

BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA

Re: Pharmacist License of	}	COMPLAINT
LISA C. BURKE	}	AND
License No. 16831	}	STATEMENT
Respondent	}	OF CHARGES

COMES NOW, Lloyd K. Jessen, Executive Secretary of the Iowa Board of Pharmacy Examiners, on the 11th day of July, 1990, and files this Complaint and Statement of Charges against Lisa C. Burke, a pharmacist licensed pursuant to Iowa Code chapter 155A, and alleges that:

1. Melba L. Scaglione, Chairperson; Alan M. Shepley, Vice Chairperson; Rollin C. Bridge; Donna J. Flower; Phyllis A. Olson; Marian L. Roberts; and John F. Rode are duly appointed, qualified members of the Iowa Board of Pharmacy Examiners.

2. Respondent was issued a license to practice pharmacy in Iowa on January 28, 1987, by reciprocity.

3. Respondent is employed as the pharmacist in charge of Main at Locust Pharmacy located at 129 West Locust in Davenport, Iowa 52803.

4. Respondent currently resides at 21 Oak Lane in Davenport, Iowa 52803.

5. Respondent's license to practice pharmacy in Iowa is current until June 30, 1992.

6. An inspection of Main at Locust Pharmacy was conducted on November 14, 1989, by Pharmacy Investigators E. Ray Shelden and James P. Theis. That inspection revealed recordkeeping discrepancies for schedule II controlled substances. As a result, Investigator Shelden conducted an investigation and accountability audit of selected controlled substances at Main at Locust Pharmacy.

7. The Board has received investigative reports dated December 6, 1989, and February 28, 1990, from Investigator Shelden. Those reports allege the following:

a. Failure by Respondent to maintain controlled substance records in a manner which establishes receipt and distribution of all controlled substances.

b. Failure by Respondent to maintain controlled substance records in a readily retrievable manner in accordance with federal requirements.

c. Failure by Respondent to provide complete accountability between May 1, 1989, and February 22, 1990, for the following schedule II controlled substances:

- (1) Oxycodone ASA tablets;
- (2) Demerol 50mg tablets;
- (3) Dilaudid/Hydromorphone 2mg tablets;
- (4) Dilaudid/Hydromorphone 3mg tablets;
- (5) Dilaudid/Hydromorphone 4mg tablets;
- (6) Codeine 30mg tablets;
- (7) Methylphenidate 20mg tablets;
- (8) Methadone 5mg tablets;
- (9) Seconal 100mg capsules;
- (10) Injectable forms of Demerol 50mg/ml
- (11) Morphine 30mg tablets;
- (12) Morphine powder; and
- (13) Injectable forms of Dilaudid

d. Failure by Respondent to properly transfer a schedule II controlled substance between registrants and to properly execute DEA order form 222.

e. Failure by Respondent to record the amount of medication dispensed on prescriptions.

f. Failure by Respondent to obtain the prescriber's signature on prescriptions for schedule II controlled substances.

g. Failure by Respondent to follow regulations pertaining to the dispensing of schedule II controlled substances upon oral authorization of a prescriber in emergency situations.

h. Failure by Respondent to provide adequate security over drugs in the prescription department.

i. Failure by Respondent to provide effective controls and procedures to guard against theft and diversion of controlled substances. Specifically, laboratory analysis of the following schedule II controlled substances obtained from the Main at Locust Pharmacy revealed the following:

(1) A vial labeled as cocaine hydrochloride powder having a net weight of 24.78 grams was found to be only 52% cocaine hydrochloride;

(2) A vial labeled as cocaine hydrochloride powder having a net weight of 2.52 grams was found to

be only 3% cocaine hydrochloride;

(3) A vial labeled as cocaine flakes having a net weight of 12.8 grams was found to be only 78.9% cocaine.

8. The Board acknowledges receipt of a letter from Respondent dated April 5, 1990. In that letter Respondent attempts to refute many of the allegations made in Investigator Sheldon's reports and offers an explanation for some of the record keeping discrepancies and shortages of schedule II controlled substances.

9. Respondent is guilty of violations of 1989 Iowa Code sections 155A.12(1), 155A.12(4), 155A.12(5), 155A.27(c), 204.306, 204.307, and 204.308 by virtue of the allegations in paragraph 7.

Iowa Code section 155A.12 provides, in part, the following:

The board may refuse to issue or renew a license or may impose a fine, issue a reprimand, or revoke, restrict, cancel, or suspend a license, and may place a licensee on probation, if the board finds that the applicant or licensee has done any of the following:

1. Violated any provision of this chapter or any rules of the board adopted under this chapter.

....

4. Failed to keep and maintain records required by this chapter or failed to keep and maintain complete and accurate records of purchases and disposal of drugs listed in the controlled substances Act.

5. Violated any provision of the controlled substances Act or rules relating to that Act.

Iowa Code section 155A.27 provides the following:

Each prescription drug order issued or filled in this state:

1. If written, shall contain:

a. The date of issue.

b. The name and address of the patient for whom, or the owner of the animal for which, the drug is dispensed.

c. The name, strength, and quantity of the drug, medicine, or device prescribed.

d. The directions for use of the drug, medicine, or device prescribed.

e. The name, address, and signature of the practitioner issuing the prescription.

f. The federal drug enforcement administration number, if required under chapter 204.

2. If oral, the practitioner issuing the prescription shall furnish the same information

required for a written prescription, except for the written signature and address of the practitioner. Upon receipt of an oral prescription, the pharmacist shall promptly reduce the oral prescription to a written format by recording the information required in a written prescription.

Iowa Code section 204.306 provides, in part, the following:

Persons registered to manufacture, distribute, dispense, or administer controlled substances under this chapter shall keep records and maintain inventories in conformance with the record keeping and inventory requirements of federal law and with such additional rules as may be issued by the board.

Iowa Code section 204.307 provides the following:

Controlled substances in schedules I and II shall be distributed by a registrant to another registrant only pursuant to an order form. Compliance with the provisions of federal law respecting order forms shall be deemed compliance with this section.

Iowa Code section 204.308 provides, in part, the following:

1. Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, no controlled substance in schedule II may be dispensed without the written prescription of a practitioner.

2. In emergency situations, as defined by rule of the board, schedule II drugs may be dispensed upon oral prescription of a practitioner, reduced promptly to writing and filed by the pharmacy. Prescriptions shall be retained in conformity with the requirements of section 204.306.

10. Respondent is guilty of violations of 657 Iowa Administrative Code sections 6.8, 9.1(4)(b)(1), 9.1(4)(b)(2), 9.1(4)(b)(4), 9.1(4)(j), 9.1(4)(u), 10.10, 10.11, 10.13(1), and 10.13(4) by virtue of the allegations in paragraph 7.

657 Iowa Administrative Code section 6.8 provides, in part, the following:

Controlled substance records shall be maintained in a readily retrievable manner in accordance with federal requirements. Those requirements, in summary, are as follows:

(1) Controlled substance records shall be maintained in a manner to establish receipt and

distribution of all controlled substances;

....

(5) Copy 1 of DEA Order Form 222C, furnished by the pharmacy or practitioner to whom Schedule II controlled substances are distributed, shall be maintained by the distributing pharmacy and shall show the quantity of controlled substances distributed and the actual date of distribution;

(6) Copy 3 of DEA Order Form 222C shall be properly dated, initialed, and filed and shall include all copies of each unaccepted or defective order form and any attached statements or other documents;

657 Iowa Administrative Code section 9.1(4) provides, in part, the following:

The board may impose any of the disciplinary sanctions set out in subrule 9.1(2), including civil penalties in an amount not to exceed \$25,000, when the board determines that the licensee or registrant is guilty of the following acts or offenses:

....

b. Professional incompetency. Professional incompetency includes but is not limited to:

(1) A substantial lack of knowledge or ability to discharge professional obligations within the scope of the pharmacist's practice.

(2) A substantial deviation by a pharmacist from the standards of learning or skill ordinarily possessed and applied by other pharmacists in the state of Iowa acting in the same or similar circumstances.

....

(4) A willful or repeated departure from, or the failure to conform to, the minimal standard or acceptable and prevailing practice of pharmacy in the state of Iowa.

....

j. Violating a statute or law of this state, another state, or the United States, without regard to its designation as either a felony or misdemeanor, which statute or law relates to the practice of pharmacy.

....

u. Violating any of the grounds for revocation or suspension of a license listed in Iowa Code sections 147.55, 155A.12 and 155A.15.

657 Iowa Administrative Code section 10.10 provides, in part, the following:

All applicants and registrants shall provide effective controls and procedures to guard against

theft and diversion of controlled substances.

657 Iowa Administrative Code section 10.11 provides, in part, the following:

All prescriptions for controlled substances shall be dated as of, and manually signed on, the day when issued and shall bear the full name and address and registration number of the practitioner. A practitioner must manually sign a prescription in the same manner the practitioner would sign a check or legal document. Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by a secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by those regulations.

657 Iowa Administrative Code section 10.13 provides, in part, the following:

In the case of an emergency situation, as defined by 10.13(5), a pharmacist may dispense a controlled substance listed in schedule II upon receiving oral authorization of a prescribing individual practitioner, provided that:

(1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription manually signed by the prescribing individual practitioner);

(2) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required except for the signature of the prescribing individual practitioner;

....

(4) Within 72 hours after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be

postmarked within the 72-hour period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the board if the prescribing individual fails to deliver a written prescription. Failure of the pharmacist to do so shall void the authority conferred by this subrule to dispense without a written prescription of a prescribing individual practitioner.

The Iowa Board of Pharmacy Examiners finds that paragraphs 9 and 10 constitute grounds for which Respondent's license to practice pharmacy in Iowa can be suspended or revoked.

WHEREFORE, the undersigned charges that Respondent has violated 1989 Iowa Code sections 155A.12(1), 155A.12(4), 155A.12(5), 155A.27(c), 204.306, 204.307, and 204.308 and 657 Iowa Administrative Code sections 6.8, 9.1(4)(b)(1), 9.1(4)(b)(2), 9.1(4)(b)(4), 9.1(4)(j), 9.1(4)(u), 10.10, 10.11, 10.13(1), and 10.13(4).

IT IS HEREBY ORDERED that Lisa C. Burke appear before the Iowa Board of Pharmacy Examiners on Tuesday, August 14, 1990, at 2:00 o'clock p.m., in the second floor conference room, 1209 East Court Avenue, Executive Hills West, Capitol Complex, Des Moines, Iowa.

The undersigned further asks that upon final hearing the Board enter its findings of fact and decision to suspend or revoke the license to practice pharmacy issued to Lisa C. Burke on January 28, 1987, and take whatever additional action that they deem necessary and appropriate.

Respondent may bring counsel to the hearing, may cross-examine any witnesses, and may call witnesses of her own. The failure of Respondent to appear could result in the permanent suspension or revocation of her license. Information regarding the hearing may be obtained from Thomas D. McGrane, Assistant Attorney General, Hoover Building, Capitol Complex, Des Moines, Iowa 50319.

IOWA BOARD OF PHARMACY EXAMINERS



Lloyd K. Jessen
Executive Secretary

BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA

RE: Pharmacist License of Lisa C. Burke License No. 16831 Respondent))))))	DIA No. 90PHB-7 FINDINGS OF FACT CONCLUSIONS OF LAW, DECISION AND ORDER
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TO: Lisa C. Burke

A Complaint and Statement of Charges was filed by Lloyd K. Jessen, Executive Secretary of the Iowa Board of Pharmacy Examiners, on July 11, 1990. The Complaint alleged that the Respondent had violated a number of pharmacy-related statutes and rules. The Complaint and Statement of Charges included the Notice of Hearing which set the hearing for August 14, 1990. The hearing was continued by the Board to October 9, 1990.

A joint hearing on the above Complaint and Statement of Charges and a nearly identical Complaint and Statement of Charges filed against the Pharmacy License of Main at Locust Pharmacy, was held on October 9, 1990 at 2:00 p.m. Present were the following members of the Board: Melba L. Scaglione, Chairperson; John F. Rode; Phyllis Olson; Rollin Bridge; Marian Roberts; and Alan Shepley. Thomas D. McGrane, Assistant Attorney General, appeared on behalf of the State. The Respondent, Lisa C. Burke, was present and was represented by her counsel, Clarence Christiansen. Present also were members of the staff of the Board and a court reporter. Margaret LaMarche, Administrative Law Judge from the Iowa Department of Inspections and Appeals, presided. The hearing was closed to the public at the request of the Licensee, pursuant to Iowa Code section 258A.6(1). After hearing the testimony and examining the exhibits the Board convened in closed executive session pursuant to Iowa Code section 21.5(1)"f"(1989) to deliberate. The undersigned Administrative Law Judge was instructed to prepare this Board's Decision and Order.

THE RECORD

The record in this case includes the Complaint and Statement of Charges; the Order of Continuance; the recorded testimony of the witnesses, and the following exhibits:

- | | |
|--------------------|---|
| State's Exhibit 1: | Investigative Report dated 12-6-89 and attachments. |
| State's Exhibit 2: | Investigative Report dated 2-28-90 and attachments. |
| State's Exhibit 3: | Computer print-out of Prescriptions at Main at Locust Pharmacy. |

- Respondent's Exhibit A: Photographs and description of Main at Locust.
Respondent's Exhibit B: Resume of Respondent.

FINDINGS OF FACT

1. Respondent was issued a license to practice pharmacy in Iowa on January 28, 1987, by reciprocity. Respondent's license is current until June 30, 1992. (Official File)
2. Respondent is employed as the pharmacist in charge of Main at Locust Pharmacy located at 129 West Locust in Davenport, Iowa. (Testimony of Respondent; State's Exhibit 1)
3. Pharmacy Investigators E. Ray Sheldon and James P. Theis conducted an inspection of Main at Locust Pharmacy on November 14, 1989. The inspection revealed record keeping discrepancies for schedule II controlled substances. As a result, Investigator Sheldon conducted an investigation and accountability audit of selected controlled substances at Main at Locust Pharmacy. (State's Exhibit 1)
4. On November 17, 1989, Investigator E. Ray Sheldon returned to the Main At Locust Pharmacy to obtain schedule II controlled drugs (CII) prescription files, Drug Enforcement Agency (DEA) forms 222C, inventories, and other information needed to audit selected CII drugs for a complete audit from May 1, 1989 to November 17, 1989. (State's Exhibit 1)
5. After examining the records of Main at Locust, Investigator Sheldon concluded that the prescription files were not complete and the computer print-outs were even less accurate. Sheldon contacted Respondent for an explanation. Respondent explained that the computer had several modules for printing prescription labels and module 02 is used to process CII prescriptions. Module 02 will print only one label. When the pharmacist needs more than one label, he or she will transfer the computer to module 09 for multiple labels. This eliminates the prescription that was printed on module 09 from printing on module 02, and completely eliminates that prescription from being printed on the CII transaction sheet. Respondent stated that this normally occurred with processing nursing home patients. Main at Locust Pharmacy services ten nursing homes. (State's Exhibit 1; Testimony of Respondent)
6. Emergency prescriptions for CII medications were written on prescriptions, logged in a notebook, and then sent to the physician for signature. No duplicate prescription was entered in the CII prescription file, as a matter of record. The prescription with the physician's signature was not always returned to the Pharmacy within seventy-two hours. Many cases were found where the signed prescription was not returned until 10 - 37 days after the "emergency"

prescription was filled. (State's Exhibit 1; Testimony of Respondent)

7. Investigator Sheldon seized several morphine and cocaine products for possible contamination and had them analyzed at the Division of Criminal Investigations laboratory. Some of these products were contaminated before Respondent became the pharmacist-in-charge, and apparently were reported to the Board. However, 24.78 grams of cocaine powder was contaminated while Respondent was in charge and was not reported to the Board. Laboratory analysis revealed that the cocaine powder contained 52% cocaine hydro-chloride. USP-NF indicates purity on a dry basis as 99 - 101%. (State's Exhibit 1; Testimony of Respondent)
8. During the audit, numerous deficiencies, discrepancies, and errors were discovered. These errors involved record keeping, preparation and dispensing of prescriptions and labels, disposal, and emergency prescriptions. (State's Exhibits 1, 2, 3)
9. Pursuant to statute, each prescription drug order issued or filled must contain the name, strength, and quantity of the drug, medicine, or device prescribed. The following prescriptions found at Main at Locust pharmacy, contained in Exhibit 1, failed to state the amount dispensed:
 - a) Rx 617734 Hydromorphone 25mg/250 ml dated 5-18-89. (Item #7)
 - b) Rx 618594 Morphine SO4 1mg/cc dated 5-25-89. (Item #8)
 - c) Rx 625243 Morphine S04 15 mg/cc dated 7-26-89 signed by Candace Canik (Item #16)
 - d) Rx 620916 Morphine S04 1mg/cc dated 6-15-89 signed by Candace Canik (Item #17)
 - e) Rx 620901 Hydromorphone 200 mg/500cc dated 6-15-89, signed by Candace Canik indicates (Item #18)
 - f) Rx 618271 Dilaudid Inj 2 mg/cc dated 5-23-89 signed by Candace Canik (Item #19)
 - g) Rx 61829? Oxycodone/Acetaminophen dated 5-23-89 signed by Candace Canik (Item #20)
 - h) Rx 618244 Hydromorphone 25 mg/250ml dated 5-23-89 signed by Candace Canik (Item #22)
 - i) Rx 617524 Dilaudid Inj 2 mg/cc dated 5-16-89 signed by Candace Canik (Item #22)
 - j) Rx 617268 Hydromorphone 25mg/250cc dated 5-15-89 signed by Karen Truesdell (Item #31)
 - k) Rx 620778 Hydromorphone 200 mg/500cc dated 6-14-89, signed by Karen Truesdell (Item #32)
 - l) Rx 619641 Hydromorphone 100 mg/500cc dated 6-4-89, signed by Karen Truesdell (Item #33)
 - m) Rx 617259 Demerol 50 mg tablets dated 5-14-89, signed by Karen Truesdell (Item #34)
 - n) Rx 617258 Demerol 50 mg tablets dated 5-14-89, signed by Karen Truesdell (Item #35)

- o) Rx 617254 Hydromorphone 25 mg/250cc dated 5-14-89, signed by Karen Truesdell (Item #36)
- p) Rx 617253 Morphine S04 1 mg/cc dated 5-12-89, signed by Karen Truesdell (Item #37)
- q) Rx 616766 Hydromorphone 25 mg/250cc dated 5-10-89, signed by Karen Truesdell (Item #38)
- r) Rx 615836 Hydromorphone 4 mg tablets dated 5-1-89 signed by Karen Truesdell (Item #39)
- s) Rx 617286 Hydromorphone 4 mg tablets dated 5-15-89 signed by Karen Truesdell (Item #40)
- t) Rx 617198 Dilaudid Inj 2 mg/cc dated 5-13-89 signed by Lisa Burke (Item #44)
- u) Rx 617221 Dilaudid Inj 25 mg/250cc dated 5-13-89 signed by Lisa Burke (Item #45)
- v) Rx 625601 Morphine S04 15 mg/cc dated 7-28-89 signed by Lisa Burke (LABEL ONLY) (Item #46)
- w) Rx 635793 M.S. Contin 60 mg dated 10-21-89 signed by Lisa Burke (Item #47)
- x) Rx 633320 Demerol 50 mg/cc dated 7-8-89 signed by Lisa Burke (Item #48)

10. Board rule requires that within 72 hours after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. The pharmacist shall notify the board if the prescribing individual fails to deliver a written prescription. The following prescriptions, contained in Exhibit 1, failed to meet these requirements:

- a) Rx 636205 Morphine S04 15mg/cc dispense 20cc. written by MEF 10-24-89 as an "emergency prescription" and returned to the Main at Locust Pharmacy signed by Dr. M. J. Gimbel MD on 11-9-89. This would be 14 days after the "emergency prescription" was dispensed. (Item #10)
- b) Rx 636221 Tuinal 200 mg. dispense 31 capsules written by MEF 10-24-89 as an "emergency prescription" and returned to the Main at Locust Pharmacy signed by Dr. J. Sunderbrush MD. on 11-8-89. The stamp on the back of the prescription indicates that Dr. Sunderbrush received this prescription on 11-7-89. This would be 15 days after the "emergency prescription" was dispensed. (Item #11)
- c) Rx 634209 Codeine S04 30 mg dispense #31 dated 10-7-89 signed by Candace Canik as an "emergency prescription" was signed by Dr. Douglas Vickstrom MD on 10-30-89 and returned to the Main at Locust Pharmacy on 11-1-89. This would be 24 days after the "emergency prescription" was dispensed. (Item #23)
- d) Rx 634103 Morphine 128 mg/500cc dispense #1000 cc dated as dispensed 10-6-89 was returned to the pharmacy on 10-26-89, signed by Dr. Karl Ahlborn. This would be 20 days after the "emergency prescription" had been dispensed. (Item #29)
- e) Rx 635627 Hydromorphone 2 mg dispense #31 tablets dated as dispensed 10-20-89 was returned to the pharmacy 11-8-89,

signed by Dr. George Kovach. This would be 18 days after the "emergency prescription" had been dispensed. (Item #30)

f) Rx 625601 Morphine S04 dispense ? dated as dispensed 7-28-89 signed by Lisa Burke as an "emergency prescription" was signed and returned to Main at Locust Pharmacy by Dr. William Irey on 8-9-89. This would be 12 days after the "emergency prescription" had been dispensed. (Item #50)

g) Rx 632021 Hydromorphone 4 mg tablets dispense #129 tablets dated as dispensed on 9-20-89 by Lisa Burke, as an "emergency prescription". This prescription was signed by Dr. Mark Hull and returned to Main at Locust Pharmacy on 10-26-89. This would be 37 days after the "emergency prescription" had been dispensed. (Item #51)

h) Rx 635795 M.S. Contin 60 mg. dispense #32 tablets dated as dispensed on 10-21-89 initialed as dispensed by LCB, as an "emergency prescription". This prescription was signed by Dr. George Kovach, and returned to Main at Locust Pharmacy on 11-8-89. This would be 17 days after the "emergency prescription" had been dispensed. (Item #52)

11. State statute requires that controlled substances in schedules I and II shall be distributed by a registrant to another registrant only pursuant to an order form. The following prescriptions, contained in State's Exhibit 1, failed to fully comply with this requirement:

a) DEA form 222c number N13700401 Dr. LeRoy H. Bell DVM indicates the purchase of 10 x 20 ml. Morphine Sulfate 15 mg/ml. This form is dated 2-28-89 and the notation signed by M. E. Fritz indicates that this order was never received by Dr. Bell but that the first carbon was forwarded to DEA. (Item #5) This incident occurred prior to the audit of 5-1-89 to 11-17-89. DEA order form N13700402 Dr. LeRoy H. Bell dated 3-29-89 for 10 x 20 ml Morphine 15mg/ml appears to have been executed on 4-4-89 in the proper manner.

b) DEA form 222c number 890423099 dated 5-2-89 was made out to St. Lukes Hospital, Davenport, Iowa, from Main at Locust Pharmacy. The word "void" with the initial M.E.F. was made on the original and first carbon, but the second carbon is missing. This copy is stapled to the second carbon of DEA form 222c and the number is 890432100. The word "void" is written on the face of this order form, but the original and first carbon are missing. This form is also initialed M.E.F. and would indicate that 2 x 20 ml of Dilaudid 2 mg/ml was never received by M.E.F. acting on behalf of Main at Locust Pharmacy. (Item #6)

c) Rx 635796 Percodan dispense #100 tablets dated 10-20-89 written for Dr. D.C. VanHecke M.D. by Dr. D.C. VanHecke M.D. Ms. Burke was informed on 8-2-89 (see Investigative report, Dr. D.C. VanHecke, dated 8-4-89) that the transfer of CII controlled substances was to be accomplished by DEA form 222c. (Item #41)

d) On the computer print-out listing New and Refill Prescriptions for 10-14-89 the following notation exists: Rx

634991 Pharmor Pharmacy Dilaudid 4 mg tablets with initials LCB Lot #10900059 Exp 4/93 (Item #42) No DEA order form 222c can be located for this transfer.

12. State statute provides that no controlled substance in schedule II may be dispensed without the written prescription of a practitioner, except when dispensed directly by the practitioner to the ultimate user. The following prescriptions, contained in State's Exhibit 1, were dispensed without a physician's signature or dispensed an amount in excess of that authorized:
 - a) Rx 633097 Hydromorphone 4 mg. dispense #279 tablets dated 10-1-89 signed by Karen Truesdell has no physicians signature. (Item #27)
 - b) Rx 621302 Oxycodone/Acetaminophen dispense #15 tablets dated 6-19-89 with initials KCT. Dr. John Collins authorized 15 doses to be dispense. The computer information indicates that #31 doses were dispensed on 6-19-89, and a notation on the prescription indicates that #30 tablets were returned to stock. (Item #28)
 - c) Rx 619162 Codeine 20 mg/10cc dispense #120 dated 5-30-89 signed by Lisa Burke has no physicians signature. (Item #43)
13. Board rule requires that when an oral order is not permitted, prescriptions must be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. In Rx 635221, contained in Exhibit 1, dated 10-17-89 and signed by Lisa Burke, the amount to be dispensed has been written over or altered. (Item #49).
14. State statute dictates the manner in which excess or undesired controlled substances are to be disposed. Exhibit 1 contains the following information:
 - a) A prescription dated 6-14-89 signed by Candace Canik (no co-signature) which indicates that she wasted 20 x 1 cc ampules of Dilaudid 4 mg/cc (Item #14).
 - b) Rx 621177 Morphine 1 mg/cc dispense 1000cc dated 6-17-89 mixed in D5W was destroyed while still at Main at Locust Pharmacy. During the interview with Ms. Canik, on 2-7-90, she stated that she had mixed the Morphine 15mg/cc in D5OW and immediately destroyed this compound rather than wait to have it destroyed in the proper manner. (Item #15).
15. State statute prohibits any person from refusing or failing to make, keep, or furnish any record, notification, order form, statement, invoice or information required under Iowa Code Chapter 204. Federal law and board rule require that controlled substance records shall be maintained in a readily retrievable manner and in a manner to establish receipt and distribution of controlled substances. Respondent's entire record keeping system for controlled substances failed to meet these requirements. In addition, the following

prescriptions contained in Exhibit 1, exhibit further record keeping deficiencies:

a) Rx 615642 Oxycodone/Acetaminophen dispense #496 tablets dated 4-29-89. The notation indicates this medication was discontinued on 4-29-89. This prescription was signed by Dr. David Seitz and the prescription label states that the prescription was issued on 5-1-89. There is no notation concerning the amount of Oxycodone/Acetaminophen returned to stock. (Item #24)

b) Rx 621179 Morphine S04 30 mg Syringe 1 mg/cc dispense #240 (8 x 30 cc) dated 6-17-89 was dispensed by Candace Canik, and delivered to the Nursing Home. The Nursing Home records signed by Karen Truesdell and Jo Swanberg RN state the 8 syringes were returned to stock. No notation appears on the prescription that indicates these syringes were returned to stock. (Item #25)

c) Rx 621088 Morphine S04 30 mg Syringe 1 mg/cc dispense #240 (8 x 30 cc) dated 6-16-89 was dispensed by Karen Truesdell, and delivered to the Nursing Home. The Nursing Home records signed by Karen Truesdell and Jo Swanberg RN state the 8 syringes were returned to stock. No notation appears on the prescription that indicate these syringes were returned to stock. (Item #26)

d) Rx 616227 Morphine dispense #60 dated 5-4-89, with the notation 300 mg. This would indicate that 60 doses of 5 mg/cc were dispensed by pharmacist Candace Canik. The administration records of the Nursing Home indicate that the item received was type of a vial or PCA pump. (Item #12)

e) Rx 618272 Oxycodone/Acetaminophen dispense #31 dated 5-23-89 contains the notation #32 were returned. How do you return more than was dispensed? (Item #13)

f) Rx 636733 Methylphenidate 10 mg dispense 90 tablets was written by Dr. Solis on 10-25-89. One dispensing record indicates this prescription was filled 10-25-89 by M.E. Fritz (signed) while a second computer label indicates this prescription was filled 10-28-89 by pharmacist MEF. (Item #9)

g) Board rule requires that when an automated patient record system is used, either a bound log book or separate file of daily statements signed by each dispensing pharmacist must be maintained which state refill information is correct or there must be a daily printout of each day's controlled substance prescription refill information. The printout provided by Respondent is missing many complete days. (Exhibit 3)

16. Board rule requires that a pharmacy maintain sufficient security to protect against loss or theft of drugs. Two audits were conducted by Investigator Sheldon for the periods from 5-1-89 to 11-17-89 and 11-17-89 to 2-22-90. (State's Exhibit 1, Item #2; Exhibit 2, Item #3) Each audit showed significant percentages of schedule II controlled substances that could not be accounted for. Large losses were noted. Prior to the audits, security at Main at Locust Pharmacy was completely deficient. All of the pharmacists, a technician, and two bookkeepers had keys to the pharmacy and knew the

safe's combination. The safe was kept in the office. Delivery personnel, clerks, and salespersons all had access to the prescription department. (State's Exhibits 1; 2; Testimony of Respondent; Respondent's Exhibit A)

17. Since the investigation and audits, Respondent has significantly improved both the record keeping and security of the pharmacy. New software was purchased for the computer and is operational. New inventory methods and emergency prescription procedures have been instituted. The pharmacy has been extensively remodeled to provide greater security. Two new safes have been purchased and placed in the prescription department. The manager randomly changes the combinations. (Testimony of Clarence Christiansen; Respondent; Respondent's Exhibit A)

CONCLUSIONS OF LAW

1. Iowa Code section 204.306 (1989) provides in relevant part:

204.306 Records of Registrants.

Persons registered to manufacture, distribute, dispense, or administer controlled substances under this chapter shall keep records and maintain inventories in conformance with the record keeping and inventory requirements of federal law and with such additional rules as may be issued by the board. A practitioner who engages in dispensing any controlled substance to the practitioner's patients shall keep records of receipt and disbursements of such drugs, including dispensing or other disposition, and information as to controlled substances stolen, lost, or destroyed. In every such case the records of controlled substance received shall show the date of receipt, the name and address of the person from whom received, and the kind and quantity of drugs received. The record of all controlled substances dispensed or otherwise disposed of, shall show the date of dispensing, the name and address of the person to whom or for whose use, or the owner and species of animal for which the drugs were dispensed and the kind and quantity of drugs dispensed.

Every such record shall be kept for a period of two years from the date of the transaction recorded. Records of controlled substances lost, destroyed or stolen, shall contain a detailed list of kind and quantity of such drugs and the date of the discovery of such loss, destruction, or theft.

* * *

2. Iowa Code section 204.307 (1989) provides:

204.307 Order forms.

Controlled substances in schedules I and II shall be distributed by a registrant to another registrant only

pursuant to an order form. Compliance with the provisions of federal law respecting order forms shall be deemed compliance with this section.

3. Iowa Code section 155A.12 (1989) provides, in part, the following:

The board may refuse to issue or renew a license or may impose a fine, issue a reprimand, or revoke, restrict, cancel, or suspend a license, and may place a licensee on probation, if the board finds that the applicant or licensee had done any of the following:

1. Violated any provision of this chapter or any rules of the board adopted under this chapter.

....

4. Failed to keep and maintain records required by this chapter or failed to keep and maintain complete and accurate records of purchases and disposal of drugs listed in the controlled substances Act.

5. Violated any provision of the controlled substances Act or rules relating to that Act.

4. 657 Iowa Administrative Code 6.8(1)(5) and (6) provide:

657-6.8(155A) Records. Every inventory or other record required to be kept under Iowa Code chapter 204, and 155A or 657-Chapter 6 shall be kept by the pharmacy and be available for inspections and copying by the board or its representative for at least two years from the date of the inventory or record. Controlled substance records shall be maintained in a readily retrievable manner in accordance with federal requirements. Those requirements, in summary, are as follows:

6.8(1) Controlled substance records shall be maintained in a manner to establish receipt and distribution of all controlled substances;

* * *

6.8(5) Copy 1 of DEA Order Form 222C, furnished by the pharmacy or practitioner to show Schedule II controlled substances are distributed, shall be maintained by the distributing pharmacy and shall show the quantity of controlled substances distributed and the actual date of distribution;

6.8(6) Copy 3 of DEA Order Form 222C shall be properly dated, initialed, and filed and shall include all copies of each unaccepted or defective order form and any attached statements or other documents;

5. The preponderance of the evidence established that Respondent's inadequate record keeping violated Iowa Code sections 204.306, 204.307, 155A.12(4) (1989) and 657 Iowa Administrative Code 6.8(1)(5) and (6). (Findings of Fact 5, 11, 15)
6. 657 Iowa Administrative Code 10.10 provides in relevant part:

657-10.10(204) Security requirements generally. All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a person has provided effective controls against diversion, the board shall use the security requirements set forth in these rules as standards for the physical security controls and operating procedures necessary to prevent diversion. Substantial compliance with these standards may be deemed sufficient by the board after evaluation of the overall security system and needs of the applicant or registrant.

10.10(1) Security requirements of substances in possession of the registrant. Physical security controls shall be commensurate with the schedules and quantity of controlled substances in the possession of the registrant in normal business operation.

* * *

10.10(3) Factors in evaluating physical security systems. In evaluating the overall security system of a registrant or applicant necessary to maintain effective controls against theft or diversion of controlled substances, the board may consider any of the following factors as it may deem relevant to the need for strict compliance with the requirements of this rule:

- a. The type of activity conducted;
- b. The quantity of controlled substances handled;
- c. The location of the premises and the relationship such location bears on security needs;
- d. The type of building construction comprising the facility and the general characteristics of the building or buildings;
- e. The type of vault, safe and secure enclosures available;
- f. The type of closures on vaults, safes and secure enclosures;
- g. The adequacy of key controls systems or combination lock controls systems;
- h. The adequacy of electric detection and alarm systems, if any;
- i. The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;
- j. The procedures for handling business guests, visitors, maintenance personnel and nonemployee service personnel;
- k. The availability of local police protection or of the registrant's or applicant's security personnel, and;
- l. The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution and disposition of controlled substances in its operations.

7. The preponderance of the evidence established that the security system in place at Main at Locust Pharmacy at the time of this investigation was totally inadequate to protect against theft or diversion of controlled substances. The security was particularly deficient when the number of employees and large amount of controlled substances regularly dispensed are considered. Moreover, the Respondent's methods for monitoring the receipt, distribution and disposition of controlled substances was completely inadequate. Respondent could not explain these losses. Respondent has violated 10.10. (Findings of Fact 5, 6, 8, 11, 15, 16)

8. Iowa Code section 155A.27(1)(c) (1989) provides:

155A.27 Requirements for prescription.

Each prescription drug order issued or filled in this state:

1. If written, shall contain:

* * *

c. The name, strength, and quantity of the drug, medicine, or device prescribed.

The preponderance of the evidence established that Respondent violated Iowa Code section 155A.27(1)(c) (1989) when numerous prescriptions failed to state the quantity of drug dispensed. (Finding of Fact 9)

9. Iowa Code section 204.308(1) (1989) provides:

204.308 Prescriptions.

1. Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, no controlled substance in schedule II may be dispensed without the written prescription of a practitioner.

The preponderance of the evidence established that Respondent violated Iowa Code section 204.308(1) (1989) when prescriptions lacking a physician's signature were filled and a signed prescription was filled with more than the authorized doses. (Finding of Fact 12)

10. 657 Iowa Administrative Code 10.11 provides in relevant part:

657-10.11(204) Manner of issuance of prescriptions.

All prescriptions for controlled substances shall be dated as of, and manually signed on, the date when issued and shall bear the full name and address and registration number of the practitioner. A practitioner must manually sign a prescription in the same manner the practitioner would sign a check or legal document. Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the

practitioner. The prescriptions may be prepared by a secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by those regulations.

* * *

The preponderance of the evidence established that Respondent violated 657 Iowa Administrative Code 10.11 when she filled a prescription on which the amount to be dispensed had been written over or altered. (Finding of Fact 13)

11. 657 Iowa Administrative Code 10.13(1) and (4) provide:

657-10.13(204) Controlled substances listed in schedule II—requirement of prescription. In the case of an emergency situation, as defined by 10.13(5), a pharmacist may dispense a controlled substance listed in schedule II upon receiving oral authorization of a prescribing individual practitioner, provided that:

10.13(1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription manually signed by the prescribing individual practitioner);

* * *

10.13(4) Within 72 hours after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the 72-hour period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the board if the prescribing individual fails to deliver a written prescription. Failure of the pharmacist to do so shall void the authority conferred by this subrule to dispense without a written prescription of a prescribing individual practitioner.

The preponderance of the evidence established that Respondent violated 657 Iowa Administrative Code 10.13 when she repeatedly allowed emergency prescriptions to be filled for greater than the amount adequate to treat the patient during

the emergency period and allowed physicians to return the written prescription long beyond the 72-hour requirement. (Finding of Fact 10)

12. 657 Iowa Administrative Code 9.1(4) provides in relevant part:

The board may impose any of the disciplinary sanctions set out in subrule 9.1(2), including civil penalties in an amount not to exceed \$25,000, when the board determines that the licensee or registrant is guilty of the following acts or offenses:

....

b. Professional incompetency. Professional incompetency includes but is not limited to:

(1) A substantial lack of knowledge or ability to discharge professional obligations within the scope of the pharmacist's practice.

(2) A substantial deviation by a pharmacist from the standards of learning or skill ordinarily possessed and applied by other pharmacists in the state of Iowa acting in the same or similar circumstances.

....

(4) A willful or repeated departure from, or the failure to conform to, the minimal standard or acceptable and prevailing practice of pharmacy in the state of Iowa.

....

j. Violating a statute or law of this state, another state, or the United States, without regard to its designation as either a felony or misdemeanor, which statute or law relates to the practice of pharmacy.

....

u. Violating any of the grounds for revocation or suspension of a license listed in Iowa Code sections 147.55, 155A.12 and 155A.15.

The preponderance of the evidence established that Respondent's completely deficient record keeping, security, and prescription and emergency prescription filling procedures constitute violations of 657 Iowa Administrative Code 9.1(b)(1), (2) and (4) and 9.1(j) and (u).

DECISION AND ORDER

WHEREFORE, IT IS THE ORDER of the Iowa Board of Pharmacy Examiners that License Number 16831 issued to the Respondent, Lisa C. Burke, shall be placed on probation for a period of one year, subject to the following terms and conditions:

(1) Within thirty (30) days of receipt of this Order, Respondent shall submit to the Board written policies and procedures for the following items:

- a) Instigation and description of a perpetual inventory on all schedule II controlled drugs;
 - b) description of how morphine drips and patient controlled anesthesia will be handled;
 - c) description of how emergency prescriptions for schedule II controlled drugs will be handled for all patients, including nursing facility patients;
 - d) description of record keeping for all controlled drugs;
 - e) description of methodology for controlled drugs audits;
 - f) description of security for the pharmacy area;
 - g) description of procedures for handling returns of controlled drugs from nursing facilities.
- (2) Respondent shall cooperate with monthly audits of all schedule II controlled drugs at Main at Locust Pharmacy while she is the Pharmacist-in-charge.
- (3) During the probationary period, Respondent must successfully pass:
- a) The Federal Drug Law Exam (FDLE) with a score of 75;
 - b) The Iowa Drug Law Exam (IDLE) with a score of 75%.
- (4) During the period of probation, Respondent shall not supervise any registered intern and shall not perform any of the duties of a preceptor.
- (5) Respondent shall obey all federal and state laws and regulations substantially related to the practice of pharmacy.
- (6) Should Respondent leave Iowa to reside or practice outside this state, Respondent must notify the Board in writing of the dates of departure and return. Periods of residency or practice outside the state shall not apply to reduction of the probationary period.
- (7) Should Respondent violate probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation and impose further discipline. If a petition to revoke probation is filed against Respondent during probation, the Board shall have continuing jurisdiction until the matter is final, and the period of probation shall be extended until the matter is final.
- (8) Upon successful completion of probation, Respondent's certificate will be fully restored.

Dated this 25th day of October, 1990.



Melba L. Scaglione, Chairperson
Iowa Board of Pharmacy Examiners



Margaret LaMarche
Administrative Law Judge