BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA

Re: Pharmacy License of
CLINIC PHARMACY,
License No. 607,
Respondent.

Case No. 2006-14

STATEMENT OF CHARGES

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. On February 15, 2005, the Board renewed Respondent general pharmacy license number 607 with Harvey J. Eernisse 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.


5. At all times material to this statement of charges, Respondent was operating a general pharmacy at 804 Kenyon Road, Fort Dodge, Iowa 50501, with Harvey J. Eernisse as the pharmacist-in-charge.

A. CHARGE

COUNT I – OPERATING WITHOUT A LICENSE

Respondent is charged with dispensing drugs and operating a pharmacy without an active license, in violation of Iowa Code §§ 155A.4, 155A.15(1) (2005) and 657 Iowa Administrative Code §§ 36.1(4)(v).

COUNT II – 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 and acceptable and prevailing practice of pharmacy in the state of Iowa.
COUNT III – FAILURE TO MAINTAIN ADEQUATE RECORDS

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).

COUNT IV – FAILURE TO MAINTAIN CONTROL OVER DRUGS

Respondent is charged 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 155A.15(2)(c) and (i) (2005), and 657 Iowa Administrative Code §§ 6.2, 6.7 and 36.1(4)(u).

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 8th day of March 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, Iowa 50319
BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA

Re: Pharmacist License of
CLINIC PHARMACY License No. 607,
Respondent. ) Case No. 2006-14

EMERGENCY ORDER

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 Clinic Pharmacy possesses pharmacy license number 607 issued by the Board. A Statement of Charges was filed against Respondent on March 8, 2006. 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

A. On February 15, 2005, the Board renewed – for the 2005 calendar year – Respondent's license to operate a pharmacy, as evidenced by license number 607 and subject to the laws of the State of Iowa and the rules of the Board.

B. Respondent was, at all material times, operating a pharmacy at 804 Kenyon Road, Fort Dodge, Iowa 50501.

C. On February 23, 2006, the board commenced an investigation of Respondent which revealed the following facts, which the Board hereby finds:

1. Respondent's pharmacist-in-charge is Harvey J. Eernisse. Eernisse is the owner, the pharmacist-in-charge, and the primary pharmacist at Respondent. No technicians work at
the pharmacy.
2. Respondent's license to operate a pharmacy expired on December 31, 2005, and has not been renewed.
3. Harvey J. Eernisse's license to practice pharmacy expired on June 30, 2004, and has not been renewed.
4. On February 23, 2006 Eernisse was working as a pharmacist at Respondent-pharmacy and Respondent was open for business and dispensing medications.
5. Inspection of Respondent revealed 21 areas of non-compliance with regulations, including the following:
   a. A prescription medication (Gastroview) was being dispensed without a prescription.
   b. Significant quantities of outdated medications were contained on Respondent's dispensing shelves and were likely being dispensed after their expiration dates.
   c. Prescription records – including records relating to controlled substances – were incomplete.
   d. An audit of schedule II controlled substances revealed fifteen shortages.
   e. Equipment, such as the medication refrigerator, was not being properly maintained and the pharmacy was dirty.
   f. No policies and procedures for pharmacy operation were in place.
   g. Unlabeled prescription vials for schedule II medications were found on Respondent's dispensing shelves.

D. The Board finds that the evidence assembled during the investigation of Respondent supports the March 8, 2006 Statement of Charges against Respondent. The Board also finds that Respondent has violated the provisions of Iowa Code Chapter 155A and Chapter 657 of the Iowa Administrative Code in the manner alleged in the Statement of Charges.

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

1. Respondent-pharmacy is operating without an active pharmacy license.
2. Respondent is operated by a pharmacist-in-charge whose license has expired (the license expired June 30, 2004). No other pharmacist or technician works a significant amount of time in the pharmacy.
3. Respondent maintains incomplete records of medications dispensed. These incomplete records relate, in part, to controlled substances.
4. Respondent's inventory includes a significant number of out-of-date medications. It is likely that these medications have been dispensed to customers of the pharmacy.
5. Respondent's practice of operating without a license, operating under the direction of an
unlicensed pharmacist-in-charge, dispensing out-of-date medications and failing to maintain records relating to the dispensing of medications, including controlled substances, constitutes an immediate and continuing threat to the public health, safety and welfare.

6. There is no evidence to indicate that the manner of operation of Clinic Pharmacy is short-term, accidental, the result of a misunderstanding as to appropriate pharmacy practices or other mistake. For example, the pharmacist license of the pharmacist-in-charge expired approximately 20 months ago. Also, the pharmacist-in-charge expressed awareness shortly after a compliance officer arrived at Respondent-pharmacy— that his pharmacist license had expired and that the pharmacy was in violation of regulations.

F. The Board finds that immediate, emergency action must be taken for the reason that if Respondent is allowed to continue to operate as a pharmacy, the public health, safety and welfare will be threatened by improper and unlawful practices related to dispensing medications to members of the public. Moreover, because the pharmacist-in-charge is unlicensed and there are no other full time employees of the pharmacy, there exists no person legally authorized to maintain the security of the records and drugs (including controlled substances) contained in the pharmacy.

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

1. Immediate suspension of Respondent’s pharmacy license.
2. Issuance of an order directing that Respondent’s pharmacy license shall remain suspended until satisfactory evidence of Respondent’s ability to resume pharmacy operations has been provided to the Board.
3. The quarantine or secure storage of prescription medications in Respondent's inventory until such time as such inventory can be lawfully dispensed and sold.

III. CONCLUSIONS OF LAW

A. 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, prevent Respondent from operating safely as a pharmacy.

B. 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:

A. Pursuant to Iowa Code § 17A.18A, chapter 155A (2005) and 657 Iowa Administrative Code § 35, the pharmacy license of Clinic Pharmacy is suspended indefinitely. This suspension is effective immediately upon issuance of this order.

B. Respondent's inventory shall be quarantined or placed in secure storage by the Board until such time as Respondent is authorized by the Board to dispense or sell such inventory.

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

D. A hearing regarding this Emergency Adjudicative Order and the Statement of Charges against Respondent shall be held on March 27, 2006. The hearing will commence at 10:00 a.m. and be held at the office of the Iowa Board of Pharmacy Examiners, 400 Southwest Eighth Street, Suite E, Des Moines, Iowa 50309.

DATED this 8th day of March 2006.
BEFORE THE BOARD OF PHARMACY EXAMINERS 
OF THE STATE OF IOWA

Re: Pharmacist License of: DIA NO: 2006-14
HARVEY J. EERNISSE ) DIA NO. 06PHB018
License No. 13015 )
Respondent )

and:

Pharmacy License of )
CLINIC PHARMACY )
License No. 607 )
Respondent )

On March 8, 2006, the Iowa Board of Pharmacy Examiners (Board) found probable cause to file Statements of Charges against Harvey J. Eernisse (Respondent), a registered pharmacist, and against Clinic Pharmacy (Respondent), a licensed pharmacy.

The Statements of Charges alleged that Respondent Eernisse:

COUNT I: DISPENSING AND PRACTICING WITHOUT A LICENSE
Violated Iowa Code sections 155A.4, .7, and .12(1)(2005) and 657 IAC 36.1(4)(v) by dispensing and practicing pharmacy without an active license.

COUNT II: DEPARTURE FROM PROFESSIONAL STANDARDS
Violated Iowa Code section 155A.12(1)(2005) and 657 IAC 36.1(4) by willful and repeated departures from, and a failure to conform to, the minimal standard and acceptable and prevailing practice of pharmacy in the state of Iowa.

COUNT III: INADEQUATE RECORD KEEPING
Violated Iowa Code sections 124.308(3), 155A.12(4), 155A.12(5) and 155A.27 (2005) and 657 IAC 6.2, 6.8, 8.15 & 36.1(4)(a)(c) and 21 CFR 1304.11 & 1306.22(b)(3) by exhibiting inadequate record keeping relating to controlled substances.

COUNT IV: VIOLATION OF CONTROLLED SUBSTANCES

The Statement of Charges alleged Respondent Clinic Pharmacy:
COUNT I: OPERATING WITHOUT A LICENSE
Violated Iowa Code sections 155A.4, 155A.15(1)(2005) and 657 IAC 36.1(4)(v) by dispensing drugs and operating a pharmacy without an active license.

COUNT II: LACK OF PROFESSIONAL COMPETENCY
Violated Iowa Code section 155A.15(2)(c)(2005) and 657 IAC 36.1(4)(b) by willful and repeated departures from, and a failure to conform to, the minimal standard and acceptable and prevailing practice of pharmacy in the state of Iowa.

COUNT III: FAILURE TO MAINTAIN ADEQUATE RECORDS
Violated Iowa Code sections 155A.15(2)(c) and 155A.15(2)(h)(2005) and 657 IAC 36.1(4)ac by failing to maintain adequate records of purchases, distribution and disposal of drugs listed in the controlled substances act.

COUNT IV: FAILURE TO MAINTAIN CONTROL OVER DRUGS
Violated Iowa Code sections 124.308(3), 124.402(1)(a), 155A.15(2)(c) and 155A.15(2)(i)(2005) and 657 IAC 6.2, 6.7 and 36.1(4)(u) by failing to maintain accurate control over and accountability for drugs, including controlled substances.

The hearing on the Statements of Charges was held on March 27, 2006 at 10:00 a.m. at the Board's offices in Des Moines, Iowa. The following members of the Board presided: Michael J. Seifert, Chairperson; Katherine A. Linder; Vernon H. Benjamin; Paul Abramowitz, and Kathleen Halloran. The Respondent appeared personally. Assistant Attorney General Scott Galenbeck represented the state. Administrative Law Judge John M. Priester assisted the Board in conducting the hearing and was instructed to prepare the Board's written Decision and Order, in conformance with their deliberations.

THE RECORD

The record includes the Statements of Charges filed against Respondents Harvey J. Eernisse and Clinic Pharmacy on March 8, 2006; Notice of Hearing; the testimony of the witnesses, and the following exhibits:

Exhibit 1: Statement of Charges, Harvey J. Eernisse, Pharmacist License No. 13015;
Exhibit 2: Statement of Charges, Clinic Pharmacy, Pharmacy License No. 607;
Exhibit 3: Emergency Order, Clinic Pharmacy, Pharmacy License No. 607;
Exhibit 4: Return of Service-Clinic Pharmacy; Harvey J. Eernisse;
Exhibit 5: Investigative Report, dated February 26, 2006;
Exhibit 6: Addendum to Investigative Report, dated March 3, 2006;
Exhibit 7: Letter from Michael W. Stitt, M.D., dated March 16, 2006;
FINDINGS OF FACT

1. On June 17, 1964, Respondent Harvey J. Eernisse was issued license number 13105 to engage in the practice of pharmacy, subject to the laws of the state of Iowa and the rules of the Board. The Respondent owns and operates Clinic-Pharmacy, which has been issued License No. 607 to operate a pharmacy in Fort Dodge, Iowa. Respondent Eernisse’s license expired on June 30, 2004. Respondent Clinic Pharmacy’s general pharmacy license expired on December 31, 2005. (Exhibits 1, 2; Testimony of Respondent)

2. Jean Rhodes, an investigator with the Iowa Board of Pharmacy Examiners, conducted a routine inspection of the Respondent’s pharmacy on February 26, 2006. At that time Respondent Eernisse was practicing as a pharmacist with an expired license and the Clinic Pharmacy’s license had expired on December 31, 2005 and had not been renewed. (Testimony of Jean Rhodes; Exhibit 1, 2, 5)

3. Investigator Rhodes conducted an inspection and a Schedule II audit of the Clinic Pharmacy. The inspector found 21 areas of non-compliance, including the following:

   • There were no policies and procedures for any operation of the pharmacy;
   • The Iowa law manual was outdated;
   • Schedule II substance, fentanyl injection, had receipts, no disbursements, and was not found during the inventory taken for the audit, resulting in a shortage of 240;
   • Schedule II audit revealed many shortages, including oxycodone ER 20mg;
   • 21 of 24 DEA 222 forms had not been filled in by the purchaser;
   • Gastrotrov, a prescription medication, was being dispensed without a prescription;
   • During the inspection, two boxes of outdated medications were pulled from the dispensing shelves, including controlled substances, legend medications, and refrigerated medications;
   • Medication refrigerator had frozen over and was filthy. Dispensing shelves were dusty.

   (Testimony of Jean Rhodes, Exhibit 5)

4. The Respondent testified and did not challenge any of the Inspector’s testimony. The Respondent explained that this all goes back ten years ago. He was in a partnership with another who embezzled from the business. It was eventually determined that the Respondent was responsible for a bill between $200,000 and $300,000. The Respondent has been personally liable for this debt and he has been trying very hard to pay off the debt. The Respondent is contemplating filing bankruptcy to discharge the debt.

   The Respondent hopes to continue practicing as a pharmacist. He hopes to act as a relief pharmacist and he will not longer operate his own pharmacy. The Respondent needs to continue working to make a living.

   The Respondent provided two letters from physicians. One indicated that the Respondent “suffers from adjustment disorder with depression and anxiety. It is not a psychiatric disorder or
impairment, rather it is an emotional status deemed to be appropriate under the process he is going through. The intense feelings of depression, anxiety, shame, guilt, etc., are through symptom formation. The recommendation is that he engage in talk therapy and use medications to help attenuate such emotions.”

(Testimony of Respondent Eernisse, Exhibit 8)

CONCLUSIONS OF LAW

The Iowa Board of Pharmacy Examiners was created pursuant to Iowa Code section 147.13 and has been empowered by statute with general authority to adopt all necessary and proper rules to implement and interpret Iowa Code chapters 147 and 155A. Iowa Code § 147.76. In addition, the legislature has vested the Board with authority to promulgate rules interpreting, implementing and enforcing the Iowa Drug, Device, and Cosmetic Act. Iowa Code §§ 126.2(3); 126.10(8); 126.11(2); 126.17.

The declared purpose of Iowa Code chapter 155A is to promote, preserve, and protect the public health, safety and welfare through the effective regulation of the practice of pharmacy and the licensing of pharmacies, pharmacists, and others engaged in the sale, delivery, or distribution of prescription drugs and devices or other classes of drugs or devices which may be authorized. Iowa Code § 155A.2.

Iowa law provides that a “person shall not dispense prescription drugs unless that person is a licensed pharmacist or is authorized by section 147.107 to dispense or distribute prescription drugs.” Iowa Code § 155A.4. Additionally, the law states that a “person shall not engage in the practice of pharmacy in this state without a license.” Iowa Code § 155A.7.

Iowa Code section 155A.12(1)(2005) authorizes the board to impose a fine, issue a reprimand, or revoke, restrict, cancel, or suspend a license, or place a license on probation, if the board finds that the licensee has violated any provision of Iowa Code chapter 155A or any rules of the Board adopted under Iowa Code chapter 155A.

Another basis of punishment is a failure “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.” Iowa Code § 155A.12(4). Also, if a licensee violates “any provisions of the controlled substances Act or rules relating to that Act” the licensee shall be disciplined. Iowa Code § 155A.12(5).

“A pharmacy subject to section 155A.13 shall not be operated until a license or renewal certificate has been issued to the pharmacy by the board.” Iowa Code § 155A.15(10). Iowa law also provides that, with respect to a pharmacy, 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 license on probation, if the board finds that the applicant or licensee has done any of the following:

...
c. Violated any provision of this chapter or any rule adopted under this chapter or that any owner or employee of the pharmacy has violated any provision of this chapter or any rule adopted under this chapter.

... 

h. Failed to keep and maintain records as required by this chapter, the controlled substances Act, or rules adopted under the controlled substances Act.

i. Failed to establish effective controls against diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels as provided by this chapter and other Iowa or federal laws or rules.

Iowa Code § 155A.15(2)

The Iowa Controlled Substances Act is found in Iowa Code chapter 124. This Act provides requirements for keeping records in section 124.306. “Prescriptions shall be retained in conformity with the requirements of section 124.306.” Iowa Code § 124.308(3). The Act also makes it unlawful for any person “who is subject to division III to distribute or dispense a controlled substance in violation of section 124.308.” Iowa Code § 124.402(1)(a).

The Board has promulgated administrative rules to effectuate the Code’s requirements. 657 IAC 36.1(4)(i) provides, in relevant part, that the board may impose any of the disciplinary sanctions set out in subrule 36.1(2) when the board determines that the licensee is guilty of willful or repeated violations of a lawful rule or regulation promulgated by the board of pharmacy examiners.

657 IAC section 6.2(1) provides in relevant part:

657-6.2(155A)Personnel

6.2(1) Pharmacist in charge. Each pharmacy shall have one pharmacist in charge who is responsible for, at a minimum, the following:

... 

k. Legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, or regulations governing the practice of pharmacy.

657 IAC chapter 6 provides, in relevant part:

657-6.7 Procurement and storage of drugs. The pharmacist in charge shall have the responsibility for procurement and storage of drugs.

... 

6.7(3) Out-of-date drugs or devices.

... 

b. Outdated drugs or devices shall be removed from dispensing stock and shall be quarantined until such drugs or devices are disposed of properly.

...
657-6.8(155A) Records. Every inventory or other record required to be kept under Iowa Code chapters 124 and 155A or 657-Chapter 6 shall be kept at the licensed location of the pharmacy and be available for inspection and copying by the board or its representative for at least two years from the date of the inventory or record except as otherwise required in this rule. Controlled substances records shall be maintained in a readily retrievable manner in accordance with federal requirements. Those requirements, in summary, are as follows:

6.8(6) Copy 3 of DEA Order Form 222 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.

6.8(8) Suppliers' invoices of prescription drugs and controlled substances shall clearly record the actual date of receipt by the pharmacist or other responsible individual.

The administrative rules state that the "board may impose any of the disciplinary sanctions set out in subrule 36.1(2) when the board determines that the licensee, registrant, or permittee is guilty of the following acts:

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 or the distribution of controlled substances, prescription drugs, or nonprescription drugs.

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

l. Practicing pharmacy without an active license and current Iowa pharmacist license, operating a pharmacy without a current pharmacy license . . .

ac. Failing to create and maintain complete and accurate records as required by state or federal law, regulation, or rule of the board.

657 IAC 36.1(4)

The preponderance of the evidence established that Respondent Eernisse was dispensing and practicing pharmacy without a license. His actions showed a lack of professional competency and a departure from professional standards as demonstrated by willful and repeated departures from and a failure to conform to the minimum standards and acceptable prevailing practice of pharmacy in the state of Iowa. The Respondent also is found to have inadequate record keeping relating to controlled substances and violated controlled substances laws.
The preponderance of the evidence also established that Respondent Clinic Pharmacy was dispensing drugs and operating without an active license. The Respondent Clinic Pharmacy also is found to lack professional competency as demonstrated by willful and repeated departures from, and a failure to conform to, the minimum standard and acceptable and prevailing practice of pharmacy in the state of Iowa. The Clinic Pharmacy is found to have failed to maintain complete and adequate records of purchases, distribution and disposal of drugs listed in the controlled substances act. The Clinic Pharmacy also failed to maintain accurate control over and accountability for drugs, including controlled substances.

Order

IT IS THEREFORE ORDERED that pharmacist license no. 13015, issued to Harvey J. Eernisse, and pharmacy license no. 607, issued to Clinic Pharmacy, are hereby indefinitely suspended. This indefinite suspension shall remain in place until the Respondent satisfies the following terms and conditions:

1) The Respondent shall submit to a full psychiatric evaluation performed by a board-approved psychiatrist and any recommended treatment. The Respondent will not be eligible for licensure until his situational depression has been addressed and a psychiatrist affirms in writing to the Board that Respondent's condition will not affect his ability to practice pharmacy.

2) TheRespondent shall complete 75 hours of continuing education. At least 50% of these hours shall be in drug therapy. Six hours of continuing education must address controlled substance record keeping and personnel policy and procedures for handling and disbursing controlled substances.

3) The Respondent shall apply for and register as a Pharmacy Intern. He shall complete an 80-hour minimum internship with a Board-approved pharmacist. The Respondent shall send written verification of this internship to the Board when completed.

4) When these terms and conditions are complete the Respondent shall petition the Board in person for reinstatement.

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

Dated this 20th day of April, 2006.

Michael Seifert, Chairperson
Iowa Board of Pharmacy Examiners

cc: Scott Galenbeck, Assistant Attorney General
    Respondent

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