if necessary)	Replenishment B- 2 dessicant packets left in cell	atorvastatin	atorvastatin	Human Error	Technician was notified that desicant was left in cell
4016	8/19/2015	N	Other (explain in pharmacy notes if necessary)	Replenishment B- dessicant packet found in cell when it would not work properly in robot	atorvastatin	atorvastatin	Human Error	Technician was notified that desicant was left in cell
4016	9/18/2015	N	Other (explain in pharmacy notes if necessary)	runner at replenishment picked up full cell to place on cart- fill door had not been closed tightly by filler- approx 200 capsules spilled onto floor- were subsequently distroyed	Omeprazole		Human Error	Instructed technicians to ensure the cell door is in the closed locked position before placing back on shelf.
4016	9/2/2015	N	Other (explain in pharmacy notes if necessary)	Dessicant was left in vial caught at PV1			Human Error	Technician was notified that desicant was left in cell
4016	9/2/2015	N	Other (explain in pharmacy notes if necessary)	Dessicant left in vial caught at PV1			Human Error	Technician was notified that desicant was left in cell

4016	9/30/2015	N	Other (explain in pharmacy notes if necessary)	pv2 - foil found in bottle	gabapentin		Human Error	Technician was notified that foil was left in cell
4016	9/24/2015	N	Other (explain in pharmacy notes if necessary)	PV1- found piece of broken blue plastic from a cell in the vial with tablets (found the cell it came from; broken piece came off door)	Gemfibrozil	Gemfibrozil	Mechanical Error	Notified technicians of error. Replaced the broken cell.
4016	9/22/2015	N	Other (explain in pharmacy notes if necessary)	Dessicant found in cell	Simvastatin	Simvastatin	Human Error	Technician was notified that desicant was left in cell
4016	9/1/2015	N	Incorrect drug	Rep B - cell had one foreign pill in it - discovered in cycle count when pouring into genie	midodrine		Human Error	Cell was not properly cleaned of all contents and ran through thorough cleaning procedure before being assigned to the next drug. The assigning technician was counseled on the error.
4016	9/14/2015	N	Incorrect quantity	pv2 - clear chunks inside, like desicant exploded	glipizide er	Glipizide er	Human Error	Technician was notified that desicant was left in cell
4016	9/27/2015	N	Other (explain in pharmacy notes if necessary)	Replishment B--dessicant in cell	atorvastatin		Human Error	Technician was notified that desicant was left in cell
Subtotal = 25	Percentage of Total Scripts(1,536,711) = 0.0016%	Reached Patient = 0	Number of prescriptions through automation 1,536,711					

Other - Inventory,Stocking

Store#	DateReported	Reached Patient	QRE Type	Desc	Prescription	Dispensed	Reason for Error	Corrective Action
4016	7/30/2015	N	Incorrect drug	Replenishment A - 1 bottle of Paroxetine 20mg (92-309) was found in location with Carvedilol 25mg (73-141)	Paroxetine		Human Error	Item was sorted in with wrong drug due to similar looking bottles. Staff was notified of the error.
4016	7/21/2015	N	Incorrect drug	GBI: selected non FE product, product in wrong palce	Microgestin	Microgestin FE	Human Error	Item was returned to stock incorrectly. Staff was notified of the error.
4016	9/8/2015	N	Incorrect drug	rep B - lorsartan 50mg shelf had 2 rts bottles of sertraline on it	Losartan	Losartan	Human Error	Instructed inventory and technician staff to double check the items put away to ensure that every bottle is shelved correctly.
4016	9/15/2015	N	Incorrect drug	bulk - 3 boxes of 132-153 found in 132-351 (boxes are same color)	bd insulin syringes 3/10-5/16-31G	bd insulin syr 3/10-5/16/31G	Human Error	Instructed inventory and technician staff to double check the items put away to ensure that every bottle is shelved correctly.
4016	9/24/2015	N	Incorrect drug	UofU PV - clobetasol label on triam/nystatin ointment, tech scanned same box twice? (there were 2 tubes in order - one correct/one incorrect) possible RTS put away in wrong location	Clobetasol ointment	Triamcinolone-nystatin ointment	Human Error	Instructed inventory and technician staff to double check the items put away to ensure that every bottle is shelved correctly.
4016	9/8/2015	N	Incorrect drug	rep A - crestor 40mg on shelf with 10mg	crestor	crestor	Human Error	Instructed inventory and technician staff to double check the items put away to ensure that every bottle is shelved correctly.
4016	9/9/2015	N	Incorrect drug	repl B - haloperidol (73-631) was put away with azathioprine (75-261)	Haloperidol	Haloperidol	Human Error	Instructed inventory and technician staff to double check the items put away to ensure that every bottle is shelved correctly.
4016	9/11/2015	N	Incorrect drug	1000mg 2 stock bottles in 500mg spot	Levetiracetam		Human Error	Instructed inventory and technician staff to double check the items put away to ensure that every bottle is shelved correctly.
4016	9/30/2015	N	Incorrect drug	Toprol xl 25 (75-662) was rts to felbatol 600mg (75-661)			Human Error	Instructed inventory and technician staff to double check the items put away to ensure that every bottle is shelved correctly.
Subtotal = 9	Percentage of Total Scripts(1,536,711) = 0.0006%	Reached Patient = 0	Number of prescriptions through automation 1,536,711					

Other - Sortation

Store#	DateReported	Reached Patient	QRE Type	Desc	Prescription	Dispensed	Reason for Error	Corrective Action
4016	7/10/2015	N	Order mix-up	Rx package went to wrong store location			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.
4016	7/28/2015	N	Order mix-up	package went to wrong store location			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.
4016	7/28/2015	N	Order mix-up	package went to wrong store location			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.
4016	7/28/2015	N	Order mix-up	package went to wrong store location			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.
4016	7/29/2015	N	Order mix-up	rx went to wrong store location			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.
4016	7/29/2015	N	Order mix-up	Rx went to wrong store location			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.
4016	7/23/2015	N	Other (explain in pharmacy notes if necessary)	Rx package for 1297 went to 1074.			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.
4016	7/22/2015	N	Other (explain in pharmacy notes if necessary)	Rx package for 1437 went to store 1449			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.
4016	7/20/2015	N	Other (explain in pharmacy notes if necessary)	Rx for 1759 got sent to 1869.			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.
4016	7/20/2015	N	Other (explain in pharmacy notes if necessary)	rx for 1632 went to 1636			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.

4016	7/20/2015	N	Other (explain in pharmacy notes if necessary)	rx for 1052 went to 1082			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.
4016	7/20/2015	N	Other (explain in pharmacy notes if necessary)	Rx for 1850 went to store 1060			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.
4016	7/20/2015	N	Other (explain in pharmacy notes if necessary)	Rx for 1850 went to store 1060			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.
4016	8/30/2015	N	Other (explain in pharmacy notes if necessary)	rx went to wrong store			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.
4016	8/30/2015	N	Other (explain in pharmacy notes if necessary)	wrong store			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.
4016	8/31/2015	N	Other (explain in pharmacy notes if necessary)	rx was sent to the wrong store			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.
4016	8/27/2015	N	Other (explain in pharmacy notes if necessary)	Rx was sent to the wrong store			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.
4016	8/4/2015	N	Other (explain in pharmacy notes if necessary)	Rx was missing from Tote			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.
4016	8/4/2015	N	Other (explain in pharmacy notes if necessary)	RX was sent to the wrong store			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.
4016	8/8/2015	N	Other (explain in pharmacy notes if necessary)	rx for 1535 went to 1890.			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.
4016	8/13/2015	N	Other (explain in pharmacy notes if necessary)	Rx sent to the wrong store			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.

4016	8/19/2015	N	Other (explain in pharmacy notes if necessary)	rx was sent to wrong store			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.
4016	9/23/2015	N	Other (explain in pharmacy notes if necessary)	rx for 1441 was sent to 1467			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.
4016	9/23/2015	N	Other (explain in pharmacy notes if necessary)	rx for 1382 was sent to 1475			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.
4016	9/15/2015	N	Other (explain in pharmacy notes if necessary)	rx was sent to wrong store			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.
4016	9/21/2015	N	Other (explain in pharmacy notes if necessary)	Rx for 1095 was sent to 1023			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.
4016	9/8/2015	N	Other (explain in pharmacy notes if necessary)	rx was sent to wrong store			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.
4016	9/1/2015	N	Other (explain in pharmacy notes if necessary)	Rx went to wrong store			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.
4016	9/5/2015	N	Other (explain in pharmacy notes if necessary)	Rx for 1297 was sent to 1410			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.
4016	9/24/2015	N	Other (explain in pharmacy notes if necessary)	Rx for 1465 was sent to 1406			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.
4016	9/14/2015	N	Other (explain in pharmacy notes if necessary)	rx was sent to wrong store			Item tipped into wrong lane at the end of the sorter machine and was not caught by two separate staff checks.	Sorter has been tuned to cause few mis dropped items. Staff were notified of the error.
Subtotal = 31	Percentage of Total Scripts(1,536,711) = 0.0020%	Reached Patient = 0	Number of prescriptions through automation 1,536,711					

Other-Miscellaneous

Store#	DateReported	Reached Patient	QRE Type	Desc	Prescription	Dispensed	Error Type	Corrective Action
4016	7/20/2015	N	Other (explain in pharmacy notes if necessary)	Rx was filled twice and sent to the store with same # of refills.			Computer Error	This is causes by a narrow timing error with information process in our relay system with retail stores. There is work being done by our software provider to eliminate the issue.
Subtotal = 1	Percentage of Total Scripts(1,536,711) = 0.0001%	Reached Patient = 0	Number of prescriptions through automation 1,536,711					

From: Bakken, Brianne K (UI Health Care)
To: Jorgenson, Debbie [IBPE]
Subject: Request To Be Added To November Board Meeting
Date: Wednesday, September 30, 2015 3:21:14 PM
Attachments: Intelliguard Executive Summary.pdf
Intelliguard Kits and Trays.pdf
Iowa System Overview (Bill Houghton).pdf

Good Afternoon Debbie,

Following up from our phone conversation this morning: I am a pharmacist at The University of Iowa Hospitals and Clinics. I have been working with Curt Gerhold regarding a new piece of technology equipment we will be implementing in our pharmacy. Terry recommended that we be on the agenda for the next Board of Pharmacy Meeting in November to present an overview of our system and some of our questions/concerns before implementation. As mentioned on the phone, we would prefer to phone conference into the meeting if possible.

Overview:

The Intelliguard® Kit and Tray Management System offers an automated solution for the medication restocking and checking of emergency kits and trays. Intelliguard® Kit and Tray Management System uses passive radio frequency identification (RFID) technology to link medication information and other specific details to a small tag on each individual medication unit used within the kits and trays. The Intelliguard® system has the ability to scan over 150 drugs within seconds, allowing for shorter kit and tray replenishment times while boasting 100% accuracy of finalized trays. Implementation of Intelliguard will improve the efficiency and accuracy of the refilling and restocking of emergency drug trays, leading directly to increased patient safety.

Additionally, the Intelliguard® Kit & Tray Management System provides more efficient record keeping and medication tracking capabilities that far surpass our current manual record keeping processes. The system records all of the following: tray name, tray number, lock number, drug items, drug NDC, drug expiration date, first expiring drug item, technician, pharmacist, deployment date, deployed to, deployed location, making our medication supply chain easier to manage.

The Intelliguard® RFID Solutions process begins by placing a small RFID tag onto each medication unit. The RFID tag consists of an antenna and a chip that contains a Unique Device Identifier (UDI). The UDI chip stores product information/data such as manufacturer, medication name, NDC number, lot number and expiration date. Initially the RFID is meaningless and does not contain any information. An entire flat of medication is labeled with blank RFID tags, the medication is placed in the Intelliguard® Kit and Tray Management Workstation and is scanned by a bar code scanner and a technician manually enters the lot number and expiration date corresponding to the package. The entire flat of medications is then placed in the Intelliguard® Kit and Tray Management Workstation and the RFID tags are encoded with the information listed above. Those medications are then scanned a second time by a pharmacist to ensure the encoding, lot and expiration are correct. After the second scan and approval by a pharmacist, the medications are ready to be used in the refilling of kits and trays.

When a kit or tray is returned to the pharmacy for refilling, it is placed in the Intelliguard® Kit and Tray Management Workstation where the system reads all pre-applied RFID tags on all products and compares it against the kit/tray formulary and predetermined medication PAR levels.

During the RFID scan the tray inventory is counted; any missing, expired or soon-to-expire medications are identified and a medication pick list is generated. After tray replenishment by a technician occurs, the entire tray is scanned a second time by a pharmacist, ensuring the tray contains the correct drugs, doses and quantities.

Background Information & Materials:

I have attached some background materials that may be helpful for The Board and the following video is a nice overview of the product as well: https://www.youtube.com/watch?v=7UzriBjQfyc

Questions For The Board:

- Intelliguard will be sending some of their staff on-site to insist in the implementation. They will be sending nationally certified pharmacy technicians that will aid in the tagging, encoding and filling of kits/trays. One of our pharmacists will be completing the final verification. The Intelliguard group will be on site for approximately 2 weeks. ***Will the Intelliguard technicians need to be registered with The Board? Would The Board allow us to request a waiver?***
- ***Is the Intelliguard Kit & Tray Management system considered to be an "Automated Medication Distribution System" or "AMDS"? If so, is it subject to all of the requirements in IAC 657 Chapter 9?***
- ***What kind of error rating and reporting would be required at implementation?***

Thank You,
Brianne Bakken

Brianne Bakken, PharmD
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Executive Summary

Time and Motion Study:

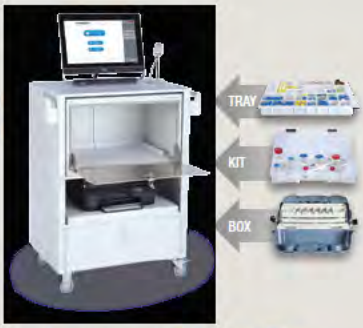
The Impact of the Intelliguard® Kit and Tray Management System on Medication Kit Checking Efficiency and Accuracy

The Problem

Managing kits, trays and tackle boxes throughout the hospital is daunting. State Boards of Pharmacy and Departments of Public Health regulations mandate every medication be checked twice – once by a Technician and once by a Pharmacist – before trays are deployed for clinical use. The same staff bear the responsibility of ensuring medication kit and tray inventories are complete and accurate at replenishment.

The Solution

In November of 2013, Scripps Memorial Hospital employed the Intelliguard® Kit and Tray Management System, an automated RFID-enabled kit and tray replenishment solution. The goals were to improve reprocessing time and eliminate errors. The hospital converted 14 tray types equaling more than 100 total trays. They each held between 16 to 139 items. Cumulatively, these trays are reprocessed approximately 6,100 times annually.

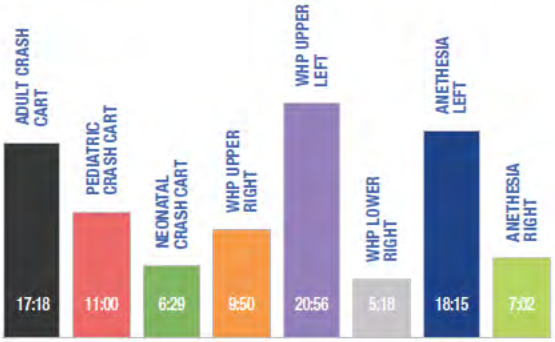


Intelliguard® Kit and Tray Management System

The Results

After 6 months in use, a Time and Motion study was conducted to validate the impact of the automated system. The purpose was to compare and record types of medication errors as well as time spent restocking and approving inventory using the current manual replenishment method versus the Intelliguard® Kit and Tray Management system.

Average Time Savings in Minutes by Tray Type



Impact on Efficiency

On average, the Intelliguard® Kit and Tray Management System saved 19.5 minutes with large trays and 6.3 minutes for even the smallest trays. These figures total almost 1,500 hours of annual staff time savings by using the Intelliguard® System for processing and approving trays.

RFID-Enabled Kit and Tray Replenishment: How it Works

Confirmation

Manual kit and tray checking allows greater possibility for human error; leaving more chance for an expired, used or incorrect medication to be left in the trays and increasing the likelihood of an audit infraction or worse, a patient medication error. Plus, it takes staff 9-27 minutes to check and replenish each tray manually.

ERRORS	Manual	Automated
Adult Crash Cart	3	
Pediatric Crash Cart	2	
Neonatal Crash Cart	1	
WHP Upper Right	0	
WHP Upper Left	0	
WHP Lower Right	0	
Anesthesia Left	1	
Anesthesia Right	2	

ERRORS 0

Using the Intelliguard® Kit and Tray Management System is proven to save staff time and assures each required task is performed with 100% accuracy.

Time and Motion Study:

The Impact of the Intelliguard® Kit and Tray Management System on Medication Kit Checking Efficiency and Accuracy

Scripps Memorial Hospital Encinitas
and MEPS Real-Time, Inc.

Abstract

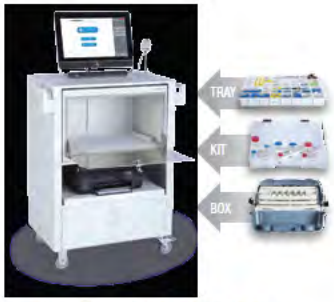
As hospitals grow in physical size, patient volume and patient complexity, there is increasing demand for a higher quantity and greater variety of medications to be kept readily accessible outside of an automated dispensing cabinet (ADC).

Medication management and oversight by the pharmacy plays a crucial role in supporting patient safety.

A common way to achieve this is with the use of kits and trays that can serve many different conditions and situations, some of which can be critical. Management of floor stock medications is defined and regulated by state and federal regulations.

The task of managing kits, trays and tackle boxes throughout the hospital is daunting. Regulatory standards demand accuracy which in turn mandates facility policies which include every medication be checked twice – once by a Technician and once by a Pharmacist – before trays are deployed for clinical use.

Pharmacy Technicians and Pharmacists bear the responsibility of ensuring medication kit and tray inventories are complete and accurate at replenishment – to ensure proper PAR level quantities, medication types/dosage, refrigerated medication re-dating, ancillary labeling, removal of recalled/expired medication and paperwork. This task is done for hundreds of kits – multiple times each day – which adds up to substantial time. Plus, there is a significant risk of human error.



Intelliguard® Kit and Tray Management System

Objectives

Scripps Memorial Hospital Encinitas and MEPS Real-Time, Inc. conducted a Time and Motion study to assess the impact of staff reprocessing time and tray errors by automating this process using the Intelliguard® Kit and Tray Management System. The purpose of this study was to compare and record types of medication errors as well as time spent restocking and approving inventory using the manual replenishment method and again using the Intelliguard® Kit and Tray Management system.

Hospital Demographics

Scripps Memorial Hospital Encinitas is a general community medical and surgical hospital based in Encinitas, California. It has an average bed census of 112 and performs approximately 4,800 inpatient and outpatient surgeries annually. The facility is licensed for 192 inpatient beds.

- Inpatient daily census of 112
- Monthly births of 180
- Monthly ED visits of 3,529
- Monthly Adjusted Patient Days of 4,973

Design

The study was designed to collect two types of data – *time and accuracy*.

Time measurements included time required for both individuals performing the tasks (Pharmacy Technician and Pharmacist) and cumulative time for the entire workflow.

Inventory accuracy was measured at completion of both Pharmacy Technician and Pharmacist workflows.

Two Pharmacy Technicians and two Pharmacists were included in the study. Errors were embedded in the trays which needed to be replenished and study subjects were informed that errors were specifically included.

Pharmacy Technicians and Pharmacists bear the responsibility of ensuring kit and tray inventories are complete and accurate at replenishment.

Tray Types Utilized:

Tray Categories	Tray Name	Annual Tray Cycles
Small (1-15)	Neonatal Crash Cart	56
Medium (16-50)	Pediatric Crash Cart	64
	WHP Lower Right	524
	Anesthesia Right	1,492
Large (51-75)	Adult Crash Cart	480
	WHP Upper Right	608
	WHP Upper Left	124
	Anesthesia Left	1504
Total	8	6,136

Trays were stocked with the following errors

Data Collection Key	Description	Quantity
EX	Expired Med	11
MI	Missing Med	30
OP	Open/Used Med	9
OV	Overage	4
SALAD	Look/Sound Alike	1
SUB	Substitution	2

Adult Code	Pediatric Code	Neonatal Code	WHP Upper Right
EX: EPINEPHrine 1:10,000	EX: calcium chloride 10%	EX: atropine PFS	OP: sodium chloride 0.9%
EX: magnesium sulfate 2mL	MI: adenosine 2mL	EX: sodium chloride 0.9% Flush	MI: lidocaine 2% AMP
MI: phenytoin 5mL	MI: amiodarone 3mL	MI: adenosine 2mL	MI: chloroprocaine 3%
MI: magnesium sulfate 2mL	MI: naloxone 1mL	MI: sodium bicarb 4.2%	MI: chloroprocaine 3%
OV: amiodarone 3mL	MI: sodium bicarb 8.4% 10mL		MI: lidocaine 2% AMP
OP: flumazenil	SALAD: DOBUTamine		
OP: vasopressin 1mL	EX: EPINEPHrine 1:10,000 PFS		
MI: diphenhydrAMINE	OP: phenytoin 5mL		
	OV: phenytoin 5mL		

WHP Upper Left	WHP Lower Right	Anesthesia Left	Anesthesia Right
EX: flumazenil	EX: phenylephrine PFS	OP: flumazenil	OV: propofol
OP: amiodarone 3mL	EX: lidocaine PFS 2%	MI: nalbuphine (out of stock)	MI: lidocaine 2% PF
MI: ondansetron 2mL	MI: phenylephrine PFS	MI: metoclopramide	MI: lidocaine 2% PF
MI: ceFAZolin 1gm	MI: phenylephrine PFS	MI: ondansetron 2mL	MI: lidocaine 2% Jelly
MI: ceFAZolin 1gm	MI: phenylephrine PFS	MI: ceFAZolin	EX: ePHEDrine PFS
MI: sodium chloride 0.9%	OP: lidocaine 2%	MI: sodium chloride 0.9%	OP: succinycholine
SUB: nalbuphine amp		OV: vasopressin	EX: succinycholine
OP: vasopressin			
SUB: atropine			
MI: oxytocin 1mL			
MI: oxytocin 1mL			

Manual Replenishment Workflow

Pharmacy Technician

Pharmacy Technician #1 restocked each tray using the standard manual process. This process was repeated for all 8 trays. Times and errors were recorded by a MEPS® employee after each tray was complete.

Manual Replenishment Workflow Steps:

- Visual check for used/open meds
- Check medications against tray formulary
- Check for tray errors
- Replenish tray
- Check replenished tray inventory
- Indicate tray ready for Pharmacist

Pharmacist

Pharmacist #1 used the standard manual process to approve each tray. This process was repeated for all 8 trays. Time and errors were recorded by a MEPS® employee after each tray was complete.

Manual Replenishment Workflow Steps:

- Visual check for used/open meds
- Check medications against tray formulary
- Check for tray errors
- Verify tray inventory
- Indicate tray ready to leave Pharmacy

Manually checking trays is a slow and tedious process. Even for the most diligent staff, it is not done accurately every time which can create quality and patient safety issues.

After the manual replenishment and approval process was complete, MEPS® reset all of the tray errors. Then, the same individuals restocked and approved each tray using the Intelliguard® Kit and Tray Management System.

Intelliguard® Kit and Tray Management System Workflow

Pharmacy Technician

- Visual check for used/open meds
- Scan to automatically compare medications against tray formulary
- Replenish tray based on medication pick list generated
- Rescan to auto-check for errors
- Log out to indicate tray is ready for Pharmacist approval

Pharmacist

- Visual check for used/open meds
- Scan restocked tray
- Approve
- Log out to indicate tray is ready to leave the Pharmacy

Touchscreen user interface scans hundreds of medications in seconds.

Data
Findings – Restocking Time

Time: Average Manual Workflow

The tables below list actual recorded times by tray type for each test subject using the manual workflow:

Technicians: Manual Workflow

	Adult Code	Pediatric Code	Neonatal Code	WHP Upper Right	WHP Upper Left	WHP Lower Right	Anesthesia Left	Anesthesia Right
Pharmacy Tech 1	0:14:02	0:11:43	0:05:08	0:07:17	0:09:14	0:04:09	0:14:36	0:04:47
Pharmacy Tech 2	0:12:02	0:10:01	0:05:17	0:10:05	0:17:38	0:05:54	0:14:15	0:07:05
Average Time	0:13:02	0:10:52	0:05:13	0:08:41	0:13:26	0:05:01	0:14:25	0:05:56

*Recorded times are listed as hh:mm:ss

Pharmacists: Manual Workflow

	Adult Code	Pediatric Code	Neonatal Code	WHP Upper Right	WHP Upper Left	WHP Lower Right	Anesthesia Left	Anesthesia Right
Pharmacist 1	0:12:03	0:10:03	0:04:32	0:06:45	0:13:06	0:04:21	0:11:45	0:04:28
Pharmacist 2	0:09:57	0:08:23	0:06:38	0:08:03	0:14:57	0:04:29	0:14:14	0:04:11
AverageTime	0:11:00	0:09:13	0:05:35	0:07:24	0:14:01	0:04:25	0:12:59	0:04:20

*Recorded times are listed as hh:mm:ss

Data Findings

Time Savings: Manual vs. Intelliguard Workflows

The tables below list recorded time savings by tray type for each test subject using the Intelliguard® Kit and Tray Management System

Phase One – Time Savings

	Adult Code	Pediatric Code	Neonatal Code	WHP Upper Right	WHP Upper Left	WHP Lower Right	Anesthesia Left	Anesthesia Right
Pharmacy Tech: Time Savings	0:08:13	0:04:07	0:01:25	0:01:15	0:03:40	0:00:13	0:05:29	0:01:54
Pharmacist: Time Savings	0:10:29	0:06:30	0:03:37	0:04:20	0:12:17	0:03:41	0:10:59	0:03:50
Total: Time Savings	**0:18:42**	**0:10:37**	**0:05:02**	**0:05:35**	**0:15:57**	**0:03:54**	**0:16:28**	**0:05:44**

*Recorded times are listed as hh:mm:ss

Phase Two – Time Savings

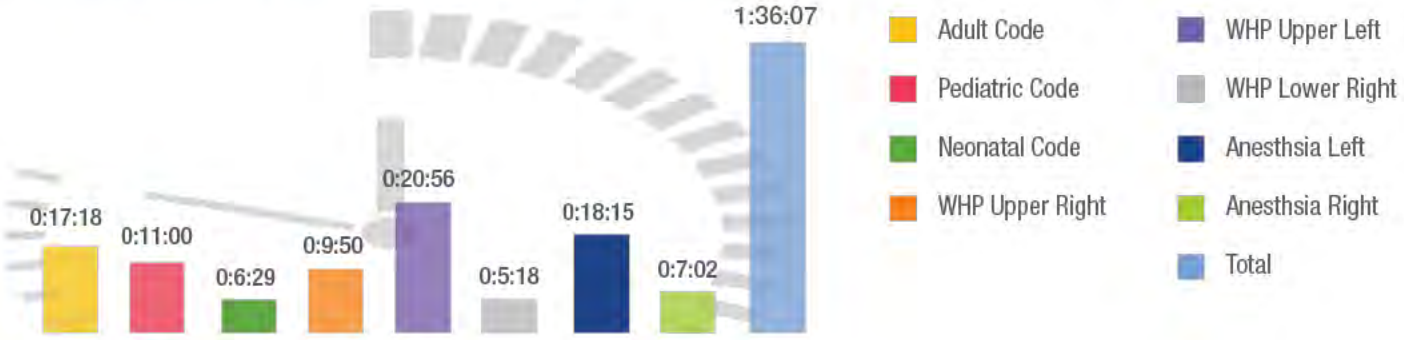
	Adult Code	Pediatric Code	Neonatal Code	WHP Upper Right	WHP Upper Left	WHP Lower Right	Anesthesia Left	Anesthesia Right
Pharmacy Tech: Time Savings	0:07:03	0:04:42	0:02:10	0:06:37	0:11:35	0:02:46	0:06:15	0:04:47
Pharmacist: Time Savings	0:08:51	0:06:41	0:05:47	0:07:27	0:14:19	0:03:56	0:13:46	0:03:33
Total: Time Savings	**0:15:54**	**0:11:23**	**0:07:57**	**0:14:04**	**0:25:54**	**0:06:42**	**0:20:01**	**0:08:20**

*Recorded times are listed as hh:mm:ss

"This system ensures that management sees that I've not only done my job, but it was done accurately and completely."
– Pharmacy Tech II, Scripps Health

In all cases, time savings was observed when using the Intelliguard® Kit and Tray Management System. Average time savings per tray processed ranged from just over 5 minutes to nearly 21 minutes depending on tray type. The cumulative average time savings for processing the 8 trays tested was **1:36 hours**: (Figure 1)

1 | Average Annual Time Savings (per tray type / in hours)



Data
Findings

RFID Smart Tag Encoding and Smart Batch™ Pharmacist Approval

To account for the task of tagging and encoding medications with an RFID Smart Tag, the study timed each test subject performing this function. The table below shows recorded time for the technicians to process 10 and 25 medications respectively. The pharmacist was timed using the Multi-Batch™ approval process to approve all 35 medications at once. The table below lists recorded time spent by each test subject to perform RFID Smart Tag encoding.

	10 Meds	25 Meds
Pharmacy Tech 1	0:03:05	0:07:00
Pharmacy Tech 2	0:02:01	0:03:40
Average Time	0:02:33	0:05:20

	35 Meds
Pharmacist 1	0:01:12
Pharmacist 2	0:01:40
Average Time	0:01:26

*Recorded times are listed as hh:mm:ss

Based on the data collected, it takes a Technician approximately 14 seconds to tag and encode one unit of medication and a Pharmacist approximately 2 seconds to approve one unit of medication.

Data
Findings – Accuracy

Specific Errors: Manual Workflow

As described, errors were embedded in the trays which needed to be replenished and study subjects were informed that errors were specifically included. The table below indicates errors still remaining in the trays after using the manual replenishment and approval process:

	Adult Code	Pediatric Code	Neonatal Code	WHP Upper Right	WHP Upper Left	WHP Lower Right	Anesthesia Left	Anesthesia Right
Total Errors	8	9	4	6	11	6	7	7
Tech 1	MI: phenytoin 5mL MI: magnesium sulfate 2mL	SALAD: DOBUTamine						EX: succinycho-line
RPh 1	MI: phenytoin 5mL	SALAD: DOBUTamine Incorrectly recorded expiration, which was originally correct						EX: succinycho-line
Total 1	1 (87%)	2 (78%)	0 (100%)	0 (100%)	0 (100%)	0 (100%)	0 (100%)	1 (86%)
Tech 2			EX: sodium chloride 0.9% Flush MI: sodium bicarb 4.2%				MI: ondansetron 2mL	
RPh 2								
Total 2	0 (100%)	0 (100%)	0 (100%)	0 (100%)	0 (100%)	0 (100%)	0 (100%)	0 (100%)

Data Findings

Errors By Percentage

	Adult Code	Pediatric Code	Neonatal Code	WHP Upper Right	WHP Upper Left	WHP Lower Right	Anesthesia Left	Anesthesia Right
Total Errors	8	9	4	6	11	6	7	7
Tech 1	2 (75%)	1 (89%)	0 (100%)	0 (100%)	0 (100%)	0 (100%)	0 (100%)	1 (86%)
RPh 1	1 (87%)	2 (78%)	0 (100%)	0 (100%)	0 (100%)	0 (100%)	0 (100%)	1 (86%)
Total 1	1 (87%)	2 (78%)	0 (100%)	0 (100%)	0 (100%)	0 (100%)	0 (100%)	1 (86%)
Tech 2	0 (100%)	0 (100%)	2 (50%)	0 (100%)	0 (100%)	0 (100%)	1 (86%)	0 (100%)
RPh 2	0 (100%)	0 (100%)	0 (100%)	0 (100%)	0 (100%)	0 (100%)	0 (100%)	0 (100%)
Total 2	0 (100%)	0 (100%)	0 (100%)	0 (100%)	0 (100%)	0 (100%)	0 (100%)	0 (100%)

Error Rates

Using the manual method, errors remained in trays after replenishment and approval, including missing, look alike/sound alike and expired medications.

Results

Error Elimination: Intelliguard® Kit and Tray Workflow

After the manual replenishment and approval process was complete, all trays were reset with the same errors. Then, the same individuals restocked and approved each tray using the Intelliguard® Kit and Tray Management System.

Using the Intelliguard® Kit and Tray Management System errors were completely eliminated:

	Adult Code	Pediatric Code	Neonatal Code	WHP Upper Right	WHP Upper Left	WHP Lower Right	Anesthesia Left	Anesthesia Right
Total Errors	8	9	4	6	11	6	7	7
Tech 1	100%	100%	100%	100%	100%	100%	100%	100%
RPh 1	100%	100%	100%	100%	100%	100%	100%	100%
Total 1	100%	100%	100%	100%	100%	100%	100%	100%
Tech 2	100%	100%	100%	100%	100%	100%	100%	100%
RPh 2	100%	100%	100%	100%	100%	100%	100%	100%
Total 2	100%	100%	100%	100%	100%	100%	100%	100%

Using the Intelliguard® Kit and Tray Management System replenishment and approval process, errors were completely eliminated

Results

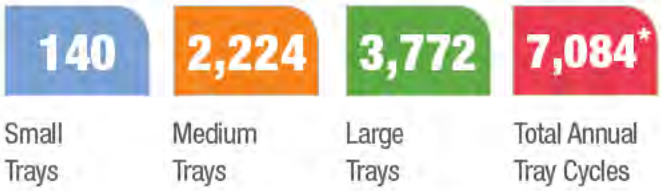
Time Savings

To calculate total expected time savings, the study considered all trays converted to the Intelliguard® Kit and Tray Management System. Each tray was divided into either a small, medium or large category based on the number of items located in the tray. The expected annual tray cycles are noted, extrapolated from actual tray cycles processed for 3 months. Trays which were not tested – but are still processed with the Intelliguard® Kit and Tray System – are highlighted in blue.

Tray Categories	Tray Name	Annual Tray Cycles
Small (1-15)	Neonatal Crash Cart	56
	Cardiopulmonary Tray	84
Medium (16-50)	Pediatric Crash Cart	64
	WHP Lower Right	524
	Anesthesia Right	1,492
	Pharmacist Code Box	140
	Regional Anesthesia Tray	40
Large (51-75)	Adult Crash Cart	480
	WHP Upper Right	608
	WHP Upper Left	124
	Anesthesia Left	1,504
	IAU-IR-Cath Right Tray	456
	IAU-IR-Cath Left Tray	228
Total	13	7,084

Based on the number of trays cycling through hospital pharmacy, the annual total number of tray cycles are projected at 7,084 or approximately 20 trays per day. Of these, the largest trays (containing between 51-75 items) are cycled through the system the most (Figure 2).

2 | Projected Annual Tray Cycles

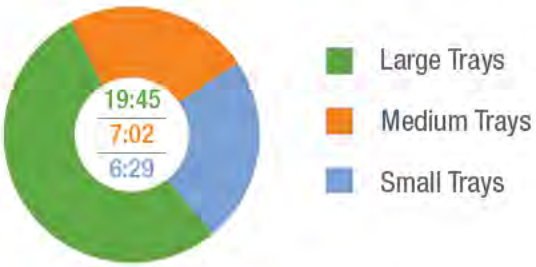


The average time savings per tray varied based upon the size of the tray. As expected, the larger the tray, the longer it took the Pharmacist and Pharmacy Technician to replenish and approve their trays.

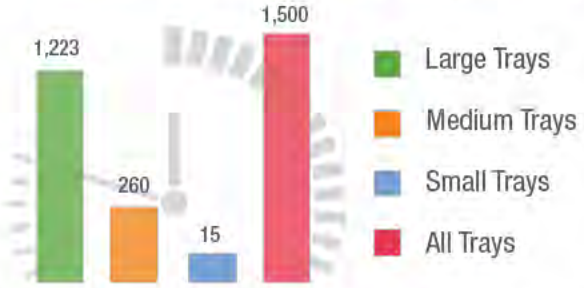
*Approximately 20 trays per day

On average, the Intelliguard® Kit and Tray Management System saved 19.5 minutes with large trays and 6.3 minutes for even the smallest trays (Figure 3). These figures total almost 1,500 hours of annual time savings by solely using the Intelliguard® System for processing and approving trays (Figure 4).

3 | Average Time Savings/Tray Type



4 | Expected Annual Time Savings (in hours)



*Even more time savings is anticipated when using the system for monthly inventory checks for expired and soon-to-expire medications as well as recalled medication events.

Analysis

As confirmed in this study, using the manual checking method allows greater possibility for human error; leaving more chance for an expired, used or incorrect medication left in these trays and increasing the likelihood of an audit infraction or worse, a patient medication error. Plus, it takes between 9-27 minutes for each team to check and replenish each tray.

Using the Intelliguard® Kit and Tray Management System is proven to save staff time and provides assurance that each task is performed with 100% accuracy. Automation eliminates human error, distraction and exhaustion that goes along with manually checking these trays – and the Intelliguard® System does not permit steps in the process to be missed or skipped.

Additional Benefits

Another advantage of automating the kit and tray management process is the ability to track where medications are located in the event of a recall. A simple report within the Intelliguard® System allows users to review the specific trays in which recalled medication is located. In the absence of an automated kit and tray management solution, a recall requires staff to open every single tray that includes the recalled medication to see whether that specific lot number is on the recall list. This process alone can take days.

Detailed reports within the Intelliguard® System also give management the ability to track medication usage to justify decreasing or eliminating medications which are infrequently or never used, or increasing PAR levels for medications which are used more frequently. Inventory reports allow for quicker and more accurate monthly inventory checks when looking for expired or soon-to-expire medication as the Intelliguard® System automatically tracks medication expiration dates. Every time a kit or tray is returned to the pharmacy for reprocesing, the Intelliguard® System instantly indicates expired and soon-to-expire medications.

From staff's perspective, the Intelliguard® workstations are ergonomically designed to maximize productivity by reducing fatigue and discomfort, and the user interface is intuitive and easy-to-use. Even new staff can navigate through the process with minimal training.

Additionally, with the Intelliguard® Virtual Logbook – management has visibility to the specific dispensed location of kits and trays once they leave the pharmacy. This function is particularly helpful during monthly inventory checks or recall events. Management simply views the Virtual Logbook report to determine which trays contain expired, expiring or recalled meds – and the specific deployed location of the tray(s). This process alone can save the hospital countless man hours by targeting staff to only those kits and trays that need attention.

"RFID systems for medication inventory, such as those from MEPS Real-Time®, have demonstrated that hospital pharmacies can achieve higher levels of efficiency while also improving patient safety."

Conclusion

Increased efficiency by eliminating the tedious manual process of kit and tray replenishment allows repurposing of over-worked staff. More importantly, serious medication errors can occur if the correct medication is not available for patient care.

The Intelliguard® Kit and Tray Management System provides an efficient, more accurate way for Pharmacy staff to manage tray restocking while providing clinicians access critical medications quickly – when and where they need them.

The Virtual Logbook provides visibility to know the who, what, where and when of each kit and tray – throughout the hospital at any given time.

About MEPS Real-Time, Inc.

Founded in 2006 and headquartered in Carlsbad, CA, MEPS Real-Time, Inc. is a leading innovator of Radio Frequency Identification (RFID) solutions for pharmacy automation and inventory management. Our suite of Intelliguard® RFID Solutions offers unprecedented real-time visibility of high-value, critical-dose drug inventory to reduce costs through inventory management and monitoring of expiration dates, NDCs, lot numbers and temperature; increase staff efficiency by eliminating manual counting and item-level scanning through automation; improve patient safety through medication error prevention; and enhance diversion prevention with embedded security features. Intelliguard® RFID Solutions include Kit and Tray Management, Inventory Management and Vendor Managed Inventory Systems.

Today, our suite of Intelliguard® RFID Solutions are used in major medical centers in the U.S. and Canada with a focus on RFID as an enabling technology for pharmacy workflow automation and inventory management systems.

For more information, call (760) 448-9500 or visit www.mepsrealtime.com.

Please note that in California a new law has passed, SB 1039, in 2014 which will allow technicians and intern pharmacists under the supervision of a licensed pharmacist in a healthcare facility to package emergency supplies, seal emergency containers and perform monthly checks of drug supplies. Unfortunately, this law currently conflicts with Ca DPH Title XXII which mandates a pharmacist perform these functions. As of Dec. 16, 2014 a California All Facilities Letter, ALF 14-34, addressed this problem. It will allow facilities interested in implementing the SB 1039, do so by developing policies and procedures, then submitting them to the Ca DPH via a program flexibility request form. This in combination with the California Tech check Tech regulations could free up significant pharmacist time to support the clinical pharmacist duties.

Phone 760-448-9500
Email sales@mepsrealtime.com
Web www.mepsrealtime.com

MEPS® REAL-TIME, INC.

MEPS®, MEPS Real-Time® and Intelliguard® are registered trademarks and RFID Solutions for Critical Inventory™ is a trademark of MEPS Real-Time, Inc., Carlsbad, CA.

900-063, rev A

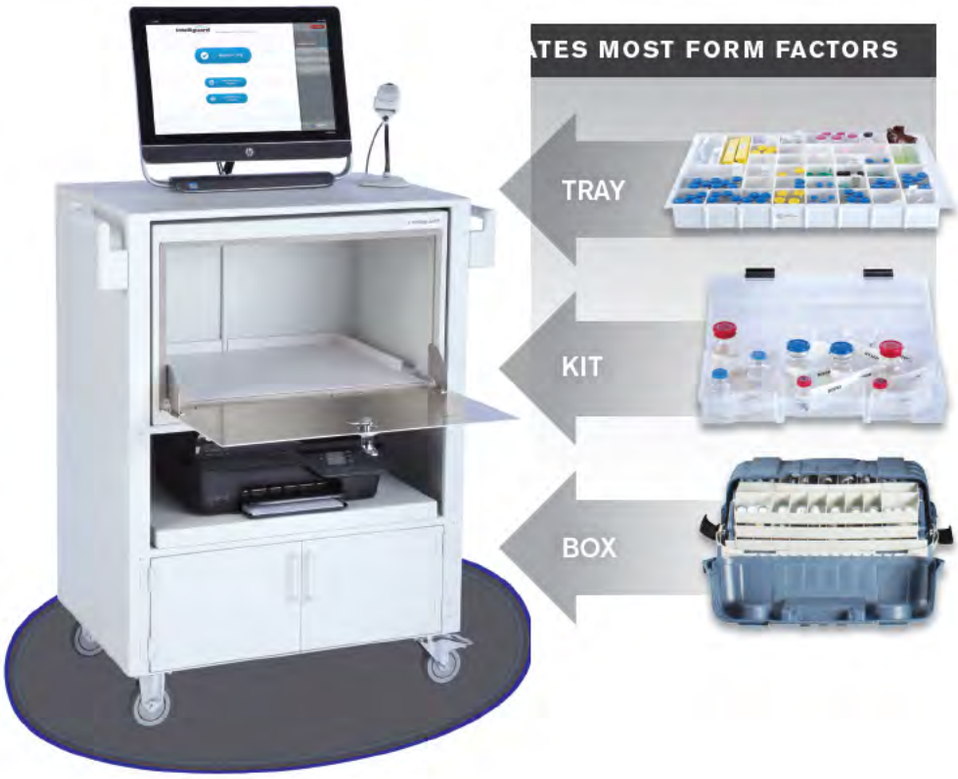
intelliguard® | RFID Solutions for Critical Inventory™

Tap Into the Automated Way to Process Pharmacy Kits, Trays and Boxes

Intelliguard® Kit and Tray Management System

The Intelliguard® Kit and Tray Management System uses advanced RFID technology to automate medication inventory management and replenishment. With the ability to read high-density trays, multi-layer tackle boxes and overlapping kit labels, this revolutionary system can scan more than 150 medications in a matter of seconds.

- A standalone accessory – no IT needed
- Touchscreen user interfac
- Increases accuracy of identifying expired, soon-to-expire and recalled medications
- Reduces the cost of held inventory
- Improves patient safety
- Provides printable reports that highlight critical information for each kit an help prepare for audits mc quickly and accurately



intelliguard® | RFID Solutions for Critical Inventory™

Intelliguard® Kit and Tray Management System

Replenishing medications, checking expiration dates and filling out paperwork for multiple medication kits – *multiple times each day* – adds up to a lot of time… and it is no one's favorite job. Plus, there's a significant risk for human error.

That's why the innovators at MEPS Real-Time® developed the smarter, automated kit checking solution. Using patented and exclusive RFID technology, our Intelliguard® Kit and Tray Management System saves you time and ensures medication kit inventories are always complete and accurate.

Smaller stations. Smaller tags.

We understand hospital pharmacies: space is limited! MEPS Real-Time® is the only company that gives you the choice of three space-saving, ergonomic solutions for your main pharmacy, satellite pharmacies and surgery centers.

We also know space is limited in your trays. Feedback from hospital anesthesiology and clinicians was unanimous. Our Intelliguard® RFID Smart Tag, the smallest in the industry, makes medications easier to handle and eliminates the potential for medications to become stuck in anesthesia cart drawers.

With its ability to read high-density trays, multi-layer tackle boxes and overlapping tags, our Intelliguard® System can inventory more than 150 medications in seconds with 100% accuracy of identifying missing, expired, soon-to-expire and recalled medications.

Contact us to set up a webinar and see how we fit your pharmacy.

Our on-site implementation and training team will have your trays fully converted and your staff replenishing faster and more accurately in days.

The smarter kit checking solution!

Three Solutions

All-in-One

Free-standing, all inclusive cart for use with multi-layer tackle boxes

Countertop

Space-saving counter-top unit for kits and trays

Under Counter

Under-counter mount option

Phone 760-448-9500
Email sales@mepsrealtime.com
Web www.mepsrealtime.com

MEPS® REAL-TIME, INC.

MEPS®, MEPS Real-Time® and Intelliguard® are registered trademarks and RFID Solutions for Critical Inventory™ is a trademark of MEPS Real-Time, Inc., Carlsbad, CA.

900-0060, rev A

Countertop for installation in Pharmacy and OR Satellites

Countertop

Space-saving counter-top unit fits kits and trays

How it Works

Encoding Intelliguard® RFID Smart Tags

Smart Batch™ Encoding of RFID Smart Tags

1

Open sealed case or flat and apply blank tags

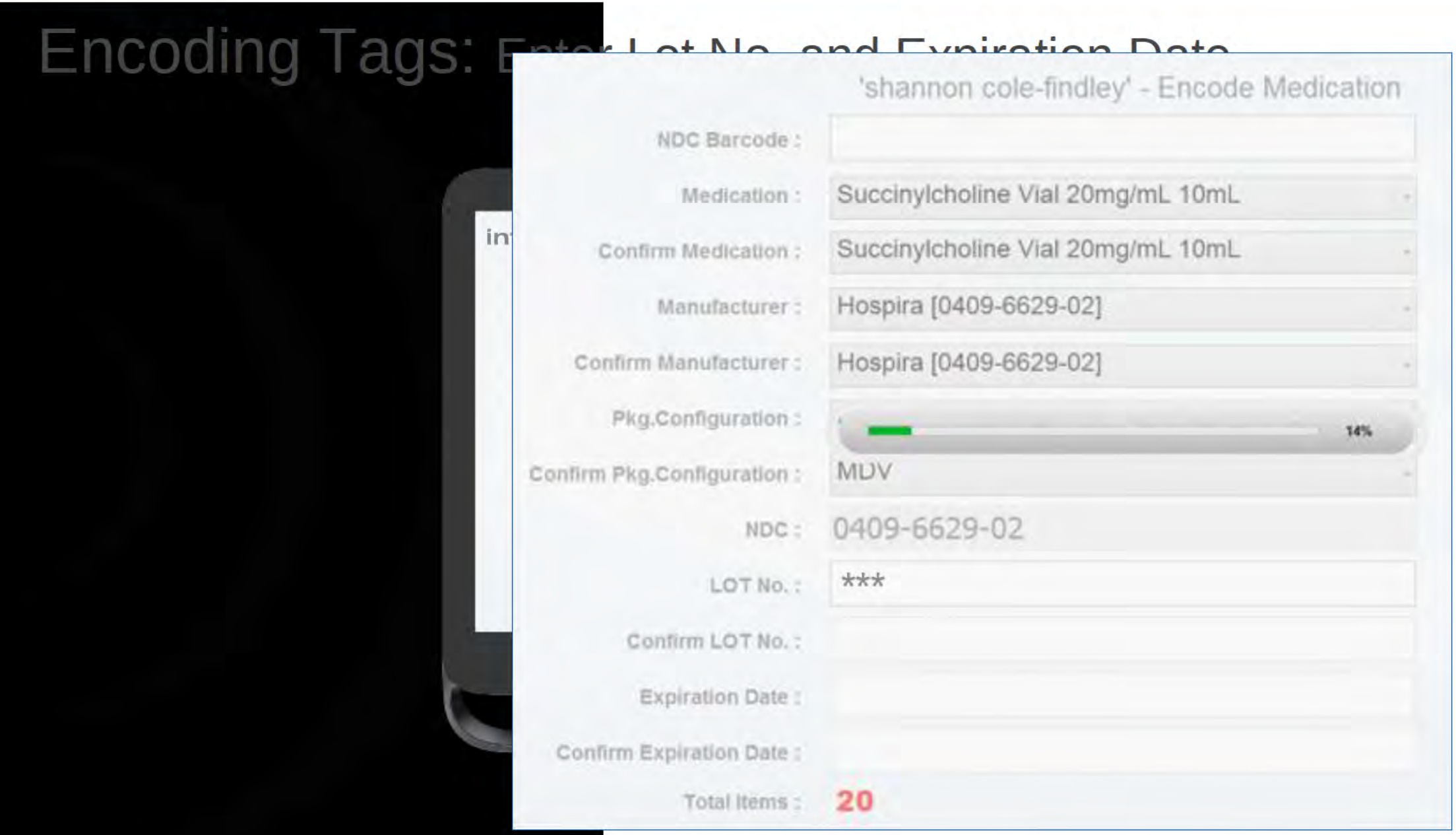
2

Place entire medication lot into workstation

3

Scan one barcode then enter Expiration and Lot Number.

Encoding Tags: Enter Lot No. and Expiration Date



Encoding Tags:

NDC Barcode :

Review Summary for Encoded Medication

Medication	Manufacturer	Lot Num	Exp. Date	Qty.	Package
Succinylcholine V...	Hospira [0409-66...	125	12/31/2019	20	MDV

Do you want to proceed with the above summary?

YES NO

Encoded Medications: Concurrent Multi-Batch™ Pharmacist Approval

Smart Multi-Batch Approval™

- Place multiple batches of medication in enclosure
- Scan to approve
- Inventory ready for use

Averages Less than 2 Minutes to Encode (Per Case/Flat)

intelliguard

Detailed View

'Awais Chaudhry' - Approve Medications

Item Name	Lot No	Exp. Date	Qty	Status	Select
Rocuronium 10mg/mL 5mL Vial	MY153	4/30/2017	10	Quarantined	☐
Succinylcholine Vial 20mg/mL 10mL	HOSP77777	1/31/2017	10	Quarantined	☐
Acetylcysteine 20% 30mL Inh 200mg/mL 30mL	APP159	12/31/2017	10	Quarantined	☐
Neostigmine 1:1000 1mg/mL 10mL	WEST3333	7/31/2017	10	Quarantined	☐

Total Items : 40

Edit Inventory | Scan | Accept | Main Menu

intelliguard

Detailed View

'Awais Chaudhry' - Approve Medications

Item Name	Lot No	Exp. Date	Qty	Status	Select
Rocuronium 10mg/mL 5mL Vial	MY153	4/30/2017	10	Approved	☐
Succinylcholine Vial 20mg/mL 10mL	HOSP77777	1/31/2017	10	Approved	☐
Acetylcysteine 20% 30mL Inh 200mg/mL 30mL	APP159	12/31/2017	10	Approved	☐
Neostigmine 1:1000 1mg/mL 10mL	WEST3333	7/31/2017	10	Approved	☐

Total Items : 40

Edit Inventory | Scan | Accept | Main Menu

Tray Replenishment: 3 Process Flows to Fit Your Needs

Standard Technician-Pharmacist Workflow
(Pharmacist Checker)

Technician-Technician Workflow
(Technician Checker)

Tray Replenishment in 3 Easy Steps - Technician

1

Visual inspection and RFID scan

2

Replace missing and expiring medication as shown on pick list

3

Final inspection for refrigerated meds & ancillary labeling

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RFID Solutions for Critical Inventory

Main Menu | Log Out

Restock the tray with

Ensure each me

Medication

Item Name

Rocuroniun

Discrepancy Summary

Medication	Lot No	Exp. Date	Description	TagID
Rocuronium 5mL Vial	123	6/10/2014	Expired	25127C

Please remove all above discrepancies to proceed.

OK

If desired,

Item Name	Manufacturer	Lot #	Expiration Date	Quantity
Rocuronium 5mL Vial	Mylan Institut...	123	6/10/2014	1

tails

ity 117

uantity 118

Pick Lists

Demo Anesthesia Tray 2

2

4

MEPS REAL-TIME, INC.

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Restock the tray with the missing items listed below then press "Rescan Tray".

Rescan Tray

Ensure each medication is in appropriate pocket within the tray.

Medication Pick List

Item Name	Needed
Succinylcholine Vial	1
Propofol 1% 20mL	1
Cisatracurium	1

If desired, replace items expiring within 30 EDIT days

Item Name	Manufacturer	Lot #	Expiration Date	Quantity
Atropine 0.4mg/1mL	American Re...	AT33	9/30/2014	1
Vecuronium	Sun	YOU1	4/30/2015	1
Pancuronium	TEVA	123	10/8/2014	4

Main Menu

Log Out

Tray Details

Par Quantity	117
Current Quantity	114

Print Pick Lists

Tray	Demo Anesthesia Tray 2
Tray #	2
Cycle #	4

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Tray Replenishment in 3 Easy Steps - Technician

1

Visual inspection and scan

2

Replace missing and expiring medication as instructed

3

Final inspection for refrigerated meds & ancillary labeling

Tray Replenishment in 3 Easy Steps - Technician

1

Visual inspection and scan

2

Replace missing and expiring medication as instructed

3

Final inspection for refrigerated meds & ancillary labeling

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RFID Solutions for Critical Inventory

Welcome **shannon cole-findley** to the Kit & Tray Management System

Main Menu | Log Out

Please confirm new expiration date(s) on the new refrigerated medication(s), multidose medication(s) and verify all ancillary label(s) are attached to the medication(s) listed below.

Save & Proceed

Refrigerated Medication Expiration Date

Item Name	Lot #	Original Expiration Date	New Expiration Date	Tag ID
Succinylcholine Vial	125	12/31/2019	08/19/2015	25B6ED

Multidose Medication Expiration Date

Item Name	Lot #	Original Expiration Date	New Expiration Date	Tag ID	Used ?
Nalbuphine 10mL MDV	123	12/31/2017	09/16/2014	250FE5	☐
Nalbuphine 10mL MDV	123	12/31/2017	09/16/2014	2511CA	☐

Please be sure to add an updated expiration date label to the medication below before proceeding.

Ancillary Labels

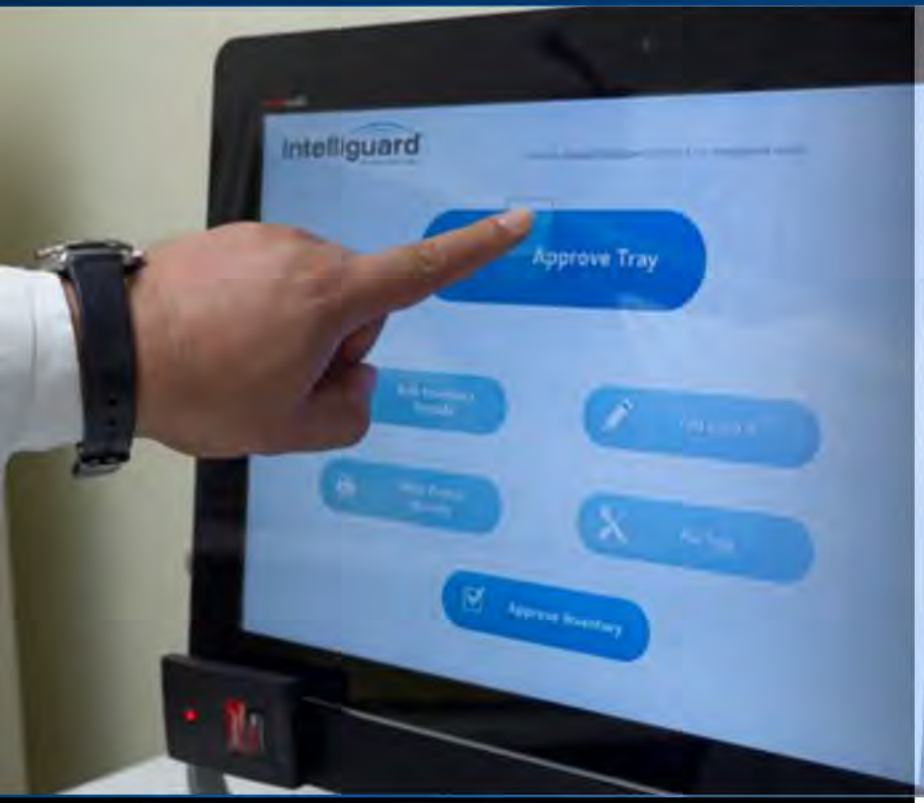
Item Name	
Rocuronium 5mL Vial	WARNING: Paralyzing Agent
Succinylcholine Vial	WARNING: Paralyzing Agent

Tray Details

Par Quantity	117
Current Quantity	117
Tray	Demo Anesthesia Tray 2
Tray #	2
Cycle #	4

MEPS REAL-TIME, INC.

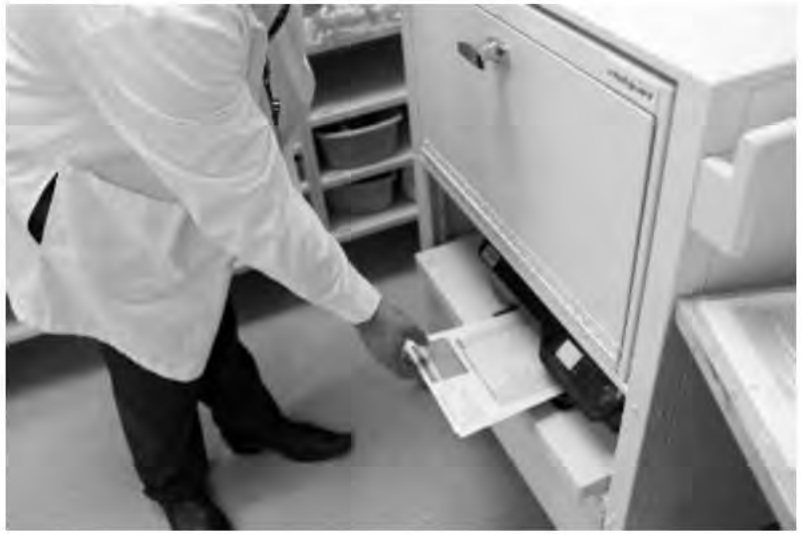
Approving the Tray– Secondary Workflow



*"The other concern was a **safety issue**: ensuring that situations never arose in which medications were unavailable when required, and that drugs nearing their expiration dates could **easily be identified and removed.**"*

– Pharmacist-in-Chief, Rady Children's Hospital

Tray Approval in 3 Easy Steps



1

RFID scan to confirm tray is complete and error free

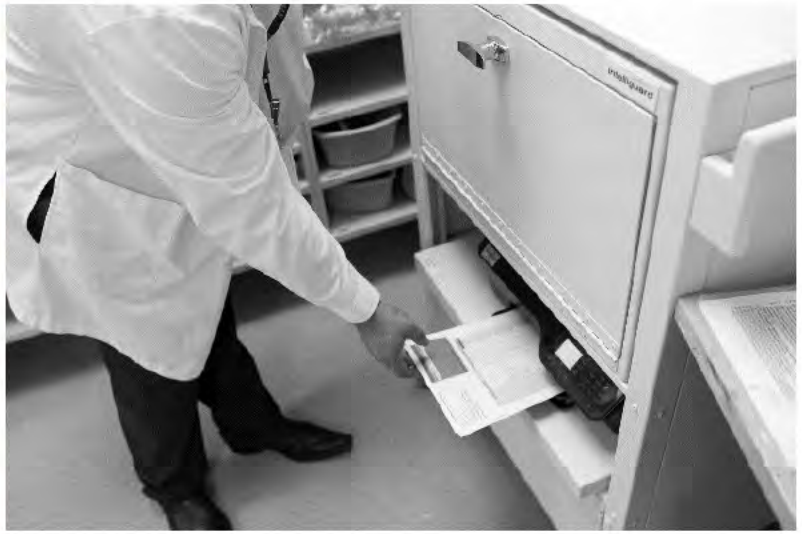
2

Capture lock number (optional)

3

Print tray inventory report

Tray Approval in 3 Easy Steps



1

Scan and confirm tray is complete and error free

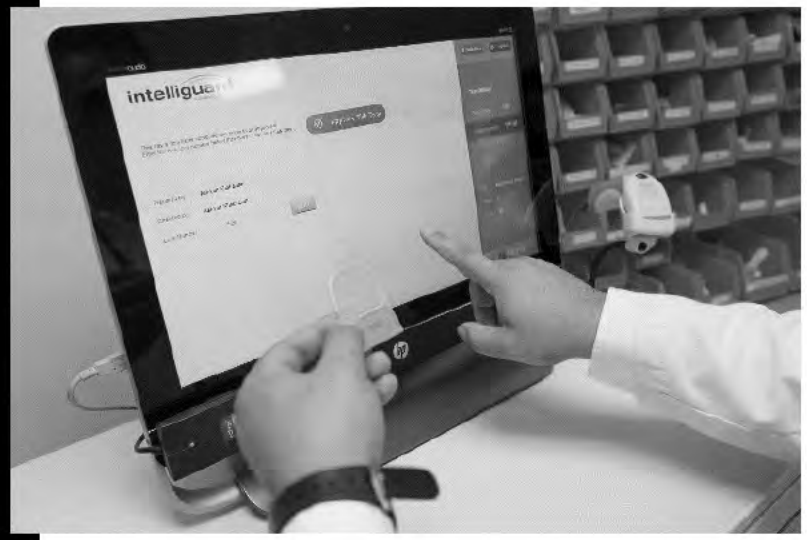
2

Capture lock number (optional)

3

Print tray inventory report

Tray Approval in 3 Easy Steps



1

Scan and confirm tray is complete and error free

2

Capture lock number (optional)

3

Print tray inventory report

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Welcome **shannon cole-findley** to the Kit & Tray Management System

Main Menu | Log Out

Tray has been saved & successfully approved.
Print the report and place with the tray.

Print Tray Report

Anesthesia Tray 2 Detail Report

Tray Number	2
Cycle Number	4
Report Date	08/19/14
Report Time	02:32 PM
Prepared By	shannon cole-findley
Approved By	Roy Jones

Ensure that the earliest expiring medication is correct.

Earliest Item(s) to Expire

Nalbuphine 10mL MDV 09/16/2014

IF EXPIRED, CALL PHARMACY @867-5309

Tray Details

Par Quantity	117
Current Quantity	117

View Completed Item List

Item Name	Expiration Date	Quantity
Etomidate 10mL	12/31/2016	2
Rocuronium 5mL Vial	08/12/2015	3
Succinylcholine Vial	08/12/2015	2
Esmolol	12/31/2015	2

MEPS REAL-TIME, INC.

Virtual Logbook

Visibility to Kit and Tray Deployment Enterprise-Wide

ed location of drug kits and
y were released

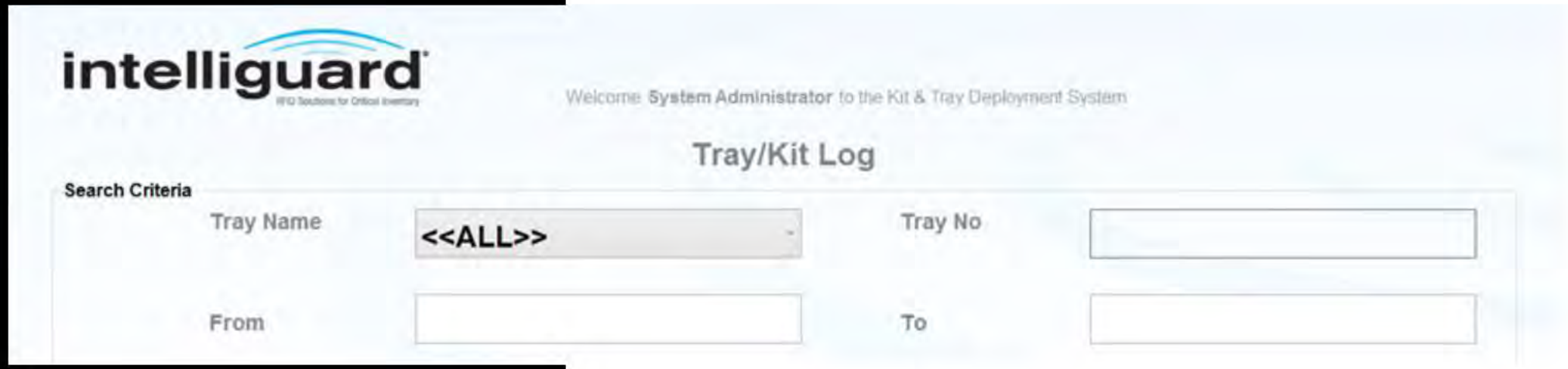
e Intelliguard® Kit and Tray

user interface, tray
sily recorded, including:

- Approving Pharmacist
- Deployment Date
- Technician Name
- Deployed Location
- Deployed to (Name)

Save staff countless hours by no longer having to search and manually check each tray to seize recalled, expiring or expired items

Virtual Logbook



Tray Name	Tray No	Cart No	Stock Date	First Exp Med	Exp Date	Approved Pharmacist	Deploy Date	Tech Name	Deployed Location	Deployed To Name
Code Tray	11	5	10/4/2014	Epinephrine 1 mg…	12/5/2014	Victor Tran	10/7/2014	Jill Hansen	Cardiology	Danielle Taber

105 4/10/2015

IOWA PHARMACIST LICENSE RENEWAL APPLICATION

REMINDER: Iowa law requires a pharmacist to notify the Board within 10 days of a change of legal name, address, or employment.

Please type or print clearly in ink. Make changes as necessary.

RECEIVED OCT 05 2015 IOWA BOARD OF PHARMACY

1 License No.: 21184
Social Security No.: XXX-XX-[redacted]

2 Name, Address:

KOLB MATTHEW
6555 W 59TH ST
CHICAGO IL 60638-

LICENSE FEE: $180.00 *

- * Fee for License renewal between July 1 and July 31: $360.00
- * Fee for License renewal between August 1 and August 31: $450.00
- * Fee for License renewal between September 1 and September 30: $540.00
- * Fee for License reinstatement after September 30: $630.00

Remit check or money order payable to:
IOWA BOARD OF PHARMACY
(DO NOT SEND CASH)

3 Iowa County: NA
Home Telephone Number: (773) 301 - 9049

4 E-mail address: ginker76@yahoo.com

5 Degrees in Pharmacy: *(check all that apply)* ____ B.S. X Pharm.D. ____ Other *(specify)* _____

6 List all other states in which you are currently licensed to practice pharmacy: IL, AR, FL, TN, IN, NE, NV

DISCIPLINARY/CRIMINAL HISTORY:

7 Since initial licensure in Iowa or another state, has your license in any state been disciplined? Discipline includes, but is not limited to, citations, reprimands, fines, license restrictions, probation, license surrender, suspension, or revocation. If yes, provide a written explanation of the discipline on a separate sheet. Provide copies of documentation from the licensing authority regarding the discipline unless complete documentation has previously been provided to this Board.

____ yes X no When _____

8 Since your last license renewal application, have you been convicted of, or entered a plea of guilty, nolo contendere, or no contest to a crime, other than a minor traffic offense, in any jurisdiction? You must include all misdemeanors and felonies, even if adjudication was withheld by the court so that you would not have a record of the conviction. For example, you must report if your conviction was expunged, you received a deferred judgment, or you received an executive pardon. Driving under the influence or driving while impaired is not a minor traffic offense and must be reported. If yes, provide a written explanation of the charge and the final outcome on a separate sheet. Provide copies of court documents related to each incident. ____ yes X no When _____

CONTINUING EDUCATION:

9 Are you a **resident of AND** are you currently **licensed to practice pharmacy in** another state that requires continuing education for pharmacist licensure? X yes ____ no If yes, State IL License Expiration Date 3-31-16
(If yes, indicate the state and license expiration date. Out of state licensure and residence combine to satisfy Iowa CE requirements UNLESS you are practicing pharmacy in Iowa. If you qualify under this provision, skip to Item 12.)

10 Is this your first license renewal following Iowa licensure by examination? ____ yes X no
If yes, you are EXEMPT from Iowa's continuing education requirements for THIS RENEWAL ONLY -- skip to Item 12.
(You will be required to complete continuing education, as indicated in Item 11, on your next Iowa license renewal.)

11 ACCREDITED/APPROVED CONTINUING EDUCATION ACTIVITIES ATTENDED OR COMPLETED.

a) I hereby certify that I have completed the required 30 contact hours (3.0 CEUs) of continuing education (or alternate requirement provided by Board rules and described below) and that none of the credits relied on for this license renewal have previously been used for Iowa license renewal. I further certify that all credits relied on for this license renewal were obtained during the following 27-month license renewal period. MK **(initial)**

RENEWAL PERIOD: April 1, 2013, through **June 30, 2015.**

I hereby further certify, by initialing following each statement below, that I have completed the specific continuing education requirement or alternative indicated by the statement during the 27-month renewal period indicated.
(You may need to certify more than one statement regarding your CE activities. Initial following each statement that applies.)

b) During the 27-month renewal period indicated, I have completed a minimum of 15 contact hours of CE in ACPE-provider activities dealing with drug therapy. The ACPE universal activity number for a drug therapy activity ends with "01" or "02." Only activities with identification numbers ending "01" or "02" will be accepted to fulfill this requirement. MK (initial)

c) During the 27-month renewal period indicated, I have completed a minimum of 2 contact hours of CE in ACPE-provider activities in pharmacy law. The ACPE universal activity number for a pharmacy law activity ends with "03." MK (initial)

d) During the 27-month renewal period indicated, I have completed a minimum of 2 contact hours of CE in activities dealing with medication or patient safety. ACPE-provider activities ending "05" may be used to fulfill this requirement. This requirement may also be fulfilled by completion of nonACPE-provider activities pursuant to 657 subrule 2.12(1)(a). MK *(initial)*

e) If I am a pharmacist engaged in the administration of vaccines pursuant to rule 657—8.33, I have completed a minimum of 1 contact hour of CE dealing with vaccines. _____ *(initial)* or MK *(Not Applicable)*

f) During the 27-month renewal period indicated, I was approved for exemption from CE requirements while continuing formal education in a health-related graduate program. _____ *(initial)* _____ *(approved exemption period)*

g) I have completed and submitted with this application a continuing professional development (CPD) portfolio pursuant to rule 657—2.17. _____ *(initial)*

If you have not completed a total of at least 30 contact hours of CE (including a minimum of 15 hours in ACPE-provider activities dealing with drug therapy, 2 hours in ACPE-provider activities in pharmacy law, and 2 hours in activities dealing with patient or medication safety), OR have not met the CE requirements of another state in which you currently reside and are licensed to practice pharmacy, OR have not been granted an exemption from CE requirements, OR have not completed and submitted a continuing professional development portfolio pursuant to rule 657—2.17, you will be issued an INACTIVE license.
AN INACTIVE LICENSEE MAY NOT PRACTICE PHARMACY IN IOWA.

CURRENT PRACTICE/EMPLOYMENT:

12 Principal place of employment.
Business Name Unemployed
Address _____
City _____ State _____ Zip _____

(a) Nature of pharmacy practice (if any) at this location *(check one)*:

____ Community ____ Mail Order/Managed Care ____ Hospital
____ Long-Term Care ____ Home Health Care ____ Nuclear
____ Correctional Facility ____ Wholesale/Distribution ____ Manufacture
____ Education ____ Government X Other (specify) N/A

(b) If primary employment is not in pharmacy or related practice, please indicate employment status *(check one)*:
X Unemployed but Not Retired ____ Retired ____ Engaged in Other Practice *(specify)* _____

13 Are you currently practicing pharmacy in Iowa? ____ yes X no If yes, complete (a), (b), and (c) below.

(a) Iowa Pharmacy License Number of primary practice site: _____

(b) Nature of pharmacy employment in Iowa *(check all that apply)*:
____ Proprietor/Sole Owner ____ Partner ____ Employee Manager *(PIC, Director, Supervisor)*
____ Employee Pharmacist *(Staff, Clinical)* ____ Retired Pharmacist, Occasional Relief Work *(Approx. hrs/year)* _____

(c) Hours worked per week in pharmacy in Iowa. *(Estimate the average number of hours spent each week in each of these practice settings. The sum of the hours should equal the total hours you typically work each week in pharmacy in Iowa.)*
_____ Independent Community Pharmacy _____ Chain Pharmacy _____ Long-Term Care Pharmacy
_____ Mail Order/Managed Care Pharmacy _____ Hospital Pharmacy _____ Home Health Care Pharmacy
_____ Industry *(Wholesale, Manufacture, etc)* _____ Nuclear Pharmacy
_____ Correctional Facility Pharmacy _____ Other Phcy-related *(Education, Government, Association, etc)*

REMIT TO: IOWA BOARD OF PHARMACY
400 S.W. EIGHTH STREET, SUITE E
DES MOINES, IA 50309-4688
PHONE: (515) 281-5944

Information provided on this application may be disclosed pursuant to 657 IAC Chapter 14.

I hereby swear under penalty of perjury that the information provided in this application is true and correct. I understand that failure to provide complete and truthful information may constitute grounds for revocation or other disciplinary sanctions against my license. I also understand that if my license is not renewed to active status prior to expiration, it is illegal to continue to practice pharmacy in Iowa.

SIGN HERE ➡ _____ *Signature of Licensed Pharmacist* 9/28/15 *Date*

INCOMPLETE APPLICATIONS WILL NOT BE ACCEPTED AND WILL BE RETURNED TO APPLICANT

Privacy Act Notice: *Disclosure of your Social Security number on this license application is required by 42 U.S.C. §666(a)(13) and Iowa Code §§ 252J.8(1), 261.126(1), and 272D.8(1) (2009). The number will be used in connection with the collection of child support obligations, college student loan obligations, and debts owed to the state of Iowa, and as an internal means to accurately identify licensees, and may be shared with taxing authorities as allowed by law including Iowa Code § 421.18 (2009).*

After filling out form, print, sign, and mail to: Iowa Board of Pharmacy 400 SW 8th Street, Suite E, Des Moines, Iowa 50309-4688. Deadline for inclusion on Board's agenda is three weeks prior to Board meeting.

Case No. or State ID No.

Rec'd:

IOWA BOARD OF PHARMACY
Petition for [x] Waiver [] Variance
(check the appropriate box)

PLEASE PRINT OR TYPE ALL INFORMATION IN INK

A waiver excuses the petitioner from the requirements of a rule in its entirety or from a part of a rule; a variance does not. Instead, a variance is a modification to the requirements of a rule or a part of a rule. Example: A rule requires the fencing of certain property and further requires that the fence be at least 6 feet in height. A waiver of that rule would excuse the petitioner from the requirement for fencing the property. A variance would require the property be fenced but would allow the petitioner to maintain the current fencing configuration of 5 feet in height (perhaps the fence was constructed prior to the height requirement). When replacement of the current fence becomes necessary as a consequence of normal wear and tear, the variance would terminate and the petitioner would be required to comply with the 6-foot height requirement.

Note: Statutory requirements that have been repeated in administrative rules are not subject to consideration for a waiver or variance.

Is this petition an initial request or is it a request for renewal? [X] Initial Request [] Request for Renewal
If a request for renewal, explain below why the renewal is necessary.

Petitioner Information (include licensee/registrant name and name of contact person, i.e. pharmacist in charge)

Name: **Matthew John Kolb**
Phone No.: **773-301-9049**
Pharmacist license# **21184**

(include area code)
Address: **6555 W 59th St**
City: **Chicago** State: **IL** Zip Code: **60638**

Petition Information

1. Chapter Number and Title.

   CH 2, P. 4

2. Rule Number(s) and Title(s).

2.11(1) LATE PAYMENT PENALTY

3. Describe in your own words the essence of each Rule Number(s) and Title(s) that pertains to this petition.

   I would like to be exempted from the late fee on my license.

4. Describe the specific nature and scope of your petition. In your description, include the anticipated time period (beginning and ending) for which the petition would apply. A waiver or variance may not be requested or granted on a permanent basis; the petition must identify an end date.

After filling out form, print, sign, and mail to: Iowa Board of Pharmacy
400 SW 8th Street, Suite E, Des Moines, Iowa 50309-4688. Deadline for inclusion on Board's agenda is three weeks prior to Board meeting.

This is a onetime request specific to only the renewal of my license occuring in 2015.

5. Describe the relevant facts and reasons that, in your opinion, justify and provide "clear and convincing evidence" as to why this petition merits consideration for waiver or variance. In your description, explain why the rule(s) poses an undue hardship. If there is a public health, safety and welfare issue associated with this rule(s), or if this rule(s) addresses security or confidentiality issues, also explain how equal protection will be maintained if this petition were granted.

I obtained my Iowa pharmacist license in 2010 as a requirement for a position with Rx Remote Solutions. I ceased working there in May of 2014 and took a new job at Midwest Benefits Pharmacy. I was not using my Iowa license at Midwest Benefit Pharmacy. But unfortunately, I was laid off from that position in June of 2015 because the pharmacy closed (in the same month that my Iowa license expired).

It came as a surprise and I was very distraught and worried about my financial situation because the job market around Chicago is very poor for pharmacists seeking employment. I had chosen at the time to not renew my Iowa license because of these financial concerns. But now I have found a potential job with Cardinal Health where they are specifically looking for Iowa licenses in order to do remote order entry with them. It is only a part-time position but at least I would be making some money again.

It would be very helpful for me to have my late fee waved because I am still in a difficult situation financially and have yet to find full-time employment after more than 2 months . Thank you very much for hearing my petition and I hope you will be able to help me in this0 situation.

6. Does anyone else (inside or outside state government) possess knowledge relevant to this petition?

[X] Yes [] No [] Do not know

If yes, list their names, addresses and phone numbers below.

Midwest Operating Engineers Human Resources (who can confirm my loss of job):
Kerriann Travis
708-482-7300

6150 Joliet Rd
Countryside, IL

7. Would anyone (inside or outside state government) be adversely affected if this petition were granted?

[] Yes **[x] No** [] Do not know

If yes, list their names, addresses and phone numbers below.

8. Do you know how the Board of Pharmacy has treated similar situations?

[] Yes **[x] No**

After filling out form, print, sign, and mail to: Iowa Board of Pharmacy
400 SW 8th Street, Suite E, Des Moines, Iowa 50309-4688. Deadline for inclusion on Board's agenda is three weeks prior to Board meeting.

If yes, describe below how similar situations were handled.

9. Have you had any past interaction with the Board of Pharmacy that might impact or relate to this petition?

[] Yes **[x] No**

If yes, describe below the issue involved and the outcome.

I authorize any person with knowledge of the relevant or important facts relating to this petition to release any pertinent information to the Iowa Board of Pharmacy. I hereby attest to the accuracy and truthfulness of the information contained herein.

Petitioner's Signature

9/28/15
Date

MATTHEW J KOLB

[redacted]

[redacted]

9/28/15
Date

Pay to the order Iowa Board of Pharmacy $ 540.00

Five hundred + forty Dollar

Security Features Details on Back

[redacted]

[redacted]

For Renewal of License # 21184

[redacted]

ROADRUNNER PHARMACY

Dear Pharmacy Board Member,

As you may know, the FDA is proposing "Guidance for Industry-Compounding Animal Drugs from Bulks Drug Substances." This guidance is remarkable in its restrictions and impact to the veterinary community such as:
-documenting clinical need on each prescription for compounded drugs
-no office stock of compounded medicinals, sterile or otherwise
-scripts to be pet-specific--no flocks, fish or groups of shelter animals
-no allowance for dispensing of acute amounts from office stock

Not only do we find these guidelines contrary to the practice of contemporary veterinary medicine, they are also detrimental to pharmacies, many of whom are no longer making sterile products.

Enclosed is the AVMA response to this proposal which addresses serious deficiencies, intensified record keeping and discusses the need and urgency for compounded sterile items for office use as well as the need to dispense compounds for acute conditions. Additionally, I am enclosing a copy of a letter to the FDA from several congressmen who oppose the FDA's process. They feel the FDA has exceeded its authority and ask that the FDA proposal be withdrawn.

Veterinary medicine is vastly different than human medicine. Vets must deal with numerous species and even more numerous body weights and unusual diseases; human pharmaceuticals rarely meet their needs. Further, industry has abandoned many veterinary products that were unprofitable, notably injectables. Lastly, dispensing small amounts of specialized medication is often essential to a pet's health in the absence of readily available customized strengths and dosage forms.

In spite of recognized shortcomings, some state boards of pharmacy are seriously considering this FDA proposal for incorporation into their own regulations through a Memorandum of Understanding. Roadrunner Pharmacy has been a partner in the veterinary community for more than 16 years; we know how important these issues are to animal health practitioners. As your board addresses veterinary compounding issues, I urge you and your board to oppose these contested FDA guidelines in the presence of an 18 page letter from an organization that represents more than 85,000 veterinarians AND given the serious misgivings from members of Congress. A number of states have granted exclusions, affording unique and often life-saving compounds to veterinarians, both sterile and non-sterile.

Thank you for your time and consideration.

ROBERT L. EATON, JR.
President/CEO
Roadrunner Pharmacy, Inc

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www.RoadrunnerPharmacy.com

AVMA
Our Passion. Our Profession.

August 14, 2015

Mr. Eric Nelson
Center for Veterinary Medicine
Division of Compliance
FDA Center for Veterinary Medicine
7519 Standish Pl
Rockville, MD 20852

RE: [Docket Nos. FDA-2015-D-1176 and FDA-2003-D-0202] Compounding Animal Drugs From Bulk Drug Substances; Draft Guidance for Industry; Availability; Withdrawal of Compliance Policy Guide; Section 608.400 Compounding of Drugs for Use in Animals

Dear Mr. Nelson:

I am writing on behalf of the American Veterinary Medical Association (AVMA), established in 1863 and the largest veterinary medical organization in the world with over 86,500 members. The AVMA's mission is to lead the profession by advocating for its members and advancing the science and practice of veterinary medicine to improve animal and human health.

The AVMA recognizes that the FDA Draft Guidance for Industry #230 sets forth the Food and Drug Administration's (FDA) policy regarding compounding animal drugs from bulk drug substances by state-licensed pharmacies, licensed veterinarians, and facilities that register with FDA as outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b). We understand this guidance describes the conditions under which FDA generally does not intend to take action for violations of the following sections of the FD&C Act: section 512 (21 U.S.C. 360b), section 501(a)(5) (21 U.S.C. 351(a)(5)), section 502(f)(1) (21 U.S.C. 352 (f)(1)), and, where specified, section 501(a)(2)(B) (21 U.S.C 351(a)(2)(B)), when a state-licensed pharmacy, licensed veterinarian, or an outsourcing facility compounds animal drugs from bulk drug substances.

Additionally, we recognize that this draft guidance only addresses the compounding of animal drugs from bulk drug substances, and that it does not apply to the compounding of animal drugs from approved new animal or new human drugs. The AVMA was a leader in the development of, and advocacy for, the enactment of the Animal Medicinal Drug Use Clarification Act on behalf of our members and the patients they serve. Extralabel drug use, including the compounding of preparations from FDA-approved drugs, continues to provide access to critical medications and our members continue to rely on this FDA-regulated activity in the practice of veterinary medicine within the confines of the 21 CFR 530.

The AVMA appreciates the FDA's recognition that there is a need for preparations compounded from bulk drug substances. We also share the agency's concern about the use of these preparations when approved alternatives exist that can be used as labeled or in an extralabel manner consistent

with the requirements of FDA's extralabel provisions. The AVMA continues to believe that three circumstances exist wherein compounds prepared from bulk drug substances might be necessary:

- the approved product is not commercially available, or
- the needed compounded preparation cannot be made from the approved product, or
- there is no approved product from which to compound the needed preparation.

While we are formally submitting these comments today, we will continue to assess whether the draft guidance can realistically address the needs of veterinary patients and ask that the FDA continue its dialog with us.

Overarching comments

Drug Availability

Veterinary medicine is unique in that we treat a multitude of species with an even greater number of unique diseases and conditions. Approval of new animal drugs is critical to veterinary medicine and engaging with the Agency in facilitating that process remains a high priority for our Association. However, compounding from bulk drug substances is still a necessary practice for veterinarians because there are, and always will be, a limited number of FDA-approved drug products for the many species and conditions that we treat. Intermittent drug shortages and commercial unavailability of FDA-approved drug products drive the need for compounded preparations within veterinary practice. While FDA has not identified cost as appropriate reason for compounding from bulk drug substances, the AVMA acknowledges that cost can be a reason veterinarians utilize compounded preparations because that is the only way a client can afford to treat their pet.

Our members have clearly conveyed that they need access to safe and efficacious drug products that can be practicably used in their patients. While recognizing FDA's jurisdiction is limited to issues related to safety and efficacy, not cost or commercial availability of drug products, we underscore the increasingly critical need for effective pathways for drug products to achieve legal marketing status. A robust, competitive animal health industry can benefit animal patients by way of increased numbers of legally marketed products that can be prescribed, dispensed or used in the preparation of compounds.

Existing pathways to legal marketing

- We continue to support the concept of user fees, so long as those fees go toward expedited reviews. Increased numbers of both pioneer and nonproprietary approved drug products can help to minimize the impacts of drug shortages.
- FDA's indexing process can be a valuable way to increase the number of legally marketed drug products for use in minor species or in major species with rare conditions. We recognize that indexing provides a process to obtain legal marketing status for eligible products. The indexing process should be utilized to a fuller extent, or revised accordingly, so that well-vetted drugs that have undergone expert panel scrutiny can be used legally for wildlife, aquaria, zoo, aquacultural, and laboratory animal species, and for major species with rare conditions.

Innovative pathways to legal marketing

- In 2010, the FDA published a Federal Register notice FDA-2010-N-0528 seeking comments related to identification of emerging paths toward legal status of drugs that are medically necessary and manufactured using good manufacturing processes. At the time, FDA conveyed that it is open to using both the agency's existing authority and new approaches to

make more drugs legally available to veterinarians, producers, and pet owners. We commended the FDA on its pursuit at the time and urge the FDA to implement innovative strategies to legal marketing. The AVMA stands ready to discuss possible approaches further with FDA.

Non-food minor species

In species including but not limited to zoo animals, laboratory animals, exotic pets, wildlife, aquaria animals, and non-food aquacultural animals, the use of compounded preparations is unquestionably necessary. We urge FDA to carefully consider the critical need for access to compounded preparations within these species, as FDA further refines its guidance. There are few choices of FDA-approved or indexed products available for use in these species; therefore, availability of properly compounded preparations to be maintained for office use in appropriate strengths and formulations, and the ability to mix and dilute medications are necessary to provide adequate veterinary care. Several provisions within this draft guidance should not apply to non-food minor species in their respective environments, such as limiting preparations to be maintained in office for urgent or emergent needs, patient-specific prescriptions, and detailed labeling requirements for compounded preparations maintained for office use.

Federal vs. State Jurisdiction

The licensure of veterinarians is regulated by state governmental authorities. Given this is a federal guidance, not a regulation, coupled with the existence of a wide range of state compounding rules, we would appreciate clarification on how GFI #230 will be enforced by the FDA. State rules regulating compounding in veterinary practice vary greatly. Some even provide substantial permissiveness for veterinarians to obtain preparations compounded for office use, and administer and dispense from the compounded preparations maintained in their office.

- How will the FDA evaluate whether the compounding of animal drugs is done in accordance with the conditions outlined in the guidance?
- Will the FDA rely on state boards of pharmacy and boards of veterinary medicine to enforce provisions within GFI #230, and how will the FDA reconcile discrepancies between state rules and GFI #230?

Enforcement

For many years the AVMA has advocated for, and applauded, the FDA's enforcement of illegal manufacturing activities. The AVMA asserts that large-scale manufacturing of animal drugs under the guise of compounding does not serve to benefit animal health; rather, circumvention of the drug approval process yields substances with unknown safety, efficacy, and potency, potentially allowing disease to progress. Animal drug manufacturers also contend that these compounded preparations result in a supply/demand disincentive for new FDA-approved drug products.

- As FDA is concerned about the use of animal drugs compounded from bulk drug substances, especially when approved alternatives exist that can be used as labeled or in an extralabel manner consistent with the requirements of FDA's extralabel provisions, how does this guidance change the FDA's ability to take action to address these concerns?
- Does the FDA currently have the needed resources and enforcement capabilities to fully enforce all egregious compounding activities, or are new authorities and appropriations necessary for the agency?
- Will the FDA develop and provide a user's guide on implementing the GFI #230 for state boards of pharmacy, state boards of veterinary medicine, individual veterinarians, and pharmacists to follow? We anticipate that time for a transition to the new paradigm will be

needed across stakeholder groups, especially given the wide array of state rules that exist related to veterinary compounding. Some veterinary state boards might not be prepared to inspect veterinary facilities for compliance with standards delineated within GFI #230.

- How will FDA's enforcement of compounded preparations be reconciled with the Drug Enforcement Administration's expectations that preparations containing controlled substances must only be prepared pursuant to patient-specific prescriptions?
- We also encourage FDA to coordinate with all relevant governmental agencies related to use of bulk drug substances in depopulation efforts, which might be needed during large-scale national emergencies. The AVMA stands ready to serve as a resource to FDA related to this topic.

Adverse Event Reporting System

The AVMA contends that there is a need for the continued development and strengthening of adverse event reporting systems for all adverse events, including lack of efficacy. We believe that there must be a strong, science-based, transparent and systematic surveillance system, especially considering the wide scope of species and disease conditions that veterinarians treat. The AVMA supports development of a user-friendly, easy to access form for all adverse events related to compounding. A user-friendly electronic system would be anticipated to promote both reporting by those compounding, and ease of review by FDA. For example, FDA could maintain a database of recently reported adverse events for veterinarians and pharmacists to use as a resource. Sufficient and meaningful data inputs, or adverse event reports, are imperative for a strong reporting system foundation.

- Does the FDA's current 1932a form, as a means of capturing adverse events, provide the robustness FDA needs to detect and act on trends? The AVMA contends that all adverse events associated with compound preparations should be reported, not just serious adverse events. Adverse events related to lack of efficacy should also be collected and analyzed.

Comments on Specific Provisions within Draft GFI #230

Scope of AVMA Comments

The AVMA has chosen to comment on the sections and questions that impact veterinary medicine. We will defer to the pharmacy community for feedback related to the practice of pharmacy and functioning of outsourcing facilities: pharmacist supervision (Section III.A.1. and Section III.C.2); compounding in advance of receipt of a prescription (Section III.A.2); determining and documenting that the compounded drug cannot be made from the FDA-approved drug(s) (Section III.A.5); current Good Manufacturing Practices (cGMP) (Section III.C.4); certain labeling requirements (Section III.C.10); and reporting requirements from 503B of the FD&C Act (Section III.C.8).

Definitions

We request the FDA provide clarification on the following terms:

- "Outsourcing facility"—Draft GFI #230 defines an "outsourcing facility" as a facility that meets the definition of an outsourcing facility under section 503B(d)(4) of the FD&C Act. Section 503B(d)(4) defines an outsourcing facility as a facility at one geographic location or address that (i) is engaged in the compounding of sterile drugs; (ii) has elected to register as an outsourcing facility; and (iii) complies with all of the requirements of that section of the law.

  As the use of outsourcing facilities in veterinary medicine is an entirely new concept, we are still assessing how the requirements for registration as an outsourcing facility would impact

the ability to meet veterinary needs. We wish to underscore that there is a substantial need for both non-sterile and sterile compounded preparations to be maintained for office use in veterinary medicine. We appreciate that the use of outsourcing facilities in the preparation of office stock is intended to increase safety of compounded preparations, yet we caution that use of outsourcing facilities might have the unintended consequence that some preparations of critical importance to animal health may no longer be available due to economic or other business considerations.

We ask the FDA to clarify how it will reconcile the clear discrepancies between statutory language and provisions in various agency documents:

- Specifically, it is our understanding that outsourcing facilities in compliance with Section 503B are only exempt from the *human drug approval requirements* in section 505 of the FD&C Act (21 U.S.C. 355), the requirement to be labeled with adequate directions for use in section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)), and the track and trace requirements in section 582 of the FD&C Act (21 U.S.C. 360eee-1). How does this guidance impact the facility's exemption from animal drug approval requirements?
- Per the FDA's draft guidance for industry *For Entities Considering Whether to Register As Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act,* referenced in draft GFI #230, outsourcing facilities are required to meet certain conditions to qualify. Of particular concern is the requirement that the outsourcing facilities must not compound drugs that appear on a list published by the FDA of drugs that have been withdrawn or removed from the market because the drugs or components of such drugs have been found to be unsafe or not effective *for humans.* We are aware of a number of such compounded preparations needed in veterinary medicine, including but not limited to cisapride, asparaginase, and chloramphenicol. In these cases, the FDA-approved product was withdrawn from the market due to human safety concerns, leaving us with no alternative to treat animal patients.
- An additional concern is that a facility, in order to meet the definition of an outsourcing facility, must be engaged in the compounding of sterile human drugs. The draft guidance clearly states that "you should not register a facility as an outsourcing facility if the only activities conducted at the facility are…animal drugs,…because none of the products produced at the facility would qualify for the exemptions provided in section 503B." A number of pharmacies currently exist that serve the needs of veterinarians and would need to register as an outsourcing facility per GFI #230, but they are explicitly prevented from registering per Section 503B because they do not meet certain requirements and were told not to register by the agency in another Guidance for Industry.

- "Compounding" as defined within 503A does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling. Defined within 503B, compounding is the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering a drug or bulk drug substance to create a drug. Is the administration of a bulk drug substance directly to an animal (for example, dissolution of metronidazole powder in aquaria for medical treatment of pet fish) considered compounding, or would administration be considered compounding only if the bulk drug

substance is mixed with another active or inactive ingredient? We ask the FDA to fully clarify its definition of animal drug compounding within this guidance.

- "Bulk drug substance" is defined within 21 CFR 207.3(a)(4) as "any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances." We understand that compressed gases, household items, herbals and homeopathics, and manufactured unapproved drugs such as glucosamine, would be outside the scope of this guidance. We ask the FDA to fully clarify what it considers a bulk drug substance for purposes of this guidance.
    - In its Table 1—Estimated Annual Recordkeeping Burden, please clarify details surrounding FDA's estimate that 75,000 pharmacies will receive approximately 6,350,000 prescriptions for compounded animal drugs annually. From where were these numbers obtained, and are these numbers specific to preparations compounded from bulk drug substances or prescriptions for all compounded preparations?

- "Patient" is defined by the AVMA (https://www.avma.org/KB/Policies/Pages/Model-Veterinary-Practice-Act.aspx) as an animal or group of animals examined or treated by a veterinarian, which would include herds, flocks, groups of shelter animals, laboratory animal colonies or groups, and zoo animal and aquaria collections. We respectfully request the use of this definition for the term "patient."

- "Non-ornamental fish" needs further clarification. Which definition is the FDA using for this term? The FDA-CVM's Program Policy and Procedures Manual *Enforcement Priorities ForDrug Use In Non-Food Fish* includes a definition of "ornamental fish." For purposes of GFI #230, are all fish not included in that definition to be considered "non-ornamental fish" and therefore food-producing animals?

- "Clinical difference" is not expressly defined within Section 503B or in the draft GFI #230. How will "clinical difference" be evaluated by the FDA, or does the FDA intend to seek state enforcement of this component?

- The terms "sale" and "transferred" need to be more clearly defined. For example, does this include the sharing of a compounded preparation between one clinic and a co-owned satellite clinic, between multiple zoological institutions or government agencies, or from one university laboratory to another within the same university system?

Section III.A.

(2) We have serious concerns with the verbiage "The drug is dispensed…for an individually identified animal patient..." AVMA fully supports the requirement that a veterinarian-client-patient relationship must exist for the use of a compounded preparation in an animal patient. However, the requirement that a patient must be 'individually identified' would eliminate the ability for veterinarians to obtain a preparation for a collection of animals, such as in a zoo, laboratory animal research facility or aquarium. In some of these situations, the patient cannot be individually identified or the entire group needs to be treated; it would not be feasible or reasonable to write an individual prescription for each animal.

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- We request the FDA delete the words "individually identified" and use the AVMA's definition of "patient": https://www.avma.org/KB/Policies/Pages/Model-Veterinary-Practice-Act.aspx.

(3) "Food-producing animal" defined to include all cattle, swine, chickens, turkeys, sheep, and goats is consistent with our understanding and definition of a "food-producing animal."

The AVMA contends that compounding from bulk drug substances in food-producing animals is medically necessary for certain poison antidotes, euthanasia, and depopulation medications. There must be some allowance for compounding from bulk ingredients for these explicit situations, when there is no FDA-approved product or the approved product cannot feasibly be used per label or in an extralabel fashion. Veterinarians must also be able to legally maintain sufficient quantities of these compounded preparations in their office for urgent administration needs or emergency situations in food animals. Without access, animals would die before the medication could be delivered; for example, methylene blue is needed to treat nitrate toxicosis in cattle in the southeastern part of the USA. We recognize veterinarians' need to ensure food safety, maintain required records, and label drugs appropriately, as required under FDA's extralabel drug use rules. We ask that FDA draft a separate guidance to address these needs.

We are not opposed to the requirement that the prescription or documentation accompanying the prescription for a non-food animal must contain the statement "This patient is not a food-producing animal." The statement also helps to distinguish those patients that could be a food-producing animal in some situations, independent of species (e.g., rabbits, captive elk, captive deer).

We also would appreciate clarification on the wording in the latter half of this provision: "…any other animal designated on the prescription or in documentation accompanying the prescription by the veterinarian as a food-producing animal, regardless of species, is considered to be a food-producing animal."

- Would this mean that a veterinarian would state "This patient is a food-producing animal" to identify for the pharmacist that a bulk drug substance is not to be used?

(4)(a) The AVMA disagrees with the requirement that a pharmacy may compound a preparation using a bulk drug substance that is a component of any marketed FDA-approved animal or human drug only if the change between the compounded drug and the FDA-approved drug would produce a clinical difference. We assert that compounding should be allowable if the approved product is not commercially available for other reasons (i.e., unavailable) and no therapeutic alternatives exist, or if the needed compounded preparation cannot be made from the approved product (such as preparation of metronidazole benzoate for use in a cat) as allowed per Section III.A.5. We ask the agency to amend the provision accordingly. Given the frequency of FDA-approved drug product shortages and backorders, including all marketed FDA-approved drugs is too restrictive for the needs of veterinary patients.

(4)(b) The AVMA has concerns with, and is opposed to, the requirement for a statement from the veterinarian that the compounded preparation "produces a clinical difference for the individually identified animal patient" with an explanation of that difference. We contend that a medical rationale is necessary for use of compounds, and is a more applicable term than "clinical difference." However, we believe documentation of why the compounded preparation was chosen is more appropriate for the medical record.

- Should FDA still choose to require inclusion of a statement in documentation, will the statements be evaluated by the FDA, or does the FDA intend to seek state enforcement of this component?

Additionally, we believe that the term "clinical difference" does not capture other medical needs for compounded preparations, such as certain worker and client safety needs, client compliance, and animal stress situations (e.g., fractious cats). These safety/animal handling needs are not related to clinical differences but rather, the ability to adequately medicate patients.

(5) Related to pharmacists documenting that a compounded preparation cannot be made from an FDA-approved drug, what does the FDA consider to be "acceptable documentation," and to whom will the documentation be provided?

(6)(b) In concept, the AVMA does not oppose the requirement that the statement "There are no FDA-approved animal or human drugs that can be used as labeled or in an extralabel manner under section 512(a)(4) or (5) and 21 CFR part 530 to appropriately treat the disease, symptom, or condition for which this drug is being prescribed" be documented on the prescription or documentation accompanying the prescription, because we believe veterinarians need to carefully consider their therapeutic options. However, the statement could inadvertently discourage use of FDA-approved drugs in preparing compounded medications. For example, we understand that sometimes the best starting ingredient for a pharmacist's preparation of a compounded medication is the FDA-approved drug. If the veterinarian includes the above statement, that essentially would direct the pharmacist to utilize a bulk drug substance. Moreover, the veterinarian writing the prescription would not necessarily know whether the FDA-approved drug or the bulk drug substance is best for the preparation. We wholeheartedly agree with the need for veterinarians to utilize FDA-approved products whenever feasible. We ask that FDA discuss this topic further with the AVMA.

(9) We would like clarification on the statement that "a sale or transfer does not include administration of a compounded drug by a veterinarian to a patient under his or her care." It is our understanding that under the guidance, the compounded preparation may only be dispensed by the pharmacy to the patient's owner or caretaker, a concept with which the AVMA disagrees. Does this provision in some way allow for the veterinarian to receive the compounded preparation from the pharmacy, and then administer and dispense the preparation to the patient's owner or caretaker? The AVMA asserts that the prescribing veterinarian should be able to dispense these preparations to help ensure that the medications are being used and administered appropriately by the client. Such dispensing also keeps the prescribing veterinarian more closely attuned to the current status of the patient should client questions or concerns (such as adverse events) arise.

We request that the FDA amend the provision to allow dispensing: "…a sale or transfer does not include administration of a compounded drug by a veterinarian to a patient under his or her care, <u>or the dispensing of a compounded drug by the veterinarian to the owner or caretaker of an animal under his or her care</u>."

Section III.B.

(1) Again, the AVMA contends that compounding should be done within the confines of a veterinarian-client-patient relationship. However, veterinarians must be able to legally maintain sufficient quantities of compounded preparations in their office for urgent administration needs or emergency situations, including compounds prepared by veterinarians and pharmacies. In fact, the

maintenance of preparations for office use is lawful for veterinarians under some states' rules. We request that the FDA include an allowance for the preparation of compounds by veterinarians in advance of a specific patient's need.

(2) For food animals, the AVMA, again, asserts that a publically available list of bulk drug substances for veterinarians to prepare poison antidotes, euthanasia, and depopulation preparations should be made available.

As previously stated in Section III (A) 3, veterinarians must also be able to legally maintain sufficient quantities of these compounded preparations in their office for urgent administration needs or emergency situations in food animals. Without access, animals would die before the medication could be delivered; for example, methylene blue is needed to treat nitrate toxicosis in cattle in the southeastern part of the USA. We recognize veterinarians' need to ensure food safety, maintain required records, and label drugs appropriately, as required under FDA's extralabel drug use rules. We ask that FDA draft a separate guidance to address these needs.

(3) If the veterinarian is prescribing a medication to be compounded in lieu of an FDA-approved drug, then there is a clinical need that has already been determined by the prescribing veterinarian. Thus the AVMA agrees with the purpose of the provision. We do not support any additional reporting or recordkeeping requirements related to this provision.

We request that the FDA amend the provision to allow for compounding from bulk ingredients if the approved product is not commercially available (either due to a backorder, shortage, or no longer marketed) or if the needed compounded preparation cannot be made from the approved product. As stated with respect to Sec. III.A.4.a., the frequency of FDA-approved drug product shortages and backorders makes inclusion of all marketed FDA-approved drugs too restrictive for the needs of veterinary patients.

(4) The AVMA supports the intentions of this provision as the AVMA believes that an FDA-approved drug product should always be used first and foremost.

(5) The AVMA supports the requirement that veterinarians compounding from bulk drug substances do so in accordance with USP—NF Chapters <795> and <797> (e.g., a sterile drug is compounded in an area with air quality that meets or exceeds ISO Class 5 standards (see USP—NF Chapter <797>, Table 1)).

(6) The AVMA agrees with the requirements for use of bulk drug substances that are accompanied by a valid certificate of analysis and that come from FDA-registered manufacturers.

(7) The AVMA agrees with the provision's allowance for veterinarians to administer the preparation to the patient or dispense to the owner or caretaker. The AVMA also agrees that this should all be done within the confines of a veterinarian-client-patient relationship.

The AVMA contends that dispensing practices by veterinarians should be regulated by individual state boards of veterinary medicine. We would like the FDA to clarify what the agency would consider to be the "transfer" of compounded preparations to another veterinarian or a satellite facility.

Section III.C.

(1) Please see our comments in the section below related to Appendix A. We have reservations about the outline drafted for the creation of such a list and whether patient needs can be met through the use of such a list.

(3) We do not oppose the requirement for a statement on the prescription or supporting documentation that "This drug will not be dispensed for or administered to food-producing animals." Including such a statement is important to help minimize the risk of the medication being used in a food animal.

As stated previously, the AVMA contends that compounding from bulk drug substances in food-producing animals is medically necessary for certain poison antidotes, euthanasia, and depopulation medications. There must be some allowance for compounding from bulk ingredients for these explicit situations, when there is no FDA-approved product or the approved product cannot feasibly be used per label or in an extralabel fashion. Veterinarians must also be able to legally maintain sufficient quantities of these compounded preparations in their office for urgent administration needs or emergency situations in food animals. Without access, animals would die before the medication could be delivered; one example also stated previously is methylene blue, which is needed to treat nitrate toxicosis in cattle in the southeastern part of the USA. We recognize veterinarians' needs to ensure food safety, maintain required records, and label drugs appropriately, as required under FDA's extralabel drug use rules. We ask that FDA draft a separate guidance to address these needs.

(6) As the draft guidance is currently written, outsourcing facilities would be the only way by which a veterinarian could obtain office stock of certain compounded preparations. Many of these preparations are not only needed for immediate in-house administration by the veterinarian but also for dispensing to the patient's owner or caretaker for treatment at home, up to a 14-day timeframe. This allows for dispensing for emerging needs, and to help ensure the drug is going to be effective in a particular patient. It would also help to avoid a client needing two prescriptions for one drug in a short timeframe (which could decrease compliance), and would allow time to detect any immediate adverse events (e.g., intolerance to the drug, such as seen when amlodipine results in inappetence in cats).

We request that the FDA amend the provision to allow dispensing: "…a sale or transfer does not include administration of a compounded drug by a veterinarian to a patient under his or her care, <u>or the dispensing of a compounded drug by the veterinarian to the owner or caretaker of an animal under his or her care</u>." This would bring the provision in line with what is allowed for physicians under Sec. 503B of the FD&C Act.

(9) At this time, the AVMA has reservations related to the requirement that a veterinarian's order state that the product will be used in a manner and in a species that complies with the list of permitted bulk ingredient uses under Appendix A. If any such list is created, it needs to be maintained properly and reflect veterinarians' needs. These concerns will be further addressed in the feedback below on Appendix A.

(10) The AVMA contends that certain information should be incorporated into labels/packaging and generally agrees with inclusion of:

a. Active ingredient(s)
b. Dosage form, strength, and flavoring, if any
c. Directions for use, as provided by the veterinarian prescribing or ordering the drug

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d. Quantity or volume, whichever is appropriate
e. The statement "Not for resale."
f. The statement "For use only in [fill in species and any associated condition or limitation listed in Appendix A]."
g. The statement "Compounded by [name of outsourcing facility]."
h. Lot or batch number of drug
i. Special storage and handling instructions
j. Date the drug was compounded, and date of dispensing, if dispensed
k. Beyond use date (BUD) of the drug
l. Name of veterinarian prescribing or ordering the drug
m. The address and phone number of the outsourcing facility that compounded the drug
n. Inactive ingredients
o. The statement "Adverse events associated with this compounded drug should be reported to FDA on a Form FDA 1932a."
p. If the drug is compounded pursuant to a patient specific prescription, the species of the animal patient, name of the animal patient, number of refills if applicable, and name of the owner or caretaker of the animal patient. We wish to underscore that "patient" can also mean a herd, collection or group of shelter animals. We assert that the AVMA's definition of "patient" should be used.

We also request that FDA require all compounded preparations be labeled that they are not FDA-approved products. We believe it is important for consumers to recognize that safety, efficacy, potency and sterility, where applicable, of compounded preparations have not been assessed or verified by the FDA.

Labeling requirements for preparations to be maintained for office use can be difficult for minor species, including but not limited to zoo, aquaria, laboratory-animal, and wildlife collections and/or facilities. For example, some compounds maintained for office use will be used to treat lameness in a number of species in a zoo collection. The labeling requirement as posed in (f) would be particularly difficult in these collections.

Pertaining to Provisions Which Appear in Multiple Sections
Related to Labeling by Pharmacies and Veterinarians (Section III.A.11 and Section III.B.9)
AVMA requests that the labeling requirements for pharmacists and veterinarians include name of client; veterinarian's name and address; identification of animal(s) treated, species and numbers of animals treated, when possible; date of dispensing; name, active ingredient, and quantity of the drug preparation to be dispensed; drug strength (if more than one strength available); dosage and duration; route of administration; number of refills; cautionary statements as needed; beyond use date; and the statement "Compounded by [name, address, and contact number of the pharmacy or veterinarian]." We also assert that compounded preparations should be labeled that they have not been approved by FDA. Patient owners or caretakers should have information available to contact the compounding entity, be it a pharmacy, veterinarian or outsourcing facility.

The AVMA agrees with inclusion of the name of the owner or caretaker and species of animal. AVMA contends that a patient may be an animal or group of animals so the "name" of the animal patient should only be required for prescriptions where applicable and appropriate.

Related to Patient-Specific Prescriptions (Section III.A.2 and Section III.B.1)
Veterinarians must be able to legally maintain sufficient quantities of compounded preparations in their office for urgent administration needs or emergency situations. These cannot be obtained through patient-specific prescriptions. Examples are many, and include: methylene blue to treat nitrate toxicosis; apomorphine to induce emesis in dogs; antibiotics, such as metronidazole, formulated into an appropriate dose for small dogs and cats and a palatable flavor for non-human primates to treat acute diarrhea; and nonsteroidal anti-inflammatory drugs, such as meloxicam, for pain control in small mammals.

This guidance's allowance that preparations that appear in a list will only be available from an outsourcing facility will greatly restrict veterinarians' access to critical medications and hamstring their ability to provide appropriate care in a timely manner. We must ask the FDA to reconsider provisions related to preparations compounded for office use and engage in discussion with the AVMA and the veterinary profession to better ascertain how to best meet the needs of both the FDA and veterinary patients.

Related to Sourcing of, and Information on, Bulk Drug Substances (Section III.A.7, Section III.B.6, and Section III.C.5)
Section III.A.7 states that "Any bulk drug substance used to compound the drug is manufactured by an establishment that is registered under section 510 of the FD&C Act (21 U.S.C. 360) (including a foreign establishment that is registered under section 510) and is accompanied by a valid certificate of analysis." How does the intent related to this statement differ from the intents for Section III.B.6 and Section III.C.5, which both state "Any bulk drug substance used is manufactured by an establishment that is registered under section 510 of the FD&C Act (21 U.S.C. 360) (including a foreign establishment that is registered under section 360(i)) and is accompanied by a valid certificate of analysis"?

The AVMA agrees with the requirement that any bulk drug substance used by either a pharmacy, veterinarian, or outsourcing facility be manufactured by an establishment that is registered under section 510 of the FD&C Act (21 U.S.C. 360) (including a foreign establishment that is registered under section 360(i)) and is accompanied by a valid certificate of analysis.

Related to USP-Related Requirements (Section III.A.8 and Section III.B.5)
The AVMA asserts that compliance with USP guidelines continues to be an element that can be utilized when a veterinarian considers the quality of a compounding pharmacy's preparations. The AVMA supports the requirement that veterinarians, outsourcing facilities, and pharmacists compounding from bulk drug substances do so in accordance with USP—NF Chapters <795> and <797> (e.g., a sterile drug is compounded in an area with air quality that meets or exceeds ISO Class 5 standards (see USP—NF Chapter <797>, Table 1)).

Related to the Sale or Transfer of Compounded Preparations (Section III.A.9 and Section III.B.7)
The AVMA advocates that compounded preparations should not be wholesaled. However, we seek clarification from FDA related to the definition of "sale" and "transfer" as indicated previously in our comments.

Related to Adverse Event Reporting Requirements (Section III.A.10, Section III.B.8, and Section III.C.7)
The AVMA advocates for robust, strong adverse event reporting systems. However, we ask whether the FDA's current 1932a form, as a means of capturing adverse events, provides the robustness FDA

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needs to detect and act on trends? The AVMA underscores that all adverse events associated with compounded preparations should be reported by those compounding the preparations, rather than just serious adverse events. Adverse events related to lack of efficacy should also be collected and analyzed.

The AVMA contends there is a need for the continued development and strengthening of adverse event reporting systems for all adverse events, including lack of efficacy. We believe there must be a strong, science-based, transparent and systematic surveillance system, especially considering the wide scope of species and disease conditions that veterinarians treat. The AVMA supports development of a user-friendly, easy to access form for all adverse events related to compounding. A user-friendly electronic system would be anticipated to promote both reporting by those compounding and ease of review by the FDA. For example, the FDA could maintain a database of recently reported adverse events for veterinarians and pharmacists to use as a resource. Sufficient and meaningful data inputs, or adverse event reports, are imperative for a strong reporting system.

Related to the proposed requirement for submission of all adverse events within 15 days, the AVMA asserts that this timeframe is acceptable for veterinarians. We hope that such a timeframe is amenable to pharmacies and outsourcing facilities.

Appendix A, List of Bulk Drug Substances That May Be Used By An Outsourcing Facility to Compound Drugs for Use in Animals

In GFI #230, the FDA conveys its general intent to enforce all adulteration and misbranding provisions of the FD&C Act against entities compounding animal drugs from bulk drug substances if they are not in accordance with provisions delineated within the guidance. The AVMA understands this to mean that while all compounding from bulk drug substances continues to be illegal, those activities not provided for within the confines of GFI #230 are subject to *greater* likelihood of enforcement.

Although we want compounded preparations that veterinarians maintain for office use to be safe, we have concerns that the explicit use of outsourcing facilities might have the unintended consequence of making some preparations unavailable.

The AVMA asserts that use of a compounded preparation should be limited to those individual patients for which no other method or route of drug delivery is practical; those drugs for which safety, efficacy, and stability have been demonstrated in the specific compounded form in the target species; or disease conditions for which a quantifiable response to therapy or drug concentration can be monitored. Needs vary greatly across species treated by veterinarians.

- Zoo animals, laboratory animals, wildlife, exotic pets, camelids, aquaria species, and non-food aquacultural species: These minor species have few FDA-approved animal or human drug products or indexed drugs that can be used as labeled or in an extralabel manner to treat conditions. For example, diminutive dosages and volumes are required for some exotic pets, so office use is critical. Zoo veterinarians have advised they need to have office stock to be able to readily treat lameness or other conditions that can arise at any time among the large collections of animals they treat. For that reason, the importance of having preparations compounded from bulk drug substances in anticipation of the patient's need and available in the hospital or clinic for administration, and dispensing when appropriate, is undeniable.
- Food-producing animals: The AVMA suggests that the FDA draft a separate guidance to address compounding from bulk drug substances for food producing animals. The draft GFI

#230 provides no allowance for the preparation of compounds from bulk drug substances for food-producing animals. The AVMA has advocated for a publically available, current list of bulk drug substances that can be legally compounded within a veterinarian-client-patient relationship specific and limited to euthanasia, depopulation, and poison antidote compounds for food-producing animals. There currently exist no FDA-approved animal or human drug products or indexed drugs that can be used for these specific needs. Therefore, it is imperative that veterinarians have these preparations available and in their clinic when the need arises. Not only is compounding from bulk drug substances necessary for food-producing animals, the FDA must allow for the preparations to be obtained in anticipation of a specific patient's need (i.e. via a nonpatient-specific prescription or prescription order) for treating certain toxicoses and for euthanasia or depopulation.

- Dogs, cats, and horses: While there are a number of FDA-approved drug products for dogs, cats and horses, there remain circumstances where there is no FDA-approved drug product available to treat a particular animal with a particular condition, because either no drug product is approved for a specific animal species or no approved drug product is available or feasible for use under the extralabel drug use provisions. For example, some shelters receive 20,000 to 30,000 animals per year and have immediate needs that require compounded preparations for adequate treatment. Another example is the need for compounded buprenorphine when an owner is unable to adequately medicate their painful cat with the injectable or oral treatment at home. In instances such as these, having access to these compounded preparations for administration and dispensing by the veterinarian is critical to preventing animal suffering and death.

The criteria that all substances must meet to be included on the list are challenging.

- As asked previously, will the identified "significant safety concern specific to the use of the bulk drug substance to compound animal drugs" be related to safety concerns for humans or for animal patients? For example, cisapride was removed from the market due to human safety concerns, but is critical in feline medicine. We contend that safety concerns related to the use of compounded medications in human medicine should have no bearing on their use in animal patients in most circumstances.
- Additionally, evidence clearly indicating the ineffectiveness of a substance to be used should be a criterion by which the substance is not included on the list.

We have concerns related to the feasibility of creating an all-encompassing list of bulk drug substances within the paradigm framed by FDA, with supporting documentation as outlined in the Docket No. FDA-2015-N-1196. In lieu of the list, we contend that compounding from bulk drug substances should be allowed in three general sets of circumstances: the approved product is not commercially available, the needed compounded preparation cannot be made from the approved product, or there is no approved product from which to compound the needed preparation.

AVMA will be providing a separate set of comments pursuant to the Federal Register notice titled, "List of Bulk Drug Substances That May be Used by an Outsourcing Facility to Compound Drugs for Use in Animals."

Specific Topics for Comment

Should the final guidance address the issue of FDA-approved animal and human drugs that are in shortage or are otherwise unavailable (e.g., disruptions in the manufacture or supply chain; business

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decisions to stop marketing the drug; drug is subject to Agency action based on safety, effectiveness, or manufacturing concerns)?
The AVMA is committed to the continued availability of medicinal products that are pure, safe, potent and efficacious for animals. While we recognize that many factors can impact a manufacturer's decision or ability to produce and make FDA-approved drug products available, the short and long-term breaks in availability or complete withdrawal of a product from the market make access to compounded preparations even more important. Lack of information regarding why the products have been removed from the market and when they might return causes frustration and uncertainty for veterinarians and pet owners as they plan for treatment of patients.

Accordingly, the AVMA contends that the lack of commercially available FDA-approved drug products is a valid reason for veterinarians to prescribe compounds prepared from bulk drug substances for patients. For example, ticarcillin-clavulanic acid is critical for treatment of certain types of bacterial otitis externa in dogs and must be compounded when commercially unavailable. We ask that the final guidance address the issue of compounding preparations from bulk drug substances when the FDA-approved drug products are unavailable for any reason. As requested earlier in our comments, does the FDA have the needed resources to address and minimize impacts of drug unavailability on patient care? Additionally, what protocols and procedures will FDA follow to assure that timely notification is made regarding emerging drug shortages that impact veterinary medicine and notification when the drug is once again commercially available? And how does FDA know when a shortage of a human FDA-approved drug will impact veterinary medicine?

How should these situations be addressed in the final guidance?
The AVMA contends that a robust, nimble, current drug shortage list should be made publically available. While we do not yet have a recommendation on whether this action should be incorporated into the provisions delineated within GFI #230, implemented elsewhere for the agency to manage, or maintained by an external stakeholder(s), appropriate resources must be dedicated toward its continual upkeep. In the interim, any role that the FDA plays with regard to identification of drug shortages needs to be well-informed and more broadly encompassing than the current list housed at
http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm267669.htm.

How should the final guidance define the terms "shortage" and "unavailable"?
A "shortage" refers to insufficient quantities of a needed FDA-approved product. "Unavailable" means that the FDA-approved product is entirely inaccessible to practitioners. Shortages and unavailability of products may be due to a back order, temporary discontinuation, or other supply interruption, resulting in limited or no accessibility through regular distribution channels.

What criteria should FDA use to determine if an approved animal or human drug is in shortage or otherwise unavailable?
FDA should consider products that are backordered, temporarily discontinued, no longer marketed, or provided intermittently in limited quantities when determining whether a product is in shortage or unavailable.

Do United States Pharmacopeia and National Formulary (USP-NF) [2] chapters <795> and <797> provide suitable standards for animal drugs compounded by veterinarians, and if not, what standards of safety, purity, and quality should apply to animal drugs compounded by veterinarians?
The USP chapters 795 and 797 are suitable standards for compounding from bulk drug substances by veterinarians.

Should licensed veterinarians be able to sell or transfer an animal drug compounded from bulk drug substances by a State-licensed pharmacy or an outsourcing facility to owners or caretakers of animals under the veterinarian's care?
We seek FDA's clarification related to the definitions of "sell," "transfer," and "dispense" before we can provide feedback related to this concept. In general, we assert that the prescribing veterinarian should be able to dispense preparations compounded by pharmacies or outsourcing facilities to his or her clients.

How should FDA apply the condition to identify an individual patient when it is not possible to identify an individual animal (e.g., koi in a koi pond)?
The AVMA contends that a "patient" is an animal or group of animals examined or treated by a veterinarian and does not need to always be individually identified. So long as the licensed veterinarian is meeting the requirements of his/her state veterinary practice act with respect to prescribing, then being able to identify an individual patient when it is not possible is unnecessary.

Should facilities registered as outsourcing facilities under section 503B of the FD&C Act be able to compound animal drugs from bulk drug substances that do not appear on Appendix A for an individually identified animal patient under conditions similar to those applicable to state-licensed pharmacies (i.e., the conditions contained in section III.A. of the draft guidance)?
Yes, so long as the outsourcing facility is a state-licensed pharmacy.

Is additional guidance needed to address the repackaging of drugs for animal use?

- *How widespread is the practice of repackaging drugs for animal use?*
- *What types of drugs are repackaged for animal use, and why are they repackaged?*
- *Have problems been identified with repackaged drugs for animal use?*

We understand repackaging to mean "The act of taking a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the drug. Repackaging also includes the act of placing the contents of multiple containers (e.g., vials) of the same finished drug product into one container, as long as the container does not include other ingredients." If this is FDA's definition, the AVMA agrees and understands that veterinarians sometimes need to repackage drugs, including compounded preparations, into smaller aliquots for administration by the owner or agent, as long as the repackaging does not affect the stability, efficacy, purity, safety, and potency of the product (e.g., light-sensitive drugs).

Is additional guidance needed to address the compounding of animal drugs from approved animal or human drugs under section 512(a)(4) or (a)(5) of the FD&C Act and part 530?
No. The AVMA was a key leader in the development and advocacy for the Animal Medicinal Drug Use Clarification Act on behalf of our members and the patients they serve. Extralabel drug use, including the preparation of compounds from FDA-approved drugs, continues to be a needed activity in veterinary medicine, and our members continue to utilize this FDA-regulated activity in the practice of veterinary medicine, within the confines of the 21 CFR 530.

Is additional guidance needed to address the compounding of animal drugs from bulk drug substances for food-producing animals?
Yes. The AVMA suggests that the FDA draft a separate guidance to address compounding from bulk drug substance for food producing animals.

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The AVMA continues to recommend that there be a publically available, current list of bulk drug substances that can be legally compounded within a veterinarian-client-patient relationship specific and limited to euthanasia, depopulation, and poison antidote compounds for food animal species. If adequate scientific information is not available to determine a withdrawal time, the AVMA contends that the compounded preparation cannot be used in a food animal or the treated animal cannot enter the food supply.

As one condition under which FDA does not generally intend to take action for certain violations of the FD&C Act if this and the other conditions are followed, FDA is proposing that State-licensed pharmacies and veterinarians report any product defect or serious adverse event associated with animal drugs they compound from bulk drug substances to FDA within 15 days of becoming aware of the product defect or serious adverse event. Outsourcing facilities are required to report adverse events associated with the drugs they compound. FDA believes it is important to receive this information from State-licensed pharmacies and veterinarians because there are no other State Departments of Health or Federal Agencies (e.g., the CDC) charged with identifying and tracing animal injuries or disease associated with an animal drug compounded by these entities. FDA has the following specific questions with respect to this proposed condition:

- *How many State-licensed pharmacies and veterinarians compound animal drugs from bulk drug substances and would potentially be reporting product defects and serious adverse events to FDA?*
  We are unaware of any data that could assist in answering this question. Anecdotally, we understand that few veterinarians personally compound from bulk drug substances.

- *Are State-licensed pharmacies and veterinarians reporting the same or similar information to any State regulatory agency (e.g., State boards of pharmacy, State boards of veterinary medicine)? If so, how many reports on average does each State-licensed pharmacy and veterinarian submit to these State agencies each year?*
  It is our understanding that adverse events are grossly underreported to FDA; however, members have conveyed that when they do report an adverse event, they generally report the adverse event to the respective compounding pharmacy. We do not know the actual number of these reports, nor are we aware of the number of events reported by veterinarians to their state boards.

- *For purposes of the guidance, how should FDA define the terms "product defect" and "serious adverse event"?*
  AVMA contends that "serious adverse events" are ones that are fatal, life-threatening, require professional intervention, cause an abortion, stillbirth, infertility, congenital anomaly, prolonged or permanent disability, or disfigurement as referenced in 21 CFR 514.3.

  A "product defect" would include any obvious physical abnormalities, such as consistency, color and precipitant materials or contents, or problems with the amount, type or effectiveness of an ingredient triggered by production errors, poor quality bulk drug substances, or problems with transportation and/or storage. Any obvious physical defects of the container, seal or stopper and of the label of the product container would also constitute a product defect.

AVMA believes lack of efficacy is an adverse event and should be included in any reporting system.

- *Can FDA achieve the same objective of identifying and tracing the source of injuries or disease associated with an animal drug compounded from a bulk drug substance through means other than product defect and serious adverse event reporting, and if so, what other means? For example, would reports of product defects alone achieve the same objective?* We are unable to provide a clear answer without additional definitions for the terms "product defect" and "serious adverse event," which would help inform our understanding and opinion.

We appreciate the opportunity to comment on the draft Guidance for Industry and provide needed feedback on behalf of the AVMA's membership. For questions or concerns regarding the AVMA's comments, please contact Drs. Ashley Morgan (amorgan@avma.org; 202-289-3210) and Lynne White-Shim (lwhite@avma.org; (800) 248-2862 ext. 6784).

Sincerely,

W. Ron DeHaven, DVM, MBA
CEO and Executive Vice President

October ##, 2015

Commissioner Stephen Ostroff, M.D.
Food & Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Ostroff:

We are writing to express our serious concern with FDA's proposed "Guidance for Industry - Compounding Animal Drugs from Bulk Drug Substances", which the agency issued on May 19, 2015. Through a draft guidance, FDA is proposing a new regulatory scheme for compounded animal drugs that prohibits veterinarians from properly treating their animal patients. These fundamental changes are proposed despite the fact that Congress has not passed any statute giving FDA the broad authority it would need to make such a substantial change in animal health.

Under the proposed guidance, veterinarians would be singled out as the only health care professionals required to document in writing a clinical need before they can prescribe a medication. The draft guidance mandates very specific language that veterinarians must include on each and every prescription for a compounded preparation. This represents an unprecedented and dangerous intrusion into the state-regulated practice of veterinary medicine

The draft guidance also eliminates the ability of veterinarians to maintain an office stock of medications from compounding pharmacies that are necessary for animal health. This access to important compounded medications, commonly referred to as "office use," is permitted under most state laws. Office use of compounded medications is critical in the practice of animal health because veterinary clinics often serve as emergency rooms and hospitals for animals, and certain compounded medications must be immediately available in order to insure proper patient outcomes.

Through the draft guidance, the agency establishes and authorizes §503B outsourcing facilities to compound and distribute medications for veterinary use. When Congress established that category of FDA-registered and regulated facilities within the Drug Quality and Security Act of 2013, it was specific to the provision of sterile drug products for human use. The agency has far exceeded its authority by presuming to extend these entities into veterinary medicine.

This proposed guidance takes portions of the statute related to compounding contained in the Drug Quality and Security Act and attempts, without authorization and through a guidance document, to apply these provisions to animal drug compounding despite the fact that the Act is expressly limited to human compounding. If FDA believes that fundamental changes are needed in the regulation of animal drug compounding, the agency should instead submit a specific legislative proposal for Congress to consider. As a result, we ask that you withdraw this proposed guidance.

Thank you for your attention in this matter. We look forward to the withdrawal of this proposed guidance and please do not hesitate to contact our offices if you require any further information.

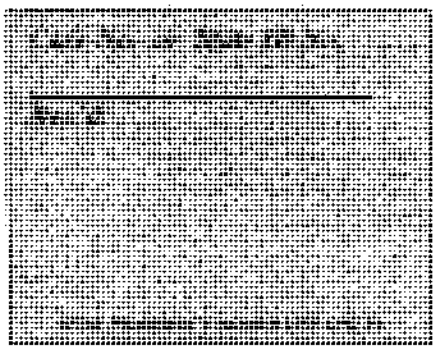
Sincerely,

Matt Salmon
Member of Congress

Kurt Schrader
Member of Congress

Contact Greg Soften (greg.safsten@mail.house.gov) in Rep. Salmon's office, or Chris Huckleberry (huck@mail.house.gov) in Rep. Schrader's with questions and to sign onto the letter.

After filling out form, print, sign, and mail to: Iowa Board of Pharmacy
400 SW 8th Street, Suite E, Des Moines, Iowa 50309-4688. Deadline for inclusion on Board's agenda is three weeks prior to Board meeting.



IOWA BOARD OF PHARMACY
Petition for [x] Waiver [☐] Variance
(check the appropriate box)

PLEASE PRINT OR TYPE ALL INFORMATION IN INK

A waiver excuses the petitioner from the requirements of a rule in its entirety or from a part of a rule; a variance does not. Instead, a variance is a modification to the requirements of a rule or a part of a rule. Example: A rule requires the fencing of certain property and further requires that the fence be at least 6 feet in height. A waiver of that rule would excuse the petitioner from the requirement for fencing the property. A variance would require the property be fenced but would allow the petitioner to maintain the current fencing configuration of 5 feet in height (perhaps the fence was constructed prior to the height requirement). When replacement of the current fence becomes necessary as a consequence of normal wear and tear, the variance would terminate and the petitioner would he required to comply with the 6-foot height requirement.

Note: Statutory requirements that have been repeated in administrative rules are not subject to consideration for a waiver or variance.

Is this petition an initial request or is it a request for renewal? [☐] Initial Request [x] Request for Renewal
If a request for renewal, explain below why the renewal is necessary.

Petitioner Information (include licensee/registrant name and name of contact person, i.e. pharmacist in charge)

Name: **Thompson & Thompson LTC/Todd Thompson aka. Victor Drug** Phone No.: **319-653-1043** *(include area code)*
Address: **1010 W. Madison**
City: Washington State: IA Zip Code: 52353

Petition Information

1. Chapter Number and Title.

   Chapter 9, AUTOMATED MEDICATION DISTRIBUTION SYSTEMS AND TELEPHARMACY SERVICES

2. Rule Number(s) and Title(s).

   9.3 (2) Telepharmacy

3. Describe in your own words the essence of each Rule Number(s) and Title(s) that pertains to this petition.

   9.11 (2) Waiver from utilization of an AMDS in the process of the Remote Dispensing. Pharmacy will still utilize an independent automated pharmacy system for the practice of telepharmacy, but not the ntilization of traditional AMDS or robotic dispensing devices.

4. Describe the specific nature and scope of your petition. In your description, include the anticipated time period (beginning and ending) for which the petition would apply. A waiver or variance may not be requested or granted on a permanent basis; the petition must identify an end date.

After filling out form, print, sign, and mail to: Iowa Board of Pharmacy
400 SW 8th Street, Suite E, Des Moines, Iowa 50309-4688. Deadline for inclusion on
Board's agenda is three weeks prior to Board meeting.

This pharmacy has operated in this capacity for nearly two years with no issues and virtually no errors. It is our understanding the Board is still in the process of development of rules regarding this practice and request this Waiver be extended for another 18 months from this date.

5. Describe the relevant facts and reasons that, in your opinion, justify and provide "clear and convincing evidence" as to why this petition merits consideration for waiver or variance. In your description, explain why the rule(s) poses an undue hardship. If there is a public health, safety and welfare issue associated with this rule(s), or if this rule(s) addresses security or confidentiality issues, also explain how equal protection will be maintained if this petition were granted.

   The pharmacy has operated as a telepharmacy for significant time with virtually no errors utilizing the current system, integration of a full blown AMDS or robotic dispensing system is neither beneficial nor feasible at this location. As a smaller aging community the residents have benefited by having more direct access to pharmacy services, pharmacist oversight of OTC medications, and direct access to and communication with a pharmacist in the community, thus creating a generally healthier community.

6. Does anyone else (inside or outside state government) possess knowledge relevant to this petition?

   [☐] Yes [☐] No [x] Do not know

   If yes, list their names, addresses and phone numbers below.

7. Would anyone (inside or outside state government) be adversely affected if this petition were granted?

   [☐] Yes [☐] No [x] Do not know

   If yes, list their names, addresses and phone numbers below.

8. Do you know how the Board of Pharmacy has treated similar situations?

   [☐] Yes [x] No

   If yes, describe below how similar situations were handled.

9. Have you had any past interaction with the Board of Pharmacy that might impact or relate to this petition?

   [☐] Yes [x] No

   If yes, describe below the issue involved and the outcome.

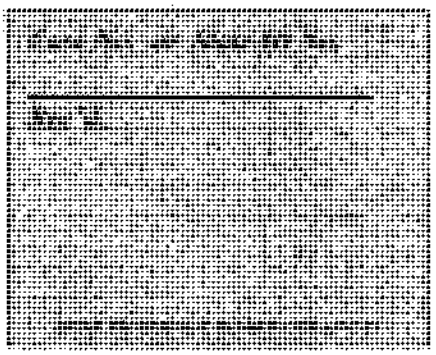
After filling out form, print, sign, and mail to: Iowa Board of Pharmacy
400 SW 8th Street, Suite E, Des Moines, Iowa 50309-4688. Deadline for inclusion on Board's agenda is three weeks prior to Board meeting.

I authorize any person with knowledge of the relevant or important facts relating to this petition to release any pertinent information to the Iowa Board of Pharmacy. I hereby attest to the accuracy and truthfulness of the information contained herein.

Petitioner's Signature

10-15-15
Date

After filling out form, print, sign, and mail to: Iowa Board of Pharmacy
400 SW 8th Street, Suite E, Des Moines, Iowa 50309-4688. Deadline for inclusion on Board's agenda is three weeks prior to Board meeting.



IOWA BOARD OF PHARMACY
Petition for [x] Waiver [☐] Variance
(check the appropriate box)

PLEASE PRINT OR TYPE ALL INFORMATION IN INK

A waiver excuses the petitioner from the requirements of a rule in its entirety or from a part of a rule; a variance does not. Instead, a variance is a modification to the requirements of a rule or a part of a rule. Example: A rule requires the fencing of certain property and further requires that the fence be at least 6 feet in height. A waiver of that rule would excuse the petitioner from the requirement for fencing the property. A variance would require the property be fenced but would allow the petitioner to maintain the current fencing configuration of 5 feet in height (perhaps the fence was constructed prior to the height requirement). When replacement of the current fence becomes necessary as a consequence of normal wear and tear, the variance would terminate and the petitioner would be required to comply with the 6-foot height requirement.

Note: Statutory requirements that have been repeated in administrative rules are not subject to consideration for a waiver or variance.

Is this petition an initial request or is it a request for renewal? [☐] Initial Request [x] Request for Renewal
If a request for renewal, explain below why the renewal is necessary.

Petitioner Information (include licensee/registrant name and name of contact person, i.e. pharmacist in charge)

Name: **Thompson & Thompson LTC/Todd Thompson** Phone No.: **319-653-1043**
aka. West Liberty Pharmacy *(include area code)*
Address: **1010 W. Madison**
City: Washington State: IA Zip Code: 52353

Petition Information

1. Chapter Number and Title.

   Chapter 9, AUTOMATED MEDICATION DISTRIBUTION SYSTEMS AND TELEPHARMACY SERVICES

2. Rule Number(s) and Title(s).

   9.3 (2) Telepharmacy

3. Describe in your own words the essence of each Rule Number(s) and Title(s) that pertains to this petition.

   9.11 (2) Waiver from utilization of an AMDS in the process of the Remote Dispensing. Pharmacy will still utilize an independent automated pharmacy system for the practice of telepharmacy, but not the utilization of traditional AMDS or robotic dispensing devices.

4. Describe the specific nature and scope of your petition. In your description, include the anticipated time period (beginning and ending) for which the petition would apply. A waiver or variance may not be requested or granted on a permanent basis; the petition must identify an end date.

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This pharmacy has operated in this capacity for nearly two years with no issues and virtually no errors. It is our understanding the Board is still in the process of development of rules regarding this practice and request this Waiver be extended for another 18 months from this date.

5. Describe the relevant facts and reasons that, in your opinion, justify and provide "clear and convincing evidence" as to why this petition merits consideration for waiver or variance. In your description, explain why the rule(s) poses an undue hardship. If there is a public health, safety and welfare issue associated with this rule(s), or if this rule(s) addresses security or confidentiality issues, also explain how equal protection will be maintained if this petition were granted.

   The pharmacy has operated as a telepharmacy for significant time with virtually no errors utilizing the current system, integration of a full blown AMDS or robotic dispensing system is neither beneficial nor feasible at this location. As a smaller aging community the residents have benefited by having more direct access to pharmacy services, pharmacist oversight of OTC medications, and direct access to and communication with a pharmacist in the community, thus creating a generally healthier community.

6. Does anyone else (inside or outside state government) possess knowledge relevant to this petition?

   [☐] Yes [☐] No [x] Do not know

   If yes, list their names, addresses and phone numbers below.

7. Would anyone (inside or outside state government) be adversely affected if this petition were granted?

   [☐] Yes [☐] No [x] Do not know

   If yes, list their names, addresses and phone numbers below.

8. Do you know how the Board of Pharmacy has treated similar situations?

   [☐] Yes [x] No

   If yes, describe below how similar situations were handled.

9. Have you had any past interaction with the Board of Pharmacy that might impact or relate to this petition?

   [☐] Yes [x] No

   If yes, describe below the issue involved and the outcome.

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I authorize any person with knowledge of the relevant or important facts relating to this petition to release any pertinent information to the Iowa Board of Pharmacy. I hereby attest to the accuracy and truthfulness of the information contained herein.

Petitioner's Signature

10-15-15
Date

After filling out form, print, sign, and mail to: Iowa Board of Pharmacy
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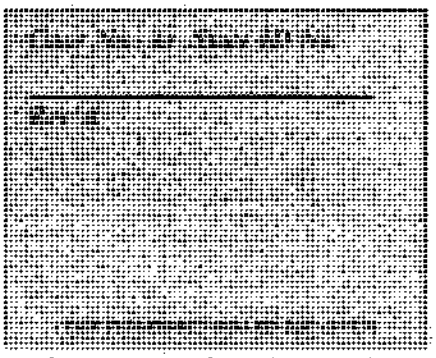

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Petitioner Information (include licensee/registrant name and name of contact person, i.e. pharmacist in charge)

Name: **Thompson & Thompson LTC/Todd Thompson aka. Brooklyn Pharmacy** Phone No.: **319-653-1043** *(include area code)*
Address: **1010 W. Madison**
City: Washington State: IA Zip Code: 52353

Petition Information

1. Chapter Number and Title.

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Petitioner's Signature _____ Date 10-15-15

From:	Greg Janes
To:	Jorgenson, Debbie [IBPE]
Subject:	Materials for Nov 3 Board Meeting
Date:	Tuesday, October 20, 2015 4:15:18 PM
Attachments:	TelepharmacyPilotProject20151103.pdf

Good afternoon Debbie,

On behalf of all parties involved with this study, please find the attached proposal for a telepharmacy pilot project. We are excited for the opportunity to work together with the Iowa Board of Pharmacy to provide world class telepharmacy operations in the State of Iowa.

We'll look forward to discussing the proposed project at the Board meeting on November 3rd.

I would also kindly request confirmation that you have received this information.

Kindest regards,
Greg Janes

--
Greg Janes
w: 319.535.0571
m: 319.899.2423
www.telepharm.com

A Pharmacy Pilot or Demonstration Research Project for a New Practice Model for Community Pharmacy

A Demonstration Project to Study the Effects of Implementing Telepharmacies in Community Practice to Increase Pharmacist Access and Medication Adherence.

Iowa Pharmacy Association
NuCara Health Solutions
TelePharm
University of Iowa Hospitals & Clinics
University of Iowa College of Pharmacy

Primary contact:
Adam Chesler, PharmD
Vice President of Operations
TelePharm
105 Iowa Ave. Suite 231
Iowa City, IA 52240
[redacted]

Re-Submitted to the Iowa Board of Pharmacy

November 3, 2015

BACKGROUND

In Iowa, almost half the population — 1.4 million people — live in a rural area. In the past 2 years, 71 pharmacies have closed in the state, most of which served rural areas. These closings have left approximately 300,000 Iowans without convenient access to a pharmacy. Access to a pharmacist has been shown to be highly effective in improving outcomes[1], and the closing of these pharmacies is having a devastating effect on access to these critical services for Iowans living in rural areas.

Seventy-seven percent of rural counties in the United States are designated as primary care health professional shortage areas. Residents in these areas, typically elderly, now have to travel long distances to pick up their prescription medications. These patients already face a number of challenges when trying to access healthcare services close to home, including weather, geography, and social barriers. Patients see their pharmacist more often than any other healthcare professional[2], and increasing their accessibility should be a top priority.

Studies have been done to evaluate the factors that contribute to decreased medication adherence; lack of access to healthcare services and prescribers has been listed as a top cause. Additionally, patients have described difficulties in receiving medication refills often leading to gaps in therapy when access to a healthcare provider is limited.[3] Medication nonadherence contributes to increased costs to taxpayers and health systems due to poor outcomes, hospital readmissions, and unnecessary doctor visits. By eliminating the barrier to accessible pharmacy services and increasing rural access to a health-care professional, there is an opportunity to decrease state healthcare costs, while improving patient outcomes. Additionally, keeping funds from healthcare services in state increases the feasibility of local health clinic services and allows the local economy to flourish. When a community loses their pharmacy, these funds disperse (some of which leaves the state) and there is an increased risk of also losing their local health provider. Local pharmacies and clinics are crucial in maintaining the health of citizens in smaller communities.

In response to the established rules by the Iowa Board of Pharmacy for pharmacy pilot or demonstration research projects (657—8.40 (155A,84GA,ch63), the purpose of this application is to study the effects of a telepharmacy on patient adherence. Telepharmacy is using technology to enable community pharmacists to deliver patient care services to rural areas across the state of Iowa. The telepharmacy model has allowed for patient access to critical health care services in areas that are not able to support a pharmacy under the traditional model. This project proposes to study the impact which an easily accessible pharmacy has on patient levels of adherence, and in turn its potential to increase outcomes from therapy.

---

[1] Improving Patient and Health System Outcomes through Advanced Pharmacy Practice; A Report to the U.S. Surgeon General 2011. Rev: 5/2011, 8/2011, 12/2011. US Public Health Service. http://www.accp.com/docs/positions/misc/improving_patient_and_health_system_outcomes.pdf

[2] George E. MacKinnon III, PhD, RPh, FASHP. *Recognizing pharmacists as healthcare providers—a solution for the Patient Protection and Affordable Care Act roll-out*. August 13, 2013.

[3] Kelly M, McCarthy S, Sahm LJ. Knowledge, attitudes and beliefs of patients and carers regarding medication adherence: a review of qualitative literature. Eur J Clin Pharmacol. 2014 Dec;70(12):1423-31. doi: 10.1007/s00228-014-1761-3. Epub 2014 Oct 4. Review. PubMed PMID: 25277162.

The partners in this study include the University of Iowa Hospitals & Clinics, University of Iowa College of Pharmacy, Iowa Pharmacy Association, NuCara Health Management, Inc., and TelePharm.

SPECIFIC STUDY AIMS

1. Implement and assess the impact of a telepharmacy program in various sites across the State of Iowa on patient safety measures

2. Implement and assess the impact of a telepharmacy program in various sites across the State of Iowa on patient adherence measures

LEADERSHIP TEAM MEMBERS

Adam Chesler, PharmD, TelePharm, will provide operational oversight on all telepharmacy services, participate in regular team meetings, and participate in the writing of the study report.

Michael Brownlee, PharmD, Chief Pharmacy Officer, Department of Pharmaceutical Care at University of Iowa Hospitals and Clinics, will serve as a research consultant to the project and provide telepharmacy oversight.

Lisa Mascardo, PharmD, FASHP, Director, Ambulatory Care Services, University of Iowa Health Care, will serve as a research consultant and provide oversight and pharmacy services for selected telepharmacy practice sites.

Brett Barker, PharmD, NuCara Pharmacy, will provide a pharmacy management perspective for coordinating telepharmacy services within the practice sites and participate in regular team meetings.

Anthony Pudlo, PharmD, MBA, BCACP, VP of Professional Affairs Iowa Pharmacy Association, will provide data collection and reporting to the Iowa Board of Pharmacy on a quarterly basis and will participate in regular team meetings.

Matthew Witry, PharmD, PhD, Assistant Professor, University of Iowa College of Pharmacy, will serve as the principal investigator, coordinate data collection, and participate in the writing of the study report.

Roby Miller, CEO, TelePharm, will serve as Project Coordinator. He will oversee the project, coordinate study activities, and chair the regular team meetings.

Kate Gainer, PharmD, Executive Vice President/CEO, Iowa Pharmacy Association will oversee coordination of data collection from the community pharmacy sites in this study.

PHARMACY SITE-SPECIFIC INFORMATION

Locations included in this project will provide a cross-section of different scenarios allowing comparison data to be collected. The various locations include community, point of care, restricted population, and rural health clinic pharmacies.

Pharmacy Site #1:
Winfield Pharmacy
102 North Locust St, Winfield, IA
Population: 1,139
Location will be downtown
Sponsor: City of Winfield
PIC: Pamela Wong Wiltfang
License #: 21754
Managing Pharmacy: NuCara Health Solutions
License #: 1543

Pharmacy Site #2:
Lake Park Pharmacy
219 Market St, Lake Park, IA
Population: 783
Location will be downtown
Sponsor: City of Lake Park
PIC: Pamela Wong Wiltfang
License #: 21754
Managing Pharmacy: NuCara Health Solutions
License #: 1543

Pharmacy Site #3
Nora Springs Pharmacy
11 S Hawkeye Ave, Nora Springs, IA
Population:1,407
Location will be downtown
Sponsor: City of Nora Springs
PIC: Pamela Wong Wiltfang
License #: 21754
Managing Pharmacy: NuCara Health Solutions
License #: 1543

Pharmacy Site #4:
Wayland Pharmacy
227 W Main St, Wayland, IA
Population: 969
Location will be inside the local health clinic building
Sponsor: City of Wayland
PIC: Pamela Wong Wiltfang
License #: 21754
Managing Pharmacy: NuCara Health Solutions
License #: 1543

Pharmacy Site #5
Humeston Pharmacy
109 Broad St, Humeston, IA
Population: 494
Location will be inside local health clinic
Sponsor: Wayne County Hospital
PIC: Todd Thompson
License #: 19039
Managing Pharmacy: Reliant Long Term Care
License #: 1464

Pharmacy Site #6
Lineville Pharmacy
101 Main St, Lineville, IA
Population: 217
Location will be inside local health clinic
Sponsor: Wayne County Hospital
PIC: Todd Thompson
License #: 19039
Managing Pharmacy: Reliant Long Term Care
License #: 1464

Pharmacy Site #7
Seymour Pharmacy
515 W Wall St, Seymour, IA
Population: 706
Location will be inside local health clinic
Sponsor: Wayne County Hospital
PIC: Todd Thompson
License #: 19039
Managing Pharmacy: UIHC Ambulatory Care Pharmacy
License #: 599

Pharmacy Site #8
Corydon Pharmacy
417 S East St, Corydon, IA
Population: 1,584
Location will be inside local health clinic
Sponsor: Wayne County Hospital
PIC: Todd Thompson
License #: 19039
Managing Pharmacy: UIHC Ambulatory Care Pharmacy
License #: 599

Pharmacy Site #9
Anita Pharmacy
720 Main St, Anita, IA
Population: 949
Location will be inside local health clinic
Sponsor: Cass County Hospital
PIC: Todd Thompson
License #: 19039
Managing Pharmacy: Reliant Long Term Care
License #: 1464

Pharmacy Site #10
Griswold Pharmacy
1109 Morningside Dr, Griswold, IA
Population: 1,005
Location will be inside local health clinic
Sponsor: Cass County Hospital
PIC: Todd Thompson
License #: 19039
Managing Pharmacy: Reliant Long Term Care
License #: 1464

Pharmacy Site #11
River Crossing Pharmacy
3056 River Crossing Ct Suite A, Riverside, IA
Population: 1,045
Location will convert to a telepharmacy in order to remain open
Sponsor: University of Iowa Hospitals & Clinics
PIC: Lisa Mascardo
License #: 18469
Managing Pharmacy: UIHC Ambulatory Care Pharmacy
License #: 599

Pharmacy Site #12
Student Health Pharmacy
4189 Westlawn South, Iowa City, IA
Population: n/a
Location will serve a restricted population (students using the Student Health Center)
Sponsor: University of Iowa Hospitals & Clinics
PIC: Lisa Mascardo
License #: 18469
Managing Pharmacy: UIHC Ambulatory Care Pharmacy
License #: 599

Pharmacy Site #13
North Dodge Pharmacy
North Dodge St, Iowa City, IA
Population: n/a
Location will be inside the new health facility to provide point of care prescription dispensing
Sponsor: University of Iowa Hospitals & Clinics
PIC: Lisa Mascardo
License # 18469
Managing Pharmacy: UIHC Ambulatory Care Pharmacy
License #: 599

Pharmacy Site #14
Bancroft Pharmacy
122 W Ramsey St, Bancroft, IA
Population: 727
Location will be inside local health clinic
Sponsor: City of Bancroft
PIC: Pamela Wong Wiltfang
License #: 21754
Managing Pharmacy: NuCara Health Solutions
License #: 1543

Pharmacy Site #15
Graettinger Pharmacy
109 W Robins St, Graettinger, IA
Population: 819
Location will be adjacent to the local health clinic
Sponsor: City of Graettinger
PIC: Pamela Wong Wiltfang
License #: 21754
Managing Pharmacy: NuCara Health Solutions
License #: 1543

Pharmacy Site #16
Odebolt Pharmacy
205/207 S Main St, Odebolt, IA
Population: 977
Location will share building with the local health clinic
Sponsor: City of Odebolt
PIC: Pamela Wong Wiltfang
License #: 21754
Managing Pharmacy: NuCara Health Solutions
License #: 1543

Pharmacy Site #17
Wyoming Pharmacy
156 W Main St
Wyoming, IA
Population: 514
Location will be where the previous pharmacy was located before it closed
Sponsor: City of Wyoming
PIC: Pamela Wong Wiltfang
License #: 21754
Managing Pharmacy: NuCara Health Solutions
License #: 1543

Pharmacy Site #18
Sioux Rapids
100 Front Street
Sioux Rapids, IA
Population: 795
Location will be 2 blocks away from local health clinic
Sponsor: City of Sioux Rapids
PIC: Todd Thompson
License #: 19039
Managing Pharmacy: Reliant Long Term Care
License #: 1464

Managing Pharmacy Information

NuCara Health Solutions
1150 5th Street Suite 150
Coralville, IA 52241
License #: 1543
(319) 354-6006

- 3 full-time pharmacists on staff
- Number of pharmacists will be scaled as necessary

University of Iowa Ambulatory Care Pharmacy
200 Hawkins Dr
CC 101 GH
Iowa City, IA 52242
License #: 599
(319) 384-6800

Reliant Long Term Care
1010 W Madison St
Washington, IA 52353
Pharmacy License #: 1464
(319) 653-1043

- 4 full-time pharmacists on staff
- Additional pharmacists will be hired to handle volume

For community letters of support, please see *Appendix C*.

PROJECT SUMMARY

To date, the Iowa Board of Pharmacy has seen a successful track record of telepharmacy operation. Building on this success, this project will look specifically at pharmacy access through telepharmacy and its impact on patient adherence measures. Locations for this study were identified and selected based on a designation of a “pharmacy desert,” and the need expressed by the community members. Each location is required to have a prescriber located nearby to ensure the maximum benefit and to evaluate patient outcomes. Currently each of these locations is struggling to provide convenient access to prescription medications as well as regular access to the expertise of a pharmacist during treatment.

Each of the proposed locations will be completed according to a proven template for telepharmacy operations that has been used in the current telepharmacy locations, specifically the Zearing and State Center locations. This pilot project is built on the following principles:

- Pharmacist time on-site will be maximized as volume allows
- Operating hours will be maximized as volume allows

The study will take place over an 18-month period. Following is a brief description of what the practice will look like:

- The pharmacist will be physically located at the Verification Site and will be readily available to the technicians and patients at the Telepharmacy at all times. Pharmacists will continue to have ultimate authority over the dispensing process in this model.

- The prescription department is staffed by certified pharmacy technicians. The pharmacist-technician relationship will remain important as the pharmacist will utilize new technologies and the leadership of head technicians to maintain safety protocols for patients.

- Prescriptions will be filled according to all the standard operating procedures of a pharmacy. As the technician is filling the prescription, they will capture images of all steps to provide to the pharmacist at the Verification Site. These images, along with any other documentation, will be sent to the pharmacist to verify the dispensing and clinical accuracy of the prescription. The prescription must be verified by the pharmacist before it is able to be dispensed to the patient.

- All of the information about the prescriptions filled at the Telepharmacy will be recorded and maintained in secure records with redundant backups for 10 years. This audit trail is readily available for any prescription processed at the Telepharmacy.

- A pharmacist will travel to the Telepharmacy at least one time per month to check all activities at the site and verify policies and procedures are being properly followed. When a pharmacist is not available on site, all verification and counseling will be provided by an Iowa licensed pharmacist.

- Medication counseling and responding to patient questions will be completed through a secure video connection in a private area when the medications are dispensed to the patient. Pharmacists will always be available for consultation with patients, prescribers, and other care providers through a secure video connection

Each location will utilize an Iowa licensed pharmacist at the Verification Site to remotely verify prescriptions and counsel patients. Each of these sites will have a pharmacist visit each telepharmacy at least monthly, and pharmacist presence will increase as patient growth allows in order to maximize the in-person pharmacist-patient relationship.

Experienced Certified Pharmacy Technicians (CPhT) will be hired to work at each telepharmacy location. Each location will have 1-2 technicians staffed daily, with an additional technician on call as needed. Every effort will be made to hire technicians who reside in or around the community for ease of commute and connection to the community.

Each location will be constructed using a standard pharmacy layout including a full community pharmacy prescription department, an OTC department for basic medical supplies, and a private clinical consultation room to be used for patient counseling and other private activities. Each of the locations will also be handicapped accessible and secured with 24/7 motion and alarm systems.

EnterpriseRx dispensing and Point-Of-Sale system will be used for each location for general operations. The telepharmacy software for remote verification and patient counseling will be provided by TelePharm.

The pharmacies will initially have approximate hours from 9:00am - 5:00pm Monday through Friday with variations in hours at certain locations depending on specific community need. Some later evening hours as well as Saturday hours will be considered depending on individual location volume.

Board of Pharmacy Rules Needed to be Waived

In order for implementation of this pilot project, it is requested that the Iowa Board of Pharmacy waive the AMDS requirements as well as references to automated pharmacy systems per the Iowa Administrative Code Rule 657 Chapter 9, and allow a Certified Pharmacy Technician (CPhT) to perform these tasks.

657—9.5(2)c *Need for remote dispensing site*. By waiving rule 657—9.5(2)c, the Board of Pharmacy would allow a telepharmacy to be located within 15 miles of another pharmacy. This waiver will allow for the research to study differences between sites under this radius restriction.

Clinical Services Provided

In addition to prescription medication drugs, each telepharmacy site will offer a variety of clinical services to patients. A comprehensive guide of services will be provided to each site. These services may include but are not limited to:

1. Medication Therapy Management
2. Comprehensive Medication review
3. Immunizations
4. Drug/Disease state education
5. Respiratory therapy
6. Durable medical equipment
7. Direct video link into clinic for clinical pharmacy services
8. Point-of-care testing with pharmacist on-site
9. Medication Synchronization

METHODS

Sites

This study will use both existing telepharmacy locations in Iowa and a set of new telepharmacies. Included pharmacies will utilize TelePharm's software platform for all telepharmacy activities and will commit to participating in all phases of the project, from design to final assessments. Agreements will be executed with the Telepharmacy Site and with the Verification Site providing the remote pharmacist verification, counseling, and other services for the telepharmacy.

Documentation by Sites

Each location agrees to document all required error reporting forms, counseling activities, and pharmacist daily activity logs. Pharmacies will agree to allow researcher access to all documentation on dispensing activities, error rates and Continuous Quality Improvement (CQI) data, including number of prescriptions processed, descriptions of any error events and how these were resolved.

The sites will also provide data on non-dispensing pharmacy services, such as medication therapy management, medication synchronization, or other services. Sites may be asked for financial data as necessary. The research team will have full access to original data to allow for proper statistical analysis.

Research Aims

<u>Aim 1: Document and investigate any dispensing errors in study telepharmacies.</u>

For each telepharmacy, a pharmacist will be on site at least once per month and will re-verify a random sample of 20 prescriptions waiting to be picked up. Also, remote pharmacists and local technicians will be tasked with completing error reporting forms should errors be identified.

In addition, in the first two weeks for each telepharmacy, prescriptions will be remotely verified by a second pharmacist to measure dispensing process accuracy.

If the error rate is greater than the comparator pharmacy, a continuous quality improvement process led by the parent pharmacy will be conducted. This process may include providing additional training to technician staff or an examination of processes and communication between the pharmacist and the telepharmacy technical staff.

Each telepharmacy will be compared to a control pharmacy serving a similar community. They will also engage in re-verifying a sample of prescriptions using the same schedule as the telepharmacy. The telepharmacies will be compared on the nature and rate of errors uncovered on a quarterly basis by the research consultant during the study period and provide a report to the Board of Pharmacy on a quarterly basis.

Aim 2: Assess patient satisfaction and service quality for patrons of the study telepharmacies. To address this aim, a survey will be conducted targeting a census of telepharmacy users. The survey will assess quality domains including counseling quality and satisfaction, access to pharmacist, barriers to medication adherence, perceived safety, availability of, or experience with, non-dispensing services, and patient demographics. There also will be a place to denote if they met with the pharmacist on one of the select days where the pharmacist was present. The survey will be provided to patrons as they are leaving the pharmacy with a postage paid return envelope.

A similar survey will be administered to a sample of patients from the comparator pharmacy through a paper-based administration with a postage paid return envelope.

Analysis

For Aim 1, error rates during the study period will be compared to those of the comparison pharmacy by means of a Chi-squared test. Error types also will be examined qualitatively to identify any circumstances leading to errors that are unique to the telepharmacy process.

For Aim 2, scaled items will be compared between the telepharmacy and comparison pharmacy using independent 2-sample t-tests for each item in addition to descriptive statistics.

STUDY PARTNERS

University of Iowa College of Pharmacy

The University of Iowa College of Pharmacy will oversee the research component of this project by working with the pharmacy partners to assure that study activities are conducted in a timely and coordinated manner. Dr. Matthew Witry will design data collection procedures, supervise data collection, manage and analyze study data, and assist in writing the study reports.

NuCara Health Solutions

NuCara Health Solutions will manage selected telepharmacy sites and will provide an Iowa licensed NuCara pharmacist for all verification and counseling at each location. Dr. Brett Barker will provide a pharmacy management perspective for coordinating Telepharmacy services within the practice sites.

University of Iowa Hospitals & Clinics
The University of Iowa Hospitals & Clinics will provide telepharmacy locations and work with researchers to collect and provide baseline and telepharmacy site data. Dr. Lisa Mascardo will oversee the telepharmacy operations at selected telepharmacy sites and provide the Iowa licensed pharmacist for all verification and counseling at these locations.

Iowa Pharmacy Association
The Iowa Pharmacy Association (IPA) will provide third party oversight of data collection for data at the telepharmacy locations. Dr. Anthony Pudlo will provide quarterly reports to the Board with data collected from the telepharmacy sites.

Iowa Board of Pharmacy
The Iowa Board of Pharmacy will evaluate each proposed telepharmacy project location pursuant to their final rules as authorized by the 2011 Iowa Acts, Chapter 63, Section 36, as amended by the 2012 Iowa Acts, House File 2464, Section 31. These sections of the Iowa Acts give authority to the Board of Pharmacy to approve a pilot or demonstration research project of innovative applications in the practice of pharmacy relating to the authority of prescription verification and the ability of a pharmacist to provide enhanced patient care for up to eighteen months.

PROJECT TIMELINE

Month 1-6	Project start-up, baseline data collection and site preparation for Telepharmacy sites
Month 6	Community pharmacies implement the Telepharmacy model, ongoing monitoring of operations & data reporting to the Board.
Months 16-18	Data analyses and report writing
Month 18	Pilot project authority expires for Telepharmacy locations unless renewed

Appendix A: Telepharmacy Policies & Procedures

POLICIES

1. Managing Pharmacy will operate and maintain a local telepharmacy that will provide access to critical pharmacy services to the community.
2. Managing Pharmacy will ensure that all Iowa Board of Pharmacy telepharmacy rules (Chapter 9) are followed while operating as a telepharmacy, with the exception of the waiver of the AMDS requirement
3. Managing Pharmacy will ensure that available technology is utilized in the operation of the telepharmacy location to protect the health and safety of all patients.
4. All Managing Pharmacy Operational Policies and Procedures will apply to the telepharmacy unless contradicted by the specific telepharmacy procedures as described in this section.
5. All pharmacy technicians working at the telepharmacy sites will be required to obtain and maintain current Certified Pharmacy Technician (CPhT) status through the Pharmacy Technician Certification Board (PTCB). They will also be required to have the following:
    a. Minimum of one year experience working in an Iowa pharmacy
    b. At least one month of training in a telepharmacy setting
    c. Must adhere to all other rules and regulations set forth by the Iowa Board of Pharmacy
6. Technicians will not perform any roles requiring the professional judgment of the pharmacist as described in Iowa Board of Pharmacy Rules
7. Technicians will be responsible for recording Continuous Quality Improvement data to include metrics such as consultation and error rates.

PROCEDURES

1. Pharmacy Overview
    a. Managing Pharmacy will maintain a licensed community pharmacy.
    b. The PIC in the community will be responsible for the oversight and operation of the telepharmacy. The PIC will be a pharmacist from the Managing Pharmacy location that has been previously trained on telepharmacy policies and procedures.
2. Personnel Responsibilities
    a. The PIC will be responsible for the oversight of the telepharmacy operation. The PIC will develop and maintain the Operational Policies and Procedures of the telepharmacy and is responsible for training the staff of the telepharmacy and the managing pharmacists in the legal and safe operation of the telepharmacy.

b. While operating as a telepharmacy, the pharmacy will be staffed with a Certified Pharmacy Technician at all times. The CPhT will be responsible for all technical functions performed at the telepharmacy. The technician will not perform any roles requiring the professional judgment of the pharmacist as described in Iowa Board of Pharmacy Rules.
c. The current pharmacist on duty for telepharmacy will be responsible for ensuring the accuracy and validity of all prescriptions dispensed by the telepharmacy. The pharmacist will also be responsible for providing counseling to all patients at the telepharmacy for new prescriptions and as requested for refill prescriptions, OTC medications, or other health information questions.
d. The pharmacists on duty for telepharmacy and the technician at the telepharmacy will be responsible for recording Continuous Quality Improvement data to include metrics such as consultation and error rates.
e. The PIC of the telepharmacy will ensure monthly controlled substance inventory counts are recorded.

3. Technology Safeguards
    a. Managing Pharmacy will install telepharmacy audio / visual equipment from TelePharm. This equipment will provide an audio / visual link between the managing and remote location and also allow for HIPAA compliant counseling of patients. The telepharmacy cannot operate as a telepharmacy if the audio / visual link cannot be established and no prescriptions may be filled or dispensed.
    b. The technician at the telepharmacy site will utilize barcode technology and the Tech Check module in the dispensing software to verify the products of all prescriptions filled.
    c. The telepharmacist on duty at will use the audio / visual link to check the hard copy of new prescriptions, the prescription label, and the contents of the package. The pharmacist will be responsible for the accuracy and validity of the finished prescription product and marking it as complete in the TelePharm software.

Appendix B: Pharmacist Monthly Inspection Checklist

Telepharmacy Site _____ DayTime of Visit _____

Inspected By _____

	Checklist Item	Y/N	Comments
1	Is a notice conspicuously displayed on the registered pharmacy premises detailing the name and registration number of the responsible pharmacist and the fact that a pharmacist is accessible for consultation at any time?		
2	Are pharmacy technicians following proper Consultation procedure?		
3	Audit 20 filled prescriptions, are they accurate?		
4	Audit 10 hard copies, is proper documentation being observed		
5	Observe technicians filling a prescription, are proper SOP being followed?		
6	Are customers greeted immediately upon entry?		
7	Are proper inventory control SOP being followed?		
8	Check 10 shelf bottles on shelf, are any of them expired?		
9	Are all staff in clean and proper uniforms and nametags are prominently visible?		
10	Is the CII cabinet locked and the key stored appropriately?		
11	Are patient required references in clear view?		
12	Is the filling area clear and uncluttered?		
13	Is the store area clear and uncluttered?		
14	Walk the perimeter, are there any concerns?		
15	Are the bathrooms clean and tended to?		

Appendix C: Community Support Letters

The following pages contain the letters of support from the communities which will benefit from a telepharmacy location.

P .O. Box 157 105 E. Ramsey St.
Bancroft, Iowa 50517
Phone: (515) 885-2382

www.bancroftiowa.com
E-mail: info@bancroftiowa.com
bmu@bancroftiowa.com

October 12, 2015

Iowa Pharmacy Board

Re: Pilot project for Telepharmacy

I am Tom Johnson, the current Mayor for the City of Bancroft. There is not a better city that you could choose to be part of a pilot project for telepharmacies in Iowa. Bancroft is the local trade center for the north half of Kossuth County serving over 3000 people. In 2006, Bancroft saw the need for a clinic and worked with Kossuth Regional Health Care to make that a reality. Business at the clinic will only increase with a pharmacy in town. Currently the closet pharmacy is 16 miles away, yet some residents will travel even further. Acute illnesses and preventative medicine care will increase at our local clinic and people will appreciate the opportunity to have a pharmacy in town. We do not preach support for local businesses, we do it.

Bancroft will be a leader in telepharmacy and rural healthcare options. It is important that you review the advantages that a telepharmacy will bring to local, rural communities and vote yes to a pilot program including Bancroft in Iowa.

Sincerely

Tom Johnson. Bancroft Mayor

P .O. Box 157 105 E. Ramsey St.
Bancroft, Iowa 50517
Phone: (515) 885-2382

BANCROFT
Since 1881
GARDEN SPOT OF IOWA

www.bancroftiowa.com
E-mail: info@bancroftiowa.com
bmu@bancroftiowa.com

October 12, 2015

Iowa Pharmacy Board

Re: Pilot project for Telepharmacy

The City Council of Bancroft, Iowa is in full support of Telepharmacies in Iowa and especially of one locating in Bancroft. We are a progressive community that not only meets the needs our residents but those of our neighboring communities. A telepharmacy will have a positive impact for the people, other businesses, our county and the state. We are excited to be a part of this new technology and Bancroft will be the model of success that you will refer to.

We the undersigned, whole heartedly support Telepharm and a telepharmacy in Bancroft, Iowa

Phil Jaren — Date: 10-12-15

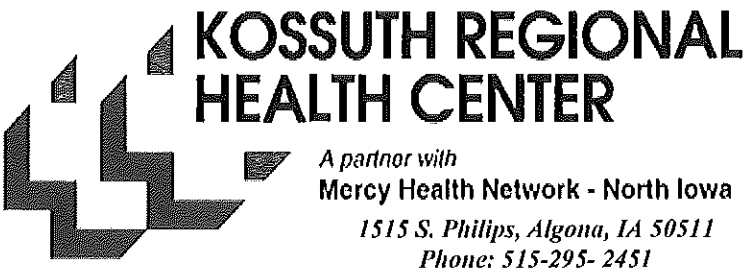
Robert Richter — Date: 10/12/15

Corey Rasch — Date: 10/12/15

Jeremy Fraker — Date: 10/12/15

Barb Schemmel — Date: 10-12-15

October 5, 2015



Iowa Board of Pharmacy
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

To Whom it May Concern:

I am pleased to write in support of the City of Bancroft's efforts to implement a tele-pharmacy. As the Administrator of Kossuth Regional Health Center, I have become very well aware of the current healthcare services that exist within the Bancroft area. Kossuth Regional Health Center encompasses a critical access hospital as well as a family practice clinic, home health, public health, hospice and retail pharmacy all located in Algona, 16 miles south of Bancroft. We are pleased to operate a satellite family practice outreach clinic within Bancroft which is staffed by a full-time physician assistant. This clinic provides access to basic primary care needs of the residents of the Bancroft community and surrounding area seeing approximately 3,600 patients per year.

As we have continually evaluated ways to improve care to the Bancroft area, consideration has been given to whether we would be able to implement a retail pharmacy operation in the community. Unfortunately, the realities of operating a retail pharmacy within a small community would not generate nearly enough volume to make a traditional retail pharmacy viable.

When we were contacted by leaders within the Bancroft Community regarding the prospect of a telepharmacy, we found that the model being proposed fits well within the needs and constraints that we have encountered for the community. Further, the partnership being considered with TelePharm would allow for the implementation of this service in a manner that meets the needs of all concerned.

Currently, patients that are seen in our Bancroft Clinic have limited choices regarding how their prescriptions would be filled. They can either travel to a pharmacy (closest one in Algona) or rely on delivery service. This arrangement would offer the ability to use reliable technology to establish the necessary personal relationship with the patient while also doing so in a manner that drastically reduces operating costs.

KRHC is very supportive of this model as it provides much needed access to a pharmacy for the community which further improves patient care. We wholeheartedly encourage your support of this proposal.

Sincerely,

Scott Curtis
Administrator

Crysti Neuman

From: info <info@ftsbbancroft.com>
Sent: Wednesday, October 07, 2015 12:24 PM
To: 'Crysti Neuman'
Subject: October 7, 2015

October 7, 2015

Iowa Pharmacy Board

To whom it may concern;

My husband and I would like to take this opportunity to say that we are in full support of the city of Bancroft, IA obtaining a tele-pharmacy, the need is here!

I have lived in Bancroft all of my 63 years and plan on living here the rest of my life. I currently am employed by the local bank and have been for over 40 years. I use the local medical clinic and wish to continue to do so. If ever the need is for a prescription we have several options, we can take time off work and drive the 20 miles one way and pick it up, we can have someone else go and pick it up, or we can have it sent up to Bancroft which means another day without the medication.

My husband has had extensive surgeries due to lung cancer and he does not drive out of town so it is not feasible for him to drive and pick meds up. My night vision is not so great so driving after work in the winter is not feasible for me and we do not know what kind of weather there will be.

Please add Bancroft to the list as one who will have a tele-pharmacy, I know for a fact that we will use it 100% for all of our prescription needs.

Thank you.

Sincerely,

David and Eileen Hagist
405 S. Walnut St.
Bancroft, IA 50517

To Whom it May Concern,

My name is Chris Doerning and I am the Chamber Director in Bancroft as well as an elementary teacher and mother of 3 children. I have lived in Bancroft for 12 years. I have seen many businesses open their doors in Bancroft over the years and have flourished thanks to the support of the community and other local business owners.

When I first arrived in Bancroft we had a pharmacy that was utilized by the community and the Heritage nursing home. Unfortunately, the owner retired and closed doors. It was a huge loss to the community. A few years after the closing of the pharmacy, we opened the Kossuth Regional Health Center Clinic in Bancroft. I have used this facility only a handful of times due to the fact that I have to drive into Algona for my prescription meds, so it is just easier to doctor there and pick up my prescription there. I recognize that the aging population in Bancroft doesn't always have the luxury of being able to drive and family members cannot always make a quick trip to Algona and back (32 miles) to pick up the prescription. I believe that bringing the pharmacy back to Bancroft will help loved ones take care of their aging parents better, with less stress, allow seniors to be more independent and allow busy parents to receive prescriptions in the same town they are seen by a doctor.

Thanks for Your Time,

Chris Doerning

WELP, INC.

P.O. BOX 77, BANCROFT, IOWA 50517-0077
PHONE: 515-885-2345 FAX: 515-885-2346d

October 7, 2015

I am Sandy Welp. My husband, Kurt, and I are owners of a small family business, Welp Hatchery, which was started by his grandfather in 1929. Welp Hatchery is located in Bancroft. We have approximately 40 employees.

We are both lifelong residents of Bancroft. My husband volunteered on the local fire department for over 18 years and also was an EMT for Bancroft's local ambulance service for 10 years. Quality health care is very important to both of us.

We are thrilled to have a new pharmacy business in Bancroft! We use the Bancroft medical clinic for our personal and business needs. Having a pharmacy in Bancroft to pick up prescriptions immediately will greatly reduce the travel time and costs.

I have an aging parent and this will have a huge impact for her purchasing prescriptions.

The whole community of Bancroft as well as several surrounding communities will benefit from a pharmacy here in town.

Sincerely,

Sandy Welp

October 5, 2015

Iowa Pharmacy Board

RE: Possibility of Pharmacy business locating in Bancroft, IA

I am an 83 yr. old woman living alone in my own home in Bancroft, IA. I was born and raised here, moved away for my husband's job for 20 years and moved back when he retired 24 years ago. Since he passed away 17 years ago, it is very inconvenient for me to go 18 miles for a prescription when I am ill. A local pharmacy would certainly be a blessing for me.

We have a great medical clinic located here in Bancroft, so a pharmacy would certainly compliment our community. The wonderful local nursing home and assisted living units that we have would also benefit from a pharmacy located here.

Our community is very progressive and we try to have the businesses that our aging population needs. We have many younger couples with small children in our community also and it would be much more convenient for them.

Please give this serious consideration and then grant the approval for this pharmacy.

Thank you for your consideration.

Darlene Jansen

Darlene Jansen
201 S. Summit
Bancroft, IA 50517

City of Ledyard
P.O. Box 23
Ledyard, IA 50556

2 October 2015

To Whom It May Concern:

SUBJECT: Tele-pharmacy

This is a letter in support of the City of Bancroft's efforts to secure a tele-pharmacy.

I am the mayor of Ledyard and have lived in Kossuth County for the past 20 years. As a mayor and long-time resident, I understand the difficulties many people in my community, especially the elderly, endure to receive medical care. The Bancroft medical clinic has been a life-saver as well as a true service to northern Kossuth County.

Likewise, the proposed tele-pharmacy would add an excellent improvement in medical service to the people living in the northern end of Kossuth County. Currently, residents in our community need to travel more than 30 miles secure prescriptions. The amount of time, trouble and expense during time of illness is more than inconvenient. A local pharmacy would save both time and money, and be a source of reassurance for many, knowing that prescriptions would be prepared in a timely and convenient manner.

For myself, I use the Bancroft clinic. But when I need prescriptions filled, I need to drive on to Algona, another 15 miles, or wait a day or two until Kossuth Regional Health Center Pharmacy can deliver the prescription to Bancroft. Either way, I currently need to make an additional trip to get my prescription filled.

In discussions with community members, all agree that the proposed tele-pharmacy would a true asset to the people living in Kossuth County.

If I can be of any additional assistance in the matter, please do not hesitate to contact me.

Sincerely,

Sharon Hackenmiller Cowin
515.646.2151 or 515.320.3222

BANCROFT COMMUNITY
ECONOMIC DEVELOPMENT COMMISSION
BANCROFT, IOWA 50517

To Whom It May Concern,

Bancroft Community Economic Development Commission is an advisory arm of the Bancroft City Council. We provide the council input on matters of the revolving loan fund, tax abatement and TIF.

In addition, we work directly with existing businesses or businesses that may have an interest in expanding to or relocating to Bancroft. Attracting a pharmacy has been a priority since the loss of our pharmacy in 2007. The biggest impediment has been the cost of a full-time pharmacist and the need for 130-150 prescriptions a day. In 2008 there was a significant effort that was embraced by the community with a broad based fund-raising. The purpose of raising the funds was a show of good faith to prospective pharmacies and pharmacists. Nothing became of that effort and the funds were returned to the donors. The need, however, is still there.

The Kossuth Regional Health Clinic in Bancroft is doing well but would be strengthened by a pharmacy in Bancroft. Many people travel to Algona or other area doctors when the treatment will likely need an immediate prescription. A local pharmacy would provide our families with immediate assistance with their prescriptions without additional travel. This will make our clinic more attractive while enhancing main street traffic.

Please look favorably upon Bancroft's application. You will not be disappointed in the support this community will provide this telepharmacy.

Very truly yours,

James Bollig

James Bollig
Bancroft Community Economic Development Commission
President

October 7, 2015

Iowa Pharmacy Board

To whom it may concern,

I would like to express my full support in the city of Bancroft, Iowa obtaining a pharmacy. My husband and I moved to Bancroft in 2013 and one of the few amenities missing from the community is a pharmacy. Currently we are able to have our health needs met through our local health care facility but to receive a prescription, we must drive 20 minutes or more. This is a hardship as it causes more time away from our jobs, possibly driving when not feeling well, or having to wait until late evening or even the next day to be able to obtain the medicine. The weather may certainly affect the time it can take to get a prescription as well. Having a pharmacy directly in Bancroft would alleviate all of these issues.

Please consider adding Bancroft to the list of cities that have/will have a tele-pharmacy. A pharmacy in Bancroft, Iowa is a greatly needed addition to the community as it will also aid others in our rural area in reducing their time and effort to obtain medication.

Thank you for your consideration.

Sincerely,

Rebecca Oppedal

10-4-2015

Barb Schemmel
514 S. Portland St.
Bancroft, IA 50517

To whom it may concern,

I am the newest member of the Bancroft city council. Living in Bancroft for the past 15 years I have come to value the traditions of a small town. A small town that does it's best to give its residents the best town possible. Since moving to Bancroft I have always worked in town. I currently work at Nyman TV & Furniture, working full time does not allow me to run to another town to get my prescriptions filled in a timely manner.

Having a pharmacy in Bancroft would be such a great convenience. Right now if I need a prescription it is necessary for me to call the clinic and have it brought up, which is usually the next day. An example of what could happen with prescription, I recently needed a prescription filled and was busy at work and never got it ordered. I did finally call the prescription in on Saturday and was able to go to Algona and get it picked up. If a prescription is needed immediately because of an illness then I would need to make a trip to Algona to retrieve my medications. A trip to Algona when you are not feeling well and should probably be in bed.

I feel that having a tele-pharmacy in Bancroft would be so helpful. We would have more of our residents getting prescriptions here and in turn would spend more here. Instead of getting groceries in Algona while they wait for their medications they could shop here instead. The residents of the towns in the surrounding area would have a chance to get their medications sooner and possibly spend their money here instead of Algona or other larger town. All small towns need to give everyone the opportunity to shop local and keep the small businesses running. Bancroft would very much like to be on the starting edge of the concept of a tele-pharmacy.

As a resident of Bancroft look forward to working towards a tele-pharmacy in Bancroft.

Sincerely,

Barb Schemmel

spa-dee-dah, too!
PO Box 177, Bancroft, Iowa 50517
515-885-2spa

Iowa Board of Pharmacy
400 SW Eighth Street Suite E
Des Moines, Iowa 50319-4688

October 2, 2015

To Whom It May Concern:

This letter is in support of the Telepharm Application for Bancroft, Iowa. In addition, to currently owning a business on main street, I have been involved for over thirty years in organizations such as Bancroft Economic Development, Chamber of Commerce, Rotary, Bancroft Childcare Board and numerous others.

There are numerous effective ways to portray the positive effect a pharmacy would have on the community and area, as well as, the extensive support a pharmacy would receive from the Bancroft community and surrounding areas. A brief history of my firsthand experience may be the most effective way for me to communicate the extensive support.

Bancroft was home to a pharmacy until December 2007, closing due to owner's personal circumstances. In 2008, in response to a series of broad based community meetings, 114 people gave actual checks in the amount of $250.00 each to show their pledge to support the establishment of a new pharmacy in Bancroft. After extensive study and research, the checks totaling $28,500 were returned to owners due to the lack of progress in securing a pharmacy.

In 2012, renewed efforts by a community group met extensively with experts from the Mercy Health Care System in Mason City, Iowa to determine the feasibility of partnering wit Kossuth Regional Health Center to establish a pharmacy in Bancroft. It was determined by KRHC and Mercy Systems that it was not feasible at that time. For a second time, the cost of securing a full time pharmacist to serve the community was cost prohibitive. At that time, KRHC agreed to next day prescription delivery service from Algona to Bancroft Medical Clinic.

Advancements in technology, along with the business plan developed by TelePharm now makes it possible for Bancroft, a rural community, to have a pharmacy.

Respectfully Submitted,

Ellengray Kennedy

Bancroft Area Rotary

September 29, 2015

Dear Members of the Iowa Pharmacy Board:

In a small town rural setting medical services are often limited. The town of Bancroft lost its pharmacy a number of years ago when our pharmacist relocated to a large city. That forces our residents to travel 15 miles to the nearest pharmacy.

Our city director is actively researching the possibility of securing a tele-pharmacy for our town. The city director and a committee are going to visit Iowa communities that have a tele-pharmacy. Health care for our residents would be enhanced with the addition of a tele-pharmacy in our community. Bancroft residents have also been very loyal supports of our local business, so would show their patronage for a tele-pharmacy in our town.

Thank you for all the support you can give to our community of Bancroft in procuring a tele-pharmacy that would be a great asset to our town.

On behalf of the Bancroft Area Rotary, I am happy to address the need of our rural town in northern Kossuth County.

Sincerely,

Eileen F. Kadow

Bancroft Area Rotary President
Eileen F. Kadow
512 E. Ramsey St
Bancroft, IA 50517
515-885-0206

IADG
Iowa Area Development Group

September 30, 2015

Crysti Neuman
City Manager
City of Bancroft
P. O. Box 157
Bancroft, IA 50517

Dear Crysti:

Iowa Area Development Group (IADG) is pleased to assist the City of Bancroft in attracting the Telepharm project to your community. As you know, IADG has worked with the City for many years on business and community development efforts. Helping to secure this type of health care service appears to be a vital element for your local leaders and citizens to consider and support.

The interest level is high across the state for expanded pharmacy services for such a project as Telepharm in many communities Bancroft's size. Your willingness to explore the possibility of expanded services and medical support and prudently evaluate the positive impact to the community is very commendable.

Access to medical prescriptions and other ancillary services can be difficult in rural Iowa. This effort should seriously be considered to help cut down on special trips to larger communities for medical and pharmaceutical needs.

Please call upon IADG when we may be of further assistance.

Sincerely,

Bruce L. Hansen
Vice President Business Development

2700 Westown Parkway, Suite 425
West Des Moines, Iowa 50266-1411
Ph (515) 223-4817
Fax (515) 223-5719
800-888-4743
iadg@iadg.com
www.IADG.com

Hello

My name is Robert Deitering . I am an owner of a New Holland Farm implement business on the edge of town and have worked here for over 40 years. We employee 20 people and have seen instances over the last few years of the inconvenience of not having a pharmacy locally, especially it is hard on the young families with sick children. I have just a month ago had an employee who had to leave work to drive to Algona to get a prescription for his wife which takes productive time from us and also cost the employee lost wages. Not all of our employees doctor in town now but with a pharmacy I would think more of them may?

I would think and hope that our town with its better than average retail draw could support a pharmacy. Along with a car dealership, there is also a Case IH farm equipment dealer in town who probably employs the same number of people. Also we have a manufacturer in town who employees over 100, plus we have many businesses on main street.

I am strongly in favor of a telepharmacy in town. I was part of an earlier group that tried to recruit a pharmacist and found the cost of a pharmacist to be the biggest issue. The telepharmacy should work.

Sincerely,

Bob Deitering
Deitering Bros., Inc.
1109 360th Street
PO Box 47
Bancroft, Iowa 50517
Ph 515-885-2314
Fax 515-885-2611
www.deiteringbrothers.com

October 1, 2015

To: Members of the Iowa Pharmacy Board

It is exciting that Bancroft may once again have a pharmacy! I have lived in Bancroft for over 50 years and have worked at the local community bank for more than 30 years. I have also been on the Bancroft Chamber of Commerce board for several years and am a charter member of the Bancroft Area Rotary Club.

This community offers a large variety of businesses, including a nursing home/assisted living facility, two farm implement dealerships, Ford dealership, nice grocery store, etc. We are extremely proud that we do not have any empty buildings on our main street. These attributes are not typical in most rural towns.

As stated previously, I am very excited about the proposed pharmacy and would contribute funds toward the project. Residents would not have to go out of town for their prescriptions, which is positive in a variety of ways. For example, our older residents would not have to drive, which is especially nice during inclement weather. And our local merchants should also benefit because when a resident goes out of town for their prescriptions, they purchase other items as well.

Another benefit for us would be having a larger selection of over-the-counter pharmaceutical products than what our grocery store can offer. This would be a win for consumers in the price and selection department and it would be a win for the grocery store since they could use the shelf space for other items.

Other residents are also excited about a pharmacy returning to Bancroft. We take pride in the business community and adding a pharmacy would certainly be a great asset for us. Thank you for considering Bancroft in your expansion.

Sincerely,

Teresa Kennedy

Teresa Kennedy

KOSSUTH COUNTY
ECONOMIC DEVELOPMENT
CORPORATION

106 South Dodge St., Suite 210
Algona, IA 50511
Ph: (515) 295-7979
Fax: (515) 295-8873
Email: kcedc@kossuthia.com
www.kossuth-edc.com

Maureen Elbert
Executive Director

Acres of Opportunity

October 1, 2015

RE: Telepharm Pharmacy

Ladies and Gentlemen:

Kossuth County Economic Development Corporation is supportive of a Telepharm Pharmacy in Bancroft. Telepharm Pharmacies are already operating successfully in over 100 stores in 12 states. Independent retail pharmacies are closing across the United States, leaving many patients without local access to these critical health services. A Telepharm Pharmacy is the solution for these rural communities.

Typically smaller communities cannot support a fully-staffed pharmacy, so by removing the on-site Pharmacist from the physical storefront, the operating costs are lowered substantially. It would operative as a traditional pharmacy except you would speak to the Pharmacist through a secure video call. The Telepharm Pharmacy will be operated by Certified Pharmacy Technicians and all prescriptions are verified for accuracy and safety.

This will greatly benefit the citizens of Bancroft and the surrounding area because it would prevent the need to travel long distances since prescriptions and over-the-counter medications would be available locally. It will also provide access to another healthcare provider, helping to fill gaps in care and improve the overall health in the community.

Kossuth County Economic Development Corporation would welcome a Telepharm Pharmacy in Bancroft since it will increase economic development by creating a storefront, quality paid jobs and keeping money locally.

Sincerely,

Maureen Elbert

Maureen Elbert
Executive Director

MFE:lk

FARMERS & TRADERS SAVINGS BANK

Sept. 30, 2015

Iowa Board of Pharmacy
400 SW 8th Street
Des Moines, IA 50309

Re: Tele-pharmacy

Dear Board Members:

I am writing a letter of support for the Iowa Board of Pharmacy to allow for an expansion in the number of tele-pharmacies to be allowed in Iowa. The reasons for my support include the following:

1. I am a resident of Bancroft, Iowa, located in the northern one-half of Kossuth County. I have been working for Farmers & Traders Savings Bank for the past 35 years, and currently hold the office of President/CEO. This bank serves Bancroft and the surrounding areas, and has no branches.

   Bancroft serves as a trade center for the north one-half of Kossuth County, which Kossuth being a double sized county, means our trade area is the size of most other counties. The population of our trade area would be 4,000-5,000 people.

   This community did have a full-time pharmacy until 2007. Since the closing of the Bancroft Pharmacy, and the retirement of Jack Van Norman in Swea City, our trade area has not had a pharmacy. An attempt to start-up a new pharmacy here in 2008 had the financial support of the community, but the model just doesn't work when a full-time pharmacist salary is included in the overhead. As a result, when people need a prescription filled quickly, they need to drive to Algona, Fairmont, MN, or Blue Earth, MN. This is a major inconvenience for the people in our trade area. Locating a tele-pharmacy here is a financially viable means of providing prescriptions, and is a perfect use of technology to add to the quality of life in more rural areas.

2. We have a full-time medical clinic, dentist, and chiropractor in Bancroft. We are a center for health care. We are missing the ability to provide prescription drugs. We have a vibrant main street area, along with a solid highway commercial area. All of our trade pull will help to insure the financial success of a tele-pharmacy.

3. We have a state recognized nursing home and 9 unit assisted living wing, doing business as Hawkeye Care Center (fka Heritage Home), along with 10 units of elderly, low & moderate income apartments owned by Bancroft Apartments, and 20 units for elderly, low income apartments operated by Pleasantview Manor HUD. Most of those tenants utilize the local medical clinic and would prefer to have prescriptions available without

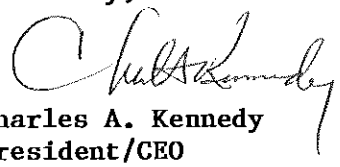
(continued)

P.O. BOX 107 • BANCROFT, IOWA 50517-0107 • TELEPHONE (515) 885-2341 • MEMBER F.D.I.C. • FAX (515) 885-2220

having to drive out of the community.

I strongly urge your favorable consideration of expanding the number of telepharmacies in Iowa. It seems that utilizing technology to facilitate the delivery of prescriptions is a very worthwhile use of technology, with very real benefits to the ultimate consumer. It is also a way to increase the quality of life in communities that are not the county seat, but have those desirable amenities that would help people to decide to locate there. Thank you.

Sincerely,



Charles A. Kennedy
President/CEO

ck

CITY OF SWEA CITY

308 4th Ave. W.
Swea City, IA 50590
Phone: (515) 272-4606
Fax: (515) 272-4606

CITY CLERK
Alycia Sandvig
PUBLIC WORKS
Travis Stevens
Blake Stevens
CITY ATTORNEY
Scott Buchanan

MAYOR
Lawrence Slifka
CITY COUNCIL
Jill Bollinger
Emily Eisenmann
Debra Ellman
Chris Stevens
Cal Wolterman

October 1, 2015

To whom it may concern:

My family and I have lived in Swea City for ten years. I have been the City Clerk here in Swea City for two years. Previously I was employed at Pharmacists Mutual in Algona. When I was working in Algona filling a script wasn't an issue as there are a couple of pharmacies there. However, now that I am not working in a bigger city it would be very nice to have the option to be able to fill scripts at a pharmacy closer to home.

I also feel that having a pharmacy closer to home would be a wonderful asset to our community. Many of our community members would benefit from a pharmacy that is closer. The assisted living facility would also be able to use a pharmacy that is located more closely.

Our nearest options of for a pharmacy are approximately 30 minutes away. For many individuals this is an extra trip and would be much more convenient if a pharmacy were located closer to home. I feel that a new pharmacy business in the area would be very beneficial not only to myself but to many of the residents.

Alycia Sandvig

Alycia Sandvig

City Clerk
Swea City IA

Dick and Jan Deitering
PO Box 428
301 South Walnut
Bancroft, IA 50517

October, 5, 2015

Dear Members of the Iowa Pharmacy Board:

We are lifelong residents of Bancroft, IA who left this community for college, but then returned to run a business and raise our family in the rural Bancroft community setting. Presently, we are both retired, but, when working, Dick was an owner and manager, along with his brother, of Deitering Bros., Inc., one of two successful farm equipment dealerships in Bancroft, both of which are still in operation. Jan was a teacher, mother, and bookkeeper for DBI. During those years, Bancroft had a local pharmacy. If a worker was injured on the job, he/she could go to the local doctor for treatment and to the local pharmacist for any needed prescription(s). The same was true for families when they experienced injuries or common ailments. What a convenience for businesses, workers and busy families! What a convenience in inclement weather! Presently we can still go to the local clinic for treatment, but are unable to get prescriptions without going to Algona. Not ideal for workers, busy families, or senior citizens.

Bancroft is a progressive, full service community in northern Iowa, but it is lacking one essential service for its 1000+ population - a pharmacy to meet the needs of those many clients of our clinic as well as our assisted living and nursing home residents. Also, many small rural towns in our area would be better served for prescription needs as many of these communities are 30+ miles from a pharmacy. (Ex. – Swea City, Lakota, Ledyard)

Each service that is added to our community helps, not only area residents, but helps existing businesses to grow and thrive. We think that having the pharmacy would increase the number of people using the clinic and consequently local businesses. When clinic clients come to Bancroft, they will be more likely to use the grocery store, gas stations, restaurants, and other mainstreet businesses. This in turn increases tax dollars which then provides added tax dollars to our local school district and our community for needed infrastructure, recreation programs, EMS, etc. improvements.

Discussion with local citizens has indicated to us that this pharmacy would be another service that they would like to have in Bancroft, and that they would use it if your board would approve the establishment of this telepharmacy. They like this idea!

Bancroft has seen a population growth in the last three years along with a significant growth in our business community. Young people are returning to begin these businesses. They are returning for the same reasons we returned - a great family and business community environment. As a board member of our local childcare center, Jan can attest to this as the childcare center has seen a tremendous growth in the infant and toddler numbers, to the point of needing to add a room to accommodate the increased numbers.

Rural communities are a great place to live and to raise a family, and Bancroft, with its strong service and retail business sector, is one of the best. In addition, the community has a golf course, bowling alley, tennis and basketball courts (inside and out), parks, health center and children's programs for recreation. If your time permitted, we invite you to visit and experience this for yourself.

Thanks for your time and your thoughtful consideration about this issue. We thank you in advance for helping our community and the state of Iowa to continue to grow and thrive!

Sincerely,

Dick Deitering
Jan Deitering

Dick and Jan Deitering

CITY OF LAKE PARK

217 Market St. Box 536
Lake Park, IA 51347
Phone: 712-832-3527 Fax: 712-832-3669

August 12, 2015

To Whom It May Concern:

Why do we need a pharmacy? This was a question that was posed to me. After some thought I decided it was not a matter of "need" but rather a "want". Unlike many other small cities across Iowa who are struggling to survive, we are thriving and growing. Rather than looking at school consolidation we just added an addition due to the need for more space. When looking at our city we can proudly boast that we have many amenities including a grocery store, convenience store, insurance agents, hairstylists, flower shop, dining establishments, chiropractors, nurse practioner, banking, churches, lawyer, implement dealers, auto repair & parts, community center, library, care center, processing plant, elevator, manufacturing plant, housing developments, plumbing, electricians, building contractors, daycares, and recreational opportunities which include boating & fishing on Silver Lake, camping, city park, swimming pool, bowling, golf, community theatre, historical museum, freedom rock, and a biking & walking trail. So, will our city survive without a pharmacy? Certainly, but the potential that a pharmacy could bring to our city makes it a desirable business opportunity to pursue. A pharmacy would be another amenity that would allow our residents to be able to fulfill their needs without having to drive 15-20 miles. We all know the more services we are able to offer the stronger a city will be. I believe a pharmacy may also aid in making our city an attractive place for further business opportunities such as, but not limited to, a dentist, doctor, and assisted living. The availability of many services locally also presents an attractiveness for families looking to make a home, which then leads to a housing need to be filled. So does Lake Park "need" a pharmacy, no, but Lake Park does want a pharmacy, not only for the additional convenience it offers to our residents but for the future potential it brings with it.

Sincerely

Marie Matthiesen
City Administrator
Lake Park, IA 51347

To whom it may concern,

My name is Julie Baumgarn, I work full time as a hairdresser here in Lake Park, IA. My husband, 3 boys, and I have lived in Lake Park for almost 5 years now.

I am writing to express my support and desire for a pharmacy in town. Currently we have to drive 15 miles to get our prescriptions every time we need them. One of my boys has diabetes and requires insulin and test strip refill prescriptions every month.

Currently, the pharmacy we use has those specific supplies on hand at all times, which we appreciate. When our prescription runs out, the pharmacy faxes a request to his doctor in Sioux Falls. These are time saving options for me, however, I don't always have time to drive over to the pharmacy to get these prescriptions. Having a pharmacy in town, where I could get prescriptions in 5 min instead of 45 would be very helpful for this busy mom.

I would say 95 % of the people I have talked to personally are also in support of a local pharmacy. It would be a great, and necessary, addition to a growing community!

Thank you for your time and consideration

Julie

John H. Wills
STATE REPRESENTATIVE
First District
Statehouse: (515) 281-3221
e-mail – john.wills@legis.iowa.gov

HOME ADDRESS
15732 Tradewind Dr.
Spirit Lake, Iowa 51360
Cell: (712) 330-9492

House of Representatives
State of Iowa
Eighty-Sixth General Assembly
STATEHOUSE
Des Moines, Iowa 50319

COMMITTEES
Environmental Protection, *Vice Chair*
Human Resources
Natural Resources
State Government

APPROPRIATIONS SUBCOMMITTEE
Agriculture & Natural Resources

8-28-2015

To Whom It May Concern,

I am House District One, State Representative, who represents Lake Park as part of my district and I have been a part of the community and have worked in the community for 8 years as part of my full-time job in Dickinson County. On top of being a State Representative, I work full-time in the community trying to improve the water quality of Silver Lake through working with landowners and farmers to reduce the amount of pollutants to the lake.

I believe that Lake Park has a population that should have a pharmacy business but the population is not one that can sustain a traditional pharmacy. As a legislator I often talk to elderly or handicapped people who express that not having pharmaceutical services readily available causes them undue problems and issues. This town needs to have a pharmacy but is a relatively small community and so the sustainment of a pharmacy would be difficult.

A pharmacy would impact on the town by reducing travel times for many people who need medication, and by providing a service that is not currently available in the community. The community is an aging community and the ability to have pharmaceuticals available in would be of tremendous benefit.

Currently the closest town with a pharmacy is Spirit Lake and that is approximately 14 miles away. So, because there is no pharmacy in Lake Park a person who is in need of medication needs to drive 28 or more miles round-trip in order to get those drugs from a pharmacy.

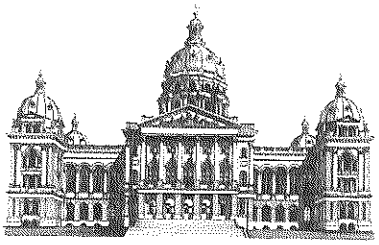
The current feeling in the community is a pharmacy needs to be in this town because of the number of people who live here, the number of elderly and handicapped persons, and the distance that people need to drive in order to fill prescriptions.

Sincerely,

John H. Wills
State Representative

AMANDA RAGAN
STATE SENATOR
Twenty-seventh District
Cerro Gordo, Butler and
Franklin Counties
Statehouse: (515) 281-3371
amanda.ragan@legis.iowa.gov

HOME ADDRESS
361 S Pennsylvania Ave 1-D
Mason City, IA 50401
H: (641) 424-0874
O: (641) 424-2316



The Senate
State of Iowa
Eighty-sixth General Assembly
STATEHOUSE
Des Moines, IA 50319

ASSISTANT MAJORITY LEADER

COMMITTEES

Agriculture, *Vice Chair*
Appropriations
Human Resources, *Vice Chair*
Natural Resources and Environment
Rules and Administration
Veterans Affairs

Health and Human Services Appropriations
Subcommittee, *Chair*

September 18, 2015

TO WHOM IT MAY CONCERN:

The purpose of this letter is express my personal support for the proposal to open a tele-pharmacy facility in Nora Springs, Iowa. I believe this is an outstanding idea which will have tremendous benefits for that community and the surrounding area.

As a state senator, I have been privileged to serve on the Senate Human Resources Committee since my first election to the legislature. During that time I have been a strong advocate for increasing health care facilities and access to health care throughout Iowa, especially in our rural regions. A tele-pharmacy facility in Nora Springs would be a great help to the citizens who live there. Even though the closest pharmacy is only 10 miles away in Mason City, that 20 mile round trip can prove daunting for people with mobility issues, disabilities, or the elderly who may be homebound or have problems with transportation.

It was my honor to represent Nora Springs and the surrounding Floyd County for a decade. Bringing access to life-giving prescriptions closer to home is a most positive development for that town and should be encouraged and supported at every level of government and regulation. I applaud those who are taking the initiative to make this proposal a reality.

Sincerely,

Amanda Ragan

Senator Amanda Ragan

Todd Prichard
STATE REPRESENTATIVE
Fifty-Second District
Statehouse: (515) 281-3221
e-mail – todd.prichard@legis.iowa.gov

HOME ADDRESS
107 Ferguson Street
Charles City, Iowa 50616
(641) 220-0798

House of Representatives
State of Iowa
Eighty-Fifth General Assembly
STATEHOUSE
Des Moines, Iowa 50319

COMMITTEES
Agriculture
State Government
Ways and Means

APPROPRIATIONS SUBCOMMITTEE
Justice System

September 22, 2015

Iowa Board of Pharmacy

Re: Telepharmacy, Nora Springs, Iowa

Dear Board of Pharmacy Member:

I respectfully request that the Board of Pharmacy approve the request for a telepharmacy in Nora Springs, Iowa. As the State Representative for Nora Springs, I know that locating a telepharmacy in Nora Springs will greatly benefit this small rural community.

Nora Springs is located in rural North Iowa and currently without a local pharmacy. Residents of Nora Springs currently have to drive 10-15 miles to access a pharmacy. For elderly residents, the distance to a pharmacy is burdensome. Further, the lack of critical services, such as a pharmacy, greatly decrease the quality of living and attractiveness of a community.

For the above stated reasons, I urge the Board of Pharmacy to approve Nora Springs' request for a telepharmacy.

Sincerely,

Todd Prichard
Iowa House of Representatives
House District 52

FIRST SECURITY
809 Clark Street
P.O. Box 577
Charles City, IA 50616
1stsecuritybank.com

August 5, 2015

Telepharm
105 Iowa Ave, # 231
Iowa City, IA 52240

RE: Telepharm Project – Nora Springs, IA

To whom it may concern:

My name is Randy Hassman, a 23 year resident of Nora Springs and the Market President of First Security Bank Charles City, IA. My office is located in Nora Springs and I oversee 9 of First Security's 15 Branch Offices. In addition to the Nora Springs branch, I am also responsible for branches in the nearby communities of Rudd and Rockford. All of these communities would benefit from a new pharmacy in Nora Springs.

As the local banker, I am very invested in the success of our small towns. The possibility of a pharmacy locating in Nora Springs is very exciting and a project I fully support. I strongly feel a pharmacy would be successful and a needed asset to our community and surrounding area. While our local medical clinic and care center provide service to a sizable number of our citizens, a drive to either Mason City or Charles City is necessary to fill prescriptions. This can be increasingly difficult on our elderly citizens.

I have spoken to several area residents about the possibility of a new pharmacy in town and I have received favorable feedback from everyone I have talked to. This has generated a very positive 'buzz' in our town and the surrounding area. There is a strong desire for this to come to fruition.

In closing, please know that I will advocate for the pharmacy in Nora Springs. I would be happy to do anything I can do to assist in this project. Please feel free to contact me with any questions, comments or requests. Thank you for your consideration of Nora Springs, Iowa.

Sincerely,

Randy Hassman, Market President
P O Box 306
Nora Springs, IA 50458
641-749-5356
rhassman@1stsecuritybank.com

To: Telepharm

105 Iowa Ave., #231

Iowa City, IA 52240

Re: Telepharm Project

Location: Nora Springs, Iowa

To: Whom It May Concern,

My name is Dale Lipp I grew up and graduated from Nora Springs, moved to Colorado for 7 years and moved my family back to my hometown. I have owned my business North Iowa Builders for 23 years.

I think bringing in a pharmacy would be a great benefit, not only to our town but surrounding towns as well. Having a pharmacy in town would also bring people into our town and potentially open up the window for other businesses to open. We are bedroom community to Mason City, Iowa and have a lot of volume of cars passing thru to go to Mason.

Our downtown has gone thru some major changes with fires and closings and there are a few trying to revive the downtown. I along with others feel the city council does not want to make changes because they are comfortable and do not like change. However we have many new young families who want to stay here and see our community grow. We are in the process of building a new aquatic center which will bring many people thru our town.

Some of the concerns with citizens is how this is going to be handled with all the differrent insurance companies. But overall everyone is excited to see this happen and would like to see not just prescriptions but other health products available.

Sincerely,

Dale Lipp

Spring Harbor

Residential Services
111 South Boulder
Nora Springs Iowa 50458
Phone 641-749-5372 Fax 641-749-2630

TO: TELEPHARM
105 Iowa Ave., #231
Iowa City, IA 52240

RE: Telepharm Project for Nora Springs, Ia

To Whom It May Concern:

Hello. My name is Simone Schmitt and I am the Executive Director of a residential care facility, Spring Harbor Res Srvc, in Nora Springs. I have worked at this facility since 1999 and been a part of the Nora Springs community. We serve a group of individuals who are from age 18 to 78 yrs old and have Chronic Mental Illness, Intellectual Disabilities, Dual Diagnosis and some physical disabilities as well.

I was thrilled when I heard of the prospect of a pharmacy in our small community. How wonderful for the elderly in our community, the disabled individuals who have such difficulty securing transportation out of town and how convenient for our facility and that of the nursing facility and assisted living as well. It would be a great resource for the town and the surrounding smaller towns that are 5-12 miles away.

We currently are fortunate enough to have a long-term pharmacy that delivers our medications and our medication record/administration sheets, however having the pharmacy local would be very enticing and great for our clients getting ready to move into their own homes in the community as well.

Thank You for the opportunity to share in this exciting venture.

Sincerely,

Simone Schmitt, LPN
Executive Director

Family DENTISTRY
DRS WEBER & OTTO

3223 4th St. SW
Mason City, IA 50401
641.424.6461

24 S. Hawkeye
Nora Springs, IA 50458
641.749.5430

Professional care and Personal service for all ages!

Telepharm

10 S. Iowa Ave, #231

Iowa City, IA 52240

RE: Telepharm Project

Location: Nora Springs, Iowa

To Whom it may Concern:

We are Nora Springs Family Dentistry and have been practicing in Nora Springs since 2009. We occupy an office built by Dr. David Miller many years ago.

We are excited to hear that a pharmacy may open across the street from us. The majority of our patients live in Nora Springs, but we treat patients from Rockford, Osage, St. Ansgar and also Mason City.

We feel that a new business here on Hawkeye Avenue in Nora Springs would be welcomed by the Nora Springs community. A pharmacy here would be of great benefit and convenience to our patients.

Best Wishes with your endeavor.

Sincerely,

Timothy J Weber, DDS

Michael D Otto DDS

Dr. Timothy J. Weber

Dr. Michael D. Otto

EAGLE FAMILY HEALTH

Lisa M. Kies, MD
903 W. Congress, PO Box 729
Nora Springs, IA 50458

August 7, 2015

Telepharm
105 Iowa Ave #231
Iowa City, IA 52240

To Whom It May Concern:

My name is Dr. Lisa Kies, MD, and I have been the sole practitioner and owner of the only medical office here in Nora Springs since I purchased it in 2008 from Dr. Patrick Ryal, who had practiced here for some 15 years before leaving to be a medical missionary.

I am delighted at the possibility of having a pharmacy here in town. It is a significant handicap to many of my patients with limited means or ability to drive to the next town. It'll also be a convenience for parents of sick children who need antibiotics sooner rather than later.
I've looked into having some sort of pharmacy option here in the office myself with medical vending machine companies, but nothing they offered suited our purposes. I would anticipate sending a large number of prescriptions from this office to any pharmacy here in town. Currently, the closest pharmacies are about 10 miles away, and there would be a large area to the east of town that would probably start getting prescriptions here rather than driving on further to Mason City.
Everyone I've mentioned this ~~to~~ possibility to has been very excited about the idea of having a local pharmacy in Nora Springs.

So, I am wholeheartedly in support of having a pharmacy here in Nora Springs to compliment my medical practice here.

Sincerely,

Lisa M. Kies, MD

LMK/jtb

(641) 749-5576 • Toll (800) 695-3745 • Fax (641) 749-5564
www.eaglefamilyhealth.com

Nora Springs Insurance
805 W Congress
PO Box 248
Nora Springs, IA 50458
Phone: (641)749-2505
Fax: (641)749-2521
office@NoraSpringsIns.com
NoraSpringsIns.com

Century 21 Preferred
2800 4th St SW
Suite 3
Mason City, IA 50401
Phone: (641)424-9400
Cell: (641)430-0123
MarkDix@Century21.com
MarkDixRealtor.com

Sirs,

I am Mark Dix owner of the Nora Springs Insurance Agency and an Associate Broker with Century 21 Preferred. I live in Nora Springs and operate my business from this community. I have been part of this community for 20 years and am very excited for the possibility for a new business coming to town.

A new pharmacy at the corner of Hawkeye and Congress will be a cornerstone for new businesses in this town. It will enhance the business district and provide a valuable service to the members of our community. Currently there are no options for purchasing pharmaceutical goods and our only option is traveling to Mason City.

The town is abuzz with excitement over the possibility of having a pharmacy in town. The location is perfect, visible from the highway and it will enhance the restaurant business located to the south. The restaurant draws from a large geographical area so they will help perpetuate the pharmaceutical business.

Sincerely

Mark Dix

Trusted Choice®

Century 21 PREFERRED

TOWN & COUNTRY INSURANCE AGENCY

30 North Hawkeye Ave Nora Spring, IA 50458
Phone: 641-749-5341 FAX: 641-749-5343

August 5, 2015

Telepharm
105 Iowa Ave., #231
Iowa City, IA 52240

Re: Telepharm Project
Location: Nora Springs, IA

To Whom It May Concern,

As a local independent insurance agency servicing Nora Springs and the surrounding area we welcome the news you are considering our town as a location for your pharmacy.

We value the people and way of life in small town America and support opportunities that improve the convenience and quality of life for our citizens. Your pharmacy will go a long way in this regard as many of your citizens have to travel a good distance to access pharmacy services and products.

We wholeheartedly support your endeavor and encourage you to choose Nora Springs.

Sincerely,

Spencer

Spencer Potter
Town & Country Insurance

August 5, 2015

Telepharm
105 Iowa Ave #231
Iowa City, IA 52240

Re: Telepharm Project
Location: Nora Springs, Iowa

To Whom It May Concern:

I am Maritz Nel, owner of a restaurant and lounge in Nora Springs. I previously owned the Elephant Keg and restaurant from 2005 – 2011 when the building burned down due to a faulty furnace in the connecting building next to me. I then opened another establishment in a neighboring community for about a year until my current location opened up for sale back in Nora Springs. I have been here for 2 years now in my current restaurant called Maritz's Ekeg.

I have lived in this community for about 15 years, my wife has lived here for over 30 years. Needless to say we like it here. We have a group of younger adults who are very active in the community. They have worked very hard to get grants and donations to improve the city and have succeeded in getting a new pool built.

I think a pharmacy in town would be a wonderful addition. The people I've spoken to about the possibility of a pharmacy moving to town thought it was a wonderful idea. I think it would draw in people from neighboring communities also which would benefit all of us with businesses in town and might even draw more businesses to open up shop here.

Currently we have to go to Mason City to pick up presciptions which isn't very convenient when you are ill or hurting and just want to go home and rest but now have to drive 15 or more miles away to fill your prescription or wait for someone else to pick them up which might be hours later.

Sincerely,

Maritz Nel, owner Maritz's Ekeg Restaurant and Lounge

15 South Hawkeye Nora Springs Iowa 50458
641-749-2577

To: Telepharm

105 Iowa Ave #231

Iowa City, IA 52240

Re: Telepharm Project

Location: Nora Springs, IA

To: Whom It May Concerns,

My Name is Karla Gordon owner of GG's Place LLC in Nora springs Iowa located downtown of Nora Springs Iowa. Recently I have established a new restaurant in downtown Nora Springs showing positive support from this community. GG's is a restaurant that has large cliental of elderly and young family with growing potential to other communities. My family and I picked this location do a large population drive through the town to go to work either in Mason City or Charles City. I myself as a former Nurse traveled and was tired and looking for a good place to eat in the area instead of traveling to Mason City. I have been living in the rural community since 2011 with my husband and children and really have enjoyed the friendly safe community to raise our last child of 2 years old.

As a resent nurse I feel having a pharmacy is this town is very vital for the dearly as well as the young and myself. Watching my own clients most of the go to the post office stop by have a roll and then go to town to get there meds or see a doctor. Mostly for the elder I have deliver meals to them and comments of it is hard to pay or find transportation to get to mason is very hard. By having is pharmacy it give a relief to our community and strongly belief that this with not just benefit the community but to us business owners. Example of my cliental base for Saturday I sold 85 breakfast buffet meals and that night 58 buffet meals. That would benefit your business and I would have strong support do to it is very hard for me to get to town to get my medication so a prime example again is that I went without my meds for couple of days till I had a chance to get them.

I would like to extend my support and feel free to contact me with any questions.

Karla Gordon

OmniTel
COMMUNICATIONS

TECHNOLOGY CAN BE DIFFICULT
We're here to help.

p: (641) 749-2531

P.O. Box 518 | 608 East Congress

Nora Springs, IA 50458

August 3, 2015

To: Telepharm
105 Iowa Ave., #231
Iowa City, IA 52240

Re: Telepharm Project
Location: Nora Springs, Iowa

To: Whom It May Concern,

Having served the North Iowa area with technology for over 100 years and as the CEO of OmniTel Communications with its principle place of business located in Nora Springs, Iowa, I have seen the dwindling main streets of our downtown communities. The citizens in the towns and rural areas we serve deserve access to economic development as well as modern health care and *Telepharm* can go a long way in providing both.

For any new business to locate in a community it is truly exciting and a real addition to the economic wellbeing of an area. The addition of *Telepharm* is just as exciting and an incredible asset to the area's population wellbeing. This addition would save time and effort in obtaining prescriptions and help to ensure the population's health when in need of medicine all of which helps to sustain a better quality of life.

Nora Springs is a tightknit, local focused community of hardworking people. Easier access to prescriptions and other health care needs will be essential to grow the lifespan of the community and help to provide the basis for additional economic growth all around. Becoming a local member of the community would advance the use of technology and help to connect the small communities we serve to the entire world and its global economy. After meeting with Nora Springs' community leaders and talking with the citizen's group involved in this project, OmniTel found it incredibly important to do all it can to promote the success of this endeavor.

Please see this letter for the reasons it was written, the support of better health, economic development and quality lifestyles of the people who live, work and play in our rural areas of Iowa. I appreciate your time and any considerations you give towards helping to ensure success in bringing *Telepharm* to Nora Springs and all of rural Iowa.

Sincerely,

Ronald Laudner

Ronald Laudner
CEO
OmniTel Communications
641-749-2531
rlaudner@omnitel.biz

Ph. (641) 749-5315
FAX (641) 749-2707

City of Nora Springs
45 N. Hawkeye • P.O. Box 336 • Nora Springs, IA 50458

Telepharm
105 Iowa Ave., #231
Iowa City, IA 52240

Re: Telepharm Project in Nora Springs, Iowa

To Whom It May Concern,

My name is Deborah Gaul and I have been a member of this community since 2002. I serve the community as the city administrator here in Nora Springs.

I am very excited about the possible opportunity our community may have with you bringing in your pharmacy. I feel that Telepharm would be very beneficial and enhance our healthcare needs. As you are aware, having our doctor's office, a dental office, and nursing home in the community; the pharmacy would be a very viable addition.

With the closest pharmacy approximately 9 miles away, many members of the community would have a direct access to a pharmacy upon leaving our local medical facilities. Another benefit that I could see would be to our surrounding communities. They too would benefit after leaving even the medical facilities in the surrounding towns. The pharmacy could be as close as 4 or 6 miles versus 14 to 16 or more miles for these outlying communities today.

I am looking forward to your company becoming a part of our wonderful community.

Sincerely yours,

Deborah Gaul

Deborah Gaul
City Administrator

September 13th, 2015

Iowa Board of Pharmacy

Re: Telepharmacy State Center, Iowa

Dear Iowa Board of Pharmacy:

I respectfully request that your board approve the request for a telepharmacy in Nora Springs, Iowa. I personally live in the Omnitel Communications service area as well as represent multiple constituents who will benefit from this delivery mechanism. Nora Springs is a rural community that has been trying to find a way to have a pharmacy in the community.

My mother was one of the first pharmacy technicians to be part of a telepharmacy in LeRoy, MN. It was a wildly successful endeavor for that clinic and community. I have seen first-hand, through my mom, the benefits this partnership will bring to the residents of Nora Springs.

Omnitel Communications is the right company to have in this partnership as they have a strong track record of helping out their rural constituents. A few years back Omnitel Communications made the investment to bring fiber to the rural residents of their district. Not only have they brought our region into the global marketplace, but they have been a strong supporter of educational initiatives throughout their service area. Truly a first-rate company.

I know that the local communities and clinics support this proposal for a pharmacy to provide those services locally and quickly. My wife is in family practice within this service area and fully supports this initiative as it will provide her patients with better services and care.

Thank you for your consideration and time.

Joshua J. Byrnes

House District 51

Winneshiek, Howard, Mitchell, Worth

MD orthopaedics

P.O. Box 125
604 North Parkway Street
Wayland, IA 52654
877-766-7384

September 16, 2015

Re: Wayland, IA Telepharmacy

To Whom it May Concern:

My name is John Mitchell, President of MD Orthopaedics, Inc. in Wayland, Iowa where we manufacture orthopaedic braces for children with clubfoot deformity. Since 2005, my business has been part of the Wayland community and currently employs 23 individuals from the Wayland area and surrounding communities.

I feel a local pharmacy would be a great asset to the community and a boost to the Wayland medical clinic. This would provide a convenient way for employees to fill their prescriptions without finding it necessary to use precious PTO hours.

While the medical clinic itself is convenient for appointments, employees often still find it necessary to drive 12-20 miles to fill a prescription.

Please feel free to contact me or my Business Manager, Emily Ferguson, if you should require further information or feedback.

Sincerely,

John R. Mitchell
President

BEST TOWN
OF ITS SIZE
IN IOWA

WAYLAND ECONOMIC DEVELOPMENT CORPORATION

Wayland, Iowa 52654

August 18, 2015

Reference – Wayland Telepharmacy

To Whom It May Concern:

My name is Russell Yoder, President of the Wayland Economic Development Corporation. The Wayland community has always been supportive in keeping medical services in the town. The Economic Development purchased the doctor's building and has been managing the clinic for years. The clinic continues to grow in usage with the professional staffing of the local hospital.

A pharmacy would be a great asset to this rural community. The closest pharmaceutical service is between 12-20 miles away depending on your personal doctor. By having the pharmacy in the local clinic, people can receive their medication without driving out of town. We are seeing that many of our senior citizens are unable to drive out of town and are needing assistance to be able to receive their prescriptions.

The Economic Development has already funded the necessary financing required to start the pharmacy. I feel this shows the community's support for this project.

We are excited as a Development Committee and are more than happy to answer any further questions you may have.

Thank you in advance.

Sincerely,

Russell Yoder,
President

Wayland State Bank

August 18, 2015

Re: Telepharmacy in Wayland

To Whom It May Concern:

I am Robert Meyer, President of the Wayland State Bank. I am a lifelong resident of the Wayland community. I have been employed with the bank for 40 years.

Wayland has always been interested and supportive of health care in our community. When the doctor decided to retire, the community raised the money to buy his building and rented it to the local hospital as a medical clinic. It has been a huge success, and this is the site where the new pharmacy will be located.

Currently, we have to go between 12-20 miles to fill a prescription. Many of our senior citizens are not able to drive out of town and find it a real inconvenience to get their prescriptions filled.

We also have a nursing home with 34 skilled nursing rooms, 25 independent living apartments, and 19 living facilities that would benefit from being able to use this local service.

The community is excited about the possibility of having this service in their community.

The Economic Development Corporation has already funded the startup requirements. This alone is an example of how excited and supportive of bringing this service to the Wayland area.

If I can be of further assistance on this matter, please feel free to contact me.

Sincerely yours,

Robert G. Meyer
President

P O BOX 157
WAYLAND IA 52654-0157
319-256-5000
319-256-2265 FAX

MEMBER FDIC
waylandstbank.com
WSBank@Farmtel.Net

301 S. MAIN STREET
MT. PLEASANT IA 52641-2226
319-385-8189
319-385-8234 FAX

August 18, 2015

RE: Telepharmacy in Wayland

To Whom It May Concern:

My name is Bradley Roth and I am a lifelong resident of Wayland. I was a City Council member for 20 years and since 1998, am serving as the Mayor of the City of Wayland. I am also a member of the Wayland Economic Development Corporation.

Keeping medical services in Wayland has always been a priority. We were fortunate to have the services of a doctor for many years and at his retirement, the community pooled resources to buy the building and rent to the County hospital as a medical clinic. Telepharm will be located within the medical clinic building which is a perfect counterpart to our successful medical clinic.

With a travel distance of up to 20 miles to fill a prescription, a hometown pharmacy will be a great asset to Wayland, especially for our senior citizens who have difficulty traveling out of town to get their medicine. The nursing home complex in Wayland would benefit from being able to use a local pharmacy for their prescription needs also.

Feedback from Wayland citizens has been extremely positive and supportive. The Economic Development Corporation, City Council, local businesses and residents are excited to have this service in our community.

Sincerely,

Bradley Roth, Mayor
City of Wayland

Orval Miller & Sons

Lennox heating and air • Backhoe, trenching and well work • Plumbing and drain work
Sewer camera and duct cleaning • Geothermal HVAC

To Whom It May Concern:

My name is Josh Miller, local business owner, farmer and member of the Wayland Economic Development Corporation. I have been a lifelong resident of the Wayland community. I have always had great pride in our community.

Medical services in Wayland is very important to me. We feel very fortunate to have a clinic in town to help meet the medical needs of our residents. I am very excited to have the opportunity to add the services of Telepharm. This will further advance the services offered to our community, furthermore, Telepharm would be an important convenience to our residents (especially senior citizens) considering the nearest pharmacy is 12-20 miles away.

I have talked to numerous people around town, and collected feedback about Telepharm. I have had nothing but positive responses. Everyone I have talked to is excited about the opportunity the have the services of Telepharm.

Sincerely,

Josh Miller

112 West Main • Wayland, IA 52654 • Phone: 319-256-2750 • Fax: 319-256-2752

My name is Tim Egli, owner of Egli Landscapes Inc. We serve Southeast Iowa with several landscape services including design, installation and management of properties. I have been a part of the community for over 12 years and have been privileged with serving the community through donations, community service and by serving on the Wayland Lions Club, as a local bank director and with our current Wayland Economic Development Corporation.

I believe the new pharmacy would bring local jobs. It may only be a few, however in this economy for small communities this is a major asset. Another benefit would be our local aging population will now have quick, easy access to knowledgeable staff to aid them when medications are needed. Along with our Wayland Clinic this fit would be great as our nurse practitioners and physician's assistants will have easy access to the prescriptions. Their current patients would have an environment where they don't have to get bounced around to find what they need. This, in my opinion, would benefit these individuals greatly especially in the winter months when they will not want to venture out on risky roads.

Having a local pharmacy would benefit me as I need monthly prescriptions for my own health reasons. As for my organization, it now allows them to go over a lunch time or at the end of a day to get their needs taken care of, so they can go home and not make an out of the way stop. Most of my team live away from any larger towns such as Washington or Mt. Pleasant.

We also have our local nursing home... Park View. This I believe would be a viable customer for a pharmacy as long as they can bring competitive prices and possibly a delivery service being they would only be three blocks away.

In closing, having a pharmacy in Wayland would be a good asset as it bring a service we currently do not have and in the medical field competitive pricing and professional service will always win. Yes, I have only been here 12 years. However, in that time, my experience is that if you become a part of the community as a business and you serve a need you will become successful.

Cordially,

Tim Egli

September 11, 2015

RE: Telepharmacy in Wayland

To Whom It May Concern:

My name is Barry Leichty and I am a member of the Wayland Economic Development Corporation. I have been employed by the City of Wayland 24 years and prior to that, worked 14 years with a local plumbing, heating, and air conditioning business in Wayland.

Our medical clinic has served us well. It is used by me and other family members and it has proven its worth to our community. Having a telepharmy business added to Wayland will make it a more viable place to live, work, and play.

Wayland is not your everyday, small community. We have industrial, commercial and residential and agricultural based businesses here that allow many families to live and work in the community.

We look forward to your consideration of Wayland as the perfect place for a telepharmacy.

Sincerely, Barry D Leichty

Barry D. Leichty

September 14, 2015

RE: Telepharmacy in Wayland

To Whom It May Concern:

My name is Lori Messer. I am a lifelong resident of Wayland and have owned and operated my beauty salon in Wayland for over 30 years. I am also a member of Wayland Economic Development Corporation and an avid volunteer in the Wayland area.

Wayland is a great supporter of health care in our community. We have a medical clinic as well as a Dental Office and Fitness Center. Having a telepharmacy would be a great asset and would complement our existing health related businesses. We currently have to travel 12-20 miles to fill a prescription, which is difficult for many who are elderly.

The Wayland Economic Development Corporation has invested the funds for the telepharmacy, secure in knowing that the Community is excited to have this amenity available in their hometown.

Sincerely,

Lori Messer

Lori Messer

September 29, 2015

Re: Wayland Telepharmacy

To Whom It May Concern:

I am Tawnya Achen, member of the Wayland Economic Development. I am a REALTOR serving in the southeast area. I am a resident of the Wayland community. I have grown up in Wayland and after college moved back to the area; were my husband and our family reside.

A pharmacy coming to our town would be a great asset. We are a small community with a lot of elderly citizens in it. Having a pharmacy would greatly benefit not just the elderly, but the younger generation whom are actively involved in many things. They may not have time to drive to other surrounding towns to get their family medications. Neighboring towns with a pharmacy are 12-20 miles from our community. In addition, talking with other community members, they are eager to have a pharmacy in our town to help with the convenience of everyday life.

We look forward to having the service of a Telepharmacy to help assist our public members. The Economic Development Corporation has already funded the startup requirements. This is how excited and supportive we are to be able to offer this service!

Yours truly,

Tawnya Achen

September 14, 2015

Reference- Wayland Telepharmacy

To Whom It May Concern:

My name is Heather Pratt, a member of the Wayland Economic Development Corporation. I moved to Wayland 5 years ago, and fell in love with community. After moving to Wayland it was not long after I decided the town of Wayland would become the community I call home. Shortly after moving to Wayland I started working at M.D. Orthopaedics. I am currently the Quality Management Representative/ Manufacturing Coordinator.

Having a pharmacy come to Wayland would be a huge asset to our community. Currently the closest pharmacy is 12-20 miles from Wayland. There are several elder citizens in the community who cannot drive and depend on other individuals to pick up their prescriptions for them.

The opportunity of getting a pharmacy in town has been quite the talk. Needless to say our community is very excited with the possibility of getting a pharmacy. Several people are over joyed with the idea of being able to receive their prescriptions while at the local medical clinic. As cold and flu season is just around the corner many mothers are pleased with the thought of having a local pharmacy on site with the medical clinic.

Not only does Wayland offer a medical clinic we also have a nursing home, 25 independent living apartments, and 19 living facilities. These facilities would all benefit greatly from having a pharmacy in town.

The Economic Development Corporation has already funded the startup requirements. I strongly believe this goes to show how excited and supportive our community is with the idea of a pharmacy coming to our community.

Wayland citizens care deeply about their community and work very hard at making our community desirable to all who visit. Having a pharmacy would help our community that we love dearly be desirable to all others as well.

With great pride in our community we are eager with the possibility of this service coming to the town we call home.

If I can be of further assistance feel free to contact me.

Kind Regards,

Heather M. Pratt

Heather M. Pratt
Quality Management Representative/Manufacturing Coordinator
MD Orthopaedics, Inc.
604 North Parkway Street
Wayland, IA 52654
Email: heather@mdorthopaedics.com
Personal: hpratt217@gmail.com

MAYOR:
Chris Finnell
CITY CLERK:
Angie Oepping

CITY OF WINFIELD

COUNCIL MEMBERS:
Ryan Kinneberg
Ryan Rees
Roger Sharp
Jan Walter
Kathy Nelson

Hello

My name is Chris Finnell. I am the Mayor of Winfield, Iowa. I have been Mayor for the last 4 years and will be running for my second term this November. My family and I have lived in Winfield for nearly 20 years. We moved here from Illinois with the idea of living in a smaller community close to family. Winfield has many positive attributes and the community is working hard to stay viable.

Winfield currently has a health clinic that is open 3 days a week. They are very close to justifying staying open full time. When the citizens of Winfield and surrounding area visit the clinic and are given a prescription they are required to travel to Mt Pleasant or other neighboring towns. Many of our citizens are senior and do not always have the means to travel. This means that they are now burdened with organizing transportation to Mt Pleasant via the SEBUS, family member, or a friend. Most times they will need to wait until the next day to receive their medicine.

Having a pharmacy in Winfield will help our citizens by providing an additional store on our main street, providing medications daily with no travel, promoting additional patients at the clinic so that our citizens can now access health care as needed.

When Tele Pharm first came to me with their business plan and proposal for a pharmacy in Winfield, my first reaction was yea right. I was concerned that this was a scam and we would lose our money. I was ready to discount the idea. I then started thinking that if this was the real deal this proposal would be great for Winfield. I decided that I owed it to the community to do the research and due diligence to determine if this was a legitimate proposal or not. I made a lot of phone calls, visited the town of Victor to look at their pharmacy and spent several hours trying to shot holes in the endeavor.

I believe that the city of Winfield and Tele Pharm will grow a partnership that will take our town forward and help create a strong vibrant town that can grow to its potential.
I am looking forward to Tele Pharm opening the doors. This is a big deal for our town and community

Thank You
Chris Finnell
Mayor, Winfield, Iowa

MAYOR:
Chris Finnell
CITY CLERK:
Angie Oepping

CITY OF WINFIELD

COUNCIL MEMBERS:
Ryan Kinneberg
Ryan Rees
Roger Sharp
Jan Walter
Kathy Nelson

August 18, 2015

To Whom It May Concern:

My name is Angie Oepping and I have been the city clerk for the City of Winfield, Iowa since September 2011. My husband and I moved to Winfield in 1997 and have a 13 year old son and a 10 year old daughter. For the past 4 ½ years, I have also been the president of our youth sports league which has been expanding on a yearly basis.

Due to the busy lifestyles that so many parents have, I am excited to see the pharmacy, Telepharm, coming to our town. With working in Winfield and my kids being involved in numerous activities, I can go weeks without leaving town. My son has asthma and takes medicine daily to control it so having a pharmacy in town will be much more convenient when having to fill his monthly prescriptions as well as any other prescribed medication that my family may need. My children currently doctor at the clinic that we have in town and if a prescription is needed, we must travel 40 minutes round trip to get the prescription filled.

With being the city clerk, I feel that Telepharm will be a great addition to our community. We currently have a significant number of elderly residents in our community that will greatly benefit from having a pharmacy in town. It is nice to see an addition to our main street business district.

After speaking with many residents about Telepharm, many of them are just as excited as I am and are looking forward to the opening of the pharmacy.

Sincerely,

Angie Oepping

Angie Oepping
City Clerk

115 N. Locust Street P.O. Box 73 Winfield, IA 52659-0073 Phone (319) 257-6661 Fax (319) 257-3602

WINFIELD BEACON/WAYLAND NEWS

PO Box 10
Winfield, IA 52659

Cathy Lauderdale, Owner/Editor

To Whom It May Concern:

My name is Cathy Lauderdale and I am the Editor and Owner of the Winfield Beacon/Wayland News. This business is a weekly newspaper with offices in the cities of Winfield and Wayland. I have lived in Winfield for the past 51 years and watched it stagnate for a while and now am enjoying watching it grow.

When Mayor Finnell first introduced the Telepharm concept, I will admit that I was a bit skeptical. After attending numerous meetings where Mayor Finnell and representatives from Telepharm explained the program, I am a firm believer that this program was 'made for Winfield'.

The Winfield community has numerous retired persons living here, some of which cannot drive or will not drive, especially during the winter months. We also have a medical clinic in our community. I have visited with the personnel at the clinic and they too believe that it would be a huge plus for our small community. Not only would this assist our local patrons, but it will also help to build our community for the future by putting another business on our main street.

Since we are a farming community, I believe the Telepharm will benefit not just Winfield, but also the other surrounding communities and farmers.

Right now, Winfield and area residents are required to travel no less than 20 miles to pick up their medications. As I said above, for some, this just is not a possibility. Therefore, I feel that adding this business to our community would be beneficial to all.

The majority of the residents in Winfield feel as I do, that this would be a huge plus for our community.

Very truly yours,

Winfield Beacon/Wayland News

Cathy Lauderdale

Cathy Lauderdale
Owner/Editor

To whom it may concern:

My name is Marcy Kinneberg and I am the Advocate for the City of Winfield, Iowa. I have been working officially in this part-time capacity for the last year, however, I have always been an advocate for Winfield.

After growing up in the community and attending the Winfield – Mt. Union School, I moved away for a short while to complete my college education only to return after graduation with my soon-to-be husband and to start our own family. We have been happily living in Winfield for the past 10 years and now have 2 children, one of which is going to starting 2nd grade at Winfield – Mt. Union School and the other eagerly awaiting her turn to start school.

I am excited about TelePharm's new venture in town. There is a clear need for access to facilities like this as there are several who require prescriptions. I was not as aware of just how many people require prescriptions until about a year ago. Last year, I was diagnosed with Thyroid cancer and while visiting several offices and with several doctors, I learned that being 'prescription-free' was a bit of a rarity. I would often get a blank stare followed by the words 'Nothing at all' when asked what medications I was taking. Apparently, I was in a minority.

Now that I am on a daily medication, I realize how important it is to have access to a pharmacy and secondly to have the ability to get there. The Betterment Committee conducted a survey a few months ago in which we learned that members in our community are lacking the resources such as time or transportation to go to other towns for things such as groceries or prescriptions. Having Telepharm in town and within walking distance is going to be such an improvement for our residents who are currently going to surrounding cities such as Mt. Pleasant, Washington or Burlington which are over 15 miles away.

I know it will also help me when I'm looking at the bottom of my medicine bottle. Now, I will not have to make a special trip to a neighboring town just to pick up my prescription – I can simply walk a couple blocks to our local Telepharm. That does sound nice!

Kind regards,
Marcy Kinneberg

Winfield Advocate

From: Funk, Andrew [IBPE]
To: Jorgenson, Debbie [IBPE]
Cc: Witkowski, Terry [IBPE]
Subject: FW: Naloxone
Date: Thursday, September 24, 2015 1:49:52 PM

Debbie,

I don't want to go over-board with giving the Board FYI articles. But last legislative session, there was a push for this to occur in Iowa. It may be rather timely.

Terry, what do you think about including Dale's linked article?

Andrew Funk, Pharm.D.
Executive Director
Iowa Board of Pharmacy
RiverPoint Business Park
400 SW 8th Street, Suite E
Des Moines, Iowa 50309-4688
515.281.5944 Main Line
andrew.funk@iowa.gov

From: Witkowski, Terry [IBPE]
Sent: Thursday, September 24, 2015 12:38 PM
To: Woolery, Dale [ODCP]
Cc: Funk, Andrew [IBPE]
Subject: RE: Naloxone

Dale,

That is correct. Naloxone is a prescription drug and, as such, may only be dispensed by a pharmacy/pharmacist on the order of a qualified and authorized prescriber. Pharmacists are not authorized prescribers in Iowa and therefore cannot dispense naloxone without a prescription.

In most, if not all, of the states where pharmacists are dispensing naloxone without a prescription, the state law has either classified naloxone under a special classification of drugs that a pharmacist may dispense without prescription (i.e. pharmacist prescribing) or the law has been amended to specifically authorize the dispensing of naloxone without a prescription, something similar to pseudoephedrine in Iowa.

Therese (Terry) Witkowski

Executive Officer
Iowa Board of Pharmacy
terry.witkowski@iowa.gov
515-281-6676

The Iowa Board of Pharmacy promotes, preserves, and protects the public health, safety, and welfare through the effective regulation of the practice of pharmacy and the licensing of pharmacies, pharmacists, and others engaged in the sale, delivery, or distribution of prescription drugs and devices. Iowa Code § 155A.2(1).

From: Woolery, Dale [ODCP]
Sent: Thursday, September 24, 2015 11:05 AM
To: Witkowski, Terry [IBPE]
Subject: Naloxone

Terry, This article seems to imply the Iowa Pharmacy Board, like many of its counterparts, does not have the authority under state law to permit the sale of Naloxone without a prescription. Is that accurate? Dale

http://www.marketwatch.com/story/cvspharmacy-commits-to-creating-safer-communities-through-multiple-prescription-drug-abuse-prevention-efforts-2015-09-23-8183300

CVS Will Sell Naloxone Without Prescription in 14 States

/By JOIN TOGETHER STAFF

SEPTEMBER 24TH, 2015

/

0

CVS announced it will add 12 states to its program to sell the opioid overdose antidote naloxone without a prescription, bringing the total to 14. The company already sells naloxone without a prescription in Massachusetts and Rhode Island.

"Over 44,000 people die from accidental drug overdoses every year in the United States and most of those deaths are from opioids, including controlled substance pain medication and illegal drugs such as heroin," Tom Davis, Vice President of Pharmacy Professional Practices at CVS, said in a statement. "Naloxone is a

safe and effective antidote to opioid overdoses and by providing access to this medication in our pharmacies without a prescription in more states, we can help save lives."

The states included in Wednesday's announcement are Arkansas, California, Minnesota, Mississippi, Montana, New Jersey, North Dakota, Pennsylvania, South Carolina, Tennessee, Utah and Wisconsin. According to The Huffington Post, pharmacy boards in these states can make decisions about offering naloxone without a prescription.

"While all 7,800 CVS/pharmacy stores nationwide can continue to order and dispense naloxone when a prescription is presented, we support expanding naloxone availability without a prescription and are reviewing opportunities to do so in other states," Davis said.

Use of naloxone kits resulted in almost 27,000 drug overdose reversals between 1996 and 2014, according to a government study published earlier this year. Providing naloxone kits to laypersons reduces overdose deaths, is safe, and is cost-effective, the researchers noted.

"U.S. and international health organizations recommend providing naloxone kits to laypersons who might witness an opioid overdose; to patients in substance use treatment programs; to persons leaving prison and jail; and as a component of responsible opioid prescribing," the researchers wrote in the Morbidity and Mortality Weekly Report.

Dale R. Woolery
Governor's Office of Drug Control Policy
Pape State Office Building, 5th Floor SW
215 East 7th Street, Des Moines, IA 50319
PH: 515.725.0310 / FX: 515.725.0304
*EM: **dale.woolery@iowa.gov***
*Web: **http://www.iowa.gov/odcp***

PHARMACY BOARD [657]

Notice of Intended Action

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 6, "General Pharmacy Practice", Chapter 7, "Hospital Pharmacy Practice", Chapter 8, "Universal Practice Standards", Chapter 10, "Controlled Substances", Chapter 17, "Wholesale Drug Licenses", and Chapter 23, "Long-term Care Pharmacy Practice", Iowa Administrative Code.

The amendments were approved at the _____ regular meeting of the Board of Pharmacy.

The proposed amendments incorporate into Board rules updated federal regulations, finalized October 2014, authorizing certain registrants to voluntarily maintain an authorized collection program to collect unwanted controlled substances from patients for the purpose of disposal. The amendments also remove rules that are in conflict with federal regulation and that would otherwise prohibit such collection activities.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on _____. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by E-mail to terry.witkowski@iowa.gov.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code Section 124.301 and 21 Code of Federal Regulations Parts 1300, 1304, et al.

The following amendments are proposed.

Item 1. Amend rule 657—6.7(124,155A) as follows:

657—6.7(124,155A) Security.

While on duty, each pharmacist shall be responsible for the security of the prescription department, including provisions for effective control against theft of, diversion of, or unauthorized access to prescription drugs, including those collected though an authorized collection program, records for such drugs and authorized collection program activities, and patient records as provided in 657—Chapter 21, 657—Chapter 10, and federal regulations for authorized controlled substance collection programs, which can be found at http://deadiversion.usdoj.gov/drug_disposal/.

Item 2. Amend rule 657—7.6(124,155A) as follows:

657—7.6(124,155A) Security.

The pharmacy shall be located in an area or areas that facilitate the provision of services to patients and shall be integrated with the facility's communication and transport systems. The following conditions must be met to ensure appropriate control over drugs and chemicals in and under the control of the pharmacy:

7.6(1) to **7.6(5)** No changes.

7.6(6) *Authorized collection programs***.** Receptacles for the authorized collection of controlled substances that are located in the hospital shall be secured pursuant to 657—Chapter 10 and federal regulations for disposal of controlled substances, which can be found at http://deadiversion.usdoj.gov/drug_disposal/.

Item 3. Adopt new subrule 8.5(9) as follows:

8.5(9) *Authorized collection programs*. A pharmacy that is registered with the United States Department of Justice, Drug Enforcement Administration to administer an authorized collection

program shall provide adequate space, equipment, and supplies for such collection program pursuant to 657—Chapter 10 and federal regulations for authorized collection programs, which can be found at http://deadiversion.usdoj.gov/drug_disposal/.

Item 4. Amend rule 657—10.1(124) as follows:

657—10.1(124) ~~**Who shall register**~~ **Purpose and definitions.** Any person or business located in Iowa that manufacturers, distributes, dispenses, prescribes, imports or exports, conducts research or instructional activities, or conducts chemical analysis with controlled substances in the state of Iowa, or that proposes to engage in such activities with controlled substances in the state, shall obtain and maintain a registration issued by the board unless exempt from registration pursuant to rule 657—10.6(124). A person or business required to be registered shall not engage in any activity for which registration is required until the application for registration is granted and the board has issued a certificate of registration to such person or business.

10.1(1) *Who shall register***.** Manufacturers, distributors, reverse distributors, importers and exporters, individual practitioners (M.D., D.O., D.D.S., D.V.M., O.D., P.A., resident physician, advanced registered nurse practitioner), pharmacies, hospitals and animal shelters, care facilities, researchers and dog trainers, analytical laboratories, and teaching institutions shall register on forms provided by the board office. To be eligible to register, individual practitioners must hold a current, active license in good standing, issued by the appropriate Iowa professional licensing board, to practice their profession in Iowa.

10.1(2) *Definitions*. For the purpose of this chapter, the following definitions shall apply:

"*Authorized collection program*" means a program administered by a registrant that has

modified its registration with DEA to collect controlled substances for the purpose of disposal. Federal regulations for such programs can be found at http://deadiversion.usdoj.gov/drug_disposal/. Modification to the registrant's Iowa Controlled Substances Act registration shall not be required.

"*DEA*" means the United States Department of Justice, Drug Enforcement Administration.

Item 5. Amend rule 657—10.6(124) as follows:

657—10.6(124) Separate registrations for separate locations; exemption from registration. A separate registration is required for each principal place of business or professional practice location where controlled substances are manufactured, distributed, imported, exported, ~~or~~ dispensed, or collected for the purpose of disposal unless the person or business is exempt from registration pursuant to Iowa Code subsection 124.302(3), ~~or~~ this rule, or federal regulations.

10.6(1) to **10.6(5)** No changes.

Item 6. Amend subrule 10.15(1) as follows:

10.15(1) *Physical security.* Physical security controls shall be commensurate with the schedules and quantity of controlled substances in the possession of the registrant in normal business operation. A registrant shall periodically review and adjust security measures based on rescheduling of substances or changes in the quantity of substances in the possession of the registrant.

a. and *b*. No changes.

c. Controlled substances collected via an authorized collection program for the purpose of disposal shall be stored pursuant to federal regulations, which can be found at http://deadiversion.usdoj.gov/drug_disposal/.

Item 7. Amend rule 657—10.18(124) as follows:

657—10.18(124) Disposal of registrant stock. Any persons legally authorized to possess controlled

substances in the course of their professional practice or the conduct of their business shall dispose of such drugs pursuant to the procedures and requirements of this rule. Disposal records shall be maintained ~~in the files of~~ by the registrant.

10.18(1) to 10.18(2) No changes.

~~**10.18(3)** *Previously dispensed controlled substances.* Controlled substances dispensed to or for a patient and subsequently requiring destruction due to discontinuance of the drug, death of the patient, or other reasons necessitating destruction may be destroyed or otherwise disposed of by a pharmacist in witness of one other responsible adult pursuant to this subrule. All licenses and registrations issued to the pharmacy, the pharmacist, and any individual witnessing the destruction or other disposition shall not be subject to sanctions relating to controlled substances at the time of the destruction or disposition. The individuals involved in the destruction or other disposition shall not have been subject to any criminal, civil, or administrative action relating to violations of controlled substances laws, rules, or regulations within the past five years. The pharmacist in charge shall be responsible for designating pharmacists authorized to participate in the destruction or other disposition pursuant to this subrule. The authorized pharmacist shall prepare and maintain in the pharmacy a readily retrievable record of the destruction or other disposition, which shall be clearly marked to indicate the destruction or other disposition of noninventory or patient drugs. The record shall include, at a minimum, the following:~~

~~*a.* The source of the controlled substance (patient identifier or administering practitioner, if applicable, prescription number or other unique identification number, and date of return);~~

~~*b.* The name, strength, and dosage form of the substance;~~

~~*c.* The quantity returned and destroyed or otherwise disposed of;~~

~~*d.* The date the substance is destroyed or otherwise disposed of;~~

~~*e.* The signatures or other unique identification of the pharmacist and the witness;~~

~~*f.* The name and address of the dispensing pharmacy or practitioner if the controlled substance was not dispensed by the pharmacy completing the destruction.~~

Item 8. Rescind current rule 657—10.19(124) adopt the following new rule in lieu thereof:

657—10.19(124) Disposal of previously dispensed controlled substances. A registrant may not dispose of previously dispensed controlled substances unless it has modified its registration with DEA to administer an authorized collection program. A registrant shall not take possession of a previously dispensed controlled substance except for reuse for the same patient.

Item 9. Amend subrule 10.34(3) as follows:

10.34(3) *Date of record.* The date on which a controlled substance is actually received, imported, distributed, exported, disposed of, or otherwise transferred shall be used as the date of receipt, importation, ~~or~~ distribution, exportation, disposal, or transfer.

Item 10. Amend subrule 10.35(1) as follows:

10.35(1) *Record and procedure.* Each inventory record, except the periodic count and reconciliation required pursuant to subrule 10.33(4), shall comply with the requirements of this subrule and shall be maintained for a minimum of two years from the date of the inventory.

a. and *b*. No changes.

c. Controlled substances shall be deemed to be on hand if they are in the possession of or under the control of the registrant. These shall include prescriptions prepared for dispensing to a patient but not yet delivered to the patient, substances maintained in emergency medical services programs or care facility emergency supplies, outdated or adulterated substances pending destruction, and substances stored in a warehouse on behalf of the registrant. Controlled substances obtained through

an authorized collection program for the purpose of disposal shall not be counted, sorted, inventoried, or otherwise handled.

d. and *e*. No changes.

f. The inventory record, unless otherwise provided under federal law, shall include the following information:

(1) The name of the substance;

(2) The strength and dosage form of the substance; ~~and~~

(3) The quantity of the substance; and

(4) Information required of authorized collection programs pursuant to federal regulations for such collection programs.

g. and *h*. No changes.

Item 11. Amend rule 657—17.1(155A) as follows:

657—17.1(155A) Definitions.

"*Authorized collection program*" means a program administered by a registrant that has modified its registration with DEA to collect controlled substances for the purpose of disposal. Federal regulations for such programs can be found at http://deadiversion.usdoj.gov/drug_disposal/. Modification to the registrant's Iowa Controlled Substances Act registration shall not be required.

"Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

"Blood component" means that part of blood separated by physical or mechanical means.

"Board" means the Iowa board of pharmacy.

"*DEA*" means the United States Department of Justice, Drug Enforcement Administration.

"Distribute" means the delivery of a prescription drug or device.

"Drug sample" means a drug that is distributed without monetary consideration to a pharmacist or practitioner. "Drug sample" does not include drugs intended for patients who would otherwise not receive needed drugs due to their inability to pay.

"Manufacturer" means a person or business engaged in the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis and includes packaging or repackaging of the substances or labeling or relabeling of the substances' containers.

"Prescription drug" means any of the following:

1. A substance for which federal or state law requires a prescription before it may be legally dispensed to the public.

2. A drug or device that under federal law is required, prior to being dispensed or delivered, to be labeled with one of the following statements:

- Caution: Federal law prohibits dispensing without a prescription.
- Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- Rx only.

3. A drug or device that is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by a practitioner only.

"Proprietary medicine" or *"over-the-counter (OTC) medicine"* means a nonnarcotic drug or device that may be sold without a prescription and that is labeled and packaged in compliance with applicable state or federal law.

"Reverse distribution" means the receipt of prescription drugs including controlled

substances, whether received from Iowa locations or shipped to Iowa locations, for the purposes of destroying the drugs or returning the drugs to their original manufacturers or distributors.

"Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

1. The sale, purchase, or trade of a drug or an offer to sell, purchase or trade a drug for emergency medical reasons. For purposes of this chapter, "emergency medical reasons" includes transfers of prescription drugs by a pharmacy to another pharmacy to alleviate a temporary shortage;
2. The sale, purchase or trade of a drug, an offer to sell, purchase or trade a drug, or the dispensing of a drug pursuant to a prescription;
3. The lawful distribution of drug samples by manufacturers' representatives or wholesale salespersons;
4. The sale, purchase or trade of blood and blood components intended for transfusion; or
5. Intracompany sales.

"Wholesale distributor" or *"wholesaler"* means a person or business operating or maintaining, either within or outside this state, a manufacturing plant, wholesale distribution center, wholesale business, or any other business in which prescription drugs, medicinal chemicals, medicines, or poisons are sold, manufactured, dispensed, stocked, exposed, or offered for sale at wholesale in this state. "Wholesaler" includes, but is not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; reverse distributors; and pharmacies that conduct wholesale distributions exceeding 5 percent of gross annual sales of prescription drugs. "Wholesaler" does not include those wholesalers who sell only OTC medicines or manufacturers' representatives lawfully distributing

drug samples to authorized practitioners.

"Wholesale salesperson" or *"manufacturer's representative"* means an individual who takes purchase orders on behalf of a wholesaler for prescription drugs, medicinal chemicals, medicines, or poisons. "Manufacturer's representative" also means a person designated by a pharmaceutical manufacturer to lawfully distribute drug samples to authorized practitioners.

Item 12. Amend rule 657—17.3(155A) as follows:

657—17.3(155A) Wholesale drug license. Every wholesaler as defined in rule 657—17.1(155A), wherever located, that engages in wholesale distribution into, out of, or within this state must be licensed by the board in accordance with the laws and rules of Iowa before engaging in wholesale distribution of prescription drugs. Where operations are conducted at more than one location by a single wholesaler, each such location shall be separately licensed in Iowa. A wholesaler located within Iowa that engages in wholesale distribution of <u>or collection via an authorized collection program of</u> controlled substances shall also register pursuant to 657—Chapter 10.

Item 13. Adopt new subrule 17.10(4) as follows:

<u>**17.10(4)** *Authorized collection programs*.</u> <u>Licensees that are authorized to conduct a controlled substances collection program shall provide security pursuant to 657—Chapter 10 and federal regulations.</u>

Item 14. Adopt new subrule 17.14(4) as follows:

<u>**17.14(4)** *Authorized collection program*.</u> <u>Substances, including controlled substances, collected through an authorized collection program shall not be examined, inspected, counted, sorted, inventoried, or otherwise handled.</u>

Item 15. Adopt new subrule 17.16(5) as follows:

17.16(5) *Authorized collection program*. A licensee that is authorized to administer a collection program shall maintain all records and inventories as required by 657—Chapter 10, this chapter, and federal regulations.

Item 16. Amend rule 657—23.1(155A) as follows:

657—23.1(155A) Definitions. For the purposes of this chapter, the following definitions shall apply:

"*Authorized collection program*" means a program administered by a registrant that has modified its registration with DEA to collect controlled substances for the purpose of disposal. Federal regulations for such programs can be found at http://deadiversion.usdoj.gov/drug_disposal/.

"Consultant pharmacist" in a long-term care facility means a pharmacist licensed to engage in the practice of pharmacy in this state who is responsible for developing, coordinating, and supervising pharmaceutical services in a long-term care facility on a regularly scheduled basis. A consultant pharmacist:

1. Reviews the distribution and storage of drugs and devices and assists facilities in establishing the policies and procedures for the distribution and storage of drugs and devices and makes appropriate recommendations to the facility and the provider pharmacist;

2. Monitors the therapeutic response and utilization of all drugs and devices prescribed for each resident. The following shall be used as minimum guidelines supplementing the pharmacist's professional expertise:

- Regulations and interpretive guidelines of the Centers for Medicare and Medicaid Services, if applicable;
- Rules of the Iowa department of inspections and appeals; and
- Other state rules and regulations;

3. Serves as a resource for pharmacy-related education services within the facility;

4. Participates in quality management of resident care in the facility;

5. Communicates with the provider pharmacist regarding areas of mutual concern and resolution thereof.

"*DEA*" means the United States Department of Justice, Drug Enforcement Administration.

"Long-term care facility" or *"facility"* means:

1. A facility licensed by the Iowa department of inspections and appeals under Iowa Code chapter 135C or Iowa Code chapter 135H;

2. A hospital-based long-term care unit certified under 42 CFR, Part 483, Subpart B;

3. An inpatient hospice certified under 42 CFR, Part 418;

4. A group living facility wherein health care related services are provided by the facility; or

5. A health care facility registered with the board under Iowa Code chapter 124.

"Long-term care pharmacy" or *"provider pharmacy"* means a hospital pharmacy, a general pharmacy, a limited use pharmacy, or a nonresident pharmacy in which drugs, chemicals, or poisons are prepared, compounded, dispensed, vended, distributed, or sold on a regular and recurring basis to or for the use of residents of a long-term care facility and from which related pharmacy services are delivered.

"Medication order," as used in these rules, means a written order from a practitioner or an oral order from a practitioner or the practitioner's authorized agent for administration of a drug or device. For purposes of this chapter, "medication order" includes a prescription.

"Provider pharmacist" means a pharmacist licensed to engage in the practice of pharmacy who is employed by or contracted to a long-term care pharmacy or a provider pharmacy and who is responsible for supervising the accurate dispensing and proper delivery of drugs and devices to a

long-term care facility located within this state. These services shall include, at a minimum, proper medication labeling, storage, transport, record keeping, and prospective drug utilization review in compliance with all federal and state laws and regulations.

"Single unit package" means a package that contains one discrete pharmaceutical dosage form.

"Unit dose dispensing system" means a drug distribution system utilizing single unit, unit dose, or unit of issue packaging in a manner that helps reduce or remove traditional drug stocks from resident care areas and enables the selection and distribution of drugs to be pharmacy-based and controlled.

"Unit dose package" means a package that contains that particular dose of a drug ordered for a resident for one administration time. A unit dose package is not always a single unit package.

"Unit of issue package" means a package that provides multiple units or doses attached to each other but separated in a card or specifically designed container.

Item 17. Amend subrule 23.11(4) as follows:

23.11(4) *Floor stock.* Prescription drugs, as defined by Iowa Code section ~~155A.3(30)~~ 155A.3(37), shall not be floor-stocked in a long-term care facility except as provided in this subrule or in subrule 23.5(2). Bulk supplies of nonprescription drugs may be maintained as provided in subrule 23.13(3). Any pharmacy that utilizes a floor stock distribution system pursuant to this subrule shall develop and implement procedures to accurately establish proof of use of prescription drugs and shall maintain a perpetual inventory, whether by electronic or manual means, of all prescription drugs so dispensed. A floor stock distribution system for prescription drugs may be permitted only under the following circumstances:

a. and *b*. No changes.

Item 18. Amend rule 657—23.21(124,155A) as follows:

657—23.21(124,155A) ~~Destruction~~ Disposal of previously dispensed controlled substances. Controlled substances dispensed to a resident in a long-term care facility and subsequently requiring ~~destruction~~ disposal due to discontinuance of the drug, death of the resident, or other reasons necessitating ~~destruction~~ disposal shall be ~~destroyed~~ disposed of by one of the following methods. Controlled substances shall not be returned to a pharmacy for disposal.

23.21(1) ~~*Destruction*~~ *Disposal in the facility.* In facilities staffed by one or more persons licensed to administer drugs, a licensed health care professional (pharmacist, registered nurse, licensed practical nurse) may ~~destroy~~ dispose of controlled substances in witness of one other responsible adult. The professional ~~destroying or otherwise~~ disposing of the drug shall prepare and maintain a readily retrievable record of the ~~destruction or other~~ disposition which shall be clearly marked to indicate the ~~destruction or other~~ disposition of resident drugs. The record shall include, at a minimum, the following:

a. Resident name and unique identification or number assigned by the dispensing pharmacy to the prescription;

b. The name, strength, and dosage form of the substance;

c. The quantity ~~destroyed or otherwise~~ disposed of;

d. The date the substance is ~~destroyed or otherwise~~ disposed of;

e. The signature or uniquely identifying initials or other unique identification of the professional and the witness;

f. The name and address of the dispensing pharmacy or the dispensing practitioner.

23.21(2) ~~*Destruction or other disposition in the long-term care pharmacy.*~~ *Authorized collection program within a facility*. ~~Controlled substances returned to the pharmacy for destruction or other disposition may be destroyed or otherwise disposed of pursuant to the requirements of 657—subrule~~

~~10.18(3).~~ Registrants allowed by DEA to administer an authorized collection program may install and maintain a collection receptacle in a long-term care facility for the purpose of disposal of prescription drugs, including controlled substances, pursuant to federal regulations, which can be found at http://deadiversion.usdoj.gov/drug_disposal/.

Proposed Telepharmacy Pilot Project Petitions
November 3-4, 2015

A petition for establishment of a telepharmacy in Iowa should address, at minimum, the following:

A. Establish the need for remote pharmacy site (telepharmacy practice)
   1) Distance to the pharmacy nearest to the proposed remote pharmacy site – identify the pharmacy or pharmacies
   2) Distance between the managing pharmacy and the proposed remote pharmacy site
   3) Population of the community; how do residents currently obtain their prescription drugs; is there a prescribing practitioner currently practicing in the community; average number of prescriptions per day anticipated?
   4) Is the community in a critical access area, a medically underserved area, or near a rural health clinic, a federally qualified health center, or a health care facility?
   5) If there was a pharmacy formerly located in the community, when did the pharmacy close and how long had the pharmacy been located in the community? Is there currently a pharmacy in the community with plans to close? If so, when is the anticipated closing?

B. Remote pharmacy site operational proposal
   1) Name and address/location of managing pharmacy and remote pharmacy site; identification of owners of both locations; identification of PIC responsible for both locations; identification of certified pharmacy technician in charge of remote site, including qualifications (minimum one year practice in Iowa pharmacy?)
   2) Number of remote pharmacy sites managed by the managing pharmacy and identification/location of currently managed remote pharmacy sites
   3) Description of the proposed telepharmacy practice including days and hours of operation, the remote pharmacy site's anticipated opening date, proposed staffing from managing pharmacy and in remote pharmacy site, and the responsibilities/activities of each staff member
   4) Plan for training personnel practicing at managing pharmacy and remote pharmacy site
   5) Identification and description of technology and communication systems to be used between the managing pharmacy and the remote pharmacy site. Will bar-code technology be utilized and if so, how and by whom; system downtime plan and procedures
      a) Type of audio-visual link and communication that will be utilized between the managing pharmacy and the remote pharmacy site
      b) How and when will the link between the managing pharmacy and the remote pharmacy site be activated or initiated; will the pharmacist be able to open a visual or audio link from the managing pharmacy without the assistance or interaction of the remote pharmacy site personnel; will multiple camera views be available from the remote pharmacy site and who controls the camera view(s)?

c) Will automated dispensing equipment be used to dispense prescription drugs from the remote pharmacy site? If so, what type of automated system will be used and to what extent will dispensing be automated?

6) Record-keeping systems and locations; drug and record security and confidentiality at the remote pharmacy site; drug inventory and control
7) Will the remote pharmacy site maintain a stock supply of prescription drugs or controlled substances; how and who will package and label drugs for delivery to the patient
8) How often and by whom will prescription drugs, including controlled substances, be inventoried; if a perpetual inventory for controlled substances is utilized, how often and by whom will the perpetual inventory be reconciled to the physical inventory; schedule and process for periodic inspection of remote pharmacy site
9) Scope of clinical pharmacy services to be provided at remote pharmacy site, who will provide those services, and frequency; statements prohibiting the OTC sale of controlled substances from remote pharmacy site and prohibiting a pharmacist intern from practicing at the remote pharmacy site unless a qualified pharmacist is physically present at the remote site
10) Continuous quality improvement plan and how it will be implemented and utilized; processes for ensuring safety and security of patients and staff
11) Patient counseling process including plans to ensure security of patient information and privacy for discussions with patients; how toll-free telephone service will be provided and available to patients for direct contact with the managing pharmacy/pharmacist

C. Identification of information and data that will be provided in periodic reports to the Board including, but not limited to:

1) Documented information regarding specific pharmaceutical services provided to patients at the remote pharmacy site; number of prescriptions dispensed from the remote pharmacy site; identification of errors in dispensing from the remote pharmacy site by number and type of error and actions taken to resolve and prevent future errors by type
2) Information regarding interactions with prescribers and community outreach efforts to patients and prescribers
3) Successful counseling rate at the remote pharmacy site including comparison with counseling rate at the managing pharmacy
4) Number of hours a pharmacist was physically present at the remote pharmacy site and identification of pharmacist activities during that time; plans for future onsite pharmacist staffing and criteria used to determine the need for onsite pharmacist staffing (i.e. up to 40 Rxs per day, 8 RPh hours per month; > 40 Rxs per day, 25% RPh staffing; >60 Rxs per day, 50% RPh staffing; >80 Rxs per day, 75% RPh staffing; >100 Rxs per day, 100% RPh staffing = conversion to traditional pharmacy)
5) Number of hours the remote pharmacy site was open for business; name and qualifications of technician in charge of remote pharmacy site

An Act making changes to the controlled substance schedules and providing penalties.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

Section 1. Section 124.204, subsection 4, Code 2015, is amended by adding the following new paragraphs:

NEW PARAGRAPH: al. 4-methyl-N-ethylcathinone. Other names: 4-MEC, 2-(ethylamino)-1-(4-methylphenyl)propan-1-one.

NEW PARAGRAPH: am. 4-methyl-alpha-pyrrolidinopropiophenone. Other names: 4-MePPP, MePPP, 4-methyl-[alpha]-pyrrolidinopropiophenone, 1-(4-methylphenyl)-2-(pyrrolidin-1-yl)-propan-1-one.

NEW PARAGRAPH: an. Alpha-pyrrolidinopentiophenone. Other names: [alpha]-PVP, [alpha]-pyrrolidinovalerophenone, 1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one.

NEW PARAGRAPH: ao. Butylone. Other names: bk-MBDB, 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one.

NEW PARAGRAPH: ap. Pentedrone. Other names: [alpha]-methylaminovalerophenone, 2-(methylamino)-1-phenylpentan-1-one.

NEW PARAGRAPH: aq. Pentylone. Other names: bk-MBDP, 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one.

NEW PARAGRAPH: ar. 4-fluoro-N-methylcathinone. Other names: 4-FMC, flephedrone, 1-(4-fluorophenyl)-2-(methylamino)propan-1-one.

NEW PARAGRAPH: as. 3-fluoro-N-methylcathinone. Other names: 3-FMC, 1-(3-fluorophenyl)-2-(methylamino)propan-1-one.

NEW PARAGRAPH: at. Naphyrone. Other names: naphthylpyrovalerone, 1-

(naphthalen-2-yl)-2-(pyrrolidin-1-yl)pentan-1-one.

NEW PARAGRAPH: au. Alpha-pyrrolidinobutiophenone. Other names: [alpha]-PBP, 1-phenyl-2-(pyrrolidin-1-yl)butan-1-one.

Sec. 2. Section 124.204, subsection 9, Code 2015, is amended by adding the following new paragraphs:

NEW PARAGRAPH: g. Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate. Other names: PB-22, QUPIC.

NEW PARAGRAPH: h. Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate. Other names: 5-fluoro-PB-22, 5F-PB-22.

NEW PARAGRAPH: i. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide. Other name: AB-FUBINACA.

NEW PARAGRAPH: j. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide. Other name: ADB-PINACA.

NEW PARAGRAPH: k. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide. Other name: AB-CHMINACA.

NEW PARAGRAPH: l. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide. Other name: AB-PINACA.

NEW PARAGRAPH: m. [1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone. Other name: THJ-2201.

NEW PARAGRAPH: n. N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide. Other name: acetyl fentanyl.

NEW PARAGRAPH: o. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide. Other names: MAB-CHMINACA; ADB-

CHMINACA.

Sec. 3. Section 124.206, subsection 2, paragraph (a), is amended as follows:

a. Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, naloxegol, naloxone, and naltrexone, and their respective salts, but including the following:

Sec. 4. Section 124.206, subsection 2, paragraph (d), is amended as follows:

d. Coca leaves and any salt, compound, derivative, or preparation of coca leaves including cocaine and ecgonine and their salts, isomers, derivatives and salts of isomers and derivatives), ~~. Decocainized coca leaves or extractions of coca leaves, which extractions do not contain cocaine or ecgonine, are excluded from this paragraph. The following substances and their salts, optical and geometric isomers, derivatives, and salts of derivatives and optical and geometric isomers,~~ and any salt, compound, derivative, or preparation thereof that is chemically equivalent or identical to any of such substances, ~~are included in this paragraph~~ except that the substances shall not include:

(1) ~~Cocaine~~ Decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine.

(2) ~~Ecgonine~~ [\123\I]ioflupane.

Sec. 5. Section 124.208, subsection 5, paragraph (a), subparagraphs (3) and (4), Code 2015, are amended by striking the subparagraphs.

Sec. 6. Section 124.210, subsection 2, Code 2015, is amended by adding the

following new paragraph:

NEW PARAGRAPH: c. 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol, its salts, optical and geometric isomers and salts of these isomers (including tramadol).

Sec. 7. Section 124.210, subsection 3, Code 2015, is amended by adding the following new paragraphs:

NEW PARAGRAPH: bb. Alfaxalone.

NEW PARAGRAPH: bc. Suvorexant.

EXPLANATION

The bill modifies the controlled substance schedules and provides penalties.

The bill adds 10 synthetic cathinones, eight synthetic cannabinoids, and acetyl fentanyl to the list of substances classified as schedule I controlled substances. The board of pharmacy has determined that these substances should be classified as schedule I controlled substances because each substance has a high potential for abuse and no accepted medical use in the United States.

The bill removes hydrocodone-combination products from the list of substances classified as schedule III controlled substances. Hydrocodone, as a single-entity substance, is currently classified as a schedule II controlled substance. The change under the bill effectively makes all hydrocodone-containing products subject to the controls, security, reporting, and penalty provisions for schedule II controlled substances.

The bill removes naloxegol, a new molecular entity and derivative of naloxone, from control as a schedule III controlled substance. The federal Food and Drug

Administration (FDA) recently approved naloxegol for the treatment of opioid-induced constipation in adults with chronic non-cancer pain. The bill also removes [\123I]ioflupane from control as a schedule II controlled substance. This substance is a new molecular entity and is the active pharmaceutical ingredient in the drug DaTscan, recently approved by the federal Food and Drug Administration for use in diagnosis of patients suspected of Parkinson's disease. Evidence supports the removal of [123\]ioflupane from control as a controlled substance.

The bill also classifies the substance commonly known as tramadol, a centrally acting opioid analgesic, as a schedule IV controlled substance. This substance was previously marketed and distributed as a noncontrolled prescription drug. Effective August 18, 2014, the federal Drug Enforcement Administration classified tramadol as a schedule IV controlled substance under federal law.

The bill also classifies alfaxalone, a neurosteroid with central nervous system depressant properties, as a schedule IV controlled substance. The federal Food and Drug Administration (FDA) recently approved this intravenous injectable anestheticfor use by or on the order of a licensed veterinarian. Alfaxalone is not available by prescription and is approved for use in veterinary practice.

The bill classifies suvorexant, a new insomnia treatment approved by the federal Food and Drug Administration, as a schedule IV controlled substance. This is a novel, first in class, chemical substance and information on actual abuse data is not available. However, data from clinical studies support the classification in schedule IV.

It is a class "C" felony pursuant to Code section 124.401(1)(c)(8) for any unauthorized person to violate a provision of Code section 124.401, involving a

classified substance placed in schedule I, II, or III pursuant to the bill. A class “C” felony for this particular offense is punishable by confinement for no more than 10 years and a fine of at least $1,000 but not more than $50,000.

It is an aggravated misdemeanor pursuant to Code section 124.401(1)(d) for any unauthorized person to violate a provision of Code section 124.401 involving a classified substance placed in schedule IV pursuant to the bill. An aggravated misdemeanor is punishable by confinement for no more than two years and a fine of at least $625 but not more than $6,250.

If a person possesses a controlled substance in violation of Code section 124.401(5) as a first offense, the person commits a serious misdemeanor. A serious misdemeanor is punishable by confinement for no more than one year and a fine of at least $315 but not more than $1,875.

SENATE FILE 453
BY COMMITTEE ON HUMAN
RESOURCES

(SUCCESSOR TO SSB 1021)

A BILL FOR

1 An Act relating to the board of pharmacy, including nonresident
2 pharmacy and outsourcing facility licensure, pharmacist
3 supervision of pharmacy technicians, alternate board
4 members, and enforcement authority.
5 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

Section 1. Section 147.107, subsection 2, paragraph a, Code 2015, is amended to read as follows:

a. A pharmacist, physician, dentist, or podiatric physician who dispenses prescription drugs, including but not limited to controlled substances, for human use, may delegate nonjudgmental dispensing functions to staff assistants only when verification of the accuracy and completeness of the dispensing is determined by the pharmacist or practitioner in the pharmacist's or practitioner's physical presence. However, the physical presence requirement does not apply when a pharmacist or practitioner is utilizing an automated dispensing system; ~~or~~ when a pharmacist is utilizing a tech-check-tech program, as defined in section 155A.3; or when a pharmacist is remotely supervising a certified pharmacy technician practicing at a telepharmacy site approved by the board of pharmacy. When using an automated dispensing system the pharmacist or practitioner shall utilize an internal quality control assurance plan that ensures accuracy for dispensing. When using a tech-check-tech program or when remotely supervising a certified pharmacy technician practicing at an approved telepharmacy site, the pharmacist shall utilize an internal quality control assurance plan, in accordance with rules adopted by the board of pharmacy, that ensures accuracy for dispensing. Verification of automated dispensing, ~~and~~ tech-check-tech, and telepharmacy practice accuracy and completeness remains the responsibility of the pharmacist or practitioner and shall be determined in accordance with rules adopted by the board of pharmacy, the board of medicine, the dental board, and the board of podiatry for their respective licensees.

Sec. 2. Section 155A.3, Code 2015, is amended by adding the following new subsection:

NEW SUBSECTION. 40A. *"Telepharmacy"* means the practice of pharmacy via telecommunications as provided by the board by rule.

Sec. 3. Section 155A.13A, Code 2015, is amended to read as follows:

155A.13A Nonresident pharmacy license — required, renewal, discipline.

1. *License required.* A pharmacy located outside of this state ~~which~~ that delivers, dispenses, or distributes by any method, prescription drugs or devices to an ultimate user in this state shall obtain a nonresident pharmacy license from the board. The board shall make available an application form for a nonresident pharmacy license and shall require such information it deems necessary to fulfill the purposes of this section. A nonresident pharmacy shall do all of the following in order to obtain a nonresident pharmacy license from the board:

a. Submit a completed application form and an application fee as determined by the board.

b. Submit evidence of possession of a valid pharmacy license, permit, or registration ~~as a pharmacy in compliance with the laws of the state in which it is located, a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located, and evidence of compliance with all legal directions and requests for information issued by the regulatory or licensing agency of the state in which it is located~~ issued by the home state licensing authority.

c. (1) ~~Submit a list of the names, titles, and locations of all principal owners, partners, or officers of the nonresident pharmacy, all pharmacists employed by the nonresident pharmacy who deliver, dispense, or distribute by any method prescription drugs to an ultimate user in this state, and of the pharmacist in charge of the nonresident pharmacy. A nonresident pharmacy shall update the list within thirty days of any addition, deletion, or other change to the list.~~ Submit an inspection report that satisfies all of the following requirements:

(a) Less than two years have passed since the date of

1 inspection.
2 (b) The inspection occurred while the pharmacy was in
3 operation. An inspection prior to the initial opening of the
4 pharmacy shall not satisfy this requirement.
5 (c) The inspection report addresses all aspects of the
6 pharmacy's business that will be utilized in Iowa.
7 (d) The inspection was performed by or on behalf of the home
8 state licensing authority, if available.
9 (e) The inspection report is the most recent report
10 available that satisfies the requirements of this paragraph
11 *"c"*.
12 (2) If the home state licensing authority has not conducted
13 an inspection satisfying the requirements of this paragraph
14 *"c"*, the pharmacy may submit an inspection report from the
15 national association of boards of pharmacy's verified pharmacy
16 program, or the pharmacy may submit an inspection report from
17 another qualified entity if preapproved by the board, if the
18 inspection report satisfies all of the other requirements of
19 this paragraph *"c"*.
20 (3) The board may recover from a nonresident pharmacy, prior
21 to the issuance of a license or renewal, the costs associated
22 with conducting an inspection by or on behalf of the board
23 for purposes of satisfying the requirement in subparagraph
24 (1), subparagraph division (d). In addition, the nonresident
25 pharmacy shall submit evidence of corrective actions for all
26 deficiencies noted in the inspection report and shall submit
27 evidence of compliance with all legal directives of the home
28 state regulatory or licensing authority.
29 *d.* Submit evidence that the nonresident pharmacy maintains
30 records of the controlled substances delivered, dispensed, or
31 distributed to ultimate users in this state.
32 *e.* Submit evidence that the nonresident pharmacy provides~~,~~
33 ~~during its regular hours of operation for at least six days~~
34 ~~and for at least forty hours per week,~~ a toll-free telephone
35 service ~~to facilitate communication between ultimate users in~~

1 ~~this state and~~, the telephone number of which is printed on the
2 label affixed to each prescription dispensed or distributed
3 in Iowa, that allows patients to speak with a pharmacist who
4 has access to ~~the ultimate user's~~ patient records ~~in the~~
5 ~~nonresident pharmacy, and that the toll free number is printed~~
6 ~~on the label affixed to each container of prescription drugs~~
7 ~~delivered, dispensed, or distributed in this state~~ at least six
8 days per week for a total of at least forty hours.
9 2. *Pharmacist license requirement.* The pharmacist who is
10 the pharmacist in charge of the nonresident pharmacy shall
11 be designated as such on the nonresident pharmacy license
12 application or renewal. Any change in the pharmacist in charge
13 shall be reported to the board within ten days of the change.
14 The pharmacist in charge must be registered, not licensed,
15 according to rules established by the board of pharmacy.
16 ~~2.~~ 3. *License renewal.* A nonresident pharmacy shall renew
17 its license on or before January 1 annually. In order to renew
18 a nonresident pharmacy license, a nonresident pharmacy shall
19 submit a ~~renewal~~ completed application and fee as determined
20 by the board, and shall fulfill all of the requirements of
21 subsection 1~~, paragraphs "b" through "e"~~. A nonresident
22 pharmacy shall pay an additional fee for late renewal as
23 determined by the board.
24 4. *License denial.* The board shall refuse to issue
25 a nonresident pharmacy license for failure to meet the
26 requirements of subsection 1. The board may refuse to issue
27 or renew a license for any grounds under which the board
28 may impose discipline. License or renewal denials shall be
29 considered contested cases governed by chapter 17A.
30 ~~3.~~ 5. *Discipline.* The board may ~~deny~~ fine, suspend, ~~or~~
31 revoke, or impose other disciplinary sanctions on a nonresident
32 pharmacy license for any ~~violation of this section, section~~
33 ~~155A.15, subsection 2, paragraph "a", "b", "d", "e", "f", "g",~~
34 ~~"h", or "i", chapter 124, 124A, 124B, 126, or 205, or a rule of~~
35 ~~the board.~~ of the following:

1 *a.* Any violation of the federal Food, Drug, and Cosmetic Act
2 or federal regulations promulgated under the Act. A warning
3 letter issued by the United States food and drug administration
4 shall be conclusive evidence of a violation.
5 *b.* Any conviction of a crime related to prescription drugs
6 or the practice of pharmacy committed by the nonresident
7 pharmacy, pharmacist in charge, or individual owner, or if the
8 pharmacy is an association, joint stock company, partnership,
9 or corporation, by any managing officer.
10 *c.* Refusing access to the pharmacy or pharmacy records to an
11 agent of the board for the purpose of conducting an inspection
12 or investigation.
13 *d.* Any violation of this chapter or chapter 124, 124A, 124B,
14 126, or 205, or rule of the board.
15 Sec. 4. NEW SECTION. **155A.13C Outsourcing facility license**
16 **— renewal, cancellation, denial, discipline.**
17 1. *License required.* Any compounding facility that is
18 registered as an outsourcing facility, as defined in 21
19 U.S.C. §353b, that distributes sterile compounded human
20 drug products without a patient-specific prescription to an
21 authorized agent or practitioner in this state shall obtain an
22 outsourcing facility license from the board prior to engaging
23 in such distribution. If an outsourcing facility dispenses
24 prescription drugs pursuant to patient-specific prescriptions
25 to patients in Iowa, the outsourcing facility shall obtain and
26 maintain a valid Iowa pharmacy license or Iowa nonresident
27 pharmacy license under this chapter. The board shall make
28 available an application form for an outsourcing facility
29 license and shall require such information it deems necessary
30 to fulfill the purposes of this section. An outsourcing
31 facility shall do all of the following in order to obtain an
32 outsourcing facility license from the board:
33 *a.* Submit a completed application form and application fee
34 as determined by the board.
35 *b.* Submit evidence of possession of a valid registration as

1 an outsourcing facility with the United States food and drug
2 administration.
3 *c.* If one or more inspections have been conducted by the
4 United States food and drug administration in the five-year
5 period immediately preceding the application, submit a copy
6 of any correspondence from the United States food and drug
7 administration as a result of the inspection, including but
8 not limited to any form 483s, warning letters, or formal
9 responses, and all correspondence from the applicant to the
10 United States food and drug administration related to such
11 inspections, including but not limited to formal responses and
12 corrective action plans. In addition, the applicant shall
13 submit evidence of correction of all deficiencies discovered in
14 such inspections and evidence of compliance with all directives
15 from the United States food and drug administration.
16 *d.* Submit evidence that the supervising pharmacist, as
17 described in 21 U.S.C. §353b(a), holds a valid pharmacist
18 license in the state in which the facility is located and that
19 such license is in good standing.
20 2. *License renewal.* An outsourcing facility shall renew
21 its license on or before January 1 annually. In order to renew
22 an outsourcing facility license, an outsourcing facility shall
23 submit a completed application and fee as determined by the
24 board, and shall fulfill all of the requirements of subsection
25 1. An outsourcing facility shall pay an additional fee for
26 late renewal as determined by the board.
27 3. *License cancellation.* If a facility ceases to be
28 registered as an outsourcing facility with the United States
29 food and drug administration, the facility shall notify the
30 board in writing and shall surrender its Iowa outsourcing
31 facility license to the board within thirty days of such
32 occurrence. Upon receipt, the board shall administratively
33 cancel the outsourcing facility license.
34 4. *License denial.* The board shall refuse to issue
35 an outsourcing facility license for failure to meet the

1 requirements of subsection 1. The board may refuse to issue
2 or renew a license for any grounds under which the board
3 may impose discipline. License or renewal denials shall be
4 considered contested cases governed by chapter 17A.
5 5. *Discipline.* The board may fine, suspend, revoke, or
6 impose other disciplinary sanctions on an outsourcing facility
7 license for any of the following:
8 *a.* Any violation of the federal Food, Drug, and Cosmetic Act
9 or federal regulations promulgated under the Act. A warning
10 letter issued by the United States food and drug administration
11 shall be conclusive evidence of a violation.
12 *b.* Any conviction of a crime related to prescription drugs
13 or the practice of pharmacy committed by the outsourcing
14 facility, supervising pharmacist, or individual owner, or
15 if the outsourcing facility is an association, joint stock
16 company, partnership, or corporation, by any managing officer.
17 *c.* Refusing access to the outsourcing facility or facility
18 records to an agent of the board for the purpose of conducting
19 an inspection or investigation.
20 *d.* Any violation of this chapter or chapter 124, 124A, 124B,
21 126, or 205, or rule of the board.
22 Sec. 5. Section 155A.26, subsections 2, 3, and 4, Code 2015,
23 are amended to read as follows:
24 2. Make audits of the supply and inventory of controlled
25 substances and prescription drugs in the possession of any and
26 all individuals or institutions authorized to have possession
27 of any controlled substances or prescription drugs, regardless
28 of the location of the individual or institution.
29 3. Conduct routine and unannounced inspections of
30 pharmacies, drug wholesalers, and the offices or business
31 locations of all individuals and institutions authorized to
32 have possession of prescription drugs including controlled
33 substances or prescription devices, regardless of the location
34 of the office or business.
35 4. Conduct inspections and investigations related to the

practice of pharmacy and the distribution of prescription drugs and devices in and into this state.

Sec. 6. Section 155A.33, Code 2015, is amended to read as follows:

155A.33 Delegation of technical functions.

A pharmacist may delegate technical dispensing functions to pharmacy technicians, but only if the pharmacist is physically present to verify the accuracy and completeness of the patient's prescription prior to the delivery of the prescription to the patient or the patient's representative. However, the physical presence requirement does not apply when a pharmacist is utilizing an automated dispensing system or a tech-check-tech program or when a pharmacist is remotely supervising a certified pharmacy technician practicing at a telepharmacy site approved by the board. When using an automated dispensing system or a tech-check-tech program, or when remotely supervising a certified pharmacy technician practicing at an approved telepharmacy site, the pharmacist shall utilize an internal quality control assurance plan that ensures accuracy for dispensing. Verification of automated dispensing, ~~and~~ tech-check-tech, and telepharmacy practice accuracy and completeness remains the responsibility of the pharmacist and shall be determined in accordance with rules adopted by the board.

Sec. 7. NEW SECTION. **155A.45 Inspection reports — disclosure.**

Notwithstanding section 272C.6, subsection 4, paragraph *"a"*, an inspection report in possession of the board, regardless of whether the report is based on a routine inspection or an inspection prompted by one or more complaints, may be disclosed to the national association of boards of pharmacy's inspection network.

EXPLANATION

The inclusion of this explanation does not constitute agreement with the explanation's substance by the members of the general assembly.

1 This bill relates to the operation of, and persons and
2 activities regulated by, the board of pharmacy.
3 The bill provides for remote pharmacist supervision of
4 a certified pharmacy technician practicing at an approved
5 telepharmacy practice site, pursuant to rules of the board.
6 The bill defines the term "telepharmacy" as it relates to the
7 practice of pharmacy.
8 The bill amends provisions relating to the licensure of
9 nonresident pharmacies that provide prescription pharmaceutical
10 products to patients located in Iowa. The bill requires the
11 pharmacist in charge of a nonresident pharmacy to be identified
12 as such on the nonresident pharmacy license application or
13 renewal, report any change in the pharmacist in charge to the
14 board within 10 days, and be registered in accordance with
15 board rules. The bill clarifies the information required for
16 license application, including evidence of recent inspection
17 of the pharmacy and defining the elements of an acceptable
18 inspection. The bill describes and identifies various entities
19 that may be employed to perform an inspection acceptable for
20 Iowa licensure. The bill authorizes the board to recoup from
21 a nonresident pharmacy any costs incurred by the board in
22 completing an inspection of the nonresident pharmacy if the
23 nonresident pharmacy cannot provide an acceptable inspection
24 report.
25 The bill eliminates the requirement that a nonresident
26 pharmacy maintain minimum hours and days of operation,
27 requiring in lieu thereof that a pharmacist with access to
28 patient records be readily available to speak to patients via
29 a toll-free telephone number at least six days per week for a
30 total of at least 40 hours.
31 The bill authorizes the board to deny an application for a
32 nonresident pharmacy license if the applicant fails to meet the
33 application requirements and authorizes the board to refuse to
34 issue or renew a nonresident pharmacy license for any grounds
35 under which the board may impose discipline.

1 The bill amends the grounds for disciplining nonresident
2 pharmacies. The board may impose discipline for any violation
3 of the federal Food, Drug, and Cosmetic Act or regulations
4 promulgated under the Act including the issuance by the United
5 States food and drug administration of a warning letter;
6 conviction of a crime related to prescription drugs or the
7 practice of pharmacy by the owner, managing officer, or the
8 pharmacy; refusal to provide the board's agent access to the
9 pharmacy or pharmacy records for purposes of inspection or
10 investigation; and any violation of Iowa law or rule of the
11 board relating to the practice of pharmacy and the distribution
12 of prescription products in Iowa. For nonresident pharmacies,
13 the bill adds that the board has the option to fine the
14 nonresident pharmacy, in addition to license suspension,
15 revocation, and other sanctions.
16 The bill adds a new license classification for outsourcing
17 facilities, for the purpose of licensing and regulating any
18 compounding facility that is registered under federal law as an
19 outsourcing facility. The bill establishes the requirements
20 for application and licensure; license renewal, cancellation,
21 and denial; and establishes grounds for discipline of the
22 outsourcing facility license identical to the disciplinary
23 procedure available regarding nonresident pharmacies.
24 The bill clarifies that the officers, agents, inspectors,
25 and representatives of the board may perform functions and
26 activities relating to authorized enforcement activities
27 regardless of the location of the office or business that is
28 the subject of the enforcement activities. The bill authorizes
29 the board to provide reports of inspections of board licensees
30 to the national association of boards of pharmacy's inspection
31 network, a closed network of information regarding individual
32 states' licensees that compiles information and makes that
33 information available to other state boards of pharmacy for
34 purposes of regulating the subject licensees.

New Nonresident Pharmacy Application Review

Name:	Professional Partners, Inc.
DBA:	Westcliff Compounding Pharmacy
Street Address:	1901 Westcliff Drive
City, State, Zip:	Newport Beach, California 92660
Date application received:	July 7, 2015
Application reviewed by:	Sue Mears
Date application reviewed:	July 8, 2015
Omission(s):	None
Area(s) of Concern:	Disclosed discipline, summarized below

Pharmacy was disciplined by the Colorado Board of Pharmacy in November 2013 for shipping 909 prescription drugs into Colorado without prescription orders over a two year period. The pharmacy had been shipping compounded medications to a prescriber for office use, which it thought to be allowable. The pharmacy agreed to a $6,600 fine and to only dispense compounded medications into Colorado pursuant to a patient-specific prescription.

UPDATE:

During this board's review of the pharmacy's application at its August / September meeting, the board was concerned about the pharmacy's response to the question of registering and reporting to the PMP for compounded controlled substances. The board asked for further follow up with the pharmacy. The pharmacist explained that if a controlled substance is compounded with a non-controlled substance, he believed the resulting compound to be non-controlled. It was explained to him that the Iowa PMP requires submission of all controlled substances dispensed to Iowa, regardless of final form. He understood and agreed that his pharmacy will register and report to the PMP all compounded medications that contain controlled substances.

APPLICATION FOR NONRESIDENT IOWA PHARMACY LICENSE

Please type or print clearly in ink. Make changes as necessary.

1 APPLICATION FOR:

☐ Renewal ☒ New ☐ Address Chg. ☐ Name Chg. ☐ Ownership Chg. ☐ Pharmacist in Charge Chg.

FOR LICENSE PERIOD:

IOWA PHARMACY LICENSE NO.:

LICENSE FEE: $135.00

2 DBA, LEGAL NAME, & LOCATION OF PHARMACY:

Name: PROFESSIONAL PARTNERS, INC.
DBA WESTCLIFF COMPOUNDING PHARMACY

Address: 1901 WESTCLIFF DR #3A

City,State,Zip: NEWPORT BEACH, CA 92660

Remit check or money order payable to:
IOWA BOARD OF PHARMACY
(DO NOT SEND CASH)

3 PHARMACY PHONE (949) 272-0115 **FAX** (949) 272-0038 **FED.TAX ID:** 900599689

E-MAIL ADDRESS: info@westcliffcompounding.com **DEA NO.:** FW2500432

4 TYPE OF OWNERSHIP: ☐Individual ☐Partnership ☒Corporation ☐Other

5 PHARMACIST IN CHARGE:

NAME	LICENSE NO.	HRS WORKED/WEEK	SIGNATURE
MICHAEL PAVLOVICH		40+	

6 ATTACH THE FOLLOWING INFORMATION:

- **a)** List of the names, titles, and addresses of all principal owners, partners, and officers of the pharmacy.
- **b)** List of all staff pharmacists currently employed *(include home state license number and average hours worked per week for each).*
- **c)** List of all technicians, pharmacist-interns, and pharmacy support persons currently employed *(include home state license or registration number and average hours worked per week for each).*
- **d)** Copy of current license, permit, or registration certificate issued by the home state regulatory authority.
- **e)** Most recent inspection report resulting from an inspection conducted by the home state regulatory authority.
- **f)** Evidence of correction of any noncompliance noted on the inspection report by the home state.
- **g)** A copy of a prescription label that includes the toll-free number for use by Iowa patients.
- **h)** A typed description of the prescription drugs and services provided to patients in Iowa.

7 CRIMINAL HISTORY:

a) Has the pharmacy, the pharmacy's owner, or any officer or partner (if the pharmacy is owned by a corporation or partnership) been convicted of any crimes (felonies or misdemeanors)? *Exclude traffic violations and alcohol-related offenses classified as misdemeanors.*

____ Yes X No *If yes, attach explanation.*

b) Has the pharmacist in charge been convicted of any crimes (felonies or misdemeanors)? *Exclude traffic violations and alcohol-related offenses classified as misdemeanors.*

____ Yes X No *If yes, attach explanation.*

8 DISCIPLINARY HISTORY: ***(NOTE:** Discipline includes, but is not limited to: citations, reprimands, fines, license restrictions, probation, and license or registration surrender, suspension, and revocation.)*

a) Has the pharmacy, the pharmacy's owner, or any officer or partner (if the pharmacy is owned by a corporation or partnership) ever been disciplined by any licensing authority?

X Yes ____ No *If yes, describe the discipline and attach all relevant disciplinary documents.*

b) Has the pharmacist in charge ever been disciplined by any licensing authority?

____ Yes X No *If yes, describe the discipline and attach all relevant disciplinary documents.*

RECEIVED
JUL 07 2015
IOWA BOARD OF PHARMACY

c) Does the pharmacy, the pharmacy's owner, any officer or partner, or the pharmacist in charge have any charges, or knowledge of any complaints or investigations, pending before any licensing authority?
_____ Yes ___X___ No *If yes, attach explanation.*

d) Has the pharmacy or the pharmacist in charge ever been denied a license by any licensing authority?
_____ Yes ___X___ No *If yes, attach explanation.*

9 PHARMACY INFORMATION:

a) What are the regular hours of operation of the pharmacy for each period/day identified?
Monday-Friday: 9-5:30 Saturday: — Sunday: —

b) Pharmacy's toll-free phone number: 855-826-6768 *(must be printed on prescription label)*

c) What are the hours of operation of the toll-free phone number?
Monday-Friday: 9-5:30 Pacific Saturday: — Sunday: —

d) Does the pharmacist responding to patient calls during the toll-free phone number hours of operation have access to patient records at the time of the call?
___X___ Yes _____ No *(Attach additional explanation if necessary).*

e) What type of pharmacy do you operate? *(Check all that apply.)*
☒ Community ☐ Home infusion ☐ Nuclear ☐ Central Rx processing ☐ Hospital
☐ Mail order ☐ Long-Term Care ☐ Internet ☐ Central Rx filling ☐ Other (*explain*)

f) Which of the following populations does the pharmacy serve? *(Check all that apply.)*
☒ Human ☒ Veterinary—companion animals ☐ Veterinary—food-producing animals

g) Approximately how many prescriptions did the pharmacy deliver into Iowa last year? ___0___

h) Which of the following accreditations does the pharmacy have? *(Check all that apply.)*
☐ VPPS ☐ VIPPS ☒ PCAB ☐ ACHC ☐ JCAHO ☐ DMEPOS ☐ Other _____ ☐ None

i) Does the pharmacy engage in compounding? ___X___ Yes _____ No
If yes, what types? *(Check all that apply.)*
☒ Sterile High-Risk ☒ Sterile Medium-Risk ☒ Sterile Low-Risk
☒ Non-sterile ☒ Pursuant to patient-specific Rx ☒ In anticipation of patient-specific Rx
☐ For hospital use ☐ For office use by prescriber

j) Does the pharmacy provide or intend to provide controlled substances to patients in Iowa?
_____ Yes ___X___ No *(Nonresident pharmacies are required to report to Iowa's Prescription Monitoring Program (PMP), including submission of zero reports. Please be aware of the reporting requirements described in 657 Iowa Administrative Code chapter 37 and the Iowa Data Reporting Manual.)*
unless Testosterone + non-control is considered reputable

10 FDA INFORMATION:

a) Has the pharmacy ever been inspected by the FDA? _____ Yes ___X___ No

b) If yes, date of last inspection: _____

c) If yes, has the FDA ever issued a 483 or a warning letter to the pharmacy? _____ Yes ___X___ No
If yes, please attach the FDA documentation and include documentation regarding your pharmacy's response to the FDA.

d) Is the pharmacy registered with the FDA as a 503(b) outsourcing facility? _____ Yes ___X___ No

REMIT TO: IOWA BOARD OF PHARMACY
400 S.W. EIGHTH STREET, SUITE E
DES MOINES, IA 50309-4688
PHONE: (515) 281-5944

Information provided in this application may be disclosed pursuant to 657 IAC chapter 14.

I hereby swear under penalty of perjury that the information provided in this application is true and correct. I understand that failure to provide complete and truthful information may constitute grounds for denial, revocation, or other disciplinary sanctions against the pharmacy license.

11 SIGN HERE ⇨ _____ PRESIDENT 2/3/15
Signature of Owner or Corporate Officer *Title* *Date*

INCOMPLETE APPLICATIONS WILL NOT BE ACCEPTED AND WILL BE RETURNED TO APPLICANT

WESTCLIFF
COMPOUNDING PHARMACY

Ownership Disclosure:

1. Michael Pavlovich, PharmD
President, Pharmacist-In-Charge

238 Savona Walk
Long Beach, CA 90803

Licenses
CA RPH42798 Exp 8/31/15
NV 10179 Exp 10/31/15
AZ Y005467 Exp 10/31/15
MD 21411 Exp 8/31/16

Interest 60%

2. John O'Connell, Pharm.D., MBA
Secretary/Treasurer

3501 Kendell Hill Dr
Santa Rosa, CA 95401

Licenses
CA RPH38957 Exp 9/30/16

Interest 40%

1901 Westcliff Dr #3A – Newport Beach, CA 92660
(949) 272-0775 – (855) 826-6768 – FAX (949) 272-0038
www.westcliffcompounding.com

WESTCLIFF
COMPOUNDING PHARMACY

Staff Pharmacists:

1. Michael Pavlovich, PharmD - PIC – CA Lic RPH42798 – 40+ hrs/wk

2. John O'Connell, Pharm.D., MBA – CA Lic RPH38957 – 8 hrs/month

3. Theresa Do, Pharm.D. – CA Lic RPH64293 – 8 hrs/wk

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WESTCLIFF
COMPOUNDING PHARMACY

Technicians:

1. Marisol Rivas – CA TCH38614 – 40 hrs/wk
2. Jeyra Frias – CA TCH64313 – 30 hrs/wk
3. Emilia Alcaraz – CA TCH83397 – 38 hrs/wk

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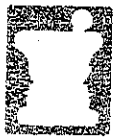

Renewal Certificate

Retail Pharmacy Permit

BOARD OF PHARMACY
1625 NORTH MARKET BLVD., SUITE N-219
SACRAMENTO, CA 95834
(916) 574-7900

LICENSE NO. PHY 50599
RECEIPT NO. 50250754

VALID UNTIL MARCH 01, 2016

WESTCLIFF COMPOUNDING PHARMACY
1901 WESTCLIFF DR #3A
NEWPORT BEACH CA 92660

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the address shown, and is subject to the rules and regulations of the California State Board of Pharmacy.
This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) administrator or pharmacist-in-charge.
This permit is valid only at the address shown.

02/09/15

02/09/15 The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

FORM WPHPHY (12/31/05) PHY

WESTCLIFF COMPOUNDING PHARMACY
1901 WESTCLIFF DR #3
NEWPORT BEACH, CA 92660-0000-000

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FW2500432	05-31-2017	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5,	RETAIL PHARMACY	04-07-2014

WESTCLIFF COMPOUNDING PHARMACY
1901 WESTCLIFF DR #3A
NEWPORT BEACH, CA 92660-0000

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FW2500432	05-31-2017	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5,	RETAIL PHARMACY	04-07-2014

WESTCLIFF COMPOUNDING PHARMACY
1901 WESTCLIFF DR #3A
NEWPORT BEACH, CA 92660-0000

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223

California State Board of Pharmacy
1625 N. Market Blvd, Suite N219 Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 12/29/2014 Inspector: Anna Yamada

Firm: WESTCLIFF COMPOUNDING PHARMACY Phone: (949) 272-0775

Address: 1901 WESTCLIFF DR #3A City: NEWPORT BEACH Zip: 92660

Ownership: CORPORATION

Permit #: PHY50599 Permit Exp: 3/1/2015 DEA#: FW2500432 DEA Exp: 5/31/2017

Date of Self Assessment Form: 6/30/2013 Other Permit #: N/A Date of DEA Inventory: 5/1/2013

Hours M-F: 9AM-5:30PM Hours Saturday closed Hours Sunday: closed

PIC MICHAEL A PAVLOVICH RPH42798 Administrator

RPH Consultant

Staff RPH Name: **License #:** **Staff Name:** **License #:**

Inspector Remarks:

Here today for follow-up inspection from Advance Outcome Management Pharmacy (PHY49946, AC 4682).

Advance Outcome pharmacy records (invoices, prescription, computer server) and dangerous devices (syringes and needles) were transferred to Westcliff Compounding Pharmacy on 12/24/14. Records and devices were boxed and sealed and stored in one of the pharmacy rooms. PIC Pavlovich was informed these items were no longer the property of Advance Outcome or Clarence Lloyd, and PIC Pavlovich wasnow responsible for these items.

Only a small number of dangerous drugs were transferred to pharmacy. Among the items were a couple of open containers of compounding ingredients and PIC Pavlovich was instructed to pull from active drug stock.

Licensee Remarks:

California State Board of Pharmacy
1625 N. Market Blvd, Suite N219 Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

INSPECTION REPORT

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) _____

Pharmacist (print) MICHAEL PAVLOVICH

Inspector (sign) _____

Inspector (print) Anna Yamada

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 4/3/2012 Inspector: Joshua Lee

Firm: WESTCLIFF COMPOUNDING PHARMACY Phone: (949) 272-0775

Address: 1901 WESTCLIFF DR #3A City: NEWPORT BEACH Zip: 92660

Ownership: CORPORATION

Permit #: PHY50599 Permit Exp: 3/1/2013 DEA#: FW2500432 DEA Exp: 5/31/2014

Date of Self Assessment Form: 4/18/2011 Other Permit #: N/A Date of DEA Inventory: 4/18/2011

Hours M-F: 9am-5pm Hours Saturday CLOSED Hours Sunday: CLOSED

PIC MICHAEL A PAVLOVICH RPH42798 Administrator

RPH Consultant

Staff RPH Name:	License #:	Staff Name:	License #:
SARAH M MICHAEL	INT24884	MARISOL RIVAS	TCH38614

	Reference	
C	CFR 1305.22(g)	Procedures for filling out electronic orders (CSOS): Purchaser must record quantity and date received. Record must be electronically linked to the original order and archived. In that, the record of schedule II drugs received from Cardinal was not electonically archived and linked to the original order. — corrected
2 C	CCR 1707.5d	Interpretive Services to be available In that, policies and procedures and a posted notice for the provision of interpretive services was not available. — done

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Phone (916) 574-7900
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www.pharmacy.ca.gov

INSPECTION REPORT

Inspector Remarks:

ROUTINE PHARMACY INSPECTION: Independent retail compounding pharmacy located adjacent to prescribers offices and retail shops. Pharmacy just recently opened on 3/28/2011.

*Patient consultation observed

*Quality Assurance Program: Incident report discussed with PIC

*CURES: reporting

*BOP e-mail notification subscription: helped pharmacy sign up

*Original Notice to Consumer posters displayed

*Original Pharmacy Permits posted

*Sink with hot and cold running water during inspection

*Refrigerator Temperature (USP 36-46F, 2-8C): 40F, temperature log in place

*Wholesalers: Cardinal (CSOS), API, Keysource

*Prescription Labeling has product description/ patient-centered

tained 1 prescription label Rx # 59203 (patient name redacted)

*Policies and Procedures: QA P+P / QA Review, TCH job duties, Temporary absence of RPH for lunch,

*Refill log: in place

Compounding: Pharmacy does nonsterile compounding
-Compounding Self-Assessment: in place

-Bulk Ingredient Invoices: in place, Letco, Medisca
-Compounding logs: in place
-Master formulas: in place
-Balance/ Temperature log: in place
-Compounding p/p: in place
-Compounding QA/ end product testing: ARL
-Labeling: reviewed

DISCUSSION:

1. Theft/Impairment policy and procedures: revise to include mental and physical impairment.

2. Discussed about requirements of Initial DEA Inventory.

In order to complete inspection, PIC to send Inspector Lee via e-mail or fax the following (Email: Joshua.lee@dca.ca..gov, Fax: (858) 618-1794):

CORRECTIONS:

California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

INSPECTION REPORT

1. The record of schedule II drugs received from Cardinal was not electonically archived and linked to the original order. Send statement of correction within 30 days. — corrected

2. Policies and procedures and a posted notice for the provision of interpretive services was not available. Send copy within 30 days. ✓

Licensee Remarks:

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) _____

Pharmacist (print) MICHAEL PAVLOVICH

Inspector (sign) _____

Inspector (print) Joshua Cope

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

WESTCLIFF
COMPOUNDING PHARMACY

Description of Prescription Drugs and Services Provided to Iowa Patients

We have developed a line of implantable medications and a tight delivery system whereby orders are placed directly to the pharmacy by way of an electronic prescription connection. The following are intended for shipment to Iowa patients and/or their physicians:

Estradiol
Naltrexone
Oxytocin
Progesterone
Testosterone/DHEA
Testosterone/Povidone

This list is not exclusive and may change upon new research and physician request.
Pellets are compounded in a ISO Class 7 cleanroom within an ISO Class 5 BioSafety Cabinet and ultimately sterilized by way of electron beam process. Batches are routinely tested for sterility and potency. The process has been validated by FDA on multiple occasions in the innovator's pharmacy.

1901 Westcliff Dr #3A – Newport Beach, CA 92660
(949) 272-0775 – (855) 826-6768 – FAX (949) 272-0038
www.westcliffcompounding.com

the DataBank

P.O. Box 10832
Chantilly, VA 20153-0832

http://www.npdb.hrsa.gov

WESTCLIFF COMPOUNDING PHARMACY

COLORADO STATE BOARD OF PHARMACY

STATE LICENSURE ACTION — **Date of Action:** 11/04/2013

Initial Action	Basis for Initial Action
- PUBLICLY AVAILABLE FINE/MONETARY PENALTY	- OPERATING BEYOND SCOPE OF LICENSE

A. REPORTING ENTITY

Entity Name:	COLORADO STATE BOARD OF PHARMACY
Address:	1560 BROADWAY, STE. 1300
City, State, Zip:	DENVER, CO 80202-0546
Country:	
Name of Office:	COLORADO STATE BOARD OF PHARMACY
Title or Department:	DORA/PROGRAM DIRECTOR
Telephone:	(303) 894-7754
Entity Internal Report Reference:	
Type of Report:	INITIAL

B. SUBJECT IDENTIFICATION INFORMATION (ORGANIZATION)

Organization Name:	WESTCLIFF COMPOUNDING PHARMACY
Other Organization Name(s) Used:	
Business Address:	1901 WESTCLIFF DR STE 3A
City, State, ZIP:	NEWPORT BEACH, CA 92660
Organization Type:	PHARMACY (345)
Names and Titles of Principal Officers and Owners (POO):	
Federal Employer Identification Numbers (FEIN):	900599689
Social Security Numbers (SSN):	
Individual Taxpayer Identification Numbers (ITIN):	
State License Number, State of Licensure:	OSP.0005969, CO
Is the Subject a health care entity that provides health care services and engages in a formal peer review process for the purpose of furthering quality health care?:	YES
Drug Enforcement Administration (DEA) Numbers:	
Clinical Laboratory Act (CLIA) Numbers:	
Food and Drug Administration (FDA) Numbers:	
National Provider Identifiers (NPI):	
Medicare Provider/Supplier Numbers:	
Name(s) of Health Care Entity (Entities) With Which Subject Is Affiliated or Associated (Inclusion Does Not Imply Complicity in the Reported Action.):	
Business Address of Affiliate:	
City, State, ZIP:	
Nature of Relationship(s):	

C. INFORMATION REPORTED

Type of Adverse Action:	STATE LICENSURE
Basis for Action:	OPERATING BEYOND SCOPE OF LICENSE (AF)
Name of Agency or Program That Took the Adverse Action Specified in This Report:	COLORADO STATE BOARD OF PHARMACY
Adverse Action	

CONFIDENTIAL DOCUMENT - FOR AUTHORIZED USE ONLY

Classification Code(s):	PUBLICLY AVAILABLE FINE/MONETARY PENALTY (3233)
Date Action Was Taken:	11/04/2013
Date Action Became Effective:	11/04/2013
Total Amount of Monetary Penalty, Assessment and/or Restitution:	$ 6,600.00
Is Subject Automatically Reinstated After Adverse Action Period Is Completed?:	
Description of Subject's Act(s) or Omission(s) or Other Reasons for Action(s) Taken and Description of Action(s) Taken by Reporting Entity:	STIPULATION AND FINAL AGENCY ORDER, DISTRIBUTED 909 PRESCRIPTION DRUGS INTO COLORADO WITHOUT PRESCRIPTION ORDERS. PLEASE REFER TO BOARD DOCUMENT FOR ADDITIONAL INFORMATION.

☐ Subject identified in Section B has appealed the reported adverse action.

D. SUBJECT STATEMENT

If the subject identified in Section B of this report has submitted a statement, it appears in this section.

E. REPORT STATUS

Unless a box below is checked, the subject of this report identified in Section B has not contested this report.

☐ If box is checked, this report has been disputed by the subject identified in Section B.

☐ If box is checked, at the request of the subject identified in Section B, this report is being reviewed by the Secretary of the U.S. Department of Health and Human Services to determine its accuracy and/or whether it complies with reporting requirements. No decision has been reached.

☐ If box is checked, at the request of the subject identified in Section B, this report was reviewed by the Secretary of the U.S. Department of Health and Human Services. The Secretary's decision is shown below:

Date of Original Submission: 11/05/2013
Date of Most Recent Change: 11/05/2013

This report is maintained under the provisions of: Section 1921

The information contained in this report is maintained by the National Practitioner Data Bank for restricted use under the provisions of Section 1921 of the Social Security Act, and 45 CFR Part 60. All information is confidential and may be used only for the purpose for which it was disclosed. Disclosure or use of confidential information for other purposes is a violation of federal law. For additional information or clarification, contact the reporting entity identified in Section A.

END OF REPORT

Office Outlook Web Access | Type here to search | This Folder | Address Book | Options | Log Off

Mail

- Deleted Items (1733)
- Drafts [40]
- Inbox (6)
- Junk E-Mail
- Sent Items

Click to view all folders

- BOP Staff Information
- CPE Monitor
- Calendar
- Complaints
- Critical Point training ...
- IPA New Practice Model
- Inspections
- NR - New application fol...
- Patient Safety Taskforce...
- Rules Clarification/Info...

Manage Folders...

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clarification

Mike Pavlovich [mike@westcliffcompounding.com]

Sent: Monday, August 03, 2015 5:33 PM
To: Mears, Sue [IBPE]

Hi Sue,

In response to the deficiency noted in our application for a non-resident pharmacy permit, we are now able to provide coverage through a "call forwarding system" making a pharmacist available on Saturdays during normal business hours (9am to 5:30pm Pacific Time). Any callers during that time will have the option of requesting a timely reply from the pharmacist on call. Therefore, we will, in fact, have availability 6 days of the week.

Should the board require further input on this or any other issue, I can be reached directly at 562-881-2534 (cell) when they meet to review the application.

Sincerely,

--
Mike Pavlovich, PharmD, FAPhA
Westcliff Compounding Pharmacy
1901 Westcliff Dr #3
Newport Beach, CA 92660
(949) 272-0775
(949) 272-0038 FAX
www.westcliffcompounding.com

Connected to Microsoft Exchange

From: Mears, Sue [IBPE]
To: Kelly Engelking; Jorgenson, Debbie [IBPE]
Cc: Gary Grove; Winn Jester
Subject: MO - Grove Pharmacy
Date: Monday, September 14, 2015 8:38:24 AM

Kelly, thank you. I have copied Debbie Jorgenson on this as well. She can work with you on being available via Skype.

Sue Mears, RPh
Compliance Officer
Iowa Board of Pharmacy
400 SW 8th Street, Suite E
Des Moines, IA 50309
515-408-7824 (cell)
515-281-4609 (Fax)
sue mears@iowa.gov

Territory: Boone, Buena Vista, Calhoun, Clay, Dickinson, Greene, Palo Alto, Pocahontas, Sac and Webster counties as well as the cities of West Des Moines, Clive and Urbandale in Polk County.

The Iowa Board of Pharmacy promotes, preserves, and protects the public health, safety, and welfare through the effective regulation of the practice of pharmacy and the licensing of pharmacies, pharmacists, and others engaged in the sale, delivery, or distribution of prescription drugs and devices or other classes of drugs or devices which may be authorized. Iowa Code § 155A.2(1).

From: Kelly Engelking [redacted]
Sent: Friday, September 11, 2015 11:51 AM
To: Mears, Sue [IBPE]
Cc: Gary Grove; Winn Jester
Subject: RE: MO - Grove Pharmacy

Sue,

Thank you very much for the information. We would love to attend the November meeting via Skype. Our owner, Pharmacist-In-Charge, General Manager and myself will be available to answer any questions.

Thank you,

Kelly Engelking, CPhT
Project Manager
Grove Pharmacy
Phone: 417.881.2910 ext 503
Fax: 417.890.1579

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From: Gary Grove
Sent: Friday, September 11, 2015 11:34 AM

To: Winn Jester [redacted]; Kelly Engelking [redacted]
Subject: Fwd: MO - Grove Pharmacy

Thank You,

Gary Grove, RPh
Grove Pharmacy
www.grovepharmacy.com<http://www.grovepharmacy.com>
www.grovespa.com<http://www.grovespa.com>
Cell 417-840-2500

Sent from my iPhone

Begin forwarded message:
From: "Mears, Sue [IBPE]" <Sue.Mears@iowa.gov<mailto:Sue.Mears@iowa.gov>>
Date: September 11, 2015 at 11:02:00 AM CDT
To: [redacted]
Subject: MO - Grove Pharmacy

Good morning. The Iowa Board of Pharmacy has received the pharmacy's application for an Iowa nonresident pharmacy license. While the application materials are complete, the Board's policy is to personally review each application in which there is any disclosure of discipline. The Board next meets in early November and will review the application in open session. At this time, I do not know the specific date and time that this will occur. You may check the board's website for updated agenda information (www.iowa.gov/ibpe<http://www.iowa.gov/ibpe>, click on "Board" then click on "Meeting Notices") as that time nears. If your pharmacy would like to be available to answer any questions the board might have, you are more than welcome to attend in person or via electronic means (Skype, conference call, etc.). If you would like to be available by phone, please provide me with a contact name and phone number that the board may call in the event there are questions. It is not required, but sometimes speeds up the process if there are questions.

Thanks so much,

Sue Mears, RPh
Compliance Officer
Iowa Board of Pharmacy
400 SW 8th Street, Suite E
Des Moines, IA 50309
515-408-7824 (cell)
515-281-4609 (Fax)
sue mears@iowa.gov<mailto:sue mears@iowa.gov>

Territory: Boone, Buena Vista, Calhoun, Clay, Dickinson, Greene, Palo Alto, Pocahontas, Sac and Webster counties as well as the cities of West Des Moines, Clive and Urbandale in Polk County.

The Iowa Board of Pharmacy promotes, preserves, and protects the public health, safety, and welfare through the effective regulation of the practice of pharmacy and the licensing of pharmacies, pharmacists, and others engaged in the sale, delivery, or distribution of prescription drugs and devices or other classes of drugs or devices which may be authorized. Iowa Code § 155A.2(1).

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any review, use, retention, dissemination, distribution, or copying of this message is strictly prohibited by law.
Confidentiality Notice: The information contained in this transmission may be privileged, confidential, and protected from disclosure. If you are not the intended recipient, or an employee, or agent responsible for delivering this message to the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this transmission is strictly prohibited. If you have received this transmission in error, please notify us immediately by replying to the message and deleting the message from your computer.

New Nonresident Pharmacy Application Review

Name:	Grove Professional Pharmacy, Inc.
DBA:	Grove Pharmacy
Street Address:	3050 S National, Suite 109
City, State, Zip:	Springfield, Missouri 65804
Date application received:	08-20-2015
Application reviewed by:	Sue Mears
Date application reviewed:	08-25-2015
Omission(s):	None
Area(s) of Concern:	Disclosed discipline, summarized below

Missouri Board of Pharmacy

The pharmacy's Missouri permit was censured in May 2013 following a loss of controlled substances due to diversion by a technician, thereby failing to maintain adequate security over inventory of controlled substances. There appears to be no other sanction.

Owner Gary Grove reported he received probation for 3 years, concluded in 2008, after a compounding issue was identified in the company's home infusion pharmacy. The home infusion pharmacy (not the pharmacy that is currently applying for licensure in Iowa) updated its policies and procedures, reportedly complies with USP standards, and no longer compounds the product in question.

The pharmacy is currently the subject of an investigation in Missouri following a complaint regarding generic and brand billing and dispensing practices. At this time, no formal disciplinary action has been taken.

APPLICATION FOR NONRESIDENT IOWA PHARMACY LICENSE

Please type or print clearly in ink. Make changes as necessary.

1 APPLICATION FOR:

☐ Renewal ☒ New ☐ Address Chg. ☐ Name Chg. ☐ Ownership Chg. ☐ Pharmacist in Charge Chg.

FOR LICENSE PERIOD:

IOWA PHARMACY LICENSE NO.:

LICENSE FEE: $135.00

2 DBA, LEGAL NAME, & LOCATION OF PHARMACY:

Name Grove Pharmacy ← DBA

Address Grove Professional Pharmacy Inc ← Legal
3050 S. National Ste 109

Remit check or money order payable to:
IOWA BOARD OF PHARMACY
(DO NOT SEND CASH)

City,State,Zip Springfield, MO 65804

3 PHARMACY PHONE (417) 881-8822 **FAX** (417) 888-0067 **FED.TAX ID:** 431023225

E-MAIL ADDRESS: National@grovepharmacy.com **DEA NO.:** FG0858108

4 TYPE OF OWNERSHIP: ☐Individual ☐Partnership ☒Corporation ☐Other

5 PHARMACIST IN CHARGE:

NAME	LICENSE NO.	HRS WORKED/WEEK	SIGNATURE
Miguel Nunez	2005033285	40	Miguel Nuñez

6 ATTACH THE FOLLOWING INFORMATION:

✓a) List of the names, titles, and addresses of all principal owners, partners, and officers of the pharmacy.
✓b) List of all staff pharmacists currently employed *(include home state license number and average hours worked per week for each).*
✓c) List of all technicians, pharmacist-interns, and pharmacy support persons currently employed *(include home state license or registration number and average hours worked per week for each).*
✓d) Copy of current license, permit, or registration certificate issued by the home state regulatory authority.
✓e) Most recent inspection report resulting from an inspection conducted by the home state regulatory authority.
✓f) Evidence of correction of any noncompliance noted on the inspection report by the home state.
✓g) A copy of a prescription label that includes the toll-free number for use by Iowa patients.
✓h) A typed description of the prescription drugs and services provided to patients in Iowa.

7 CRIMINAL HISTORY:

a) Has the pharmacy, the pharmacy's owner, or any officer or partner (if the pharmacy is owned by a corporation or partnership) been convicted of any crimes (felonies or misdemeanors)? *Exclude traffic violations and alcohol-related offenses classified as misdemeanors.*
____ Yes X No *If yes, attach explanation.*

b) Has the pharmacist in charge been convicted of any crimes (felonies or misdemeanors)? *Exclude traffic violations and alcohol-related offenses classified as misdemeanors.*
____ Yes X No *If yes, attach explanation.*

8 DISCIPLINARY HISTORY: ***(NOTE:** Discipline includes, but is not limited to: citations, reprimands, fines, license restrictions, probation, and license or registration surrender, suspension, and revocation.)*

a) Has the pharmacy, the pharmacy's owner, or any officer or partner (if the pharmacy is owned by a corporation or partnership) ever been disciplined by any licensing authority?
X Yes ____ No *If yes, describe the discipline and attach all relevant disciplinary documents.*

b) Has the pharmacist in charge ever been disciplined by any licensing authority?
____ Yes X No *If yes, describe the discipline and attach all relevant disciplinary documents.*

RECEIVED
AUG 20 2015
IOWA BOARD OF PHARMACY

c) Does the pharmacy, the pharmacy's owner, any officer or partner, or the pharmacist in charge have any charges, or knowledge of any complaints or investigations, pending before any licensing authority?
X Yes _____ No *If yes, attach explanation.*

d) Has the pharmacy or the pharmacist in charge ever been denied a license by any licensing authority?
_____ Yes X No *If yes, attach explanation.*

9 PHARMACY INFORMATION:

a) What are the regular hours of operation of the pharmacy for each period/day identified?
Monday-Friday: 9am-10pm Saturday: 9am-1pm Sunday: Closed

b) Pharmacy's toll-free phone number: 1-844-706-3050 *(must be printed on prescription label)*

c) What are the hours of operation of the toll-free phone number? ← See attachment
Monday-Friday: _____ Saturday: _____ Sunday: _____

d) Does the pharmacist responding to patient calls during the toll-free phone number hours of operation have access to patient records at the time of the call?
X Yes X No ★*(Attach additional explanation if necessary).* ← See attachment

e) What type of pharmacy do you operate? *(Check all that apply.)*
☒ Community ☐ Home infusion ☐ Nuclear ☐ Central Rx processing ☐ Hospital
☒ Mail order ☐ Long-Term Care ☐ Internet ☐ Central Rx filling ☐ Other (*explain*)

f) Which of the following populations does the pharmacy serve? *(Check all that apply.)*
☒ Human ☒ Veterinary—companion animals ☐ Veterinary—food-producing animals

g) Approximately how many prescriptions did the pharmacy deliver into Iowa last year? Ø

h) Which of the following accreditations does the pharmacy have? *(Check all that apply.)*
☐ VPPS ☐ VIPPS ☐ PCAB ☐ ACHC ☐ JCAHO ☐ DMEPOS ☐ Other _____ ☒ None

i) Does the pharmacy engage in compounding? _____ Yes X No
If yes, what types? *(Check all that apply.)*
☐ Sterile High-Risk ☐ Sterile Medium-Risk ☐ Sterile Low-Risk
☐ Non-sterile ☐ Pursuant to patient-specific Rx ☐ In anticipation of patient-specific Rx
☐ For hospital use ☐ For office use by prescriber

j) Does the pharmacy provide or intend to provide controlled substances to patients in Iowa?
X Yes _____ No *(Nonresident pharmacies are required to report to Iowa's Prescription Monitoring Program (PMP), including submission of zero reports. Please be aware of the reporting requirements described in 657 Iowa Administrative Code chapter 37 and the Iowa Data Reporting Manual.)*

10 FDA INFORMATION:

a) Has the pharmacy ever been inspected by the FDA? _____ Yes X No

b) If yes, date of last inspection: _____

c) If yes, has the FDA ever issued a 483 or a warning letter to the pharmacy? _____ Yes X No
If yes, please attach the FDA documentation and include documentation regarding your pharmacy's response to the FDA.

d) Is the pharmacy registered with the FDA as a 503(b) outsourcing facility? _____ Yes X No

REMIT TO: IOWA BOARD OF PHARMACY
400 S.W. EIGHTH STREET, SUITE E
DES MOINES, IA 50309-4688
PHONE: (515) 281-5944

Information provided in this application may be disclosed pursuant to 657 IAC chapter 14.

I hereby swear under penalty of perjury that the information provided in this application is true and correct. I understand that failure to provide complete and truthful information may constitute grounds for denial, revocation, or other disciplinary sanctions against the pharmacy license.

11 SIGN HERE ⇨ Gary W. Hume — President — 8-11-15
Signature of Owner or Corporate Officer *Title* *Date*

INCOMPLETE APPLICATIONS WILL NOT BE ACCEPTED AND WILL BE RETURNED TO APPLICANT

Owner			
Name	Title	Address	% of Ownership
Gary Grove	Owner/President	4475 S. State Hwy J, Rogersville, MO 65742	100%

Pharmacists		
Name	License Number	Average Hours Worked
Nancy M. Miller	041109	4
Ashley Tennis	2009014964	25
Stefanie L Warden	2011007382	15
Miguel A. Nunez	2005033285	40
Jennifer L. Essary	2004033683	40
Kristie Meacheam-Wallace	044157	35
Thomas Lale	041361	4

Technician List		
Technician Name	License Number	Average Hours Worked
Devin McCarthy	2010021867	30
Diane T. Hare	2003030383	39
Jordan Turner	2012020422	4
Julie Hall	2008025084	39
Laura Kay Nagel	2000143450	39
Mallori Kay Sweeney	2009033833	39
Nathaniel Chambers	2006026989	39
Courtney E. Nicholson	2012002198	39
Debra Louise Robinson	2004032449	39
Elizabeth Totten	2012002359	39
John "Tucker" Dunham	2013012036	20
Melissa Lynn Pearcy	2000161393	39
Rachel F. Garrison	2011027425	38
Robert "Taylor" Maus	2013018738	39
Mary Witt	2014035278	39
Audrey Monholland	2011011790	39
Cindy McGee	1999142729	39
Belinda D Browning	2013005011	40 (Office)
Brandi Rachelle Johnson	2005016995	37 (Office)
Francis Godwin Jester	2009018909	40 (Office)
Kelly Engelking	2004032468	40 (Office)
Rhonda D Davisson	2015010043	40 (Office)

State of Missouri

Department of Insurance, Financial Institutions and Professional Registration
Division of Professional Registration
Missouri Board of Pharmacy

Pharmacy

Class A, C, J

VALID THROUGH OCTOBER 31, 2015
ORIGINAL CERTIFICATE/LICENSE NO. 2008014865
Miguel A Nunez - 2005033285

GROVE PROFESSIONAL PHARMACY, INC
GROVE PHARMACY
MIGUEL A NUNEZ, PIC
3050 S NATIONAL AVE STE 109
SPRINGFIELD MO 65804
USA

EXECUTIVE DIRECTOR

DIVISION DIRECTOR

Board of Pharmacy

PR Home (/) » Pharmacy Home (pharmacists.asp)

Pharmacy Detail

Pharmacy Primary Source Verification

The licensee search function of this website provides data extracted from our database and constitutes a Primary Source Verification.

Licensee Name:	Grove Professional Pharmacy, Inc
Profession Name:	Pharmacy
Licensee Number:	2008014865
Expiration Date:	10/31/2015
Original Issue Date:	6/2/2008
Address:	Miguel A Nunez, PIC
Address Con't:	3050 S National Ave Ste 109
City, State Zip:	Springfield, MO 65804
County:	Greene
Practitioner DBA Name:	Grove Pharmacy
Classification:	Class A, C, J

Current Discipline Status:	Previous
Action Taken:	Censure
Start Date:	5/29/2013
End Date:	5/29/2013
Terms:	Censure of permit. Loss of controlled substances due to diversion by technician, failed to maintain adequate security over inventory of controlled substances. Section 338.055.2(5), (6), (13), and (15), RSMo.

Board of Pharmacy (http://pr.mo.gov/pharmacists)
3605 Missouri Boulevard
P.O. Box 625
Jefferson City, MO 65102-0625
573.751.0091 Telephone
573.526.3464 Fax
800.735.2966 TTY
800.735.2466 Voice Relay
MissouriBOP@pr.mo.gov (mailto:MissouriBOP@pr.mo.gov)
http://pr.mo.gov/pharmacists (http://pr.mo.gov/pharmacists)

STATE OF MISSOURI
BOARD OF PHARMACY

OBSERVATION REPORT

MAILING ADDRESS
MISSOURI BOARD OF PHARMACY
PO BOX 625
JEFFERSON CITY, MO 65102
(573) 526-6985
(573) 526-3464 FAX
PHARMACY@PR.MO.GOV

NAME/ADDRESS OF PHARMACY OR DRUG DISTRIBUTOR	LICENSE NUMBER	CLASS	INSPECTION DATE
Grove Pharmacy 3050 S National Ave Ste 109 Springfield MO 65804	2008014865	A C	10/13/2014

PHARMACIST OR MANAGER-IN-CHARGE	PIC/MIC LICENSE NO
Miguel Nunez	2005033285

PHONE	Fax	Email
417-881-8822		ggrove@grovepharmacy.com

INSPECTION TYPE: **Routine**

Inspector: Lisa Thompson

Acknowledged By: Miguel Nunez

Observations:

Controlled substance distribution records (store to store transfers) need DEA number of both stores.
Failure to take initial tramadol inventory

Comments:

Update delivery policy to include temperature controlled products
Update LTC policy to include labeling, timely dispensing and returns/destruction
Missing compound logs for "First Compound Kits"

- The Pharmacist will return the stock bottle to the locked C-II cabinet immediately after counting.
- C-II should never be out of the sight/direct supervision of the Pharmacist

5) Ordering Controlled II Substances

- All controlled II substances must be ordered using a paper 222 form or using the electronic CSOS signing system.
    - All pharmacists must use their own CSOS signing certificate and must keep their signing password confidential.
    - Pharmacists must review the order before submitting to validate its accuracy both for quantity and product requested.

6) Checking and Applying Controlled Drug Order to the Inventory

- For Drugs C-III-C-V:
    - Once the order is received by the Pharmacy, the Technician will immediately notify and deliver the sealed packages to the Pharmacist on duty.
    - The Pharmacist will be responsible for checking the physical order against the invoices in a timely manner.
    - The Pharmacist will be responsible for incorporating the delivery into inventory securely in accordance with procedure.
    - The pharmacist must electronically record the receipt of medication from the wholesaler's website and save a copy of the log for future reference.
- For C-II Drugs
    - After verifying the invoice amount matches the delivery, the Pharmacist will immediately secure the drugs into the C-II cabinet.
    - The Pharmacist is responsible for inventory of C-II in accordance with C-II handling policies and procedures laid out herein.
        - The Technician should have no contact with the C-II drugs at any step in this process.
    - The pharmacist must electronically record the receipt of medication from the wholesaler's website and save a copy of the log for future reference.
    - All C-II medications received must be recorded in the perpetual inventory log book

7) Prescription Delivery Requirements

- Except as otherwise provided herein, prescriptions filled by Grove Pharmacy may not be left at, accepted by, or delivered to a location, place of business or entity not licensed as a pharmacy:
    - At the request of the patient of the patient or the patient's authorized designee, drivers may deliver a filled prescription for and individual patient directly to the patient or the patient's authorized designee or to:

        - The office of a licensed health care practitioner authorized to prescribe medication in the state of Missouri
        - A long-term care facility as defined by Missouri Board of Pharmacy document CSR 2220-2.140 where the patient resides
        - A hospital office, clinic, or other medical institution that provides health care services
        - A residence designated by the patient or the patient's authorized designee
        - The patient's office or place of employment.
    - All temperature sensitive medications will be designated for expedited delivery once it leaves the confines of the pharmacy and must be sent with an ice pack to maintain proper temperature during the delivery to ensure that when medications are received they are within the temperature requirements recommended by the manufacturer or the *United States Pharmacopeia* (USP).
        - The driver must notify the customer receiving the medication that they have received a temperature sensitive medication and that it must be stored in a refrigerated area as soon as possible.
    - At the request of a customer, legally filled prescriptions for veterinary use may be delivered to a residence, business, or clinic designated by the customer.
    - Grove Pharmacy shall comply with all applicable controlled substance laws and regulations, including, but not limited to, all applicable security requirements.
    - Returns of medications delivered pursuant to this section of the policies and procedures manual shall be governed by, and handled in accordance with chapter 338, and RSMo, and the rules set forth by the Missouri Board of Pharmacy.
    - Delivery drivers are not allowed within the confines of the pharmacy as they do not possess pharmacy technician licenses.
        - Drivers must follow the delivery driver company guidelines outlines in the Driver Standard Operating Procedure

8) Prescription Check-Out Procedure

In the event that a customer does not want to purchase a particular filled drug, the Technician will notify the Pharmacist and he or she will return the drug to stock. This includes a prescription that has not yet been bagged because counseling was required.

- The Technician will finalize register transactions for prescriptions that require counseling.

Policies & Procedures
For
Nursing Home Orders

May 2015

1. Nursing Home prescriptions are received either via fax to the pharmacy or they will be called-in by nursing home personnel.
2. New orders are verified by prescribing physician.
3. If the day's supply is not specified, a month's supply is dispensed by bubble pack. If the medication is controlled substance, 30 doses are dispensed.
4. All medications will be labeled in accordance with Missouri Board of Pharmacy guidelines CSR 338.059 and will meet the needs of the facility they are being sent to.
5. All medication prescribed that is not readily available either due to manufacture backorder or limited availability/supply from a wholesale house/distributor will be communicated immediately to the prescribing physician for further direction and guidance to ensure timely dispensing of the necessary medication to the patient.
6. Medication is bubbled packed and a duplicate copy of the receipt or medical expense summary is printed for the pharmacy book-keeper for packing charge.
7. Rubber gloves are worn by technician or pharmacists bubble packing medication.
8. Bubble packed medication is checked by a pharmacist and charged for delivery by technician.
9. Medication is delivered to the nursing home along with the sheet for nursing home personnel to sign verifying receipt of medication.
10. Medications that have been received by the patient cannot be returned to the pharmacy to return to stock.
    a. Excess medication obtained as a result of a dosing change or because a medication has been discontinued will be stored and disposed of at the nursing home at the discretion of their facility. They cannot be returned to the pharmacy for destruction.
11. Medication delivery verification sheet is returned to the pharmacy by a delivery driver and filed in an appropriate folder.
12. Discontinued medication that has not been received by the patient and was rejected by the nursing home facility will be credited by the book keeping office and medication is returned to stock in blister pack with 12 month dating from the dispense date or the manufacture expiration date whichever is shorter.

Grove Pharmacy
1522 E. Sunshine
Springfield, MO 65804
Phone: **417-881-2910**
Fax: **417-881-3014**

Grove Pharmacy
3050 S. National Ste. #109
Springfield, MO 65804
Phone: **417-881-8822**
Fax: **417-888-0667**

Care/Services available to our Out of State Customers

- All of our Care/Services are offered at no additional charge to our Customers, unless otherwise noted.
- Hours of Operation
  - Monday through Friday
    - 9am to 6pm (Central Standard Time)
  - Saturday
    - 9am to 1pm (Central Standard Time)
  - Sunday
    - Closed
  - Holidays observed (Pharmacy is Closed unless otherwise noted)
    - New Year's Day
    - Memorial Day
    - 4th of July
    - Labor Day
    - Thanksgiving Day
    - Christmas Eve (If on a weekday, Pharmacy will close early at 2pm)
    - Christmas Day
    - New Year's Eve (If on a weekday, Pharmacy will close early at 1pm for end of the year inventory)
- On call availability
  - Our Pharmacists are on call 24/7.
    - Customers can call our normal or toll free pharmacy number and follow the instructions to reach the answering service.
  - Website Requests
    - Anyone who has access to our website (www.grovepharmacy.com) can submit for a Pharmacist to contact them.
      - *Messages sent using this form are not considered private or HIPAA compliant. Avoid sending confidential information via email.*
  - Messages
    - Customers can call the pharmacy number after hours and opt to leave a message for the pharmacy staff to receive the next business day.
- Toll Free Numbers
  - Grove Pharmacy's Toll Free Number is available for anyone to use.
    - 3050 S. National Ste. 109
      - 1-844-706-3050
- Bilingual Services
  - Grove Pharmacy offers our customers' assistance with any of their healthcare needs from our bilingual Spanish speaking pharmacist, Miguel Nunez. Our software system is also able to print labels and medication education sheets in Spanish.
- Counseling Services
  - Grove Pharmacy's Pharmacists will provide in depth counseling to every customer.

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- Counseling can include if applicable, but is not limited to:
  - What the medication is
  - What the medication is typically used for
  - How to properly take the medication
  - Possible side effects to watch for
    - What to do if the customer experiences a side effect
  - Possible drug interactions
  - Allergy sensitivity
  - Items to avoid taking/eating/drinking while on a particular medication
  - Answer any questions the customer may have

- Med Sync Program
  - Grove Pharmacy offers our Med Sync program to all of our customers.
  - Once enrolled into the program, our technicians note the customer's profile.
    - The pharmacy staff then reviews the customer's profile with them to determine what medications they are currently on. Outdated prescriptions are discontinued.
    - The pharmacy staff helps the patient select the best sync date based on what they take and the most recent fill dates.
    - Any questions about their medications or the process of looking at therapeutic alternatives are handled directly by the Pharmacist.
    - If the customer is unsure of what they should be taking, our pharmacy staff will reach out to the physician and review what they should be taking with them.
    - Each month the customer's profile is reviewed by the pharmacy staff. If there are medications due to be filled, the pharmacy staff then contacts the customer to refill it.
      - If the customer indicates they do not need the medication filled, the pharmacist will cover the following with them:
        - Are they taking the medication as prescribed?
          - If not, stress the importance of this to the customer. Discuss the non-compliance issue with the physician's office and ways to remedy the situation.
        - Has the physician changed the directions/dosage?
          - If so, contact the physician's office for clarification.
        - Is the copay too expensive?
          - Discuss therapeutic alternatives with the customer and physician's office.
        - Discuss any other issues that is preventing them from filling their medication on time and what can be done to solve them.
    - A delivery method is arranged and the customer is contacted as soon as the medication has been filled.

- Auto Fill
  - Grove Pharmacy offers an Auto Fill program within our software system, Pioneer Rx. Once a customer verbally consents to be a part of the Auto Fill program, our pharmacy staff then marks their maintenance medications for Auto Fill. A customer can notify the pharmacy at any time to remove them from the program.

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        - The program prompts the pharmacy staff to fill the medications 3 days before it is due. The software determines the due date, based off of the day supply and last pick-up date.
        - Controlled medications (DEA Schedule C II-V) are not to be put on Auto Fill.
        - Any customers with medications deemed "Specialty" (HIV, Hepatitis C, etc.) are to be enrolled in the Med Sync program.
        - All Auto Fill customers must be called when their medications are ready.
- Online Refill Requests
    - Any customer that has access to our website (www.grovepharmacy.com) can request prescription refills online. This a secure program, managed by our software system, Pioneer Rx.
- Smart Phone Mobile App
    - Any customer that owns an iPhone or Android smart phone can download the Grove Pharmacy App. (The App itself is free, Grove Pharmacy is not responsible for any fees their mobile carrier may charge to download or operate the App)
    - The App allows the customers to:
        - Manage their profile
        - Manage multiple profiles
        - Set reminders to take their medication
        - Request refills
        - Contact the pharmacy
    - This is a secure program, managed by our software system, Pioneer Rx.
- Text and/or Email Notifications
    - Grove Pharmacy offers Text and/or Email Notifications within our software system, Pioneer Rx. Once a customer verbally consents, our pharmacy staff will enter their information into their profile and select the option requested.
        - After the pharmacist checks a prescription, the system will automatically notify the customer that their prescription is ready via Text and/or Email.
            - Grove Pharmacy does not charge for this service, but is not responsible for any fees the customer's mobile carrier may charge to receive these notifications.
            - The customer can opt out of this service at any time.
- Discount Program
    - Grove Pharmacy offers all of their customers the opportunity to use the Redeem Discount Program.
    - This program is managed by Pharm Assess and ensures the customers receive the best pricing compared to other discount programs.
- Prescription Savings Program
    - For eligible customers, the pharmacy staff will go through the Prescription Savings Program and use any available free trial or copay cards for their medication.
        - *If the customer has a State and/or Federally funded insurance plan they are considered non-eligible for this program.*
- Medication Cost Evaluation
    - The Pharmacist, with assistance from the pharmacy staff, will review a customer's profile to see if there are any opportunities to save the customer money.
        - Current out of pocket costs will be compared to what our Discount Program offers.

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        - If the customer is eligible, the pharmacy staff go through the Prescription Savings Program and apply any available options to their medications.
        - If the above savings options are not available the Pharmacist will discuss with the customer and

- Mail
    - Grove Pharmacy utilizes USPS and UPS to mail medications to customers that request it. The mailing option is open to all of Grove Pharmacy's customers.
    - See attached procedures
    - There is a $10 mailing fee, unless the customer is deemed exempt from the fee.
        - Exempt customers include, but are not limited to:
            - Aids Project of the Ozarks patients
            - Specialty Medication patients
            - Out of State patients

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Fax: **417-888-0667**

Out of State Mailing Procedures

- Out of state mailing must be specifically requested by the patient.
- Procedure for non-temperature-sensitive items
  - Item(s) are requested by patient.
  - Item(s) are filled and checked by the pharmacist on staff.
  - Item(s) are checked out through the point of sale. Any copay amounts or out-of-pocket cost will be applied to a credit card on file.
  - Item(s), receipt, and drug information are packaged in a padded envelope or box with packing peanuts.
  - The shipping information is processed via UPS World Ship for overnight delivery at no charge to the patient. The label for shipping is then applied to the package.
  - Packages are picked up by UPS near the end of the business day.
  - Signature is required for receipt of any prescription item(s).
- Procedure for temperature-sensitive items
  - Item(s) are requested by patient.
  - Item(s) are filled and checked by the pharmacist on staff.
  - Item(s) are checked out through the point of sale. Any copay amounts or out-of-pocket cost will be applied to a credit card on file.
  - The shipping information is processed via UPS World Ship for overnight delivery at no charge to the patient.
  - Item(s) are then stored in the refrigerator until the UPS driver arrives at the pharmacy.
  - When the UPS driver in on-site, the item(s) are packaged and labeled in an insulated (foam lined) box with ice packs.
  - Packages are picked up by the UPS driver near the end of the business day.
  - Signature is required for receipt of any prescription item(s).

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Springfield, MO 65804
Phone: **417-881-8822**
Fax: **417-888-0667**

To Whom It May Concern:

I, Gary Grove, received probation during 12/01/2005 to 11/30/2008 from the Missouri State Board of Pharmacy due to an issue in our compounding pharmacy. Our compounding pharmacy is a separate entity from our retail location that is applying for a Kansas Pharmacy License.

The issue in question occurred when the compounding pharmacy had packaged and dispense testosterone in oil for injection and inhalation solutions for a doctor's office to administer to their patients at the time of their visit. The pharmacy packaged them in 10ml vials instead of individual 1ml vials for each individual patient.

We remedied the situation to the Missouri State Board's satisfaction by doing the following:

- We updated our policy and procedures to reflect the change in how items were to be dispensed and packaged.
- We comply to all USP Compounding Standards
    - Our policy and procedures reflect compliance with USP Compounding Standards as well
- We no longer compound testosterone in oil for injection

Please also reference the attached inspect reported dated 10/13/2014 for our compounding pharmacy. We receive a perfect inspection with no observations, comments or issues.

If you have any questions in regards to this response please let us know and we would be happy to answer them.

Thank you,

Gary W. Grove

Gary Grove
Owner
Grove Pharmacy
3050 S. National Ste. 109
Springfield, MO 65804
Phone: 417-881-8822
Email: ggrove@grovepharmacy.com

STATE OF MISSOURI
BOARD OF PHARMACY

OBSERVATION REPORT

MAILING ADDRESS
MISSOURI BOARD OF PHARMACY
PO BOX 625
JEFFERSON CITY, MO 65102
(573) 526-6985
(573) 526-3464 FAX
PHARMACY@PR.MO.GOV

NAME/ADDRESS OF PHARMACY OR DRUG DISTRIBUTOR	LICENSE NUMBER	CLASS	INSPECTION DATE
Grove Pharmacy - Home Infusion Divison 3050 South National Ave Ste 109 Springfield MO 65804	005915	A C D H	10/13/2014

PHARMACIST OR MANAGER-IN-CHARGE	PIC/MIC LICENSE NO
Jennifer Essary	2004033683

PHONE	Fax	Email
4178818822		

INSPECTION TYPE: **Routine**

Inspector: Lisa Thompson

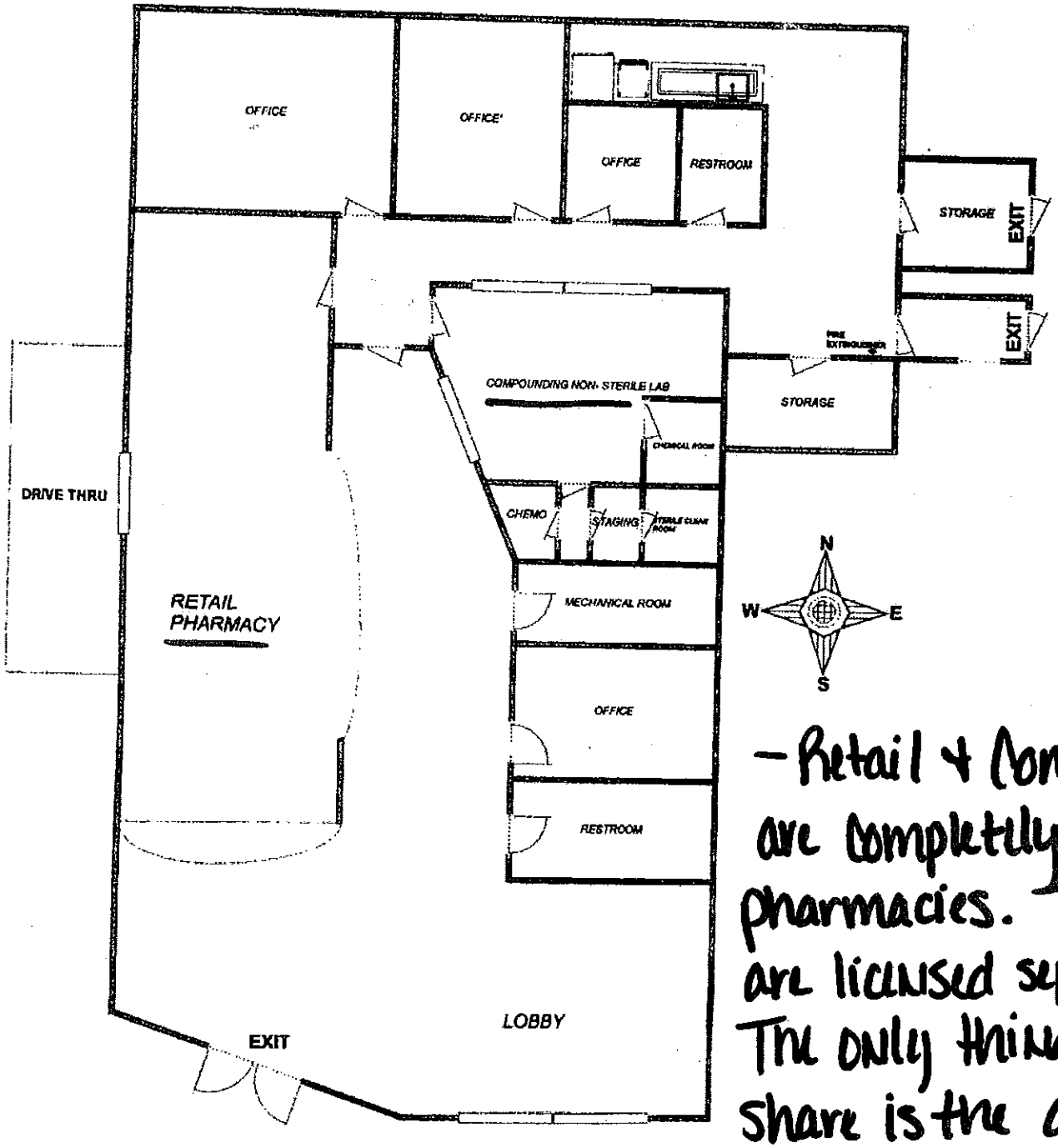
Acknowledged By: Jennifer Essary

Observations:

None

Comments:

Need clock to determine how long to determine how long hands are being washed before sterile compounding.



- Retail + Compounding are completely separate pharmacies. They are licensed separately. The only thing they share is the address.

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To Whom It May Concern:

Grove Pharmacy's location at 3050 S. National Ste. #109, received a censure from the Missouri State Board of Pharmacy because of a theft of controlled substances by a technician. As soon as the theft was discovered we notified the Springfield Police Department, Missouri State Board of Pharmacy, DEA and Missouri BNDD and filled out the proper forms. The technician that was involved in the theft was dismissed and has been placed on the technician disqualification list with the State of Missouri.

We remedied the situation to the Missouri State Board's satisfaction by doing the following:

- Put all controls on perpetual inventory.
- All controlled medications have to be double counted
- Any expired controlled medications are stored in the locked C2 cabinet
- We had a Springfield Police Officer come out to do an onsite inspection to determine if we had any areas which may be opportunities for theft or burglaries.
- Additional surveillance cameras were added
- No employee bags, purses, coats, etc. are allowed in the pharmacy
- Additional employee training for spotting theft
- Our PIC performs a monthly inventory of all C2 medications
- Only the pharmacist on duty is allowed to count C2 medications
- The C2 cabinet is locked at all times and only the pharmacist on duty is in possession of the keys.
- All applicants are required to pass a drug screening before employment is offered.
- Random mandatory drug screens are done with all pharmacy employees throughout the year.

We have also purchased the Eyecon filling machines within the last year. These help keep track of everything filled in the pharmacy by taking pictures of what is filled and storing them on our secured server. The Eyecon machines also electronically counts the pills to ensure an accurate count.

If you have any questions in regards to this response please let us know and we would be happy to answer them.

Thank you,

Gary W. Grove

Gary Grove
Owner
Grove Pharmacy
3050 S. National Ste. 109
Springfield, MO 6S804
Phone: 417-881-8822
Email: ggrove@grovepharmacy.com

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Fax: **417-888-0667**

To Whom It May Concern:

Grove Pharmacy's license number 2008014865 at 3050 S. National Ste. #109, is considered under investigation with the Missouri State Board of Pharmacy at this time. This was prompted by a complaint about brand and generic billing and dispensing practices. Grove Pharmacy has fully cooperated with the board, answered all questions presented and provided all record requests in a timely manner.

Please contact us if you have any additional questions.

Thank you,

Gary W. Grove

Gary Grove
Owner
Grove Pharmacy
3050 S. National Ste. 109
Springfield, MO 65804
Phone: 417-881-8822
Email: ggrove@grovepharmacy.com

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Pharmacy Information Attachment

c) Toll Free Number availability

- Patients can call out toll free number 24 hours, 7 days per week
- Patients will reach a pharmacy staff member during normal business hours
  - Monday-Friday 9am to 6pm
  - Saturday 9am to 1pm
- Outside of normal business hours, Patients who call the toll free number can follow the prompts and choose:
  - To leave a message
  - Contact a Pharmacist via our on call service

d) If a Pharmacist is responding to a patient calling from our toll free number during normal business hours will have access to their profile. If it is after normal business hours, they will not have access to the patient's profile.

GROVE PROFESSIONAL PHARMACIES, INC.
GROVE PHARMACY
1522 EAST SUNSHINE STREET
SPRINGFIELD, MO 65804-0000-000

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FG0858108	09-30-2017	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5,	RETAIL PHARMACY	08-28-2014

GROVE PROFESSIONAL PHARMACIES, INC.
DBA GROVE PHARMACY
3050 SOUTH NATIONAL AVENUE
SUITE 109
SPRINGFIELD, MO 65804-0000

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FG0858108	09-30-2017	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5,	RETAIL PHARMACY	08-28-2014

GROVE PROFESSIONAL PHARMACIES, INC.
DBA GROVE PHARMACY
3050 SOUTH NATIONAL AVENUE
SUITE 109
SPRINGFIELD, MO 65804-0000

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (4/07)

Indiana
Online Licensing

New Search
Litigation Documents
Digital Certification
Pharmacy Board

Person Information

Grove Pharmacy

Address Information

3050 S. National Ste 109
Springfield MO 65804

License Information

License No:	64001940A
Profession:	Pharmacy Board
License Type:	Non-Resident Pharmacy
Obtained By Method:	Application
Issue Date:	8/13/2015
Expiration Date:	12/31/2015
License Status:	Active

Previous Action

Previous Action - None

Related Licenses

No Prerequisite Information

Kansas State Board of Pharmacy

800 SW Jackson St., Suite 1414
Topeka, Kansas 66612-1244
Phone (785) 296-4056
Fax (785) 296-8420

e-mail pharmacy@pharmacy.state.ks.us
web site www.accesskansas.org/pharmacy

NON-RESIDENT PHARMACY REGISTRATION CERTIFICATE

MAILING ADDRESS

22-44864
MIGUEL NUNEZ
GROVE PHARMACY
3050 S NATIONAL STE 109

SPRINGFIELD MO 65804

Schedules 2,2N,3,3N,4,5

STATE OF KANSAS
STATE BOARD OF PHARMACY

N° 22-44864 ***NON-RESIDENT PHARMACY*** This registration Must Be Renewed Annually by June 30

GARY GROVE

has complied with the Pharmacy Act of the State of Kansas providing for the registration or licensing of ***Pharmacies or Drug Stores*** *outside the State of Kansas, and is hereby granted a registration to establish and maintain a pharmacy to be known as* **GROVE PHARMACY**

at 3050 S NATIONAL STE 109 SPRINGFIELD MISSOURI

from this date until June 30, 2016, unless this registration is surrendered, or revoked or suspended by the Kansas State Board of Pharmacy.

This registration issued **May 27, 2015.**

LICENSED PHARMACIST IN CHARGE

Name **MIGUEL NUNEZ** *Certificate No.* **2005033285**

KANSAS STATE BOARD OF PHARMACY

By Debra J. Billingsley Executive Secretary

THIS REGISTRATION MUST BE POSTED IN A CONSPICUOUS PLACE - NOT TRANSFERABLE
DO NOT DESTROY - Return to Secretary for change in ownership or location

Not transferable for change of owner, name or address - Must be conspicuously displayed

Oklahoma State Board of Pharmacy
2920 N Lincoln Blvd, Ste A • Oklahoma City, OK 73105
Phone: (405) 521-3815 / Fax: (405) 521-3758
www.pharmacy.ok.gov

EXPIRES JUN 30, 2016

Amount: $350.00
Receipt: 2015-2318
Date: 6/30/2015

99-7335

GROVE PROFESSIONAL PHARMACY, INC.
GROVE PHARMACY
3050 S NATIONAL, STE 109
SPRINGFIELD, MO 65804

NON-RESIDENT
Pharmacy

Date: INCOME WORKSHEET ☐ DAILY ☐ DEPOSIT

TOTAL # CHECKS = _____ TOTAL DEPOSIT: $ _____

LICENSE FEE – Fund: 0001 Department: 588 Unit: 2092 Revenue: 0573 TOTAL $ _____

Pharmacy # = _____ Fee $ 135 Subtotal of Fee $ _____
PhcyPen # = _____ Fee $ 135 Subtotal of Pen $ _____
PhcyPen # = _____ Fee $ 225 Subtotal of Pen $ _____
PhcyPen # = _____ Fee $ 315 Subtotal of Pen $ _____
PhcyPen # = _____ Fee $ 405 Subtotal of Pen $ _____
Wholesaler # = _____ Fee $ 270 Subtotal of Fee $ _____
WhsrPen # = _____ Fee $ 270 Subtotal of Pen $ _____
WhsrPen # = _____ Fee $ 360 Subtotal of Pen $ _____
WhsrPen # = _____ Fee $ 450 Subtotal of Pen $ _____
WhsrPen # = _____ Fee $ 540 Subtotal of Pen $ _____
Pharmacist # = _____ Fee $ 180 Subtotal of Fee $ _____
RPhPen # = _____ Fee $ 180 Subtotal of Pen $ _____
RPhPen # = _____ Fee $ 270 Subtotal of Pen $ _____
RPhPen # = _____ Fee $ 360 Subtotal of Pen $ _____
Delinq. RPh # = _____ Fee $ 630 Subtotal of Fee $ _____

PENALTY FEE - Fund:0001Dept:588 Unit: 2092 Revenue: 0649
TOTAL $ _____
PhcyPen # _____ $ _____
WhsrPen # _____ $ _____
RPhPen # _____ $ _____

REGISTRATION FEE – Fund: 0001 Dept: 588 Unit: 2092 Revenue: 0581 TOTAL $ _____

CSA # = _____ Fee $ 90 Subtotal of Fee $ _____
CSAPen # = _____ Fee $ 90 Subtotal of Pen $ _____
Precursor # = _____ Fee $ 180 Subtotal of Fee $ _____
PrecPen # = _____ Fee $ 180 Subtotal of Pen $ _____
TechCertified # = _____ Fee $ 40 Subtotal of Fee $ _____
TechPen # = _____ Fee $ 40 Subtotal of Pen $ _____
TechPen # = _____ Fee $ 50 Subtotal of Pen $ _____
TechPen # = _____ Fee $ 60 Subtotal of Pen $ _____
TechPen # = _____ Fee $ 70 Subtotal of Pen $ _____
TechTrainee # = _____ Fee $ 20 Subtotal of Fee $ _____
TechTr Pen # = _____ Fee $ 20 Subtotal of Pen $ _____
SupportPerson # = _____ Fee $ 25 Subtotal of Fee $ _____
PSP-Pen # = _____ Fee $ 25 Subtotal of Pen $ _____

CSAPen # _____ $ _____
PrecPen # _____ $ _____
TechPen # _____ $ _____
PSP-Pen # _____ $ _____

EXEMPT: # Pharmacy_____ # Wholesalers_____ # CSAs_____ # Precursors_____

REV 1/8/2014 PREPARED BY: _____ VERIFIED BY: _____

New Nonresident Pharmacy Application Review

Name:	G&K Pharmacy
DBA:	Glades Pharmacy
Street Address:	4680 Broadway
City, State, Zip:	Allentown, PA 18104
Date application received:	10-09-2015
Application reviewed by:	Sue Mears
Date application reviewed:	10-13-2015
Omission(s):	None
Area(s) of Concern:	Disclosed discipline, summarized below

Glades Pharmacy entered into a Consent Agreement in June 2015 with the Maine Board of Pharmacy for not filing a change of pharmacist in charge application within 7 days. The Consent Agreement included a $1,500 civil penalty along with a warning, but no further sanction.

APPLICATION FOR NONRESIDENT IOWA PHARMACY LICENSE

Please type or print clearly in ink. Make changes as necessary.

1 APPLICATION FOR:

☐ Renewal ☒ New ☐ Address Chg. ☐ Name Chg. ☐ Ownership Chg. ☐ Pharmacist in Charge Chg.

FOR LICENSE PERIOD:

IOWA PHARMACY LICENSE NO.:

LICENSE FEE: $135.00

2 DBA, LEGAL NAME, & LOCATION OF PHARMACY:

Name: G&K Pharmacy

Address: DBA Glades Drugs
4680 Broadway
&

City,State,Zip: Allentown, PA 18104

Remit check or money order payable to:
IOWA BOARD OF PHARMACY
(DO NOT SEND CASH)

3 PHARMACY PHONE (610) 351-2666 **FAX** (610) 351-2662 **FED.TAX ID:** 27-3540506

E-MAIL ADDRESS: info@gladesdrugs.com **DEA NO.:** FG2796590

4 TYPE OF OWNERSHIP: ☐ Individual ☐ Partnership ☒ Corporation ☐ Other _____

5 PHARMACIST IN CHARGE:

NAME	LICENSE NO.	HRS WORKED/WEEK	SIGNATURE
Heather Stanton	RP032537L	45/5	Heather J Stanton

6 ATTACH THE FOLLOWING INFORMATION:

a) List of the names, titles, and addresses of all principal owners, partners, and officers of the pharmacy. ✓
b) List of all staff pharmacists currently employed *(include home state license number and average hours worked per week for each).* ✓
c) List of all technicians, pharmacist-interns, and pharmacy support persons currently employed *(include home state license or registration number and average hours worked per week for each).* N/A
d) Copy of current license, permit, or registration certificate issued by the home state regulatory authority. ✓
e) Most recent inspection report resulting from an inspection conducted by the home state regulatory authority. ✓
f) Evidence of correction of any noncompliance noted on the inspection report by the home state. ✓
g) A copy of a prescription label that includes the toll-free number for use by Iowa patients. ✓
h) A typed description of the prescription drugs and services provided to patients in Iowa. ✓

7 CRIMINAL HISTORY:

a) Has the pharmacy, the pharmacy's owner, or any officer or partner (if the pharmacy is owned by a corporation or partnership) been convicted of any crimes (felonies or misdemeanors)? *Exclude traffic violations and alcohol-related offenses classified as misdemeanors.*
_____ Yes ___X___ No *If yes, attach explanation.*

b) Has the pharmacist in charge been convicted of any crimes (felonies or misdemeanors)? *Exclude traffic violations and alcohol-related offenses classified as misdemeanors.*
_____ Yes ___X___ No *If yes, attach explanation.*

RECEIVED
OCT 09 2015
IOWA BOARD OF PHARMACY

8 DISCIPLINARY HISTORY: ***(NOTE:** Discipline includes, but is not limited to: citations, reprimands, limited license restrictions, probation, and license or registration surrender, suspension, and revocation.)*

a) Has the pharmacy, the pharmacy's owner, or any officer or partner (if the pharmacy is owned by a corporation or partnership) ever been disciplined by any licensing authority?
___X___ Yes _____ No *If yes, describe the discipline and attach all relevant disciplinary documents.*

b) Has the pharmacist in charge ever been disciplined by any licensing authority?
_____ Yes ___X___ No *If yes, describe the discipline and attach all relevant disciplinary documents.*

c) Does the pharmacy, the pharmacy's owner, any officer or partner, or the pharmacist in charge have any charges, or knowledge of any complaints or investigations, pending before any licensing authority?
_____ Yes ___X___ No *If yes, attach explanation.*

d) Has the pharmacy or the pharmacist in charge ever been denied a license by any licensing authority?
_____ Yes ___X___ No *If yes, attach explanation.*

9 PHARMACY INFORMATION:

a) What are the regular hours of operation of the pharmacy for each period/day identified?
Monday-Friday: 9:00am-6:00pm Saturday: 10:00am-3pm Sunday: closed

b) Pharmacy's toll-free phone number: 844-452-3371 *(must be printed on prescription label)*

c) What are the hours of operation of the toll-free phone number?
Monday-Friday: 24hrs Saturday: 24hrs Sunday: 24hrs

d) Does the pharmacist responding to patient calls during the toll-free phone number hours of operation have access to patient records at the time of the call?
___X___ Yes _____ No (*Attach additional explanation if necessary*).

e) What type of pharmacy do you operate? *(Check all that apply.)*
☒ Community ☐ Home infusion ☐ Nuclear ☐ Central Rx processing ☐ Hospital
☐ Mail order ☐ Long-Term Care ☐ Internet ☐ Central Rx filling ☐ Other (*explain*)

f) Which of the following populations does the pharmacy serve? *(Check all that apply.)*
☒ Human ☐ Veterinary—companion animals ☐ Veterinary—food-producing animals

g) Approximately how many prescriptions did the pharmacy deliver into Iowa last year? ___Ø___

h) Which of the following accreditations does the pharmacy have? *(Check all that apply.)*
☐ VPPS ☐ VIPPS ☐ PCAB ☐ ACHC ☐ JCAHO ☐ DMEPOS ☐ Other _____ ☒ None

i) Does the pharmacy engage in compounding? _____ Yes ___X___ No
If yes, what types? *(Check all that apply.)*
☐ Sterile High-Risk ☐ Sterile Medium-Risk ☐ Sterile Low-Risk
☐ Non-sterile ☐ Pursuant to patient-specific Rx ☐ In anticipation of patient-specific Rx
☐ For hospital use ☐ For office use by prescriber

j) Does the pharmacy provide or intend to provide controlled substances to patients in Iowa?
_____ Yes ___X___ No (*Nonresident pharmacies are required to report to Iowa's Prescription Monitoring Program (PMP), including submission of zero reports. Please be aware of the reporting requirements described in 657 Iowa Administrative Code chapter 37 and the Iowa Data Reporting Manual.*)

10 FDA INFORMATION:

a) Has the pharmacy ever been inspected by the FDA? _____ Yes ___X___ No

b) If yes, date of last inspection: _____

c) If yes, has the FDA ever issued a 483 or a warning letter to the pharmacy? _____ Yes _____ No
If yes, please attach the FDA documentation and include documentation regarding your pharmacy's response to the FDA.

d) Is the pharmacy registered with the FDA as a 503(b) outsourcing facility? _____ Yes _____ No

REMIT TO: IOWA BOARD OF PHARMACY
400 S.W. EIGHTH STREET, SUITE E
DES MOINES, IA 50309-4688
PHONE: (515) 281-5944

Information provided in this application may be disclosed pursuant to 657 IAC chapter 14.

I hereby swear under penalty of perjury that the information provided in this application is true and correct. I understand that failure to provide complete and truthful information may constitute grounds for denial, revocation, or other disciplinary sanctions against the pharmacy license.

11 SIGN HERE ➡ _____ Treasurer 10/7/15
Signature of Owner or Corporate Officer *Title* *Date*

INCOMPLETE APPLICATIONS WILL NOT BE ACCEPTED AND WILL BE RETURNED TO APPLICANT

Glades Drugs Inc.
Owner Info

Terrence Myers-President

Home Address:
3220 Bellericay Lane
Land O Lakes, FL 34638

Ryan Goodkin –Secretary

Home Address:
110 Flagler Lane
West Palm Beach, FL 33407

Santo Leo-Vice President

Home Address:
498 NE 37th St
Boca Raton, FL 33834

Daniel Lansman-Treasurer

Home Address:
10145 Emerson St
Parkland, FL 33076

LIST OF PHARMACISTS
G&K Pharmacy

Pharmacist in charge:

Heather Lee Stanton
License # RP032537L
Exp: 9/30/16
50 hours

ADDRESS:
169 Lone Pine Rd
Barto, PA 19504

Ph: 610-223-5363

Saturday Pharmacist

Purvi Shah
License # RP441618
Exp: 9/30/16
5 hours

ADDRESS:
305 Milkweed Drive
Allentown, PA 18104

Ph: 610-866-3788

2070

Commonwealth of Pennsylvania Department of State
Bureau of Professional and Occupational Affairs
Pharmacy

License Number
PP482156

Expiration Date
08/31/2017

Registration Code
zrfMenu8

License Status
Active

G & K PHARMACY
HEATHER LEE STANTON
4680 BROADWAY
Allentown PA 18104

OFFICIAL DOCUMENT

READ THE FOLLOWING INFORMATION CAREFULLY CONCERNING YOUR LICENSE:

1. SIGN THE WALLET CARD AND CERTIFICATE WHERE INDICATED.
2. DETACH THE WALLET CARD AND CERTIFICATE AT PERFORATION.

G & K PHARMACY
HEATHER LEE STANTON
4680 BROADWAY
Allentown PA 18104

Registration Code

Your **registration code** is found on the attached wallet card.

Use this **registration code** online to: renew your license, change your personal or license address, or order duplicate licenses.

Visit our website at: www.mylicense.state.pa.us

First time users will be required to use this **registration code** to create a user ID and password.

Commonwealth of Pennsylvania
Department of State
Bureau of Professional and Occupational Affairs
PO Box [illegible] Harrisburg PA [illegible]

15 0165854

License Type
Pharmacy

License Status
Active

Initial License Date
08/10/2011

G & K PHARMACY
HEATHER LEE STANTON
4680 BROADWAY
Allentown PA 18104

License Number
PP482156

Expiration Date
08/31/2017

Commissioner of Professional and Occupational Affairs

PA STATE BOARD OF PHARMACY
PO Box 2649
Harrisburg, PA 17105-2649
(717) 783-7156 (PHONE) • (717) 787-7769 (FAX)

FACILITY
G & K PHARMACY
4680 BROADWAY
Allentown 18104
Phone:
Owner:

LICENSE
License No: PP482156
Profession:
License Type: Pharmacy

Inspection Type:	17-Non-Directed Routine
Inspection Date:	9/2/2015
Result:	Pass

Notes:

Remarks: No technician help. Application for change in pharmacist manager filed. New pharmacist manager is Heather Lee Stanton RP032537L, new pharmacist manager began working as pharmacist manager on 8/14/2015.Former pharmacist manager Shalu Gupta last worked as pharmacist manager on 8/13/2015. Pharmacist on duty is Heather Lee Stanton RP032537L, (610)351-2666.

The undersigned licensee, designee, or other authorized representative of the licensee acknowledges the completion of this inspection and the results as indicated on the summary and checklist reports.

If this is a New Business Inspection, this PASS inspection form will serve as a temporary authority to operate pending final review and approval by the State Board. The temporary authority must be prominently displayed and will expire upon receipt of a properly issued license or six months from the date of inspection.

Signature of Inspector	9/2/2015 Date/Time	Signature of Owner/Representative

PA STATE BOARD OF PHARMACY
PO Box 2649
Harrisburg, PA 17105-2649
(717) 783-7156 (PHONE)
• (717) 787-7769 (FAX)

FACILITY
G & K PHARMACY
4680 BROADWAY
Allentown 18104

LICENSE
License No: PP482156
Profession:
License Type: Pharmacy

Inspection Type:	17-Non-Directed Routine
Inspection Date:	9/2/2015
Result:	Pass

Notes:
Remarks: No technician help. Application for change in pharmacist manager filed. New pharmacist manager is Heather Lee Stanton RP032537L, new pharmacist manager began working as pharmacist manager on 8/14/2015.Former pharmacist manager Shalu Gupta last worked as pharmacist manager on 8/13/2015. Pharmacist on duty is Heather Lee Stanton RP032537L, (610)351-2666.

Checklist Results

QUESTIONS

Question	Answer
1. Are all licenses current and posted?	Yes
2. Are there signed and dated protocols for each pharmacy technician?	Yes
Number of pharmacy technicians employed:	0
3. Are prescription files properly maintained? (electronic files are acceptable)	Yes
4. Are outdated drugs appropriately removed from active stock?	Yes
5. Does the pharmacy have adequate equipment and supplies to enable it to properly prepare and dispense consistent with the pharmacy's scope of practice?	Yes
6. Is there a refrigerator with temperature monitoring for drug storage only?	Yes
7. Are current copies of all Federal, State, and Board statues and regulations pertaining to pharmacy practice available? (Internet access is acceptable)	Yes
8. Is hot and cold water available in the prescription area?	Yes
9. Do labels have all the required information and match the license record?	Yes
10. Are transferred prescriptions properly recorded?	Yes
11. Are all prescriptions verified by registered pharmacists?	Yes
12. Is the name or initials of the dispensing pharmacist noted on the prescriptions?	Yes
13. Have any automated medication systems been properly validated?	N/A
14. Are there policies and procedures for the operation of any automated medication systems?	N/A
15. Is there a program for quality assurance for any automated medication systems?	N/A
16. Does the pharmacy meet all security requirements?	Yes
17. Are the required records maintained for the administration of injectable medications, biologicals, or immunizations?	N/A
18. Is the pharmacy in compliance with all sanitation, cleanliness, maintenance, and construction requirements?	Yes
19. Are Schedule II drugs dispersed throughout the stock or securely locked in a substantially constructed cabinet?	Yes
20. Is the generic equivalent sign and list of commonly used equivalents properly posted?	Yes

STATE OF MAINE
DEPARTMENT OF PROFESSIONAL
AND FINANCIAL REGULATION
OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION
MAINE BOARD OF PHARMACY
COMPLAINTS AND INVESTIGATION
35 STATE HOUSE STATION
AUGUSTA, MAINE
04333-0035

Paul R. LePage
Governor

Anne L. Head, Esq.
Commissioner

Geraldine L. Betts
Administrator

June 25, 2015

Jack P. Herick, Inc
Attn: Terry Myers, President
1095 Broken Sound Pkwy NW Suite 300
Boca Raton, FL 33487-3503

RE: 2015 PHA 10983

Dear Mr. Myers:

Please find enclosed the fully-executed consent agreement made by you, the Board of Pharmacy, and the Department of Attorney General in this matter.

This letter also acknowledges receipt of your fine payment of $1,500.00 (check number 10334)

As all conditions of the Consent Agreement have been met; the above-mentioned complaint file is now closed.

If you have any questions, please feel free to contact this office.

Sincerely,

Kelly L. McLaughlin, Senior Consumer Assistant Specialist
(email:kelly.l.mclaughlin@maine.gov)

Enclosure

cc: Andrew Black, Assistant Attorney General
Geraldine L. Betts, Board Administrator
Thomas Avery, Chief Field Investigator & Complainant

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
JACK P. HERICK, INC.	)	CONSENT AGREEMENT
	)	
Complaint No. 2015 PHA 10983	)	

PARTIES

This document is a Consent Agreement regarding disciplinary action against the mail order pharmacy license of Jack P. Herick, Inc. d/b/a Glades Drugs in the State of Maine. The parties to this Consent Agreement are: Jack P. Herick, Inc. ("JPH Inc."), the Maine Board of Pharmacy ("the Board"), and the Maine Office of the Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

FACTS

1. At all times relevant to this matter, JPH Inc. was licensed by the Board as a mail order pharmacy, license no. MO40001718, located at 109 South Lake Avenue in Pahokee, Florida.
2. On November 5, 2014, Oemar Iershad replaced Alan M. Kruger as the Pharmacist in Charge ("PIC") of JPH Inc.
3. On December 1, 2014, JPH Inc. filed an online renewal application for its mail order pharmacy license with the Board.
4. In this application JPH Inc. stated that its PIC was Mr. Kruger, and JPH Inc. certified that the information provided on the application was true and accurate.

5. Based on the information provided in the application, the Board approved JPH Inc.'s renewal application.

6. On December 5, 2014, the Board received a change in PIC application from JPH Inc. that indicated that on November 5, 2014, Mr. Iershad had assumed the role of PIC of JPH Inc.

7. On March 23, 2015, Board Investigator Thomas Avery filed a complaint with the Board alleging that JPH Inc. had failed to file a timely PIC change application with the Board and had made a misrepresentation in its online renewal application.

8. The Board docketed this complaint as complaint no. 2015 PHA 10983.

9. Under 32 M.R.S. § 13753(1)(C) a pharmacy must report to the Board by mail or fax any change of PIC no later than seven (7) days after the change.

10. In addition, under Board Rule Chapter 11, § 3, upon a change of PIC, a mail order pharmacy must file a new application with the Board by registered mail no later than seven (7) days after the change.

11. On June 4, 2015, following a presentation of the complaint, the Board voted to offer JPH Inc. this Consent Agreement in order to finally resolve Complaint No. 2015 PHA 10983.

12. Absent acceptance of this Consent Agreement by signing and dating it and returning it to Kelly McLaughlin, Senior Consumer Assistance Specialist, 35 State House Station, Augusta, Maine 04333-0035 by July 10, 2015, the Board will resolve this matter by holding an adjudicatory hearing.

COVENANTS

13. JPH Inc. admits to the facts as stated above and admits that such conduct constitutes grounds for discipline as follows:

a. Pursuant to 10 M.R.S. §§ 8003(5-A)(A)(1) by making a misrepresentation in its license renewal application with the Board;

b. Pursuant to 10 M.R.S. §§ 8003(5-A)(A)(4) for violating a governing law of the Board, specifically 32 M.R.S. § 13753(1)(C) by failing to report to the Board by mail or fax a change of PIC no later than 7 days after the change; and

c. Pursuant to 10 M.R.S. §§ 8003(5-A)(A)(5) for violating a rule of the Board, specifically Board Rule Chapter 11, § 3, by failing to file a new application with the Board by registered mail no later than 7 days after a change of PIC.

14. As DISCIPLINE for the conduct admitted to in paragraph 13 above, JPH Inc. agrees to accept the imposition of:

a. A WARNING; and

b. A CIVIL PENALTY in the amount of one thousand five hundred dollars ($1500.00), payment of which civil penalty shall be made by certified check or money order payable to the "Treasurer, State of Maine" and delivered to Kelly McLaughlin, Senior Consumer Assistance Specialist, Maine Department of Professional and Financial Regulation, 35 State House Station, Augusta, Maine 04333, within thirty (30) days of the execution of this Consent Agreement.

15. This Consent Agreement is not appealable and is effective until modified or rescinded by the parties hereto.

16. Violation of any of the terms or conditions of this Consent Agreement by JPH Inc. shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

17. The Board and the Office of the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

18. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408.

19. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

20. The Board and JPH Inc. agree that no further agency or legal action will be initiated against JPH Inc. by the Board based upon the specific violations admitted to herein, except or unless JPH Inc. fails to comply with the terms and conditions of this Consent Agreement. The Board may however consider the conduct described above as evidence of a pattern of misconduct in the event that other allegations are brought against JPH Inc. The Board may also consider the fact that disoipline was imposed by this Consent Agreement in determining appropriate discipline in any further complaints against JPH Inc.

21. JPH Inc. acknowledges by its duly authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

JACK P. HERICK, INC.

DATED: 6-12-15

BY: [signature]
Authorized Representative

Santo Silva
Printed Name

DATED: 6/25/15

[signature]
JOSEPH BRUNO, R.Ph., President
MAINE BOARD OF PHARMACY

DATED: 6/25/2015

[signature]
ANDREW L. BLACK
Assistant Attorney General

LM2 HP-1

G&K Pharmacy
4680 Broadway Allentown , PA 18104
844-452-3371 NABP #
Caution: Federal law prohibits transfer of this drug to any other person than patient for whom prescribed.

Rx 00109265 JOHNATHAN DOE DR.
JOHN M DOE
1234 MAIN ST LAKE WORTH, FL 33460
KETOPROFEN/LIDOCAINE
10%/4% CREAM
120 GM Lot# Discard after
APPLY 1-2 PUMPS (1 PUMP = 1.5 GRAMS) TO THE FOCAL SITE OF PAIN 3-4 TIMES DAILY
KK **No refills authorized** 08/05/2015
Rx Safety cap ☑ Patient pay $0.00 Disp. DAW 0 Cost $7.10

FOR EXTERNAL USE ONLY

[redacted]

KETOPROFEN USP MICRONIZED POWDER
NDC:62991273306 Mfg:LETCO Exp:04/30/2019
Lot#:1406250045 LIDOCAINE USP
NDC:62991-1094-06 Mfg:LETCO Exp:05/06/2019
Lot#:1410280062

Signature Log
JOHN M DOE
1234 MAIN ST LAKE WORTH, FL 33460
Rx 00109265
08/05/2015 KK Signature _____

00109265 08/05/2015 KK CASH CUSTOME
JOHN M DOE 10/10/2000 123-456-7890
1234 MAIN ST LAKE WORTH, FL 33460
KETOPROFEN/LIDOCAINE 10%/4% CREAM 120 GM $0.00
APPLY 1-2 PUMPS (1 PUMP = 1.5 GRAMS) TO THE FOCAL SITE OF PAIN 3-4 TIMES DAILY
JOHNATHAN DOE DR. JD5555 (561)555-5555
5555 LAKE WORTH RD LAKE WORTH, FL 33460 Refills 0

21019

JOHN M DOE
1234 MAIN ST
LAKE WORTH, FL 33460

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Ketoprofen- NSAID, Topical Anti-Inflammatory
Lidocaine- Topical Anesthetic

BEFORE USING THIS MEDICINE:
* Inform your Doctor or Pharmacist if you are allergic to any prescription or non-prescription medicine; taking other medicines or have other medical problems; pregnant, planning a pregnancy, or breastfeeding.
* Check with your Doctor, Pharmacists, or Nurse if information in this leaflet causes you special concern or if you want additional information about your medicine and its use.

COMMON USE FOR THIS MEDICINE:
For the potential treatment of: Osteoarthritis/Rheumatoid Arthritis TMJ Neuropathy/Diabetic Peripheral Neuropathy Fibromyalgia Post Herpetic Neuralgia Radiculopathy Failed Back Syndrome Tendonitis Epicondylitis Myofascial Pain Syndrome Trigeminal Neuralgia

HOW TO USE THIS MEDICINE:
Use this medicine exactly as directed on the label, unless instructed differently by your doctor
* This medication is for EXTERNAL USE only.
* CLEANSE & DRY area first before applying.
* WASH hands prior to administration.
* WASH hands immediately after using medication.
* DO NOT USE on irritated, denuded, or damaged skin.

WHAT TO DO IF YOU MISS A DOSE:
If you miss a dose, apply as soon as possible when remembered; then resume regular dosing schedule.

HOW TO STORE THIS MEDICINE:
Keep in original closed container in a dark, cool, and dry place away from children. Ingredients may separate upon prolonged exposure to heat. Refrigeration of the medication for several hours may help the product remix. Discard unneeded medicine.

CALL YOUR DOCTOR IMMEDIATELY IF YOU EXPERIENCE:
Skin inflammation; Skin rash; Dry skin; Itching.

PRECAUTIONS AND WARNINGS:
* There are no adequate or well-controlled safety studies for this medication.

TK21019

G&K Pharmacy Receipt
4680 Broadway Allentown , PA 18104
844-452-3371 NABP #
JOHN M DOE
1234 MAIN ST 08/05/2015
LAKE WORTH, FL
33460 123-456-7890
HIPAA check ☑
Rx 00109265 10day supply NDC
120 GM
KETOPROFEN/LIDOCAINE 10%/4% CREAM
JOHNATHAN DOE DR. CASH CUSTOMERS
5555 LAKE WORTH RD LAKE WORTH, FL 33460
(561)555-5555 JD5555 **$0.00**
Sales tax $0.00

G&K Pharmacy Receip
4680 Broadway Allentown , PA 18104
844-452-3371 NABP #
JOHN M DOE
1234 MAIN ST 08/05/2015
LAKE WORTH, FL
33460 123-456-7890
Rx 00109265
00109265
$0.00

G&K Pharmacy, DBA Glades Drugs

Description

Pharmacy practice of the establishment G&K Pharmacy. DBA Glades Drugs is an independent retail and non-sterile compounding facility. Prescription drugs from retail filled are Schedules II-V and legend drugs. Compounded non-sterile drugs are Schedule III-V and legend drugs. USP <795> guidelines are used for the non-sterile compounding practice at this site.

Offer to Counsel

All Patients are given an offer to counsel in a separate writing with their prescription. On this offer to counsel are the pharmacy hours, toll-free phone number and on-call phone number where the pharmacist may be reached after hours. This telephone service is free and has multiple lines to ensure reasonable access.

Normal delivery process

All prescriptions are mailed FedEx ground the day they are processed and the normal arrival time is 2-3 business days after the prescription is received at the pharmacy. The patient is contacted before the prescription is sent and informed of the expected arrival time. Overnight shipments are available upon request.

Delivery Delays

If the prescription is not available or there is going to be a delay in the processing of the prescription, the patient is contacted to either inform the patient of the delay or t set up an alternative means for acquiring the prescription.

Non Delivery

If the prescription has not been received, we contact the courier to find out the reason(s) for the delay and overnight replacement medication.

Temperature sensitive drugs

All temperature-sensitive drugs are sent in appropriate thermal packaging to ensure proper storage temperature upon delivery.

Acute Illness

For an acute illness, the prescription can either be sent overnight or transferred to a local pharmacy for immediate pickup.

New Nonresident Pharmacy Application Review

Name:	HDK Enterprises Inc.
DBA:	Southside Infusion
Street Address:	7700 Main Street, Suite 210
City, State, Zip:	Houston, TX 77030
Date application received:	Date unknown (not date stamped)
Application reviewed by:	Sue Mears
Date application reviewed:	09-28-2015
Omission(s):	None
Area(s) of Concern:	Disclosed discipline, summarized below

Texas Board of Pharmacy

Southside Infusion was fined $1,000 in 1994 for “failure to maintain complete and accurate records of the distribution of controlled substances to an agency for delivery to an ocean vessel”.

Southside Infusion was reprimanded in 2001 for prescription records that did not have accurate prescriber information.

The pharmacy is not currently subject to any disciplinary action or probation.

Owner Harish Katharani failed to report the above actions on new pharmacy applications for two other pharmacies he took ownership of in Texas and was fined $1,000 for each application, and the applications were granted with no additional sanctions.

APPLICATION FOR NONRESIDENT IOWA PHARMACY LICENSE

Please type or print clearly in ink. Make changes as necessary.

1 APPLICATION FOR:

☐ Renewal ☒ New ☐ Address Chg. ☐ Name Chg. ☐ Ownership Chg. ☐ Pharmacist in Charge Chg.

FOR LICENSE PERIOD:

IOWA PHARMACY LICENSE NO.:

LICENSE FEE: $135.00

2 DBA, LEGAL NAME, & LOCATION OF PHARMACY:

Name HDK ENTERPRISES INC. DBA SOUTHSIDE INFUSION

Address 7700 MAIN ST. STE 210

City,State,Zip HOUSTON, TX 77030

Remit check or money order payable to:
IOWA BOARD OF PHARMACY
(DO NOT SEND CASH)

3 PHARMACY PHONE (713) 660-8888 FAX (713) 661-4828 FED.TAX ID: 76-0356751

E-MAIL ADDRESS: INFUSION@SSRX.COM **DEA NO.:** BS3104522

4 TYPE OF OWNERSHIP: ☐Individual ☐Partnership ☒Corporation ☐Other

5 PHARMACIST IN CHARGE:

NAME	LICENSE NO.	HRS WORKED/WEEK	SIGNATURE
RUBIN SHAH	51241	45/WK	

6 ATTACH THE FOLLOWING INFORMATION:

a) List of the names, titles, and addresses of all principal owners, partners, and officers of the pharmacy.
b) List of all staff pharmacists currently employed *(include home state license number and average hours worked per week for each)*.
c) List of all technicians, pharmacist-interns, and pharmacy support persons currently employed *(include home state license or registration number and average hours worked per week for each)*.
d) Copy of current license, permit, or registration certificate issued by the home state regulatory authority.
e) Most recent inspection report resulting from an inspection conducted by the home state regulatory authority.
f) Evidence of correction of any noncompliance noted on the inspection report by the home state.
g) A copy of a prescription label that includes the toll-free number for use by Iowa patients.
h) A typed description of the prescription drugs and services provided to patients in Iowa.

7 CRIMINAL HISTORY:

a) Has the pharmacy, the pharmacy's owner, or any officer or partner (if the pharmacy is owned by a corporation or partnership) been convicted of any crimes (felonies or misdemeanors)? *Exclude traffic violations and alcohol-related offenses classified as misdemeanors.*
____ Yes _X_ No *If yes, attach explanation.*

b) Has the pharmacist in charge been convicted of any crimes (felonies or misdemeanors)? *Exclude traffic violations and alcohol-related offenses classified as misdemeanors.*
____ Yes _X_ No *If yes, attach explanation.*

8 DISCIPLINARY HISTORY: (*NOTE: Discipline includes, but is not limited to: citations, reprimands, fines, license restrictions, probation, and license or registration surrender, suspension, and revocation.)*

a) Has the pharmacy, the pharmacy's owner, or any officer or partner (if the pharmacy is owned by a corporation or partnership) ever been disciplined by any licensing authority?
_X_ Yes ____ No *If yes, describe the discipline and attach all relevant disciplinary documents.*

b) Has the pharmacist in charge ever been disciplined by any licensing authority?
____ Yes _X_ No *If yes, describe the discipline and attach all relevant disciplinary documents.*

c) Does the pharmacy, the pharmacy's owner, any officer or partner, or the pharmacist in charge have any charges, or knowledge of any complaints or investigations, pending before any licensing authority?
_____ Yes __X__ No *If yes, attach explanation.*

d) Has the pharmacy or the pharmacist in charge ever been denied a license by any licensing authority?
_____ Yes __X__ No *If yes, attach explanation.*

9 PHARMACY INFORMATION:

a) What are the regular hours of operation of the pharmacy for each period/day identified?
Monday-Friday: 9AM-6PM Saturday: 9AM-3PM Sunday: _____

b) Pharmacy's toll-free phone number: 1-888-660-6337 *(must be printed on prescription label)*

c) What are the hours of operation of the toll-free phone number?
Monday-Friday: 24X7 Saturday: 24X7 Sunday: 24X7

d) Does the pharmacist responding to patient calls during the toll-free phone number hours of operation have access to patient records at the time of the call?
__X__ Yes _____ No (*Attach additional explanation if necessary*).

e) What type of pharmacy do you operate? *(Check all that apply.)*
☒ Community ☒ Home infusion ☐ Nuclear ☐ Central Rx processing ☐ Hospital
☒ Mail order ☐ Long-Term Care ☐ Internet ☐ Central Rx filling ☐ Other (*explain*)

f) Which of the following populations does the pharmacy serve? *(Check all that apply.)*
☒ Human ☐ Veterinary—companion animals ☐ Veterinary—food-producing animals

g) Approximately how many prescriptions did the pharmacy deliver into Iowa last year? ZERO

h) Which of the following accreditations does the pharmacy have? *(Check all that apply.)*
☐ VPPS ☐ VIPPS ☐ PCAB ☒ ACHC ☐ JCAHO ☒ DMEPOS ☒ Other URAC, The compliance team ☐ None

i) Does the pharmacy engage in compounding? ✓ Yes _____ No
If yes, what types? *(Check all that apply.)*
☑ Sterile High-Risk ☑ Sterile Medium-Risk ☑ Sterile Low-Risk
☐ Non-sterile ☐ Pursuant to patient-specific Rx ☐ In anticipation of patient-specific Rx
☐ For hospital use ☐ For office use by prescriber

j) Does the pharmacy provide or intend to provide controlled substances to patients in Iowa?
__X__ Yes _____ No (*Nonresident pharmacies are required to report to Iowa's Prescription Monitoring Program (PMP), including submission of zero reports. Please be aware of the reporting requirements described in 657 Iowa Administrative Code chapter 37 and the Iowa Data Reporting Manual.*)

10 FDA INFORMATION:

a) Has the pharmacy ever been inspected by the FDA? _____ Yes __X__ No

b) If yes, date of last inspection: _____

c) If yes, has the FDA ever issued a 483 or a warning letter to the pharmacy? _____ Yes __X__ No
If yes, please attach the FDA documentation and include documentation regarding your pharmacy's response to the FDA.

d) Is the pharmacy registered with the FDA as a 503(b) outsourcing facility? _____ Yes __X__ No

REMIT TO: IOWA BOARD OF PHARMACY
400 S.W. EIGHTH STREET, SUITE E
DES MOINES, IA 50309-4688
PHONE: (515) 281-5944

Information provided in this application may be disclosed pursuant to 657 IAC chapter 14.

I hereby swear under penalty of perjury that the information provided in this application is true and correct. I understand that failure to provide complete and truthful information may constitute grounds for denial, revocation, or other disciplinary sanctions against the pharmacy license.

11 SIGN HERE ➡ [signature] *Signature of Owner or Corporate Officer* President *Title* 9/22/15 *Date*

INCOMPLETE APPLICATIONS WILL NOT BE ACCEPTED AND WILL BE RETURNED TO APPLICANT

HDK Enterprises
Southside Infusion

"One SOURCE for ALL your Medical Need"

7700 S.Main Street, Suite # 210
Houston TX 77030
Tel: 713-660-8888
Fax: 713-661-4828

September 22, 2015

Re: **Three (3) Disciplinary Actions Explained**

Dear Sir/Madam,

Please accept this, as our Letter of Explanation, for the Southside Infusion state license disciplinary action.

Agreed Board Order #B-93-019-B, on or about October 26, 1994 the Texas State Board of Pharmacy entered an Agreed Board Order in the matter of Southside Infusion Pharmacy for failure to maintain complete and accurate records of the distribution of controlled substances to an agency for delivery to an ocean vessel. A $1,000.00 fine on the pharmacy license held by Southside Infusion Pharmacy, which informally settled the matters that had come to the attention of this Agency, but it does not represent either an admission or denial of the allegations set out in the Order on the part of the licensee.

Agreed Board Order #B-99-011, on December 15, 1997 through November 10, 1998, failed to properly keep and maintain prescription records, in that, prescription records did not document the correct name of the practitioner. An informal conference was held in the office of the Texas State Board of Pharmacy on February 28, 2001, with Harish Katharani, and other pharmacy staff members and legal counsel. The Order of the Board dated May 23, 2001 was for the pharmacy license to be reprimanded, which informally settled the matters that had come to the attention of this Agency, but it does not represent either an admission or denial of the allegations set out in the Order on the part of the licensee.

Please accept this, as our Letter of Explanation, for the Fulton Pharmacy state license disciplinary action.

Agreed Board Order #F-14-011, on 10/21/2014, Alleged violation: failure to disclose disciplinary action against corporate officer on pharmacy licensure application. License was granted and fined $1,000.00 dollars.

Please accept this, as our Letter of Explanation, for the RC Pharmacy state license disciplinary action.

Agreed Board Order #F-14-010, on 10/21/2014, Alleged violation: failure to disclose disciplinary action against corporate officer on pharmacy licensure application. License was granted and fined $1,000.00 dollars.

Respectfully,

Harish Katharani
President

Fulton Pharmacy, Applicant for Pharmacy License, Katy, TX. Alleged violation: failure to disclose disciplinary action against corporate officer on pharmacy licensure application. Agreed Board Order accepted by applicant and entered by the Board on 10-21-14: license granted and fined $1000.

AGREED BOARD ORDER #F-14-011

RE: IN THE MATTER OF FULTON PHARMACY (APPLICANT FOR PHARMACY LICENSE)

BEFORE THE TEXAS STATE BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of the Application for Pharmacy License submitted by Fulton Pharmacy (Applicant), 1331 West Grand Parkway North, Suite #111, Katy, Texas 77493.

By letter dated October 1, 2014, the Board gave preliminary notice to Applicant of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Applicant may have violated:

Section 565.002(a)(3) and (10) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2013); and

Section 281.8(c) of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2014), in that allegedly:

COUNT

On or about October 26, 1994, the Texas State Board of Pharmacy (TSBP) entered Agreed Board Order #B-93-019-A in the matter of Harish D. Katharani. The Order was based on allegations that Mr. Katharani failed to maintain complete and accurate records of the distribution of controlled substances to an agency for delivery to an ocean vessel. The Order imposed a $1,000 administrative penalty.

On or about March 27, 2014, Fulton Pharmacy submitted an application for a pharmacy license (change of ownership) to the TSBP, which listed Mr. Katharani as an officer. On the application, it was falsely indicated that no officer had been the subject of any professional disciplinary action by a regulatory authority, when, as described above, Mr. Katharani had been subject to disciplinary action by the TSBP.

By letter dated October 1, 2014, Applicant was notified that the matters previously set out in this Order could be disposed of without the scheduling of an informal conference or a formal administrative hearing. By signing this Order, Harish D. Katharani, Managing Member of Katy Procare Pharmacy, LLC, on behalf of Applicant, and Darby C. Allen, Legal Counsel for Applicant, neither admit nor deny the truth of the matters previously set out in this Order, and

agrees that the Board has jurisdiction in this matter and waives the right to informal conference, notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that:

(1) Applicant shall be granted a Texas Pharmacy License after successfully completing the requirements of licensure as set forth in the Texas Pharmacy Act, TEX. OCC. CODE ANN., Title 3, Subtitle J (2013) and the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2014).

(2) Applicant shall pay an administrative penalty of one thousand dollars ($1,000) due ninety (90) days after the entry of this Order.

(3) Applicant shall allow Board staff to directly contact Applicant on any matter regarding the enforcement of this Order.

(4) Failure to comply with any of the requirements in this Order constitutes a violation and shall be grounds for further disciplinary action. The requirements of this Order are subject to the Texas Pharmacy Act, TEX. OCC. CODE ANN., Title 3, Subtitle J (2013), and Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2014).

And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

Signed and entered by the Executive Director on behalf of the Texas State Board of Pharmacy on this 21st day of October, 2014.

Gay Dodson, R.Ph., Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Harish D. Katharani, R.Ph., Managing Member of Katy Procare Pharmacy, LLC,
for and on behalf of Fulton Pharmacy

Darby C. Allen, Legal Counsel for Fulton Pharmacy
BakerHostetler, LLP
811 Main Street, Suite, #1100
Houston, Texas 77002-6111

APPROVED AS TO FORM:

Kerstin E. Arnold, General Counsel
Texas State Board of Pharmacy

RC Pharmacy, Applicant for Pharmacy License, Houston, TX. Alleged violation: failure to disclose disciplinary action against corporate officer on pharmacy licensure application. Agreed Board Order accepted by applicant and entered by the Board on 10-21-14: license granted and fined $1000.

AGREED BOARD ORDER #F-14-010

RE: IN THE MATTER OF
RC PHARMACY
(APPLICANT FOR
PHARMACY LICENSE)

BEFORE THE TEXAS STATE
BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of the Application for Pharmacy License submitted by RC Pharmacy (Applicant), 7515 Main Street, Suite #780, Houston, Texas 77030.

By letter dated October 1, 2014, the Board gave preliminary notice to Applicant of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Applicant may have violated:

Section 565.002(a)(3) and (10) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2013); and

Section 281.8(c) of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2014), in that allegedly:

COUNT

On or about October 26, 1994, the Texas State Board of Pharmacy (TSBP) entered Agreed Board Order #B-93-019-A in the matter of Harish D. Katharani. The Order was based on allegations that Mr. Katharani failed to maintain complete and accurate records of the distribution of controlled substances to an agency for delivery to an ocean vessel. The Order imposed a $1,000 administrative penalty.

On or about March 27, 2014, RC Pharmacy submitted an application for a pharmacy license (change of ownership) to the TSBP, which listed Mr. Katharani as an officer. On the application, it was falsely indicated that no officer had been the subject of any professional disciplinary action by a regulatory authority, when, as described above, Mr. Katharani had been subject to disciplinary action by the TSBP.

By letter dated October 1, 2014, Applicant was notified that the matters previously set out in this Order could be disposed of without the scheduling of an informal conference or a formal administrative hearing. By signing this Order, Harish D. Katharini, R.Ph., Managing Member, Specialized Transdermal, LLC, for and on behalf of Applicant, and Darby C. Allen, Legal Counsel for Applicant, neither admit nor deny the truth of the matters previously set out in this

Order, and agrees that the Board has jurisdiction in this matter and waives the right to informal conference, notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that:

(1) Applicant shall be granted a Texas Pharmacy License after successfully completing the requirements of licensure as set forth in the Texas Pharmacy Act, TEX. OCC. CODE ANN., Title 3, Subtitle J (2013) and the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2014).

(2) Applicant shall pay an administrative penalty of one thousand dollars ($1,000) due ninety (90) days after the entry of this Order.

(3) Applicant shall allow Board staff to directly contact Applicant on any matter regarding the enforcement of this Order.

(4) Failure to comply with any of the requirements in this Order constitutes a violation and shall be grounds for further disciplinary action. The requirements of this Order are subject to the Texas Pharmacy Act, TEX. OCC. CODE ANN., Title 3, Subtitle J (2013), and Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2014).

And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

Signed and entered by the Executive Director on behalf of the Texas State Board of Pharmacy on this 21st day of October, 2014.

Gay Dodson, R.Ph., Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Harish D. Katharani, R.Ph., Managing Member, Specialized Transdermal, LLC
for and on behalf of RC Pharmacy

Darby C. Allen, Legal Counsel for RC Pharmacy
BakerHostetler, LLP
811 Main Street, Suite #1100
Houston, Texas 77002-6111

APPROVED AS TO FORM:

Kerstin E. Arnold, General Counsel
Texas State Board of Pharmacy

AGREED BOARD ORDER #B-99-011

RE:	IN THE MATTER OF SOUTHSIDE PHARMACY (PHARMACY LICENSE # 14797)	BEFORE THE TEXAS STATE BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy the matter of pharmacy license number 14797 issued to Southside Pharmacy, 4009 J Bellaire Blvd., Houston, Texas 77025.

By letter dated September 7, 2000, the Texas State Board of Pharmacy gave preliminary notice to Southside Pharmacy of its intent to take disciplinary action with respect to pharmacy license number 14797 issued to Southside Pharmacy. This action was taken as a result of information received by the Texas State Board of Pharmacy, which produced evidence indicating that Southside Pharmacy may have violated:

> Section 26(a)(1), (2), (8), (9), (12), and (13), Section 26(b)(3) and (8) of the Texas Pharmacy Act, TEX. REV. CIV. STAT. ANN. art. 4542a-1 (Vernon Supp. 1997);
>
> Section 281.24(a)(3), (6), (12), and (13), Section 291.32(a)(2)(K) and (N), Section 291.32(b)(1)(D), Section 291.34(c)(3)(G)(iii), Section 291.34(e)(2)(B)(4), and Section 295.3(a) and (b) of the Texas Pharmacy Rules of Procedure, 22 TEX. ADMIN. CODE ANN. (1997);
>
> Section 481.067 of the Texas Controlled Substances Act, TEX. HEALTH & SAFETY CODE ANN. (Vernon 1992); and
>
> Section 13.64(b)(2)(D) of the Texas Controlled Substances Rules, 37 TEX. ADMIN. CODE ANN. Part 1 (1996).

PREVIOUS HISTORY

On or about October 26, 1994, the Texas State Board of Pharmacy entered Agreed Board Order #B-93-019-B in the matter of Southside Pharmacy, 4009-I Bellaire Blvd., Houston, Texas 77072. The Agreed Board Order included 37 Counts of failure to maintain complete and accurate records of the distribution of controlled substances to an agency for delivery to an ocean vessel, and imposed a $1,000.00 fine on the pharmacy license held by Southside Pharmacy.

COUNT

On or about December 15, 1997 through on or about November 10, 1998, pharmacists, while acting as employees of Southside Pharmacy, 4009 J Bellaire Blvd., Houston, Texas 77025, failed to properly keep and maintain prescription records, in that, prescription records did not document the correct name of the practitioner.

An informal conference was held in the office of the Texas State Board of Pharmacy on February 28, 2001, with Harish D. Katharani, staff pharmacist and managing officer (president) at Southside Pharmacy; Askar Hasnain Naqvi, pharmacist-in-charge at Southside Pharmacy; Syed Zafar Hussaini, staff pharmacist at Southside Pharmacy; K. Walji, Legal Counsel for Southside Pharmacy; and Behroze Daruwalla, Legal Assistant for Southside Pharmacy, in attendance. The Texas State Board of Pharmacy was represented by: Kerstin E. Arnold, General Counsel; Julie C. Hildebrand, Assistant General Counsel; Gay Dodson, R.Ph., Executive Director/Secretary; Carol Fisher, R.Ph., M.P.A., Director of Enforcement; Joe Lewis, Chief Investigator; Allison Benz, R.Ph., M.S., Assistant Director of Enforcement; and Rosemary Combs, Board Member.

At the aforementioned conference, Harish D. Katharani and K. Walji stated they were present for and on behalf of Southside Pharmacy. By their appearance at the informal conference and by their signatures on this Order, Harish D. Katharani and K. Walji agree that the Texas State Board of Pharmacy has jurisdiction in this matter and do hereby waive the pharmacy's right to notice of hearing, to a formal administrative hearing and to judicial review of this Order.

After discussion of the matters previously outlined in this Order, and subsequent communications, Harish D. Katharani and K. Walji, on behalf of Southside Pharmacy, agreed

to the entry of an Order disposing of the need for further disciplinary action in this matter. By their signature on this Order, Harish D. Katharani and K. Walji neither admit nor deny the truth of the matters previously set out in this Order with respect to the above alleged violations.

Should this Order not be accepted by the Board, it is agreed that neither the presentation of the Order to the Board nor the Board's consideration of the Order, will be deemed to have unfairly or illegally prejudiced the Board or its individual members and, therefore, will not be grounds for precluding the Board or any individual member of the Board from further participation in proceedings related to the matters set forth in the Order.

Harish D. Katharani and K. Walji, on behalf of Southside Pharmacy, understand that any failure to comply with the terms of this Order is a basis for discipline under the Texas Pharmacy Act.

At the conclusion of the aforementioned conference, and subsequent communications, it was agreed among the parties that Southside Pharmacy shall be subject to the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Texas State Board of Pharmacy does hereby ORDER that pharmacy license number 14797 held by Southside Pharmacy be, and such license is hereby reprimanded.

And it is so ORDERED.

SIGNED AND DATED THIS 23rd day of May, 2001.

TEXAS STATE BOARD OF PHARMACY

ATTEST:

Gay Dodson, R.Ph., Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Harish D. Katharani, R.Ph., Managing Officer (President), for and on behalf of Southside Pharmacy

K. Walji, Legal Counsel for Southside Pharmacy
1200 Smith Street, Suite 1400
Houston, Texas 77002-4401

Kerstin E. Arnold, General Counsel
Texas State Board of Pharmacy

S:\Attorneys\PNL2\Southside_ABO.wpd

AGREED BOARD ORDER #B-93-019-B

RE: IN THE MATTER OF SOUTHSIDE PHARMACY

BEFORE THE TEXAS STATE BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy the matter of pharmacy license number 14797 issued to Southside Pharmacy, 4009-I Bellaire Blvd., Houston, Texas 77072.

By letter dated June 29, 1994, the Texas State Board of Pharmacy gave preliminary notice to Southside Pharmacy of its intent to take disciplinary action with respect to pharmacy license number 14797 issued to Southside Pharmacy. This action was taken as a result of a complaint and subsequent investigation which produced evidence indicating that Southside Pharmacy may have violated Section 26(a)(1), (2), (5), (8), (9), (12), and (13), Section 26(b)(3), (4) and (8) and Section 28(a) of the Texas Pharmacy Act, Tex. Rev. Civ. Stat. Ann. art 4542a-1 (Vernon Supp. 1993); Section 281.24(a)(3), (6), (12), (13), and Section 281.24(c)(1), (2) and (3) of the Texas Pharmacy Rules of Procedure, Tex. Admin. Code Ann. tit. 22 (1993); Section 481.067 of the Texas Controlled Substances Act, Tex. Health and Safety Code Ann. (Vernon 1993); and 21 C.F.R., Section 1301.28(a), (b), (d), and (f), in that, allegedly:

On or about the dates listed below, Harish D. Katharani, while acting as an employee (pharmacist-in-charge) and managing officer (President) of the corporate owner of Southside Pharmacy, 4009-I Bellaire Blvd., Houston, Texas 77025, failed to maintain complete and accurate records of the distribution of the controlled substances listed below to an agency for delivery to an ocean vessel.

	DATE	RX#	DRUG	QTY.
(1)	07-12-92	705377	Diazepam 10 mg.	50
(2)	07-12-92	705376	Diazepam 5 mg.	50
(3)	08-18-92	706504	APAP/COD #3	15
(4)	08-18-92	706508	Xanax 0.5 mg.	100
(5)	09-01-92	707012	Diazepam 10 mg.	50
(6)	09-01-92	707011	Diazepam 5 mg.	50
(7)	09-01-92	707007	Guiatussin/Syp/COD	300cc
(8)	10-08-92	708149	Diazepam 10 mg.	30
(9)	10-08-92	708148	Soma/CPD/COD	13
(10)	10-11-92	708213	APAP/COD 300/15 mg.	47
(11)	10-11-92	708214	Diazepam 10 mg.	60
(12)	10-26-92	708670	APAP/COD 300/30	47
(13)	10-26-92	708672	Diazepam 10 mg.	40
(14)	11-09-92	709065	Diazepam 10 mg	50
(15)	11-09-92	709066	APAP/COD 30/30	40
(16)	11-11-92	709065	Diazepam 10 mg.	50
(17)	11-11-92	709066	APAP/COD 300/30	40
(18)	11-18-92	709409	APAP/COD #3	50
(19)	11-18-92	709412	Diazepam 10 mg.	10
(20)	11-30-92	709802	Propacet 100 mg.	30
(21)	11-30-92	709795	APAP/COD 300/30 mg.	50
(22)	11-30-92	709796	APAP/COD 300/60 mg.	10
(23)	11-30-92	709799	Diazepam 10 mg.	50
(24)	11-30-92	709800	Diazepam 5 mg.	25
(25)	12-04-92	709802	Propacet 100 mg.	30
(26)	12-18-92	710600	Diazepam 10 mg.	60
(27)	12-18-92	710601	APAP/COD #3	50
(28)	12-18-92	710602	APAP/COD #4	20
(29)	01-04-93	711206	Diazepam 10 mg.	40
(30)	01-04-93	711205	APAP/COD 300/60 mg.	20
(31)	01-04-93	711204	APAP/COD 300/30 mg.	40
(32)	01-04-93	711203	Diazepam 10 mg.	50
(33)	01-19-93	711958	Vicodin E.S.	30
(34)	01-19-93	711959	Diazepam 10 mg.	60
(35)	01-19-93	711960	APAP/COD 300/30 mg.	100
(36)	02-02-93	712398	Diazepam 5 mg.	100
(37)	02-02-93	712399	APAP/COD 300/30	100

An informal conference was held in the office of the Texas State Board of Pharmacy on August 24, 1994, with Harish D. Katharani, owner and pharmacist-in-charge of Southside Pharmacy, K. Walji, Legal Counsel for Southside Pharmacy, and Behroze Desai, Paralegal, in attendance as well as Fred S. Brinkley, Jr., R.Ph., Executive Director/Secretary, Carol Fisher, R.Ph., Director of Adjudication and Legal Support Services, James Moore, Director of Investigations, Robert D. Johnson, R.Ph., Senior Enforcement Officer, Allison Benz, Enforcement Officer, Belinda R. Perkins, General Counsel, Cynthia Villarreal-Reyna, Assistant General Counsel, Donna Perot, Administrative Assistant, and Charlie Bethea, R.Ph., Board Member.

At the aforementioned conference, K. Walji stated he was present for and on behalf of Southside Pharmacy. By their appearance at the informal conference and by their signatures on this Order, Harish D. Katharani and K. Walji do hereby waive right to Notice of Hearing, to a formal Administrative Hearing, and to judicial review of this Order.

After discussion of the matters previously outlined in this Order, and subsequent communications, Harish D. Katharani and K. Walji agreed to the entry of an Order disposing of the need for further disciplinary action in this matter. By his signature on this Order, Harish D. Katharani neither admits nor denies the truth of the matters previously set out in this Order with respect to the above alleged violations.

Should this Order not be accepted by the Board, it is agreed that presentation to and consideration of this Order by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation or resolution of these proceedings.

At the conclusion of the aforementioned conference, and subsequent communications, it was agreed among the parties that pharmacy license number 14797 held by Southside Pharmacy be fined $1,000.00. This fine is to be paid in one installment of $1,000.00 due 30 days from the date of this Order.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Texas State Board of Pharmacy does hereby ORDER that pharmacy license number 14797 held by Southside Pharmacy be, and such license is hereby fined $1,000.00. This fine is to be paid in one installment of $1,000.00 due 30 days from the date of this Order.

And it is so ORDERED.

SIGNED AND DATED THIS 26th day of October, 1994.

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Fred S. Brinkley, Jr., R.Ph., Executive Director/Secretary

APPROVED AS TO FORM AND AGREED TO:

Harish D. Katharani, R.Ph., Owner and Pharmacist-in-Charge of Southside Pharmacy

K. Walji, Legal Counsel for Southside Pharmacy
6300 Hillcroft, Suite 310
Houston, Texas 77081

Belinda R. Perkins, General Counsel
Texas State Board of Pharmacy

Window on State Government Glenn Hegar Texas Comptroller of Public Accounts

Taxable Entity Search Results
Taxable Entity Search

Officers and Directors

HDK ENTERPRISES, INC.
Report Year: 2013

Return to: Taxable Entity Search Results

Officer and director information on this site is obtained from the most recent Public Information Report (PIR) processed by the Secretary of State (SOS). PIRs filed with annual franchise tax reports are forwarded to the SOS. After processing, the SOS sends the Comptroller an electronic copy of the information, which is displayed on this web site. The information will be updated as changes are received from the SOS.

You may order a copy of a Public Information Report from open.records@cpa.state.tx.us or Comptroller of Public Accounts, Open Government Division, PO Box 13528, Austin, Texas 78711.

Title	Name and Address
DIRECTOR	**HARISH KATHARANI** 7700 MAIN STREET STE 200 HOUSTON , TX 77030
MANAGER	**HARISH KATHARANI** 7700 MAIN STREET STE 200 HOUSTON , TX 77030

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Franchise Tax Account Status

As of: 09/22/2015 11:25:11 AM

This Page is Not Sufficient for Filings with the Secretary of State

HDK ENTERPRISES, INC.	
Texas Taxpayer Number	17603567516
Mailing Address	1111 MEDICAL PLAZA DR STE 160 THE WOODLANDS, TX 77380-3477
Right to Transact Business in Texas	ACTIVE
State of Formation	TX
Effective SOS Registration Date	02/07/2003
Texas SOS File Number	0800171451
Registered Agent Name	HARISH KATHARANI
Registered Office Street Address	7700 MAIN STREET, SUITE 210 HOUSTON, TX 77030

SOUTHSIDE INFUSION STAFF LISTING

Pharmacist Name	License #	Hrs/wk	Expir. Date	Emp. Status
UPADHYAYA, SEJAL PATEL	41366	30	07/31/2017	Staff
SHAH, RUBIN	51241	45	11/30/2015	PIC
PATEL, ROMIL SATISHBHAI	52072	5-10	01/31/2017	Relief
NAQVI, ASKARI HASNAIN	22740	45	08/31/2016	Staff
MATTA, SELVANA M	54706	30	04/30/2016	Staff
KATHARANI, HARISH D.	23791	5-10	10/31/2015	Staff

Technician/Trainee Name	License #	Hrs/wk	Expir. Date	Emp. Status
BHUTANI, LAXMI NARAIN	117640	45	11/30/2016	Staff
GOHEL, DIVYANG	198769	40	07/31/2017	Staff
SHAH, BHRUGUSHA R	135562	40	09/30/2016	Staff
VIRJEE, SALIM AMIRALI	117739	30	07/31/2017	Staff
ZAIDI, SYED ALI HUSNAIN	123373	40	10/31/2016	Staff

TEXAS STATE BOARD OF PHARMACY
333 GUADALUPE ST STE 3 600
AUSTIN TX 78701

SOUTHSIDE INFUSION
7700 MAIN ST STE 210
HOUSTON TX 77030

This certifies that the pharmacy named below is hereby licensed to operate as a Class **AS** pharmacy.

License No. **14797** Expiration Date: **3/31/2017**

Balances: **1**

SOUTHSIDE INFUSION
7700 MAIN ST STE 210
HOUSTON TX 77030

Gay Dodson, R.Ph.
Executive Director/Secretary

MUST BE DISPLAYED IN FULL PUBLIC VIEW

TEXAS CONTROLLED SUBSTANCES REGISTRATION CERTIFICATE

TEXAS DEPARTMENT OF PUBLIC SAFETY
REGULATORY SERVICES DIVISION, LICENSING AND REGISTRATION SERVICE
CONTROLLED SUBSTANCES REGISTRATION, PO BOX 4087, AUSTIN, TEXAS 78773

DPS REGISTRATION NUMBER	DATE EXPIRED	FEE PAID
70081044	09/30/2015	YES

SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
2, 2N, 3, 3N, 4, 5	PHARMACY	09/30/2014

REGISTERED NAME AND ADDRESS

SOUTHSIDE INFUSION
7700 MAIN ST STE 210
HOUSTON, TX 77030-4457

THE TEXAS CONTROLLED SUBSTANCES ACT, CHAPTER 481 OF THE HEALTH AND SAFETY CODE, PROVIDES THAT THE TEXAS DEPARTMENT OF PUBLIC SAFETY MAY DENY A CONTROLLED SUBSTANCES REGISTRATION OR THAT A CONTROLLED SUBSTANCES REGISTRATION MAY BE SUSPENDED OR REVOKED.

THE STATE OF TEXAS

THIS REGISTRATION IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY AND NOT VALID AFTER THE EXPIRATION DATE.

NAR-79 (6-10) CERTIFICATE MUST BE READILY RETRIEVABLE AT ALL TIMES

TEXAS DEPARTMENT OF PUBLIC SAFETY

DPS REGISTRATION NUMBER
70081044

DATE EXPIRED
09/30/2015

SCHEDULES
2, 2N, 3, 3N, 4, 5

REGISTERED NAME AND ADDRESS
SOUTHSIDE INFUSION
7700 MAIN ST STE 210
HOUSTON, TX 77030-4457

Texas Department of Public Safety
Courtesy • Service • Protection

Controlled Substances Registration

Current date/time: 9/22/2015 11:30:57 AM

New Search Disclaimer Back to Search Results

This registrant information was last updated at 9/21/2015 10:11:24 PM

Detailed View - SOUTHSIDE INFUSION

DPS Number:	70081044
Address:	7700 MAIN ST STE 210 HOUSTON, TX 77030
Business Activity:	PHARMACY
Brd. Lic. #:	14797
Schedule:	2 2N 3 3N 4 5
Exp. Date:	08-31-2016
Original App Entered:	03-23-1992
Last App Recd Date:	09-29-2014

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
BS3104522	02-29-2016	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5,	RETAIL PHARMACY	01-04-2013

SOUTHSIDE INFUSION
7700 MAIN STREET
SUITE 210
HOUSTON, TX 77030-0000

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (4/07)

TEXAS STATE BOARD OF PHARMACY INSPECTION REPORT

CLASS: A B C (BEDS ____) D Other AS

me of Pharmacy Southside Infusion
armacist in Charge Rubin Shah
rsonnel -See attached-

TSBP License # 14797
Lic 51241 Exp 1-30-15
Lic ____ Exp ____
Lic ____ Exp ____
Lic ____ Exp ____
Lic ____ Exp ____

EY: Circled items need improvement; √ items in Column One Refer to Legal Division (R/L) for review and possible discipline.
√ items in Column Two receive a Warning Notice (W/N).
For an explanation of specific violations noted, refer to remarks section of inspection report.

R/L		W/N	
	1		Licenses not posted
	2		Insufficient Equipment
	3		Orderly/Clean
	4		Balance Failed
	5		Equipment Inspection
	6		Inadequate Library
	7		Improper security
	8		Environment
	9		Delinquent licenses/certifications
	36		No notification of substitution
	90		No complaint notification
	38		Area for non sterile compounding
	43		Records for non sterile compounding
	47		Out of date/mislabeled drug stock
	48		Improper drug storage
	53		Illegal possession of C/S
	57		Corresponding Responsibility
	59		Improper drug destruction
	61		Improper supervision of supportive personnel
	62		Aiding and abetting
	65		Improper registration procedures
	66		Grey Market diversion/ Samples
	76		No PIC
	34		Notification Violation
	79		Nametags
	60	✓	Improper documentation of training
	92		Improper automated dispensing procedures

R/L		W/N	
			Date of last inventory 4-14-14
	15		~~No~~ PIC inventory 10-10-14
	69		No annual inventory
	68		No change of ownership inventory
	31		Closed Phcy/Change of owner improper
	17		Incomplete inventory
	18		Records not available
	46		Improper distribution
	54		Improper prepackaging procedures
	24		Theft/Loss not reported 4-14-14
	30	✓	Invoices not dated/initialed
	86		Absence of RPh pick up records
	19		Rx lacks proper information
	25		No documentation of refill authorization
	32		Rx label is incorrect
	40		Non emergency C-II Rx
	26		C II Rx noncompliance
	37		Illegal dispensing
	45		Improper dispensing/ labeling
	44		Refill CIII-V over 5x/6mo
	55		Refill prn past one year
	78		Counseling area
	80		No counseling by RPh
	56		Improper transfer of Rx
	50		Out of state verbal Rx for C/S
	49		Substitution noncompliance
	33		Rx records not in numerical order

R/L		W/N	
	10		Rxs not separated
	35		Invoices not separated
	67		No written information
	21		Computer records incomplete
	22		Computer system noncompliance
	82		PMR Incomplete
	83		PMR Absent
	84		No drug regimen review
	16		No perpetual inventory
	27		Improper inpatient records
	51		Improper ER dispensing
	75		Improper absence of RPh procedures
	70		No P&P manual
	71		Incomplete P&P manual
	72	✓	Improper procedures for IV preparation
	81	✓	Area for preparation of sterile products
	85		Patient Care Guidelines incomplete
	87		Quality Control/Assurance
	88		Cytotoxic/Biohazardous Procedures
	89		Refrigerator Temperature Log
	28		No provision log
	29		Incomplete provision log
	52		Improper provision/ dispensing in Class D
	66		Prohibited drugs in Class D pharmacy
	64		Violation of limited formulary
	91		RPh visits/contact documentation
	73		Formulary not complete

Remarks

(cont. pg 2)
W/N (72) a. Weighing & mixing for high risk level compounded sterile preparations must be completed in no worse than an ISO Class 8 environment.
W/N (81) Comply with all environmental rules for low, med. & high risk sterile compounding. Fix/seal areas in ante. room that show cracks/holes. Ensure sink is clean (area on surface discolored) Remove any cardboard/unnecessary supplies (paper). All surfaces must be smooth, impervious, non-shedding & resistant to damage by disinfecting agents. (Remove frames with cardboard backs by sink).
W/N (72) b. Follow required gowning & garbing order (from dirtiest to cleanest) Include routine application of sterile 70% IPA throughout the compounding day & whenever non-sterile surfaces are touched.

Action Taken

(1) ✓ Inspection
(2) ___ Pre-Inspection
(3) ___ Partial Inspection
(4) ___ Visit
(5) ___ Other _____

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted. Items marked in Column One will be referred to the Legal Division for review and possible disciplinary action. Items marked in Column Two are conditions that have resulted in the issuance of a Warning Notice and must be corrected to ensure compliance with the laws and rules governing the practice of pharmacy. Circled items need improvement.

I acknowledge that the noted conditions, which are not in compliance, have been explained to me and I have received a copy of this report.

Kathy A. Salinas
Agent of the Texas State Board of Pharmacy

MB
Authorized Individual for the Pharmacy

2-2-15
Date

Time of Exit

RUBIN B. SHAH PIC
Printed Name and Title of Authorized Individual

Texas State Board of Pharmacy
333 Guadalupe Street, Suite 3-600, Box 21
Austin, Texas 78701-3942
Phone: 512/305-8000

WARNING NOTICE

Pharmacy License # 14797
Name of Facility Southside Infusion
Address 7700 main St. Ste. 210 City Houston Zip 77030
Pharmacist License # 51241
NAME OF PERSON RESPONSIBLE Rubin Shah

Notice is hereby given that you are not complying with the following laws and or rules governing the practice of pharmacy:

1. Law/Rule 291.133(12)(C)
Explanation of violation Personnel shall don personal protective equipment in an order that proceeds from the dirtiest to cleanest. Include routine application of sterile 70% IPA.

2. Law/Rule 291.133(6)(B)
Explanation of violation Presterilization procedures for high-risk level compounded sterile preps, such as weighing & mixing, must be done in no worse than an ISO Class 8 environment.

3. Law/Rule 291.133(6)(A)
Explanation of violation Comply with all environmental rules for low, med & high risk sterile compounding. All surfaces must be smooth, impervious, free from cracks & crevices.

Notice is also hereby given that unless the conditions noted above are corrected and a written report detailing the corrections is submitted to the Executive Director/Secretary of the Texas State Board of Pharmacy on or before ~~April~~ May 2, 2015, disciplinary action may be instituted against your license.

KAS

By Kathy A. Salinas
Agent, Texas State Board of Pharmacy
Date 2-2-15

I hereby acknowledge that the laws and or rules cited above have been explained to me and that I have received a copy of this notice.

Signed [signature]

11/00

Texas State Board of Pharmacy

WARNING NOTICE

RESPONSE TO WARNING NOTICE

Texas State Board of Pharmacy

333 Guadalupe Street, Suite 3-600, Box 21
Austin, Texas 78701-3942
Phone: 512/305-8000

WARNING NOTICE

Pharmacy License # 14797
Name of Facility Southside Infusion
Address 7700 main St. Ste 210 City Houston Zip 77030
Pharmacist License # 51241
NAME OF PERSON RESPONSIBLE Rubin Shah

Notice is hereby given that you are not complying with the following laws and or rules governing the practice of pharmacy:

1. Law/Rule 291.133 (c)(4)(F)(K)
Explanation of violation Conduct, document & have available acceptable results for media fill & gloved finger tip testing for all personnel who prepare, or who supervise preparation of sterile preps (Every 6 months)

2. ~~Law/Rule~~
Explanation of violation

3. Law/Rule 291.34 (i)(4)
Explanation of violation A pharmacist must verify that the controlled drugs listed on the invoices were actually received by clearly recording his/her initials and date

Notice is also hereby given that unless the conditions noted above are corrected and a written report detailing the corrections is submitted to the Executive Director/Secretary of the Texas State Board of Pharmacy on or before March 2, 2015, disciplinary action may be instituted against your license.

I hereby acknowledge that the laws and or rules cited above have been explained to me and that I have received a copy of this notice.

By Kathy A. Salinas
Agent, Texas State Board of Pharmacy
Date 2-2-15

Signed [signature]

11/00

Texas State Board of Pharmacy

WARNING NOTICE

RESPONSE TO WARNING NOTICE

TEXAS STATE BOARD OF PHARMACY

Jeanne D. Waggener, R.Ph.
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Lufkin

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Austin

Gay Dodson, R.Ph.
Executive Director/Secretary
Austin

June 26, 2015

Rubin Shah, R.Ph.
Southside Infusion
7700 Main Street, Ste. 210
Houston, TX 77030

Re: License # 14797

Dear Rubin Shah:

This letter is to acknowledge the receipt of your written response assuring the Texas State Board of Pharmacy that you have corrected those procedural violations specified on the "Warning Notice" issued during the pharmacy compliance inspection of February 2, 2015.

We appreciate your voluntary compliance with the law. In addition, we must make you aware that this pharmacy may be visited by a Compliance Officer in the near future for the purpose of checking compliance with the violations noted in the "Warning Notice." If the Compliance Officer finds that the violations noted in the "Warning Notice" have not been corrected, disciplinary action will be instituted against your license and the license of the pharmacy.

Again, your timely show of concern and cooperation is appreciated. If you encounter any problems or have any questions concerning the changes you have made, please contact me at 512-305-8041.

Sincerely,

Ben Santana, RPhe

Ben Santana, R.Ph.
Chief of Compliance

BJS:ad

cc: Kathy Salinas, R.Ph.
Compliance Officer

(713) 660-8888 7700 MAIN, SUITE #210
INFUSION HOUSTON, TX 77030
Rx 1051511 04/28/14 Dr. TEST, DOCTOR
TEST, PATIENT
TAKE ONE TABLET BY MOUTH EVERY NIGHT AT BEDTIME. **TEST LABEL***

SIMVASTATIN 10 MG TABLET
Toll Free 1-888-660-6337 **Qty 5** Mfg: DR.REDDY'
No Refills NSS/

CAUTION: FEDERAL LAW PROHIBITS TRANSFER OF THIS DRUG TO ANY PERSON OTHER THAN PATIENT FOR WHOM PRESCRIBED.
peach / shield
735

WARNING: DO NOT USE IF YOU ARE PREGNANT, PLAN TO BECOME PREGNANT OR WHILE BREASTFEEDING. CONSULT YOUR DOCTOR OR PHARMACIST.

TAKE IN EVENING AS DIRECTED

DO NOT EAT GRAPEFRUIT OR DRINK GRAPEFRUIT JUICE WITHIN 2-4 HOURS OF TAKING THIS MEDICATION.

DO NOT FLUSH UNUSED MEDICATION OR POUR DOWN SINK OR DRAIN.

TEST, PATIENT
7700 MAIN STREET
Houston, TX 77030
Dr TEST, DOCTOR
7700 MAIN STREET
DEA BS-1111118

1051511 0 0
04/28/14 Rph: NSS
NSS PP:
Houston, TX 77030
NPI 1259846722 Price $19.42

Mfg: DR.REDDY'S **NDC: 55111-735-90**
SIMVASTATIN 10 MG TABLET **Qty 5** QRem 0
TAKE ONE TABLET BY MOUTH EVERY NIGHT AT BEDTIME. **TEST LABEL*** DAW: 0

Rx 1051511 - 0
TEST, PATIENT
Copay $19.42 NSS /
04/28/14
Sig:_____

Rx 1051511 - 0
TEST, PATIENT
Copay $19.42 NSS /
04/28/14
SIMVASTATIN 10 MG TABLET

SOUTHSIDE INFUSION
7700 MAIN, STE 210 HOUSTON, TX 77030

TEST, PATIENT
7700 MAIN STREET
Houston, TX 77030
Rx Pickup

(713) 660-8888 7700 MAIN, SUITE #210
INFUSION HOUSTON, TX 77030
RECEIPT
Rx 1051511 0 04/28/14
TEST, PATIENT
7700 MAIN STREET
Houston, TX 77030
Dr TEST, DOCTOR
SIMVASTATIN 10 MG TABLET
NDC: 55111-735-90
No Refills
Tech:
Rph: NILESH SHETH
Plan:
Qty 5
Copay $19.42

(713) 660-8888 7700 MAIN, SUITE #210
INFUSION HOUSTON, TX 77030
DUPLICATE RECEIPT
Rx 1051511 0 04/28/14
TEST, PATIENT
7700 MAIN STREET
Houston, TX 77030
Dr TEST, DOCTOR
SIMVASTATIN 10 MG TABLET
NDC: 55111-735-90
No Refills
Tech:
Rph: NILESH SHETH
Plan:
Qty 5
Copay $19.42

(713) 660-8888 7700 MAIN, SUITE #210
INFUSION HOUSTON, TX 77030
PATIENT EDUCATION

Rx: 1051511 Dr: TEST, DOCTOR **TEST, PATIENT**
SIMVASTATIN 10 MG TABLET 04/28/14

DO NOT POUR OR FLUSH UNUSED MEDICATION DOWN SINK OR DRAIN.

OTHER NAMES: SIMVASTATIN - ORAL, SIMVASTATIN

USES: Simvastatin is used along with a proper diet to help lower "bad" cholesterol and fats (such as LDL, triglycerides) and raise "good" cholesterol (HDL) in the blood. It belongs to a group of drugs known as "statins." It works by reducing the amount of cholesterol made by the liver. Lowering "bad" cholesterol and triglycerides and raising "good" cholesterol decreases the risk of heart disease and helps prevent strokes and heart attacks. In addition to eating a proper diet (such as a low-cholesterol/low-fat diet), other lifestyle changes that may help this medication work better include exercising, losing weight if overweight, and stopping smoking. Consult your doctor for more details.

HOW TO USE: Take this medication by mouth with or without food as directed by your doctor, usually once daily in the evening. Dosage is based on your medical condition, response to treatment, age, and other medications you may be taking. Be sure to tell your doctor and pharmacist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products). Chinese patients taking niacin may require lower doses of simvastatin. Ask your doctor for more details. The usual maximum dose for this medication is 40 milligrams a day. If you have been instructed by your doctor to take more than 40 milligrams, continue on that same dose. However, promptly talk with him or her about the risks and benefits of your higher dose. Do not increase your dose or take this medication more often than prescribed. Your condition will not improve any faster, and the risk of serious side effects may be increased. Avoid eating grapefruit or drinking grapefruit juice while using this medication unless your doctor instructs you otherwise. Grapefruit can increase the amount of this medication in your bloodstream. Consult your doctor or pharmacist for more details. Take this medication regularly in order to get the most benefit from it. Remember to take it at the same time each day. It is important to continue taking this medication even if you feel well. Most people with high cholesterol or triglycerides do not feel sick. It is very important to continue to follow your doctor's advice about diet and exercise. It may take up to 4 weeks before you get the full benefit of this drug.

SIDE EFFECTS: Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. A very small number of people taking simvastatin may have mild memory problems or confusion. If these rare effects occur, talk to your doctor. Rarely, statins may cause or worsen diabetes. Talk to your doctor about the benefits and risks. This drug may rarely cause muscle problems (which can rarely lead to very serious conditions called rhabdomyolysis and autoimmune myopathy). Tell your doctor right away if you develop any of these symptoms during treatment and if these symptoms persist after your doctor stops this drug: muscle pain/tenderness/weakness (especially with fever or unusual tiredness), change in the amount of urine. This medication may rarely cause liver problems. If you notice any of the following rare but serious side effects, tell your doctor right away: yellowing eyes/skin, dark urine, severe stomach/abdominal pain, persistent nausea/vomiting. A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US - Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS: Before taking simvastatin, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details. Before using this medication, tell your doctor or pharmacist your medical history, especially of: liver disease, kidney disease, alcohol use. Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products). Limit alcoholic beverages. Daily use of alcohol may increase your risk for liver problems, especially when combined with simvastatin. Ask your doctor or pharmacist for more information. Older adults may be more sensitive to the side effects of this drug, especially muscle problems. This medication must not be used during pregnancy. Simvastatin may harm an unborn baby. Therefore, it is important to prevent pregnancy while taking this medication. Consult your doctor for more details and to discuss the use of reliable forms of birth control (such as condoms, birth control pills) while taking this medication. If you become pregnant or think you may be pregnant, tell your doctor right away. It is unknown if this medication passes into breast milk. Because of the possible risk

Do not flush unused medications or pour down a sink or drain, unless otherwise directed.
Call your doctor for medical advice about side effects. You may report side effects to **FDA** at **1-800-FDA-1088**.

HDK Enterprises
Southside Infusion

"One SOURCE for ALL your Medical Needs"
7700 S.Main Street, Suite # 210
Houston TX 77030
Tel: 713-660-8888
Fax: 713-661-4828

Date: September 22, 2015

To:

IOWA BOARD OF PHARMACY
400 S.W. EIGHTH ST. STE E
DES MOINES, IA 50309-4688
PH: 515-281-5944

Re: Non-Resident Pharmacy Application for Southside Infusion

Sir/Madam

Southside is pharmacist owned and operated company that was established in 1992. We have been helping thousands of families to get well and stay well. As part of Southside's national expansion plan we are expanding our services to Iowa. Southside will be happy to provide patients in Iowa with these services:

- **Retail drugs**
  - What started as a small retail pharmacy over 20 years ago has grown into much more. Southside continues to strive to be one of the leading health care providers in the areas we serve.
  - We want to provide the best products and services for the most important part of our business; "the customer."
  - Our pharmacists are passionate about providing individualized care to each customer, including one-on-one counseling for prescription and health issues, and care coordination to ensure that prescriptions are authorized and expedited.
  - We listen to and care about our patients' concerns and tailor all of our compounded medications to the needs of each individual patient.
  - We also work very closely with physicians and other health care providers to determine the best possible therapy for our patients.

- **Specialty drugs**
  - Southside Specialty is a pharmacy dedicated to healing patients who are suffering from long term complex disease states, which typically, require medications that need special handling, administration, shipping and/or storage.
  - Our specialized staff has undergone extensive training to be able to monitor, counsel/educate, and intervene all for our patient's optimal health outcome.
  - At Southside Specialty we work hand in hand with your physician to ensure the medication has the greatest benefit and minimize unwanted side effects.

HDK Enterprises
Southside Infusion

"One SOURCE for ALL your Medical Needs"

7700 S.Main Street, Suite # 210
Houston TX 77030
Tel: 713-660-8888
Fax: 713-661-4828

- We treat a variety of disease states which includes:
  - Hepatitis C,
  - Rheumatoid Arthritis,
  - Oncology,
  - Multiple Sclerosis
  - and many more

- **Infusion Drugs:**
  - Southside Infusion is a community sterile compounding pharmacy that has the capability to prepare high-quality low, medium and high risk sterile preparations.
  - We have a USP 797 certified Clean Room.
  - Our highly skilled Infusion pharmacists are ACPE certified. They use their training and clinical skills to treat patients that need home infusion therapy.
  - Our pharmacists understand the patient's needs, use their clinical knowledge to design, implement and monitor individualized care plans.
  - Our team works closely with case managers at various hospitals and physician offices for care coordination. Our dedicated intake staff communicates with nursing agencies to coordinate patient care.
  - Common disease states treated:
    - Infectious Diseases
    - Oncology
    - Fluid Management
    - Nutrition Support- TPN Therapy

We will be honored to serve your patients in need of quality care treatment. We would like to request you to accept our application for a non-resident pharmacy license in your state.

Thank you

Harish Katharani
President
7700 Main St. Ste 210
Houston TX 77030

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SEP 28 2015

IOWA BOARD OF PHARMACY

Cover Letter

Jisoo Lee

301 Hawk Drive #3117D, Iowa City, IA 52246

September 28, 2015 Dear Iowa Board of Pharmacy:

I am requesting that I would like to apply for an internship registration with the board office, but since I don't have a social security number, I am requesting a waiver for the social security number requirement. The social security number is not issued to international students, unless it is employed. Thereby, I would like the Iowa Board of Pharmacy to consider a waiver for Chapter 4.6(1).

The internship is present from this year (2015) to May 15, 2019 if the Board of Pharmacy approves this petition. I plan to become employed next summer and apply for social security number when I get the job. If I still need a social security number before next year, I also plan to get a part-time job on the campus, which is legally approved by the University of Iowa.

If board of Pharmacy needs to discuss a petition with me, I can be easily reached by phone at 319-400-2067 or via e-mail at jisoo-lee@uiowa.edu Thank you for your time and consideration.

Sincerely,
Jisoo Lee

After filling out form, print, sign, and mail to: Iowa Board of Pharmacy
400 SW 8th Street, Suite E, Des Moines, Iowa 50309-4688. Deadline for inclusion on Board's agenda is three weeks prior to Board meeting.

Case No. or State ID No.

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IOWA BOARD OF PHARMACY
(FOR PHARMACY BOARD USE ONLY)

IOWA BOARD OF PHARMACY
Petition for [☑] Waiver [☐] Variance
(check the appropriate box)

PLEASE PRINT OR TYPE ALL INFORMATION IN INK

A waiver excuses the petitioner from the requirements of a rule in its entirety or from a part of a rule; a variance does not. Instead, a variance is a modification to the requirements of a rule or a part of a rule. Example: A rule requires the fencing of certain property and further requires that the fence be at least 6 feet in height. A waiver of that rule would excuse the petitioner from the requirement for fencing the property. A variance would require the property be fenced but would allow the petitioner to maintain the current fencing configuration of 5 feet in height (perhaps the fence was constructed prior to the height requirement). When replacement of the current fence becomes necessary as a consequence of normal wear and tear, the variance would terminate and the petitioner would be required to comply with the 6-foot height requirement.

Note: Statutory requirements that have been repeated in administrative rules are not subject to consideration for a waiver or variance.

Is this petition an initial request or is it a request for renewal? [☑] Initial Request [☐] Request for Renewal
If a request for renewal, explain below why the renewal is necessary.

Petitioner Information (include licensee/registrant name and name of contact person, i.e. pharmacist in charge)

Name: Jisoo Lee Phone No.: 319-400-2067 *(include area code)*

Address: 301 Hawk Ridge Drive #3117 D

City: Iowa City State: IA Zip Code: 52246

Petition Information

1. Chapter Number and Title.

   Chapter 4 pharmacist - Interns

2. Rule Number(s) and Title(s).

   4.6(1) Application for registration - required information

3. Describe in your own words the essence of each Rule Number(s) and Title(s) that pertains to this petition.

   The social security number is not issued to international students, unless employed

4. Describe the specific nature and scope of your petition. In your description, include the anticipated time period (beginning and ending) for which the petition would apply. A waiver or variance may not be requested or granted on a permanent basis; the petition must identify an end date.

   The internship is present from this year (2015) to May 15, 2019
   I am requesting a waiver for the social security number requirement

After filling out form, print, sign, and mail to: Iowa Board of Pharmacy
400 SW 8th Street, Suite E, Des Moines, Iowa 50309-4688. Deadline for inclusion on Board's agenda is three weeks prior to Board meeting.

5. Describe the relevant facts and reasons that, in your opinion, justify and provide "clear and convincing evidence" as to why this petition merits consideration for waiver or variance. In your description, explain why the rule(s) poses an undue hardship. If there is a public health, safety and welfare issue associated with this rule(s), or if this rule(s) addresses security or confidentiality issues, also explain how equal protection will be maintained if this petition were granted.

6. Does anyone else (inside or outside state government) possess knowledge relevant to this petition?

   [☐] Yes [☐] No [☒] Do not know

   If yes, list their names, addresses and phone numbers below.

   Patrica A McCormak
   Michael W Kelly

7. Would anyone (inside or outside state government) be adversely affected if this petition were granted?

   [☐] Yes [☒] No [☐] Do not know

   If yes, list their names, addresses and phone numbers below.

8. Do you know how the Board of Pharmacy has treated similar situations?

   [☐] Yes [☒] No

   If yes, describe below how similar situations were handled.

9. Have you had any past interaction with the Board of Pharmacy that might impact or relate to this petition?

   [☐] Yes [☒] No

   If yes, describe below the issue involved and the outcome.

I authorize any person with knowledge of the relevant or important facts relating to this petition to release any pertinent information to the Iowa Board of Pharmacy. I hereby attest to the accuracy and truthfulness of the information contained herein.

Jisoo Lee
Petitioner's Signature

23/09/15
Date

APPLICATION FOR REGISTRATION AS A PHARMACIST-INTERN

(To be completed by pharmacist-intern)

Name Jisoo Lee Telephone No. [redacted]

E-Mail Address [redacted]

Date of Birth 1992/11/24 Social Security No. _____

Permanent address Hyperion 2cha 203dong 203ho mok1dong Yangcheon-gu

~~Iowa City~~ Seoul South Korea ~~IA~~ ~~CE~~

City State Zip Code

Address while attending college 301 Hawks Ridge 311 7D

Iowa City IA 52246

City State Zip Code

College of Pharmacy _____

Current Status as a Student (circle which year) (1) 2 3 4 5 6

Anticipated date of graduation or date degree granted May 10, 2019

Date internship training will begin August 17, 2015

Have you ever been convicted of or pleaded guilty to a misdemeanor or a felony charge? Yes [ ] No [✓]

If yes, provide details separately.

Have you ever been convicted of or pleaded guilty to a drug- or alcohol-related offense? Yes [ ] No [✓]

If yes, provide details separately.

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NOTE: *Do not complete the pharmacy name and address information below if you currently do not have a preceptor. When you do have a preceptor and internship site, please notify the Board office.*

Name of Pharmacy _____

Address of Pharmacy _____

City State Zip Code

I am aware that I cannot legally compound or dispense drugs except when I do so under the immediate and personal supervision of a licensed pharmacist and I understand that I may not be left in charge of a pharmacy.

I hereby swear under penalty of perjury that the information provided in this application is true and correct. I understand that failure to provide complete and truthful information may constitute grounds for revocation or other disciplinary sanctions against my pharmacist-intern registration.

Jisoo Lee 19/08/15

(Signature of Applicant) *(Date)*

Registration Fee $30.00. Remit Check or Money Order Payable to: Iowa Board of Pharmacy (DO NOT SEND CASH)

Privacy Act Notice: *Disclosure of your Social Security number on this registration application is required b 42 U.S.C. §666(a)(13) and Iowa Code §252J.8(l) and 261.126(1) (207), and Iowa code §272D.8(1) (Supp. 2008). The number will be used in connection with the collection of child support obligations, student loan obligations, and debts owed to the State of Iowa, and as an internal means to accurately identify registrants, and may be shared with taxing authorities as allowed by law including Iowa Code §421.18 (2007).*

6428

Fields of Opportunities

STATE OF IOWA

TERRY BRANSTAD
GOVERNOR
KIM REYNOLDS
LT. GOVERNOR

BOARD OF PHARMACY
THERESE WITKOWSKI
INTERIM DIRECTOR

CERTIFICATE OF ELIGIBILITY

(To be completed by college of pharmacy)

I certify that Jisoo Lee is registered as a student in the college of pharmacy named below, is enrolled in the first professional year in the college of pharmacy, and is satisfactorily progressing toward completion of academic requirements for a degree in pharmacy. The above-named student is eligible for registration as a Pharmacist-Intern effective August 17, 2015.
(Date)

Any derogatory information on file? Yes* _____ No X

Donald E. Letendre
(Signed)

Dean, 319-335-8795
(Title and phone number)

The University of Iowa College of Pharmacy
(Name of College)

School Seal

115 S. Grand Avenue
(Address of College)

Iowa City, IA 52242

August 17, 2015
(Date)

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* Explain or provide copies of any derogatory information on file.