

**BEFORE THE BOARD OF PHARMACY EXAMINERS  
OF THE STATE OF IOWA**

Re:	)	Case No. 2005-89
Pharmacy License of	)	
<b>HY-VEE CARE (4013)</b>	)	<b>STATEMENT OF CHARGES</b>
License No. 1211	)	
Respondent	)	

**COMES NOW**, the Complainant, Lloyd K. Jessen, and states:

1. He is the Executive Secretary/Director for the Iowa Board of Pharmacy Examiners and files this Statement of Charges solely in his official capacity.
2. The Board has jurisdiction in this matter pursuant to Iowa Code Chapters 155A and 272C (2005).
3. Effective December 15, 2004, the Board renewed the general pharmacy license of Respondent Hy-Vee Care, with Gary Levine as pharmacist in charge, allowing Respondent to engage in the operation of pharmacy subject to the laws of the State of Iowa and the rules of the Board.
4. General pharmacy license number 1211 is current until December 31, 2005.
5. Respondent is currently operating a general pharmacy at 3998 Northwest Urbandale Drive, Urbandale, Iowa 50322, with Gary Levine as the pharmacist in charge.

**A. CHARGES**

**COUNT I – LACK OF PROFESSIONAL COMPETENCY**

Respondent is charged under Iowa Code § 155A.15(2)(c) (2005) and 657 Iowa Administrative Code § 36.1(4)(b) with a lack of professional competency as demonstrated by willful and repeated departures from, and a failure to conform to, the minimal standard or acceptable and prevailing practice of pharmacy in the state of Iowa.

**COUNT II – FAILURE TO MAINTAIN RECORDS AND CONTROL OVER DRUGS**

Respondent is charged with failing to maintain complete and adequate records of purchases, distribution and disposal of drugs listed in the Controlled Substances Act in violation of Iowa Code §§ 155A.15(2)(c) and 155A.15(2)(h) (2005), and 657 Iowa Administrative Code § 36.1(4)(ac), and with failing to maintain accurate control over and accountability for drugs,

including controlled substances, in violation of Iowa Code §§ 124.308(3), 124.402(1)(a), 155A.15(2)(c) and (2)(i) (2005), and 657 Iowa Administrative Code § 6.7.

### COUNT III – ILLEGAL DISTRIBUTION OF DRUGS

Respondent is charged with distribution of drugs for other than lawful purposes in violation of Iowa Code § 155A.15(2)(c-d) (2005) and 657 Iowa Administrative Code § 36.1(4)(h), specifically, distribution of prescription medications in the absence of a prescription.

### COUNT IV – PROCURING AND EMPLOYING PERSONS TO PERFORM AS TECHNICIANS

Respondent is charged with knowingly aiding, assisting and procuring and employing non-technicians to perform the functions of a pharmacy technician in violation of Iowa Code § 155A.15(2)(c) (2005) and 657 Iowa Administrative Code § 36.1(4)(l).

### COUNT V – FAILURE TO TRAIN TECHNICIANS

Respondent is charged with failure to develop and implement policies for training and utilization of technicians in violation of Iowa Code § 155A.15(2)(c) (2005) and 657 Iowa Administrative Code § 3.17.

### COUNT VI – ENGAGING IN UNETHICAL CONDUCT

Respondent is charged with engaging in unethical conduct in violation of Iowa Code § 155A.15(2)(c) (2005) and 657 Iowa Administrative Code §§ 8.11(5) and 36.1(4)(c) by, among other things, offering free medication administration forms to long-term healthcare facilities.

### COUNT VII – DISPENSING MISLABELED DRUGS

Respondent is charged with dispensing mislabeled prescription drugs in violation of Iowa Code § 155A.15(2)(f) (2005) and 657 Iowa Administrative Code § 36.1(4)(c).

## **B. CIRCUMSTANCES**

On or about September 28, 2005 an investigation was commenced, which revealed the following:

1. Respondent Hy-Vee Care specializes in service to long-term healthcare facilities. Respondent employs 7 pharmacists and had over 60 employees acting as pharmacy technicians.
2. As of September 29, 2005, 39 of the 69 acting technicians employed at Respondent were not registered with the Board. As of October 27, 2005, 10 of the 62 acting technicians

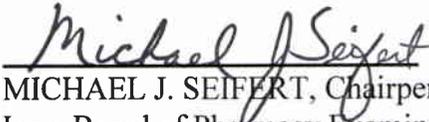
- employed at Respondent were not registered with the Board. Technicians employed by Respondent have worked as long as 24 months without registering with the Board.
3. An audit of schedule II controlled substances revealed numerous, substantial shortages including shortages of Fentanyl patches (-585 units), Methylin solution (-565), morphine 15mg ER (-1238), Roxanol solution (-599). The audit disclosed that, as to 86 medications stocked by Respondent, supplies of 20 (23%) were significantly short – while supplies of 31 (36%) were significantly ‘long.’
  4. An inspection of Respondent-pharmacy revealed the following deficiencies:
    - a. Respondent had no program of technician training
    - b. technician utilization policies and procedures – specific to the nature of pharmacy service provided by Respondent – were not maintained
    - c. Respondent had operated an uncertified sterile compounding hood for a year
    - d. Respondent had no policies regarding sterile compounding
    - e. outdated drugs were observed on dispensing shelves and in the controlled substance storage room
    - f. Respondent maintained an incomplete controlled substance inventory
    - g. pharmacy technicians were not wearing identification badges
    - h. no permanent log of the employee work hours was maintained
    - i. NDC and manufacturer information on medication labels did not match the medication dispensed
    - j. Respondent had no policies and procedures relating to delivery of prescription drugs and devices
    - k. Respondent had no policies relating to unit dosing systems
    - l. documentation of pharmacist review of medications being dispensed was incomplete
    - m. prescription documentation forms – relating to emergency supplies of Schedule 2 medications – failure to seek authorization for dispensing for periods in excess of any emergency
    - n. Respondent is providing incomplete information on "DEA form 222" forms
    - o. technicians are compounding medications without adequate pharmacist supervision
    - p. Respondent has not calibrated and inspected automated equipment
    - q. bulk compounding records are incomplete
    - r. Respondent is not affixing a unique identification number for each med pak dispensed
    - s. Respondent does not maintain policies and procedures for effecting a drug recall
    - t. Respondent does not maintain policies and procedures for packaging and dispensing to residents of a long-term healthcare facility
    - u. 62 of 184 "DEA form 222" forms maintained by Respondent did not have invoices
    - v. faxed partial fill orders for Schedule II controlled substances did not contain information indicating the medication was dispensed to an LTCF (Long Term Care Facility) patient
    - w. records of partial fills were not maintained on the prescription or medication order
    - x. Respondent dispensed partial fills of Schedule II medications to long term care patients more than 60 days after the date of the prescription

- y. Respondent dispensed medications in the absence of a signed prescription
  - z. Respondent failed to maintain documentation of the NDC or the manufacturer information relating specific medication dispensed
  - aa. Respondent 's personnel were unable to retrieve requested information from the computer system
  - bb. compounded products lack adequate ingredient identification
  - cc. Respondent maintained incomplete records regarding the formulae used in compounding products
  - dd. Respondent did not maintain batch records relating to compounded products
5. Respondent's customers indicate that a significant number of dispensing errors are being made by Respondent in the course of providing pharmacy service.

WHEREFORE, the Complainant prays that a hearing be held in this matter and that the Board take such action as it may deem to be appropriate under the law.

  
LLOYD K. JESSEN  
Executive Secretary/Director

On this 28<sup>th</sup> day of November 2005, the Iowa Board of Pharmacy Examiners found probable cause to file this Statement of Charges and to order a hearing in this case.

  
MICHAEL J. SEIFERT, Chairperson  
Iowa Board of Pharmacy Examiners  
400 SW Eighth Street, Suite E  
Des Moines, Iowa 50309-4688

cc: Scott M. Galenbeck  
Assistant Attorney General  
Hoover State Office Building  
Des Moines, Iowa 50319

**BEFORE THE BOARD OF PHARMACY EXAMINERS  
OF THE STATE OF IOWA**

Re:	)	Case No. 2005-89
Pharmacy License of	)	
<b>HY-VEE CARE (4013)</b>	)	<b>EMERGENCY ORDER</b>
License No. 1211,	)	
Respondent.	)	

**I. JURISDICTION**

The Iowa Board of Pharmacy Examiners (hereinafter, "Board") has jurisdiction over pharmacy licensees pursuant to Iowa Code Chapters 155A and 272C (2005). Respondent Hy-Vee Care (4013) possesses pharmacy license number 1211 issued by the Board. A Statement of Charges was filed against Respondent on November 28, 2005. After receipt and review of the Statement of Charges, and careful review of evidence relating to the Statement of Charges, the Board has adopted the following Findings of Fact and Conclusions of Law and Emergency Order.

**II. FINDINGS OF FACT**

1. Effective December 14, 2004, the Board renewed Respondent's license to engage in the practice of pharmacy as evidenced by license number 1211, subject to the laws of the State of Iowa and the rules of the Board.
2. Respondent operates a pharmacy at 3998 Northwest Urbandale Drive, Urbandale, Iowa 50322, with Gary Levine as the pharmacist in charge.
3. On or about September 28, 2005, an investigation of Respondent was commenced, which revealed the following:
  - A. Respondent specializes in service to long-term healthcare facilities. Respondent employs 7 pharmacists and over 60 employees acting as pharmacy technicians.

- B. As of September 29, 2005, 39 of the 69 acting technicians employed by Respondent were not registered with the Board. As of October 27, 2005, 10 of the 62 technicians employed at Respondent were not registered with the Board. Technicians employed by Respondent have worked as long as 24 months without registering with the Board.
- C. An audit of schedule II controlled substances revealed numerous, substantial shortages including shortages of Fentanyl patches (-585 units), Methylin solution (-565 ml), morphine 15mg ER (-1238 units), Roxanol solution (-599 ml). The audit disclosed that, as to 86 medications stocked by Respondent, supplies of 20 (23%) were significantly short – while supplies of 31 (36%) were significantly 'long.'
- D. An inspection of Respondent-pharmacy revealed the following deficiencies:
1. Respondent had no program of technician training
  2. technician utilization policies and procedures – specific to the nature of pharmacy service provided by Respondent – were not maintained
  3. Respondent had operated an uncertified sterile compounding hood for a year
  4. Respondent had no policies regarding sterile compounding
  5. outdated drugs were observed on dispensing shelves and in the controlled substance storage room
  6. Respondent maintained an incomplete controlled substance inventory
  7. pharmacy technicians were not wearing identification badges
  8. no permanent log of the employee work hours was maintained
  9. NDC and manufacturer information on medication labels did not match the medication dispensed
  10. Respondent had no policies and procedures relating to delivery of prescription drugs and devices
  11. Respondent had no policies relating to unit dosing systems
  12. documentation of pharmacist review of medications being dispensed was incomplete
  13. prescription documentation forms – relating to emergency supplies of Schedule 2 medications – failure to seek authorization for dispensing for periods in excess of any emergency
  14. Respondent is providing incomplete information on "DEA form 222" forms
  15. technicians are compounding medications without adequate pharmacist supervision
  16. Respondent has not calibrated and inspected automated equipment
  17. bulk compounding records are incomplete
  18. Respondent is not affixing a unique identification number for each med pak dispensed
  19. Respondent does not maintain policies and procedures for effecting a drug recall
  20. Respondent does not maintain policies and procedures for packaging and dispensing to residents of a long-term healthcare facility
  21. 62 of 184 "DEA form 222" forms maintained by Respondent did not have invoices

22. faxed partial fill orders for Schedule II controlled substances did not contain information indicating the medication was dispensed to an LTCF (Long Term Care Facility) patient
  23. records of partial fills were not maintained on the prescription or medication order
  24. Respondent dispensed partial fills of Schedule II medications to long term care patients more than 60 days after the date of the prescription
  25. Respondent dispensed medications in the absence of a signed prescription
  26. Respondent failed to maintain documentation of the NDC or the manufacturer information relating specific medication dispensed
  27. Respondent 's personnel were unable to retrieve requested information from the computer system
  28. compounded products lack adequate ingredient identification
  29. Respondent maintained incomplete records regarding the formulae used in compounding products
  30. Respondent did not maintain batch records relating to compounded products
4. The Board finds that the evidence assembled during the investigation of Respondent supports the November 28, 2005, Statement of Charges against Respondent. The Board also finds that Respondent has violated the provisions of Iowa Code Chapter 155A (2005) and Chapter 657 of the Iowa Administrative Code in the manner alleged in the Statement of Charges.
5. The Board finds that Respondent is an immediate danger to the public health, safety and welfare for the following reasons:
- A. Respondent-pharmacy is operating with a large, untrained staff of persons who function as pharmacy technicians. These persons are not registered as pharmacy technicians and Respondent is lacking a program for training and utilization of technicians. The lack of training is particularly troublesome in light of the fact the unregistered technicians outnumber the licensed pharmacist staff by approximately ten to one. The untrained staff of pseudo-technicians employed at Respondent represents a threat to the public health,

safety and welfare because they are assembling and packaging medications upon which the lives of pharmacy patients depend.

- B. Respondent-pharmacy appears to be operating in general disregard for regulations designed to secure the public health, safety and welfare. For example, Respondent is operating without written policies and procedures in six specific areas relevant to providing pharmacy services to long-term healthcare facilities. Such policies and procedures are especially important because Respondent maintains a large staff of apparently untrained and unregistered pharmacy technicians. An inadequately trained and poorly supervised staff is likely to make dispensing errors which result in a threat to the public health, safety and welfare. Substantial dispensing errors are being experienced by Respondent's patients, which constitutes an immediate threat to the public health, safety and welfare.
- C. Respondent's records relating to Schedule II controlled substances are incomplete and inaccurate. An audit of Respondent's drug inventory disclosed that, as to 86 medications stocked by Respondent, supplies of 20 (23%) were significantly short – while supplies of 31 (36%) were significantly 'long.' Of greater concern is the fact that the audit of schedule II controlled substances revealed numerous substantial shortages, including shortages of Fentanyl patches (-585 units), Methylin solution (-565 ml), morphine 15mg ER (-1238 units) and Roxanol solution (-599 ml). Because of the amount of controlled substances unaccounted for, there is a strong possibility drugs are being diverted from Respondent to "street" sale and use, constituting an immediate and continuing danger to the public health, safety and welfare.

- D. Respondent's records suggest that some Schedule II prescription medications are being distributed without the necessary prescription. The failure to obtain prescriptions results in medications being dispensed without the usual and requisite involvement of a prescribing practitioner. This creates a substantial possibility of misuse or incorrect use of Schedule II prescription medications which might adversely affect the health of members of the public. Respondent-pharmacy's practices constitute an immediate and continuing threat to the public health, safety and welfare.
6. The Board finds that immediate, emergency action must be taken for the reason that if Respondent is allowed to continue to operate in the manner it is currently operating, the public health, safety and welfare will be threatened by improper and unlawful practices related to dispensing medications to members of the public.
7. The Board finds that the minimum emergency action needed to protect the public health, safety and welfare is as follows:
- A. Respondent should submit to the Board, within 72 hours of the issuance of this order, a plan to bring the operations of Respondent into compliance with state and federal laws and regulations (hereinafter, "compliance plan").
  - B. Respondent's compliance plan should address, at a minimum, the 30 deficiencies revealed by the Board's inspection of Respondent.
  - C. Respondent's compliance plan should address the status, operational responsibilities, training and hours of duty of each support person employed by respondent.
  - D. Respondent's compliance plan should address the status, operational responsibilities, training, and hours of on-site duty of the pharmacist in charge.

- E. Respondent's compliance plan should be subject to review by the Board and the Board should take additional action to remedy any deficiencies in the plan.

### **III. CONCLUSIONS OF LAW**

1. Respondent's disregard for the provisions of Iowa Code chapter 155A.15 and chapter 657 of the Iowa Administrative Code, as well as the provisions of state and federal law relating to controlled substances, pose an immediate and continuing threat to the public health, safety and welfare.
2. The provisions of Iowa Code § 17A.18A (2003) permit the Board of Pharmacy Examiners to take emergency action to protect the health, safety and welfare of the public. A basis for emergency action against Respondent, pursuant to the provisions of the Iowa Code and the Iowa Administrative Code, has been established by the findings of fact adopted above.

### **IV. EMERGENCY ORDER**

The Board ORDERS as follows:

1. Pursuant to Iowa Code § 17A.18A, chapter 155A (2003) and 657 Iowa Administrative Code Chapter 35, the Board directs Respondent as follows:
  - A. Respondent shall submit to the Board, within 72 hours of the issuance of this order, a plan to bring the operations of Respondent into compliance with state and federal laws and regulations (hereinafter, "compliance plan").

B. Respondent's compliance plan shall address, at a minimum, the 30 deficiencies revealed by the Board's inspection of Respondent.

C. Respondent's compliance plan shall address the status, operational responsibilities, training and hours of duty of each support person employed by respondent.

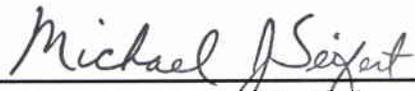
D. Respondent's compliance plan shall address the status, operational responsibilities, training, and hours of on-site duty of the pharmacist in charge.

E. Respondent's compliance plan shall be subject to review and approval by the Board. Upon approval by the board, the plan shall be implemented.

2. Respondent shall be notified of this order as provided in 657 Iowa Administrative Code subrule 35.30(2).

3. A hearing regarding this Emergency Adjudicative Order and the Statement of Charges against Respondent shall be held on December 28, 2005. The hearing will commence at 10:00 a.m. and be held at the office of the Iowa Board of Pharmacy Examiners, 400 Southwest 8<sup>th</sup> Street, Suite E, Des Moines, Iowa 50309.

**DATED** this 28<sup>th</sup> day of November 2005.



MICHAEL J. SEIFERT, Chairperson  
Iowa Board of Pharmacy Examiners  
400 SW Eighth Street, Suite E  
Des Moines, Iowa 50309-4688

cc: Scott M. Galenbeck  
Assistant Attorney General  
Hoover State Office Building  
Des Moines, Iowa 50319

**BEFORE THE BOARD OF PHARMACY EXAMINERS  
OF THE STATE OF IOWA**

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Re:	)	
Pharmacy License of	)	Case No. 2005-89
<b>HY-VEE CARE (4013)</b>	)	
License No. 1211,	)	<b>EMERGENCY ORDER # 2</b>
Respondent.	)	

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**I. JURISDICTION**

The Iowa Board of Pharmacy Examiners (hereinafter, "Board") has jurisdiction over pharmacy licensees pursuant to Iowa Code Chapters 155A and 272C (2005). Respondent Hy-Vee Care (4013) possesses pharmacy license number 1211 issued by the Board. A Statement of Charges was filed against Respondent on November 28, 2005. After receipt and review of the Statement of Charges, and careful review of evidence relating to the Statement of Charges, the Board adopted Findings of Fact and Conclusions of Law and Emergency Order # 1 which was issued on November 28, 2005. An Amended Statement of Charges was filed against Respondent on May 17, 2006. After receipt and review of the Amended Statement of Charges, and careful review of evidence relating to the Amended Statement of Charges, the Board has adopted the following Findings of Fact and Conclusions of Law and Emergency Order # 2.

**II. FINDINGS OF FACT**

1. Effective December 5, 2005, the Board renewed Respondent's license to engage in the practice of pharmacy as evidenced by license number 1211, subject to the laws of the State of Iowa and the rules of the Board.
2. Respondent operates a pharmacy at 3998 Northwest Urbandale Drive, Urbandale, Iowa 50322, with Sue Mears as the pharmacist in charge.

3. On March 30, 2006, the Board received a report from the Iowa department of inspections and appeals (DIA) relating to the Respondent. An investigation of the matter revealed the following, which the Board hereby finds:

- A. On or about September 5, 2005, Respondent took over as the pharmacy provider for the Osceola Nursing & Rehab Center in Osceola, Iowa.
- B. One resident of this facility, "Jane Doe," age 81, had been receiving the drug Levbid 0.375mg BID since October 9, 2002, for a gastrointestinal disorder.
- C. When Respondent received the medication administration record (MAR), it indicated Levobid. There is no such drug.
- D. Pharmacist Sue Mears entered the order as Levothroid 0.375 mg BID. It was dispensed as Levothroid 0.175mg and Levothroid 0.2mg. Pharmacist Mears admits that she was responsible for entering the medication incorrectly. The report from DIA states "she [Mears] said she was probably in 'a hurry' and did not see the order should be Levbid as Levobid did not exist." It also states "she [Mears] reported she did not recognize Levothroid 0.375mg twice a day as a high dose.....and that she had 'over-looked' the order."
- E. "Jane Doe" received 52 doses of Levothroid 0.375 mg until September 26, 2005, when she went into atrial fibrillation and suffered a stroke at 11:00 p.m.
- F. After "Jane Doe" was admitted to the hospital, a hospital pharmacist contacted the pharmacy that "Jane Doe" used prior to September 5, 2005, and ascertained that "Jane Doe" had been receiving Levbid 0.375 BID.
- G. "Jane Doe's" T-4 Free test, which was completed at the hospital on September 27, 2005, revealed that her thyroid level was 3.9, noted as high, with normal values ranging from 0.6 to 1.6.
- H. Prior to the stroke, "Jane Doe" had diagnoses of hypertension, peptic ulcer disease, history of hypercholesterolemia, psychotic disorder and chronic anxiety.
- I. "Jane Doe" was discharged from the hospital and returned to the facility on September 29, 2005. Her family refused tube feeding placement. She died on November 12, 2005.
- J. The medication error was listed as a cause of death on "Jane Doe's" death certificate.
- K. DIA conducted a survey at the Osceola Nursing & Rehab Center on February 28, 2006.
- L. At that time, DIA found that the facility had failed to report the medication error and the death of "Jane Doe" to DIA as required under I.A.C. 135C.26.
- M. Respondent failed to report the medication error to the Board of Pharmacy pursuant to 657 I.A.C. subrule 36.2(3).
- N. Respondent failed to inform "Jane Doe's" family of the medication error.

4. On April 4, 2006, Respondent provided the following information to the Board regarding the operation of Hy-Vee Care Pharmacy which the Board hereby finds:

They employ 19 pharmacists, of which three are full-time consultant pharmacists. They have an average of 545 non-consultant pharmacist hours weekly. They have hired two new full-time pharmacists and would also hire a pharmacy school graduate starting in May 2006. They have an average of 2,100 technician hours weekly, or the equivalent of 53 full-time technicians. The pharmacy's current pharmacist to technician ratio is 1 to 3.85, and as the pharmacy's business continues to grow, Respondent claims to be committed to keeping this ratio as low as possible to insure adequate supervision and training for pharmacy technicians. The pharmacy averages 17,500 prescriptions weekly. Of those 17,500 prescriptions, 81% (15,150) are refills or reorders. Approximately 86% of the reorders are cycle or exchange medications which are filled routinely depending on the distribution system utilized at the care facility. A survey of the Respondent's pharmacists reveals that they spend approximately one minute on each exchange prescription they check as these orders have already been screened for allergies, drug-to-drug interaction and medical history. The main focus is whether or not the prescription was filled with the correct medication, correct dose, and administration time as well as prospective drug review. They currently fill a weekly average of 2,351 new orders. Each of these new orders is reviewed by two different pharmacists. They employ 27 drivers, providing delivery to all of their facilities up to six days a week and twice daily delivery to approximately half of their facilities. They have on-call drivers to provide round-the-clock delivery capability.

5. Because of the figures provided by Respondent, the Board finds that the pharmacy is doing 32 prescriptions per pharmacist per hour, which would be one prescription every 1.8 minutes. As a result, the Board directed its compliance officers to conduct visits with the care facilities serviced by Respondent to review all incident reports and dispensing errors that have occurred since Respondent has been providing pharmacy services. The compliance officers surveyed over 80 care facilities, compiling data on 77 facilities. Of all the care facilities surveyed, the average number of dispensing errors made per week by Respondent was 52.

6. Board compliance officer Jean Rhodes submitted a supplemental investigative report to the Board on April 20, 2006. That report includes the following information, which the Board hereby finds:

- A. Gary Levine was the pharmacist in charge of Hy-Vee Care Pharmacy at the time of “Jane Doe’s” medication error, but he was not involved in the order entry, filling or dispensing of the medication.
- B. On April 11, 2006, another medication error was discovered at the Osceola Nursing & Rehab Center. The error involved the wrong strength of Lotrel, a blood pressure medication. The patient should have received Lotrel 5/20 and instead received Lotrel 10/20 for two weeks.
- C. Hy-Vee Care Pharmacy is taking several corrective actions to reduce medication errors.
- D. There have been problems with the emergency drug kits provided by Hy-Vee Care Pharmacy. The kits have not been thoroughly checked before being sent to care facilities. This has resulted in a policy change that requires a pharmacist to completely check the entire contents of the emergency drug kit.
- E. Hy-Vee Care Pharmacy has been acting as a central fill pharmacy for two originating pharmacies. Labeling of the prescriptions does not comply with Board rules. In addition, 10% of the centrally-filled prescriptions have been delivered directly to the care facility instead of to the originating pharmacy, in violation of Board rules.
- F. Hy-Vee Care Pharmacy has recorded five medication errors that reached patients since January 2006.

7. The Board finds that the evidence assembled during the continued investigation of Respondent supports the May 17, 2006, Amended Statement of Charges against Respondent.

The Board also finds that Respondent has violated the provisions of Iowa Code Chapter 155A (2005) and Chapter 657 of the Iowa Administrative Code in the manner alleged in the Amended Statement of Charges.

8. The Board finds that Respondent is an immediate danger to the public health, safety and welfare for the following reasons:

- A. Respondent-pharmacy made a medication dispensing error in September 2005 which caused or contributed to the death of patient “Jane Doe.”
- B. Respondent-pharmacy is currently processing approximately 17,500 prescriptions per week. Approximately 2,350 of those prescriptions are new orders. Respondent-pharmacy is processing approximately 32 prescriptions per pharmacist per hour or approximately one prescription every 1.8 minutes. Processing prescriptions at a rate of one prescription every 1.8 minutes does not allow pharmacists enough time to satisfy all the professional standards, obligations, and requirements relating to the filling and dispensing of prescriptions as established by the Board.
- C. Respondent-pharmacy is continuing to make approximately 52 dispensing errors per

week, which constitutes an immediate threat to the public health, safety and welfare.

- D. Respondent-pharmacy is engaged in the central filling of some prescriptions but is not in compliance with Board rules for central fill.
- E. Respondent-pharmacy has failed to provide proper oversight for emergency drug kits that have been provided to care facilities.
- F. Respondent-pharmacy's practices constitute an immediate and continuing threat to the public health, safety and welfare.

9. The Board finds that immediate, emergency action must be taken for the reason that if

Respondent is allowed to continue to operate in the manner it is currently operating, the public health, safety and welfare will be threatened by unsafe, improper and unlawful practices related to dispensing medications to members of the public.

10. The Board finds that the minimum emergency action needed to protect the public health, safety and welfare is as follows:

- A. Respondent-pharmacy should not be allowed to serve patients or residents of any care facilities not currently being served by Respondent-pharmacy without prior approval of the Board.
- B. Respondent-pharmacy's practices, systems, and operation should be evaluated by a consultant selected by Respondent. Such evaluation should be completed as soon as possible. A final written report including recommendations should be provided to the Board for its review. The Board reserves the right to order Respondent-pharmacy to undergo further evaluation including peer review if deemed necessary by the Board.
- C. Respondent-pharmacy should conduct prospective drug use review, as provided in 657 Iowa Administrative Code rule 8.21, for every new prescription drug order filled for every patient or care facility resident served by Respondent-pharmacy at the time of dispensing.
- D. Respondent-pharmacy should conduct retrospective drug regimen review of all medications dispensed to every patient or care facility resident served by Respondent-pharmacy at a frequency of not less than every two weeks.
- E. Respondent-pharmacy should discontinue central fill practices or should immediately comply with Board rules pertaining to the central filling of prescriptions.
- F. Respondent-pharmacy should report to the Board in writing all medication dispensing errors that leave the pharmacy, regardless of whether the medication is administered to patients or residents of care facilities. Such reports should be submitted to the Board every 7 days and should be signed by the pharmacist in charge of Respondent-pharmacy and the director of nursing of the care facility involved. Such reports should provide complete and detailed information about each medication dispensing error, including the

identity of the patient or care facility resident, the effect of the error on the patient or care facility resident, and the Respondent-pharmacy's response to the error.

- G. In the event that there is a change in the pharmacist in charge at Respondent-pharmacy, Respondent-pharmacy should submit the name of the new pharmacist in charge to the Board and obtain Board approval before filing an application for pharmacy license.

### **III. CONCLUSIONS OF LAW**

1. Respondent's failure to comply with the provisions of Iowa Code chapter 155A.15 and chapter 657 of the Iowa Administrative Code poses an immediate and continuing threat to the public health, safety and welfare.
2. The provisions of Iowa Code § 17A.18A (2005) permit the Board of Pharmacy Examiners to take emergency action to protect the health, safety and welfare of the public. A basis for emergency action against Respondent, pursuant to the provisions of the Iowa Code and the Iowa Administrative Code, has been established by the findings of fact adopted above.

### **IV. EMERGENCY ORDER**

The Board ORDERS as follows:

1. Pursuant to Iowa Code § 17A.18A, chapter 155A (2005) and 657 Iowa Administrative Code chapter 35, the Board directs Respondent as follows:
  - A. Respondent-pharmacy shall not be allowed to serve patients or residents of any care facilities not currently being served by Respondent-pharmacy without prior approval of the Board.
  - B. Respondent-pharmacy's practices, systems, and operation shall be evaluated by a consultant selected by Respondent. Such evaluation shall be completed as soon as possible. A final written report including recommendations shall be provided to the Board for its review. The Board reserves the right to order Respondent-pharmacy to undergo further evaluation including peer review if deemed necessary by the Board.
  - C. Respondent-pharmacy shall conduct prospective drug use review, as provided in 657 Iowa Administrative Code rule 8.21, for every new prescription drug order filled for

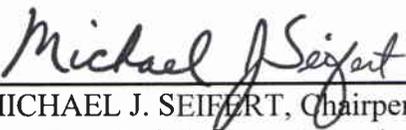
every patient or care facility resident served by Respondent-pharmacy at the time of dispensing.

- D. Respondent-pharmacy shall conduct retrospective drug regimen review of all medications dispensed to every patient or care facility resident served by Respondent-pharmacy at a frequency of not less than every two weeks.
- E. Respondent-pharmacy shall discontinue central fill practices or shall immediately comply with Board rules pertaining to the central filling of prescriptions.
- F. Respondent-pharmacy shall report to the Board in writing all medication dispensing errors that leave the pharmacy, regardless of whether the medication is administered to patients or residents of care facilities. Such reports shall be submitted to the Board every 7 days and shall be signed by the pharmacist in charge of Respondent-pharmacy and the director of nursing of the care facility involved. Such reports shall provide complete and detailed information about each medication dispensing error, including the identity of the patient or care facility resident, the effect of the error on the patient or care facility resident, and the Respondent-pharmacy's response to the error.
- G. In the event that there is a change in the pharmacist in charge at Respondent-pharmacy, Respondent-pharmacy shall submit the name of the new pharmacist in charge to the Board and obtain Board approval before filing an application for pharmacy license.

2. Respondent shall be notified of this order as provided in 657 Iowa Administrative Code subrule 35.30(2).

3. A hearing regarding this Emergency Adjudicative Order and the Statement of Charges against Respondent shall be held on June 7, 2006. The hearing will commence at 10:00<sup>AM</sup> and be held in the conference room at the West Des Moines Community Schools Learning Resource Center, 3550 Mills Civic Parkway, West Des Moines, Iowa 50265.

DATED this 23<sup>rd</sup> day of May 2006.

  
MICHAEL J. SEIFERT, Chairperson  
Iowa Board of Pharmacy Examiners  
400 SW Eighth Street, Suite E  
Des Moines, Iowa 50309-4688

cc: Scott M. Galenbeck

Assistant Attorney General  
Hoover State Office Building  
Des Moines, Iowa 50319

Hy-Vee Care-Emerg Or 2a.doc

**BEFORE THE BOARD OF PHARMACY EXAMINERS  
OF THE STATE OF IOWA**

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Re:	)	Case No. 2005-89
Pharmacy License of	)	
<b>HY-VEE CARE (4013)</b>	)	<b>AMENDED</b>
License No. 1211	)	<b>STATEMENT OF CHARGES</b>
Respondent.	)	

---

**COMES NOW**, the Complainant, Lloyd K. Jessen, and states:

1. He is the Executive Secretary/Director for the Iowa Board of Pharmacy Examiners and files this Statement of Charges solely in his official capacity.
2. The Board has jurisdiction in this matter pursuant to Iowa Code Chapters 155A and 272C (2005).
3. Effective December 5, 2005, the Board renewed Respondent's general pharmacy license number 1211 with Sue Mears as pharmacist in charge, allowing Respondent to engage in the operation of pharmacy subject to the laws of the State of Iowa and the rules of the Board.
4. General pharmacy license number 1211 is current until December 31, 2006.
5. Respondent is currently operating a general pharmacy at 3998 Northwest Urbandale Drive, Urbandale, Iowa 50322, with Sue Mears as the pharmacist in charge.
6. A Statement of Charges was filed by the Board against Respondent on November 28, 2005.

**A. ADDITIONAL CHARGES**

**COUNT I – LACK OF PROFESSIONAL COMPETENCY**

Respondent is charged under Iowa Code § 155A.15(2)(c) (2005) and 657 Iowa Administrative Code 36.1(4)(b)(3) with a lack of professional competency as demonstrated by a failure of a pharmacist to exercise in a substantial respect that degree of care which is ordinarily exercised by the average pharmacist in the state of Iowa acting under the same or similar circumstances.

**COUNT II – MEDICATION DISPENSING ERRORS**

Respondent is charged under Iowa Code § 155A.15(2)(c) (2005) and 657 Iowa Administrative Code 36.1(4)(b)(4) with making numerous medication dispensing errors

as demonstrated by a repeated departure from, or the failure to conform to, the minimal standard or acceptable and prevailing practice of pharmacy in the state of Iowa.

COUNT III – FAILURE TO COMPLY WITH CENTRAL FILL RULES

Respondent is charged under Iowa Code § 155A.15(2)(c) and (f) (2005) and 657 Iowa Administrative Code chapter 18 with failing to comply with Board rules pertaining to centralized prescription filling and processing.

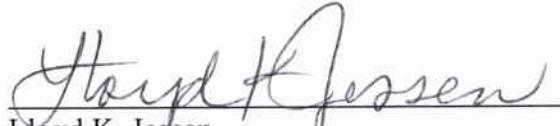
COUNT IV – FAILURE TO REPORT

Respondent is charged under Iowa Code § 155A.15(2)(c) (2005) and 657 Iowa Administrative Code 36.1(4)(q) with failing to file the reports required by subrule 36.2(3) concerning acts or omissions committed by another licensee or registrant.

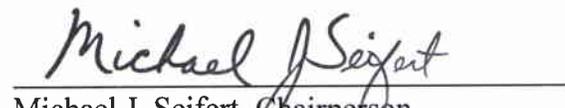
B. CIRCUMSTANCES

Circumstances supporting the above charges are set forth in Attachment A.

WHEREFORE, the Complainant prays that a hearing be held in this matter and that the Board take such action as it may deem to be appropriate under the law.

  
Lloyd K. Jessen  
Executive Secretary/Director

On this 23<sup>rd</sup> day of May 2006, the Iowa Board of Pharmacy Examiners found probable cause to file this Statement of Charges and to order a hearing in this case.

  
Michael J. Seifert, Chairperson  
Iowa Board of Pharmacy Examiners  
400 SW Eighth Street, Suite E  
Des Moines, Iowa 50309-4688

cc: Scott M. Galenbeck  
Assistant Attorney General  
Hoover State Office Building  
Des Moines, IA 50319

**BEFORE THE BOARD OF PHARMACY EXAMINERS  
OF THE STATE OF IOWA**

Re:	)	Case No. 2005-89
Pharmacy License of	)	
<b>HY-VEE CARE PHARMACY,</b>	)	<b>STIPULATION</b>
License No. 1211,	)	<b>AND</b>
Respondent.	)	<b>CONSENT ORDER</b>
	)	

Pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (2005), the Iowa Board of Pharmacy Examiners (hereinafter, "Board") and Hy-Vee Care Pharmacy (hereinafter, "Respondent"), enter into this Stipulation and Consent Order settling a pending contested case. The pending contested case is a licensee disciplinary proceeding before the Iowa Board of Pharmacy Examiners based on allegations specified in a Statement of Charges and Emergency Order filed November 28, 2005, and an Amended Statement of Charges and Emergency Order #2 filed May 23, 2006. The Board and Respondent, who hereby agree that the contested case shall be resolved without proceeding to hearing, stipulate to the following:

1. Respondent's license to operate a pharmacy in Iowa was renewed on December 5, 2005, as evidenced by General Pharmacy License Number 1211, which is recorded in the permanent records of the Iowa Board of Pharmacy Examiners.
2. General Pharmacy License Number 1211, issued to and held by Respondent, is active and current until December 31, 2006.
3. A Statement of Charges and Emergency Order were filed against Respondent on November 28, 2005. An Amended Statement of Charges and Emergency Order #2 were filed against Respondent on May 23, 2006.

4. The Board has jurisdiction over Respondent and the subject matter herein.
5. Respondent denies the allegations set forth in the Statement of Charges and Amended Statement of Charges, but enters into this Agreement voluntarily in order to resolve the Statements of Charges without the necessity of a hearing and agrees, for the purpose of this Stipulation and Consent Order, to adhere to certain terms and conditions on its license to operate a pharmacy in the State of Iowa.
6. Upon the date of the Board's approval of this Stipulation and Consent Order, Respondent's license to operate a pharmacy shall be placed on probation for two (2) years, subject to the following terms and conditions:
  - a) Respondent has submitted to the Board a written report that evaluates Respondent's practices, systems, and operation as specified in the Emergency Order #2 issued by the Board on May 23, 2006.
  - b) Respondent agrees to provide to the Board an Assurance of Regulatory Compliance signed by the pharmacist in charge in which Respondent agrees to obey all federal and state laws and regulations related to the practice of pharmacy.
  - c) Respondent agrees to not serve patients or residents of any care facilities not currently being served by Respondent without the prior approval of the executive director of the Board until it has presented an operational plan to the Board which adequately addresses all of the issues contained in the Statement of Charges, the Amended Statement of Charges, the Emergency Order, and the Emergency Order #2. In the event that such a plan is presented and Board approval is obtained, this limitation on Respondent's pharmacy license shall be lifted. Once lifted,

Respondent agrees to notify the Board, in writing, when it provides services to new facilities and when it provides expanded services to existing facilities for which it had not previously been the primary pharmacy provider. Such notification shall be made as soon as possible, and in any event, no later than 7 days prior to providing such service.

- d) Respondent agrees to maintain a pharmacist-to-pharmacy technician ratio of not less than 1:5. Respondent agrees that consultant pharmacists and managerial pharmacists who are not involved in the daily prescription filling activities of the pharmacy shall not be included in the calculation of the pharmacist-to-pharmacy technician ratio. Respondent also agrees to implement a formal pharmacy technician training and education program for both existing pharmacy technicians and newly-hired pharmacy technicians and will submit documentation of such to the Board as requested.
- e) Respondent agrees to the following process for new prescription orders: (1) A pharmacy technician will enter the new order into Respondent's software system from an image of the order; (2) a pharmacist will check and verify the order entry of the pharmacy technician and will complete an initial review of the order as specified in the "initial pharmacist review checklist," including prospective drug utilization review; (3) a pharmacy technician will fill the prescription as directed by the order and the label; and (4) a different pharmacist will complete a final review of the order as specified in the "pharmacist final review checklist," including drug regimen review.

- f) Respondent agrees to comply with Board rules pertaining to the central filling of prescriptions if it engages in the central filling of prescriptions.
- g) Respondent agrees to report to the Board in writing all medication dispensing errors that leave the pharmacy, regardless of whether the medication is administered to patients or residents of care facilities. Such reports shall be submitted to the Board within 30 days of discovery of the error and shall be signed by the pharmacist in charge of Respondent-pharmacy and the director of nursing of the care facility involved. Such reports shall provide complete and detailed information about each medication dispensing error, including the identity of the patient or care facility resident, the name and address of the care facility where the patient or resident resides, the effect of the error on the patient or care facility resident, and the Respondent's response to the error.
- h) In the event that there is a change in the pharmacist in charge at Respondent-pharmacy, Respondent agrees to submit the name of the new pharmacist in charge to the Board and obtain Board approval before filing an application for pharmacy license. The new pharmacist in charge will provide to the Board an Assurance of Regulatory Compliance signed by the pharmacist in charge in which Respondent agrees to obey all federal and state laws and regulations related to the practice of pharmacy.
- i) During probation, Respondent agrees to provide notification, in writing, to all facilities currently being served, and to all new facilities which may be served by Respondent in the future, of the fact that Respondent's license to operate a

pharmacy in Iowa is on probation with the Board of Pharmacy Examiners and is subject to certain terms and conditions. Respondent shall cause the administrator of each facility and the director of nursing of each facility, to acknowledge to the Board, in writing, that they have received a copy of this Stipulation and Consent Order, that they have read it, and that they understand it. For all existing facilities, such notification and acknowledgement shall be accomplished within 30 days of the Board's approval of this Stipulation and Consent Order. For all new facilities, such notification and acknowledgement shall be accomplished within 15 days of the commencement of pharmacy services by Respondent.

7. Should the Respondent violate or fail to comply with any of the terms or conditions of this Stipulation and Consent Order, the Board may initiate action to revoke or further suspend the Respondent's Iowa pharmacist license, or to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A (2005), and 657 IAC 36.
8. This Stipulation and Consent Order is the resolution of a contested case. By entering into this Stipulation and Consent Order, the Respondent waives all rights to a contested case hearing on the allegations contained in the Statement of Charges, and waives any objections to this Stipulation and Consent Order.
9. This proposed settlement is subject to approval by a majority of the full Board. If the Board fails to approve this settlement, it shall be of no force or effect to either party. If the Board approves this Stipulation and Consent Order, it shall be the full and final resolution of this matter.

10. The Board's approval of this Stipulation and Consent Order shall constitute a FINAL ORDER of the Board in a disciplinary action.

This Stipulation and Consent Order is voluntarily submitted by Respondent to the Board for its consideration on the 13<sup>th</sup> day of July 2006.

Sue Mears RA

Sue Mears, R.Ph., P.I.C.  
on behalf of  
Hy-Vee Care Pharmacy,  
Respondent

State of Iowa

County of Polk

Signed and sworn (or affirmed) before me

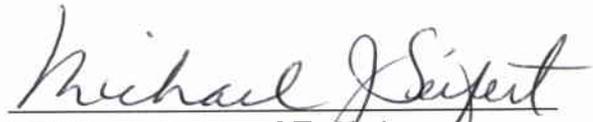
on July 13, 2006  
Date

by Aaron Wiese  
Name(s) of Person(s)

Aaron Wiese  
Signature of Notary Public



This Stipulation and Consent Order is accepted by the Iowa Board of Pharmacy Examiners on the 17 day of July 2006.



MICHAEL J. SEIFERT, Chairperson  
Iowa Board of Pharmacy Examiners  
400 SW Eighth Street, Suite E  
Des Moines, Iowa 50309-4688

cc: Scott M. Galenbeck  
Assistant Attorney General  
Office of the Attorney General  
Hoover State Office Building  
Des Moines, Iowa 50319

Ed McIntosh  
Dorsey & Whitney LLP  
801 Grand Avenue  
Suite 3900  
Des Moines, IA 50309-2790

**BEFORE THE BOARD OF PHARMACY  
OF THE STATE OF IOWA**

Re:	)	Case No. 2005-89
Pharmacy License of	)	
<b>HY-VEE CARE (4013)</b>	)	<b>THIRD</b>
License No. 1211	)	<b>STATEMENT OF CHARGES</b>
Respondent.	)	

**COMES NOW**, the Complainant, Lloyd K. Jessen, and states:

1. He is the Executive Director for the Iowa Board of Pharmacy and files this Statement of Charges solely in his official capacity.
2. The Board has jurisdiction in this matter pursuant to Iowa Code Chapters 155A and 272C (2007).
3. Effective November 17, 2006, the Board renewed Respondent's general pharmacy license number 1211 with Michael A. Cuesta as pharmacist in charge, allowing Respondent to engage in the operation of pharmacy subject to the laws of the State of Iowa and the rules of the Board.
4. General pharmacy license number 1211 is current until December 31, 2007.
5. Respondent is currently operating a general pharmacy at 3998 Northwest Urbandale Drive, Urbandale, Iowa 50322, with Michael A. Cuesta as the pharmacist in charge.
6. Pursuant to a "Stipulation and Consent Order" approved by the Board, Respondent's license to operate a pharmacy was placed on probation with conditions for two (2) years effective July 17, 2006.

**A. CHARGES**

**COUNT I – VIOLATION OF PROBATION**

Respondent is charged under Iowa Code § 155A.15(2)(c) (2005) and 657 Iowa Administrative Code 36.1(4)(i), 36.1(4)(j), and 36.1(4)(u) with violating the terms and conditions of probation as established in the "Stipulation and Consent Order" approved by the Board on July 17, 2006.

**COUNT II – FAILURE TO MEET MINIMUM STANDARDS OF PRACTICE**

Respondent is charged under Iowa Code § 155A.15(2)(c) (2005) and 657 Iowa Administrative Code 6.2, 6.7, 6.8, 6.10, 6.16, 8.4, 9.2, 10.22, 10.23, 10.34, 10.35, 20.10,

21.3, 21.4, and 22.5 with repeated violations of the minimum standards of pharmacy practice as established by Board rules.

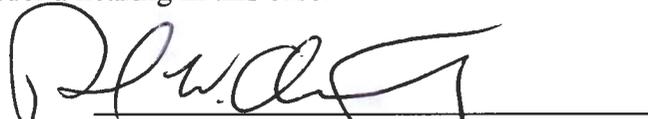
B. CIRCUMSTANCES

Circumstances supporting the above charges are set forth in Attachment A.

WHEREFORE, the Complainant prays that a hearing be held in this matter and that the Board take such action as it may deem to be appropriate under the law.

  
Lloyd K. Jessen  
Executive Director

On this 3<sup>rd</sup> day of July 2007, the Iowa Board of Pharmacy found probable cause to file this Statement of Charges and to order a hearing in this case.

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

cc: Scott M. Galenbeck  
Assistant Attorney General  
Hoover State Office Building  
Des Moines, IA 50319

**BEFORE THE BOARD OF PHARMACY  
OF THE STATE OF IOWA**

---

Re:	)	
Pharmacy License of	)	Case No. 2005-89
<b>HY-VEE CARE (4013)</b>	)	
License No. 1211,	)	<b>EMERGENCY ORDER # 3</b>
Respondent.	)	

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**I. JURISDICTION**

The Iowa Board of Pharmacy (hereinafter, "Board") has jurisdiction over pharmacy licensees pursuant to Iowa Code Chapters 155A and 272C (2007). Respondent Hy-Vee Care (4013) possesses pharmacy license number 1211 issued by the Board. A third Statement of Charges was filed against Respondent on July 3, 2007. After receipt and review of the third Statement of Charges, and careful review of evidence relating to the third Statement of Charges, the Board has adopted the following Findings of Fact and Conclusions of Law and Emergency Order # 3.

**II. FINDINGS OF FACT**

1. Effective November 17, 2006, the Board renewed Respondent's license to engage in the practice of pharmacy as evidenced by license number 1211, subject to the laws of the State of Iowa and the rules of the Board.
2. Respondent operates a pharmacy at 3998 Northwest Urbandale Drive, Urbandale, Iowa 50322, with Michael A. Cuesta as the pharmacist in charge.
3. On or about June 19, 2007, an inspection, audit, and compliance review was commenced, revealing the following:
  - A. Respondent has repeatedly violated the following terms and conditions of probation as established in the "Stipulation and Consent Order" dated July 17, 2006, as follows:

- 6(b) A Quality Assurance Plan for AMDS was not submitted to the Board in a timely manner.
- 6(c) Notification to the Board of new or expanded service to care facilities was not submitted in a timely manner.
- 6(d) The pharmacist to pharmacy technician ratio of 1:5 was exceeded. Also, there was no documentation of technician training for the AMDS.
- 6(e) All new prescription orders were not processed by two different pharmacists (one for initial review and one for final review).
- 6(g) Reports of dispensing errors were incomplete and untimely.
- 6(i) Notification to care facilities of the fact that Respondent's license is on probation was not accomplished in a timely manner, nor were notices filed with the Board as required. Also, Respondent has misrepresented its licensure status to prospective care facilities when soliciting new business.

B. Respondent has repeatedly failed to meet the following minimum standards of pharmacy practice in the following manner:

- 657 IAC 6.2. Respondent's pharmacist in charge has failed to ensure that the pharmacy employs an adequate number of qualified personnel, has failed to maintain all necessary records, and has failed to maintain effective controls over prescription drugs and records.
- 657 IAC 6.7. Respondent has failed to ensure adequate security of prescription records.
- 657 IAC 6.8. Respondent has failed to retain original prescriptions at the licensed location.
- 657 IAC 6.10. Respondent has failed to provide accurate information regarding the name of the prescribing practitioner on prescription labels.
- 657 IAC 6.16. Respondent has failed to maintain original prescriptions at the licensed location for a period of two years following the date of last activity.
- 657 IAC 8.4. Respondent has failed to display original pharmacist licenses and renewal certificates for all pharmacists employed at the licensed location.
- 657 IAC 9.2. Respondent has failed to provide the Board with written notice at least 30 days prior to the installation of an AMDS which included all required information. Specifically, Respondent has failed to submit a final quality assurance plan that satisfied board requirements at least 30 days before the operation of the AMDS.
- 657 IAC 10.22. Respondent has failed to comply with recordkeeping requirements for Schedule II emergency prescriptions.
- 657 IAC 10.23. Respondent has failed to comply with the requirements for partial filling of Schedule II controlled substances.
- 657 IAC 10.34. Respondent has failed to properly process DEA form 222 in numerous instances.

- 657 IAC 10.35. Respondent has failed to comply with controlled substance inventory requirements.
- 657 IAC 20.10. Respondent has failed to comply with controls for drug compounding and recordkeeping requirements for drug compounding.
- 657 IAC 21.3. Respondent has failed to comply with requirements for electronically transmitted prescriptions.
- 657 IAC 21.4. Respondent has failed to maintain computerized prescription records that identify all dispensing pharmacists.
- 657 IAC 22.5. Respondent has failed to comply with requirements for patient med paks.

C. Respondent has failed to provide accurate accountability for Schedule II controlled substances as evidenced by an audit conducted for the time period beginning September 30, 2006, and ending June 19, 2007.

7. The Board finds that the evidence assembled during the continued investigation of Respondent supports the July 3, 2007, Statement of Charges against Respondent. The Board also finds that Respondent has violated the provisions of Iowa Code Chapter 155A (2005) and Chapter 657 of the Iowa Administrative Code in the manner alleged in the Statement of Charges.

8. The Board finds that Respondent is an immediate danger to the public health, safety and welfare for the following reasons:

- A. Respondent-pharmacy made a medication dispensing error in September 2005 which caused or contributed to the death of patient "Jane Doe."
- B. At that time, Respondent-pharmacy was processing approximately 17,500 prescriptions per week. Approximately 2,350 of those prescriptions were new orders. Respondent-pharmacy was processing approximately 32 prescriptions per pharmacist per hour or approximately one prescription every 1.8 minutes. Processing prescriptions at a rate of one prescription every 1.8 minutes did not allow pharmacists enough time to satisfy all the professional standards, obligations, and requirements relating to the filling and dispensing of prescriptions as established by the Board.
- C. Respondent-pharmacy was continuing to make approximately 52 dispensing errors per week, which constituted an immediate threat to the public health, safety and welfare.
- D. Respondent-pharmacy was engaged in the central filling of some prescriptions but was not in compliance with Board rules for central fill.

- E. Respondent-pharmacy previously failed to provide proper oversight for emergency drug kits that have been provided to care facilities.
- F. Respondent-pharmacy's previous practices constituted an immediate and continuing threat to the public health, safety and welfare.
- G. Respondent-pharmacy has *repeatedly* failed to comply with the terms and conditions of probation as established by the Board on July 17, 2006.
- H. Respondent-pharmacy has *repeatedly* failed to comply with the minimum standards of pharmacy practice as established by rules of the Board.
- I. Respondent-pharmacy's continued disregard for Iowa pharmacy law, Board rules, and an Order of the Board demonstrate that it does not take its responsibilities seriously.

9. The Board finds that immediate, emergency action must be taken for the reason that if Respondent is allowed to continue to operate in the manner it is currently operating, the public health, safety and welfare will be threatened by unsafe, improper and unlawful practices related to dispensing medications to members of the public.

10. The Board finds that the minimum emergency action needed to protect the public health, safety and welfare is as follows:

- A. Respondent-pharmacy should not provide pharmaceutical products or services to any additional patients or to any additional residents of any care facilities.
- B. Respondent-pharmacy should immediately comply with all the terms and conditions of its probation as established by the Board effective July 17, 2006.
- C. Respondent-pharmacy should immediately employ an adequate number of pharmacists so that the pharmacist to pharmacy technician ratio of 1:5 is never exceeded.
- D. Respondent-pharmacy should correct all inspection deficiencies no later than August 1, 2007, and should demonstrate complete compliance upon re-inspection.
- E. Respondent-pharmacy should demonstrate controlled substance accountability for all controlled substances upon re-audit within 30 days of the receipt of this Order.

F. Respondent-pharmacy should continue to conduct prospective drug use review, as provided in 657 Iowa Administrative Code rule 8.21, for every new prescription drug order filled for every patient or care facility resident served by Respondent-pharmacy at the time of dispensing.

G. Respondent-pharmacy should continue to conduct retrospective drug regimen review of all medications dispensed to every patient or care facility resident served by Respondent-pharmacy at a frequency of not less than every two weeks.

H. Respondent-pharmacy should continue to report to the Board in writing all medication dispensing errors that leave the pharmacy, regardless of whether the medication is administered to patients or residents of care facilities. Such reports should be submitted to the Board every 7 days and should be signed by the pharmacist in charge of Respondent-pharmacy and the director of nursing of the care facility involved. Such reports should provide complete and detailed information about each medication dispensing error, including the identity of the patient or care facility resident, the effect of the error on the patient or care facility resident, and the Respondent-pharmacy's response to the error.

I. Respondent-pharmacy should submit a written action plan to the Board for discontinuing its business as a pharmacy by September 1, 2007. Such action plan should provide for the orderly transition of pharmaceutical services from Respondent-pharmacy to another pharmacy or other pharmacies for all patients and residents of care facilities currently served by Respondent-pharmacy. Such action plan should be submitted to the Board before August 1, 2007, and should be reviewed and approved by the Board on August 1, 2007.

J. In the event that there is a change in the pharmacist in charge at Respondent-pharmacy, Respondent-pharmacy should submit the name of the new pharmacist in charge to the Board and obtain Board approval before filing an application for pharmacy license.

### **III. CONCLUSIONS OF LAW**

1. Respondent's failure to comply with the provisions of Iowa Code chapter 155A.15 and chapter 657 of the Iowa Administrative Code and with the terms and conditions of probation poses an immediate and continuing threat to the public health, safety and welfare.
2. The provisions of Iowa Code § 17A.18A (2005) permit the Board of Pharmacy Examiners to take emergency action to protect the health, safety and welfare of the public. A basis for emergency action against Respondent, pursuant to the provisions of the Iowa Code and the Iowa

Administrative Code, has been established by the findings of fact adopted above.

#### **IV. EMERGENCY ORDER**

The Board ORDERS as follows:

1. Pursuant to Iowa Code § 17A.18A, chapter 155A (2005) and 657 Iowa Administrative Code chapter 35, the Board directs Respondent as follows:

- A. Respondent-pharmacy shall not provide pharmaceutical products or services to any additional patients or to any additional residents of any care facilities.
- B. Respondent-pharmacy shall immediately comply with all the terms and conditions of its probation as established by the Board effective July 17, 2006.
- C. Respondent-pharmacy shall immediately employ an adequate number of pharmacists so that the pharmacist to pharmacy technician ratio of 1:5 is never exceeded.
- D. Respondent-pharmacy shall correct all inspection deficiencies no later than August 1, 2007, and shall demonstrate complete compliance upon re-inspection.
- E. Respondent-pharmacy shall demonstrate controlled substance accountability for all controlled substances upon re-audit within 30 days of the receipt of this Order.
- F. Respondent-pharmacy shall continue to conduct prospective drug use review, as provided in 657 Iowa Administrative Code rule 8.21, for every new prescription drug order filled for every patient or care facility resident served by Respondent-pharmacy at the time of dispensing.
- G. Respondent-pharmacy shall continue to conduct retrospective drug regimen review of all medications dispensed to every patient or care facility resident served by Respondent-pharmacy at a frequency of not less than every two weeks.
- H. Respondent-pharmacy shall continue to report to the Board in writing all medication dispensing errors that leave the pharmacy, regardless of whether the medication is administered to patients or residents of care facilities. Such reports shall be submitted to the Board every 7 days and shall be signed by the pharmacist in charge of Respondent-pharmacy and the director of nursing of the care facility involved. Such reports shall provide complete and detailed information about each medication dispensing error, including the identity of the patient or care facility resident, the effect of the error on the patient or care facility resident,

and the Respondent-pharmacy's response to the error.

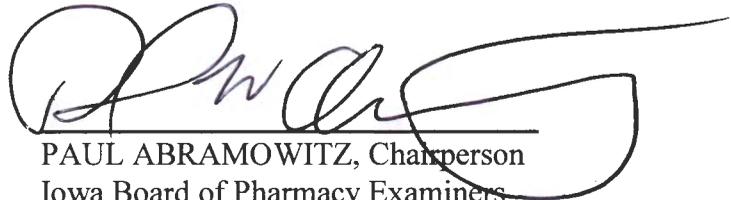
I. Respondent-pharmacy shall submit a written action plan to the Board for discontinuing its business as a pharmacy by September 1, 2007. Such action plan shall provide for the orderly transition of pharmaceutical services from Respondent-pharmacy to another pharmacy or other pharmacies for all patients and residents of care facilities currently served by Respondent-pharmacy. Such action plan shall be submitted to the Board before August 1, 2007, and shall be reviewed and approved by the Board on or about August 1, 2007.

J. In the event that there is a change in the pharmacist in charge at Respondent-pharmacy, Respondent-pharmacy shall submit the name of the new pharmacist in charge to the Board and obtain Board approval before filing an application for pharmacy license.

2. Respondent shall be notified of this order as provided in 657 Iowa Administrative Code subrule 35.30(2).

3. A hearing regarding this Emergency Adjudicative Order and the Statement of Charges against Respondent shall be held on Wednesday, August 1, 2007. The hearing will commence at or about 9 a.m. and will be held in the conference room at the Iowa Board of Pharmacy, RiverPoint Business Park, 400 SW 8<sup>th</sup> Street, Suite E, Des Moines, Iowa 50309.

**DATED** this 3rd day of July 2007.



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

cc: Scott M. Galenbeck  
Assistant Attorney General  
Hoover State Office Building  
Des Moines, Iowa 50319

Hy-Vee Care-Emerg Order 3 final.doc

**BEFORE THE BOARD OF PHARMACY  
OF THE STATE OF IOWA**

Re: )	
Pharmacy License of )	Case No. 2005-89
<b>HY-VEE CARE (4013)</b> )	<b>AMENDMENT TO</b>
License No. 1211, )	<b>EMERGENCY ORDER # 3</b>
Respondent. )	

Comes now on behalf of the Iowa Board of Pharmacy (hereinafter, "Board") Lloyd K. Jessen, Executive Director of the Board, and amends paragraph 1(A) of Division IV (EMERGENCY ORDER) of Emergency Order # 3 issued on July 3, 2007, in the above-captioned matter, as follows:

A. Respondent-pharmacy shall not provide pharmaceutical products or services to any additional patients or to any additional residents of any care facilities, except that Respondent-pharmacy may accept new skilled patients or residents of a care facility with whom Respondent-pharmacy has the contract to provide skilled services. Respondent-pharmacy shall provide to the Board via e-mail to [jean.rhodes@iowa.gov](mailto:jean.rhodes@iowa.gov), no later than 4:30 p.m. on July 10, 2007, a list of all care facilities with whom Respondent-pharmacy has the contract to provide skilled services. In addition, within 24 hours of accepting any new skilled patient or resident pursuant to this paragraph, Respondent-pharmacy shall notify the Board via e-mail to [jean.rhodes@iowa.gov](mailto:jean.rhodes@iowa.gov) identifying that patient by name and including the name and address of the care facility.

**DATED** this 6th day of July 2007.



LLOYD K. JESSEN, Executive Director  
Iowa Board of Pharmacy Examiners  
400 SW Eighth Street, Suite E  
Des Moines, Iowa 50309-4688

cc: Scott M. Galenbeck  
Assistant Attorney General  
Hoover State Office Building  
Des Moines, Iowa 50319

**BEFORE THE BOARD OF PHARMACY  
OF THE STATE OF IOWA**

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Re:	)	Case No. 2005-89
Pharmacy License of	)	
<b>HY-VEE CARE (4013)</b>	)	<b>FOURTH</b>
License No. 1211	)	<b>STATEMENT OF CHARGES</b>
Respondent.	)	

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**COMES NOW**, the Complainant, Lloyd K. Jessen, and states:

1. He is the Executive Director for the Iowa Board of Pharmacy and files this Statement of Charges solely in his official capacity.
2. The Board has jurisdiction in this matter pursuant to Iowa Code Chapters 155A and 272C (2007).
3. Effective November 17, 2006, the Board renewed Respondent's general pharmacy license number 1211 with Michael A. Cuesta as pharmacist in charge, allowing Respondent to engage in the operation of pharmacy subject to the laws of the State of Iowa and the rules of the Board.
4. General pharmacy license number 1211 is current until December 31, 2007.
5. Respondent is currently operating a general pharmacy at 3998 Northwest Urbandale Drive, Urbandale, Iowa 50322, with Michael A. Cuesta as the pharmacist in charge.
6. Pursuant to a "Stipulation and Consent Order" approved by the Board, Respondent's license to operate a pharmacy was placed on probation with conditions for two (2) years effective July 17, 2006.

**A. CHARGES**

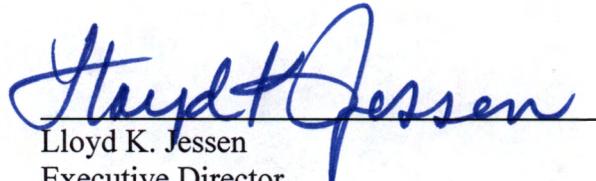
**COUNT I – FAILURE TO COMPLY WITH BOARD ORDER**

Respondent is charged with failure to comply with the terms of Emergency Order #3 issued by the Iowa Board of Pharmacy on July 3, 2007, and the Amendment to Emergency Order #3 issued by the Board on July 6, 2007, in violation of Iowa Code § 272C.3(2)(a)(2007).

B. CIRCUMSTANCES

Circumstances supporting the above charges are set forth in Attachment A.

WHEREFORE, the Complainant prays that a hearing be held in this matter and that the Board take such action as it may deem to be appropriate under the law.

  
Lloyd K. Jessen  
Executive Director

On this 3rd day of August 2007, the Iowa Board of Pharmacy found probable cause to file this Statement of Charges and to order a hearing in this case.

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

cc: Scott M. Galenbeck  
Assistant Attorney General  
Hoover State Office Building  
Des Moines, IA 50319

**BEFORE THE BOARD OF PHARMACY  
OF THE STATE OF IOWA**

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Re:	)	
Pharmacy License of	)	Case No. 2005-89
<b>HY-VEE CARE (4013)</b>	)	
License No. 1211,	)	<b>EMERGENCY ORDER # 4</b>
Respondent.	)	

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**I. JURISDICTION**

The Iowa Board of Pharmacy (hereinafter, "Board") has jurisdiction over pharmacy licenses pursuant to Iowa Code Chapters 155A and 272C (2007). Respondent Hy-Vee Care (4013) possesses pharmacy license number 1211 issued by the Board. A fourth Statement of Charges was filed against Respondent on August 3, 2007. After receipt and review of the fourth Statement of Charges, and careful review of evidence relating to the fourth Statement of Charges, the Board has adopted the following Findings of Fact and Conclusions of Law and Emergency Order # 4.

**II. FINDINGS OF FACT**

1. Effective November 17, 2006, the Board renewed Respondent's license to engage in the practice of pharmacy as evidenced by license number 1211, subject to the laws of the State of Iowa and the rules of the Board.
2. Respondent operates a pharmacy at 3998 Northwest Urbandale Drive, Urbandale, Iowa 50322, with Michael A. Cuesta as the pharmacist in charge.
3. Notifications to the Board regarding pharmacist and technician employment changes indicate a loss of existing pharmacist and technician staff. The pharmacy is now utilizing temporary

employees to supplement the remaining staff. Continued and increased utilization of temporary staff increases the potential for patient harm.

4. The Board is aware that Respondent is in the process of negotiating for the sale of its business.
5. On August 1, 2007, a re-inspection and compliance review was commenced, revealing the following:
  - A. Respondent has violated paragraph 1(A) of section IV of Emergency Order #3, as amended, by accepting five patients from facilities with which Respondent did not have a contract to provide skilled services.
  - B. Respondent has violated paragraph 1(A) of section IV of Emergency Order #3, as amended, by failing to report new patients to the Board within 24 hours of accepting them.
  - C. Respondent has violated paragraph 1(A) of section IV of Emergency Order #3, as amended, by failing to timely submit a complete and accurate list of all care facilities with whom Respondent had a contract to provide skilled services.
  - D. Respondent has violated paragraph 1(B) of section IV of Emergency Order #3 by failing to ensure that new prescription orders were initially reviewed by one pharmacist and checked by a second pharmacist on July 7 and 8, 2007.
  - E. Respondent has violated paragraph 1(C) of section IV of Emergency Order #3 by failing to maintain a pharmacist to pharmacy technician ratio of 1:5 for 15 hours between July 10 and July 17, 2007. For five of those hours, there was no pharmacist scheduled.
  - F. Respondent has violated paragraph 1(D) of section IV of Emergency Order #3 by failing to demonstrate complete compliance by August 1, 2007.
6. The Board finds that the evidence assembled during the continued investigation of Respondent supports the August 3, 2007, Fourth Statement of Charges against Respondent. The Board also finds that Respondent has violated the provisions of Iowa Code Chapter 272C (2007) in the manner alleged in the Statement of Charges.

7. The Board finds that Respondent is an immediate danger to the public health, safety and welfare due to the fact that Respondent has repeatedly failed to comply with three (3) Emergency Orders of the Board.
8. The Board finds that immediate, emergency action must be taken for the reason that if Respondent is allowed to continue to operate in the manner it is currently operating, the public health, safety and welfare will be threatened by unsafe, improper and unlawful practices related to dispensing medications to members of the public.
9. The Board finds that the minimum emergency action needed to protect the public health, safety and welfare is as follows:

Respondent's pharmacy license should be suspended effective October 3, 2007, and Respondent should discontinue its business as a pharmacy by October 3, 2007. Respondent should either sell its business or should follow the action plan for discontinuing business which it submitted to the Board on July 30, 2007. If Respondent has not sold its business by September 3, 2007, Respondent should immediately implement the action plan approved by the Board on July 31, 2007. Implementation of the action plan would ensure the orderly transition within 30 days of pharmaceutical services from Respondent to another pharmacy or other pharmacies for all patients and residents of care facilities currently served by Respondent.

### **III. CONCLUSIONS OF LAW**

1. Respondent's failure to comply with the provisions of Iowa Code chapter 272C and with the terms and conditions of probation poses an immediate and continuing threat to the public

health, safety and welfare.

2. The provisions of Iowa Code § 17A.18A (2005) permit the Board of Pharmacy Examiners to take emergency action to protect the health, safety and welfare of the public. A basis for emergency action against Respondent, pursuant to the provisions of the Iowa Code and the Iowa Administrative Code, has been established by the findings of fact adopted above.

#### **IV. EMERGENCY ORDER**

The Board ORDERS as follows:

1. Pursuant to Iowa Code § 17A.18A, chapter 155A (2005) and 657 Iowa Administrative Code chapter 35, the Board directs Respondent as follows:  
  
Respondent's pharmacy license shall be suspended effective October 3, 2007, and Respondent shall discontinue its business as a pharmacy by October 3, 2007. Respondent shall either sell its business or shall follow the action plan for discontinuing business which it submitted to the Board on July 30, 2007. If Respondent has not sold its business by September 3, 2007, Respondent shall immediately implement the action plan approved by the Board on July 31, 2007. Implementation of the action plan shall ensure the orderly transition within 30 days of pharmaceutical services from Respondent to another pharmacy or other pharmacies for all patients and residents of care facilities currently served by Respondent.
2. Respondent shall be notified of this Order as provided in 657 Iowa Administrative Code subrule 35.30(2).
3. A hearing regarding this Emergency Adjudicative Order and the Statement of Charges against Respondent shall be held on September 11, 2007. The hearing will commence at or about 9 a.m. and will be held in the conference room at the Iowa Board of Pharmacy, RiverPoint

Business Park, 400 SW 8<sup>th</sup> Street, Suite E, Des Moines, Iowa 50309.

**DATED** this 3rd day of August 2007.

A handwritten signature in black ink, appearing to read "Paul W. Abramowitz", written over a horizontal line.

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

cc: Scott M. Galenbeck  
Assistant Attorney General  
Hoover State Office Building  
Des Moines, Iowa 50319

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