

BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA

Re:	:	
Pharmacy License Application of	:	
WILDEN PHARMACY, INC.	:	
717 Lyon Street	:	ORDER
Des Moines, IA 50309	:	GRANTING LICENSE
	:	WITH RESTRICTIONS

COMES NOW the Iowa Board of Pharmacy Examiners on June 14, 1994, and states as follows:

1. The Iowa Board of Pharmacy Examiners has received a new application for a general pharmacy license for Wilden Pharmacy, Inc., dated June 10, 1994.

2. The Board has considered the license application and has granted preliminary approval. Final approval of the license application is contingent upon receipt of the name of the pharmacist in charge and upon the board's approval of that individual.

3. The pharmacy license, when issued, will be subject to the following restrictions:

a. Steven J. Weiss shall have no involvement in the operation of the pharmacy and shall not be physically present at the pharmacy at any time. Steven J. Weiss may not work in the pharmacy in any capacity. Steven J. Weiss shall not train the new pharmacist in charge with respect to the operation of the equipment and facilities prior to the opening of the pharmacy.

b. Wilden Pharmacy, Inc., shall in no way rely on any existing information contained in the Des Moines Pharmacy's computer system. All prescriptions filled must be new prescriptions which have been issued by an authorized prescriber. New patient profiles shall also be established in the pharmacy computer system.

c. Wilden Pharmacy, Inc., shall pass a formal, routine inspection of the premises conducted by a board inspector prior to commencement of business and before prescription drugs are received and stocked at the pharmacy.

d. Wilden Pharmacy, Inc., shall submit to random, unannounced visits or inspections by the board or agents of the board to verify compliance with this Order and with the statutes and rules regulating the operation of a pharmacy and the practice of pharmacy in the State of Iowa.



Lloyd K. Jessen
Executive Secretary/Director
Iowa Board of Pharmacy Examiners

cc: Theresa O'Connell Weeg
A.A.G.

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

Re:)	EMERGENCY ORDER
Pharmacy License of)	AND
DES MOINES PHARMACY)	COMPLAINT
License No. 242)	AND
Stephen J. Weiss,)	STATEMENT OF CHARGES
Pharmacist in charge,)	AND
Respondent)	NOTICE OF HEARING

NOW on this 4th day of March 1994, the Iowa Board of Pharmacy Examiners has reviewed the following evidence:

1. Respondent is licensed to operate a pharmacy at 717 Lyon Street, Des Moines, Iowa 50309, and holds license number 242.

2. General pharmacy license number 242, issued in the name of Des Moines Pharmacy, Inc., with Stephen J. Weiss as pharmacist in charge, was renewed on February 1, 1994, and is current until December 31, 1994.

3. Stephen J. Weiss is part owner of Des Moines Pharmacy, Inc., 717 Lyon Street, Des Moines, Iowa 50309.

4. The Board has received a complaint which alleges that Stephen J. Weiss dispensed medications by mail to "Jane Doe," a Medicaid recipient who had not requested the medications. A subsequent investigation has revealed that, between August 1992 and April 1993, Stephen J. Weiss mailed or delivered sixty

(60) prescriptions to "Jane Doe" which "Jane Doe" allegedly did not want or need.

The Board has also received investigative information which alleges that Stephen J. Weiss has delivered unneeded and unwanted prescription drugs to "John Doe," a Medicaid recipient. During January 1994, Stephen J. Weiss delivered fifteen (15) prescriptions to "John Doe." In addition, it is alleged that Stephen J. Weiss has delivered unneeded and unwanted prescriptions to "John Doe" for more than two years. Furthermore, Stephen J. Weiss allegedly has failed to conduct effective prospective drug use review, has failed to prevent drug overutilization, and has failed to provide effective patient consultation.

On March 2, 1994, the Board received a written, sworn statement from Stephen J. Weiss dated March 1, 1994, which included certain admissions of wrongdoing. In the statement, Stephen J. Weiss admitted the following: (1) that he routinely mailed out prescription medications every 28 days to Medicaid recipients unless the recipients notified him that they didn't need the drugs; (2) that he mailed out some prescription medications to Medicaid recipients without prescriber authorization; (3) that he allowed Medicaid recipients to return prescription medications which he had previously dispensed to them; (4) that he allowed a Medicaid recipient with AIDS to return the prescription drug, AZT (Zidovudine), for which he gave the patient \$150; (5) that a physician had notified him that she believed he was sending prescription medications to certain Medicaid recipients which they did not need; and (6) that he had told people if they got business for him he would give them \$20 worth of over-the-counter medications.

In addition to the sworn statement, Stephen J. Weiss also notified the Board on March 2, 1994, that unknown quantities of various controlled substances were missing from his pharmacy, the Des Moines Pharmacy, Inc. The missing controlled substances are said to include the following: Xanax, Vicodin,

Tylenol with Codeine No. 3, and Tylenol with Codeine No. 4. Stephen J. Weiss alleged that on September 3, 1993, a pharmacy technician who was employed at his pharmacy confessed to taking unknown quantities of these drugs during the period of her employment. Stephen J. Weiss failed to report this loss of controlled substances from his pharmacy until March 2, 1994.

5. The information contained in paragraph 4, together with other investigative information in the possession of the Board, indicates that the Des Moines Pharmacy, Inc., would pose a threat to the public health and safety if it were allowed to continue to operate.

Based upon the above evidence, the Iowa Board of Pharmacy Examiners finds that the public health, safety, and welfare would be jeopardized if the Des Moines Pharmacy, Inc., were to be allowed to continue to operate until a hearing can be conducted. Therefore, the Board finds that the public health, safety, and welfare makes emergency summary license suspension imperative, and so directs the Executive Secretary-Director to issue such order.

It is the further order of the Board that Stephen J. Weiss shall establish a pre-recorded telephone message on the main, incoming telephone line of the Des Moines Pharmacy, Inc., which shall advise all callers that the Des Moines Pharmacy, Inc., has been closed and that patients needing prescription medication should contact their physician for assistance in obtaining medication from another pharmacy. This shall be done by no later than 5:00 p.m. CST on March 4, 1994. The recorded message and telephone line shall be maintained by Stephen J. Weiss until at least April 19, 1994.

IT IS HEREBY ORDERED, pursuant to the authority of Iowa Code section 17A.18(3), that the license of the Des Moines Pharmacy, Inc., to operate a pharmacy in Iowa be temporarily suspended until such time as a hearing before the Board of Pharmacy Examiners can be conducted.

With this notice, the Board also directs the Executive Secretary-Director of the Iowa Board of Pharmacy Examiners to file a Complaint and Statement of Charges and Notice of Hearing against Respondent, who is a pharmacy licensed pursuant to Iowa Code Chapter 155A. In filing said Complaint and Statement of Charges and Notice of Hearing, the secretary-director alleges that:

6. Marian L. Roberts, Chairperson; Phyllis A. Olson, Vice Chairperson; Phyllis A. Miller; Mary Pat Mitchell; Matthew C. Osterhaus; and Arlan D. Van Norman are duly appointed, qualified members of the Iowa Board of Pharmacy Examiners.

7. Respondent is guilty of violations of 1993 Iowa Code sections 155A.15(2)(c), 155A.15(2)(d), 155A.15(2)(h), 155A.15(2)(i), 155A.19(1)(g), 155A.23(2), and 155A.23(4) by virtue of the allegations contained in paragraph 4.

1993 Iowa Code section 155A.15 provides, in part, the following:

2. ...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:...

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.

d. Delivered without legal authorization prescription drugs or devices to a person other than one of the following:

(1) A pharmacy licensed by the board.

(2) A practitioner.

(3) A person who procures prescription drugs or devices for the purpose of lawful research, teaching, or testing, and not for resale.

(4) A manufacturer or wholesaler licensed by the board.

....

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.

1993 Iowa Code section 155A.19 provides, in part, the following:

1. A pharmacy shall report in writing to the board, pursuant to its rules, the following:...

g. Theft or significant loss of any controlled substance on discovery of the theft or loss.

1993 Iowa Code section 155A.23 provides, in part, the following:

A person shall not:...

2. Willfully make a false statement in any prescription, report, or record required by this chapter.

....

4. Make or utter any false or forged prescription or written order.

8. Respondent is guilty of violations of 657 Iowa Administrative Code sections 6.10, 8.5(1), 8.18, 8.19, 8.20, 9.1(4)(b)(2), 9.1(4)(b)(4), 9.1(4)(c), 9.1(4)(i), 9.1(4)(j), 9.1(4)(t), 9.1(4)(u), and 10.10(5). by virtue of the allegations contained in paragraph 4.

657 Iowa Administrative Code section 6.10 provides the following:

For the protection of the public health and safety, no prescription drugs of any description or items of personal contact nature which have been removed from the original package or container after sale, shall be accepted for return, exchanged, or resold by any pharmacist except as authorized in subrule 8.9(6).

657 Iowa Administrative Code section 8.5 provides, in part, the following:

Unethical conduct or practice. The provisions of this section apply to licensed pharmacists and registered pharmacist-interns.

8.5(1) Misrepresentative deeds. A pharmacist shall not make any statement tending to deceive, misrepresent, or mislead anyone, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in pharmacy or in the operation or conduct of a pharmacy.

657 Iowa Administrative Code section 8.18 provides, in part, the following:

Pharmaceutical care -- patient records.

1. A patient record system shall be maintained by all pharmacies for patients for whom prescription drug orders are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist shall be responsible for making a reasonable effort to obtain, record, and maintain the following information:

- a. Full name of the patient for whom the drug is intended;
 - b. Address and telephone number of the patient;
 - c. Patient's age or date of birth;
 - d. Patient's gender;
 - e. Significant patient information including a list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record during the two years immediately preceding the most recent entry showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber; and
 - f. Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.
- 2.

The pharmacist shall be responsible for making a reasonable effort to obtain for the patient or the patient's caregiver, and shall be responsible for recording any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs, including over-the-counter drugs, or devices currently

being used by the patient which may relate to prospective drug review.

657 Iowa Administrative Code section 8.19 provides the following:

Pharmaceutical care -- prospective drug review. A pharmacist shall review the patient record and each prescription drug order presented for initial dispensing or refilling for purposes of promoting therapeutic appropriateness by identifying:

1. Overutilization or underutilization;
2. Therapeutic duplication;
3. Drug-disease contraindications;
4. Drug-drug interactions;
5. Incorrect drug dosage or duration of drug treatment;
6. Drug-allergy interactions;
7. Clinical abuse/misuse.

Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the prescriber. The review and assessment of patient records shall not be delegated to staff assistants other than pharmacist interns.

657 Iowa Administrative Code section 8.20 provides, in part, the following:

Pharmaceutical care -- patient counseling.

1. Upon receipt of a new prescription drug order and following a review of the patient's record, a pharmacist shall counsel each patient or patient's caregiver. The counseling shall be on matters which, in the pharmacist's professional judgment, will enhance

or optimize drug therapy. Appropriate elements of patient counseling may include:

- a. The name and description of the drug;
- b. The dosage form, dose, route of administration, and duration of drug therapy;
- c. Intended use of the drug, if known, and expected action;
- d. Special directions and precautions for preparation, administration, and use by the patient;
- e. Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
- f. Techniques for self-monitoring drug therapy;
- g. Proper storage;
- h. Prescription refill information;
- i. Action to be taken in the event of a missed dose;
- j. Pharmacist comments relevant to the individual's drug therapy including any other information peculiar to the specific patient or drug.

2. When the patient or the patient's caregiver is present, counseling shall be in person.

3. When the patient or patient's caregiver is not present, the pharmacist shall counsel the patient or patient's caregiver either by initiating telephone discussion or by sending with the medication or device legible written notice including all of the following:

- a. patient-specific information satisfying all elements identified in subrule 8.20(1) and shall include the statement: "If any of this information is unclear or contrary to the instructions of the prescriber, contact the pharmacist at [insert toll-free telephone number]."

b. a statement of the patient's right to request consultation; and

c. a toll-free telephone number at which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

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:...

(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.

c. Knowingly making misleading, deceptive, untrue or fraudulent representations in the practice of pharmacy or engaging in unethical conduct or practice harmful to the public. Proof of actual injury need not be established.

....

i. Willful or repeated violations of the provisions of Iowa Code chapter 147. Willful or repeated violations of this Act include but are not limited to a

pharmacist intentionally or repeatedly violating a lawful rule or regulations promulgated by the board of pharmacy examiners or the state department of health or violating the provisions of Title VII (Public Health) or Title VIII (Practice Acts), Code of Iowa, as amended.

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.

....

t. Obtaining any fee by fraud or misrepresentation.

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(5) provides the following:

A registrant shall report in writing, on forms provided by the board, any theft or significant loss of any controlled substance upon discovery of the theft or loss. The report shall be submitted to the board office within two weeks of discovery of the occurrence.

441 Iowa Administrative Code section 78.2(6) provides the following:

Consultation. In accordance with Public Law 101-508 (Omnibus Budget Reconciliation Act of 1990), a pharmacist shall offer to discuss with each Medicaid recipient or the caregiver of a recipient presenting a prescription, information regarding the use of the medication. The consultation is not required if the

person refuses the consultation. Standards for the content of the consultation shall be found in rules of the Iowa board of pharmacy examiners.

441 Iowa Administrative Code section 79.2(2) provides, in part, the following grounds for sanctioning Medicaid providers:

Sanctions may be imposed by the department [of human services] against a provider for any one (1) or more of the following reasons:...

h. Overutilization of the medical assistance program by inducing, furnishing or otherwise causing the recipient to receive services or merchandise not required or requested by the recipient.

The Iowa Board of Pharmacy Examiners finds that paragraphs 7 and 8 constitute grounds for which Respondent's license to operate a pharmacy in Iowa can be disciplined.

WHEREFORE, the undersigned charges that Respondent has violated 1993 Iowa Code sections 155A.15(2)(c), 155A.15(2)(d), 155A.15(2)(h), 155A.15(2)(i), 155A.19(1)(g), 155A.23(2), and 155A.23(4) and 657 Iowa Administrative Code sections 6.10, 8.5(1), 8.18, 8.19, 8.20, 9.1(4)(b)(2), 9.1(4)(b)(4), 9.1(4)(c), 9.1(4)(i), 9.1(4)(j), 9.1(4)(t), 9.1(4)(u), and 10.10(5).

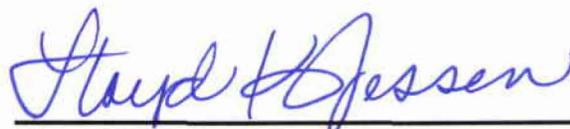
IT IS HEREBY ORDERED, pursuant to Iowa Code section 17A.12 and 657 Iowa Administrative Code section 1.2, that Stephen J. Weiss appear on behalf of Des Moines Pharmacy, Inc., before the Iowa Board of Pharmacy Examiners on Tuesday, April 19, 1994, at 10:00 a.m., in the second floor conference room, 1209 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 discipline the license to operate a pharmacy issued to Des Moines Pharmacy, Inc., on February 1, 1994, 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 its own. If Respondent fails to appear and defend, Iowa Code section 17A.12(3) provides that the hearing may proceed and that a decision may be rendered. The failure of Respondent to appear could result in disciplinary action, including the permanent suspension or revocation of its license.

The hearing will be presided over by the Board which will be assisted by an administrative law judge from the Iowa Department of Inspections and Appeals. The office of the Attorney General is responsible for representing the public interest in these proceedings. Information regarding the hearing may be obtained from Theresa O'Connell Weeg, Assistant Attorney General, Hoover Building, Capitol Complex, Des Moines, Iowa 50319 (telephone 515/281-6858). Copies of all filings with the Board should also be served on counsel.

IOWA BOARD OF PHARMACY EXAMINERS



Lloyd K. Jessen
Executive Secretary/Director