

WISCONSIN DEPARTMENT OF REGULATION & LICENSING



Wisconsin Department of Regulation & Licensing Access to the Public Records of the Reports of Decisions

This Reports of Decisions document was retrieved from the Wisconsin Department of Regulation & Licensing website. These records are open to public view under Wisconsin's Open Records law, sections 19.31-19.39 Wisconsin Statutes.

Please read this agreement prior to viewing the Decision:

- The Reports of Decisions is designed to contain copies of all orders issued by credentialing authorities within the Department of Regulation and Licensing from November, 1998 to the present. In addition, many but not all orders for the time period between 1977 and November, 1998 are posted. Not all orders issued by a credentialing authority constitute a formal disciplinary action.
- Reports of Decisions contains information as it exists at a specific point in time in the Department of Regulation and Licensing data base. Because this data base changes constantly, the Department is not responsible for subsequent entries that update, correct or delete data. The Department is not responsible for notifying prior requesters of updates, modifications, corrections or deletions. All users have the responsibility to determine whether information obtained from this site is still accurate, current and complete.
- There may be discrepancies between the online copies and the original document. Original documents should be consulted as the definitive representation of the order's content. Copies of original orders may be obtained by mailing requests to the Department of Regulation and Licensing, PO Box 8935, Madison, WI 53708-8935. The Department charges copying fees. *All requests must cite the case number, the date of the order, and respondent's name as it appears on the order.*
- Reported decisions may have an appeal pending, and discipline may be stayed during the appeal. Information about the current status of a credential issued by the Department of Regulation and Licensing is shown on the Department's Web Site under "License Lookup." The status of an appeal may be found on court access websites at: <http://ccap.courts.state.wi.us/InternetCourtAccess> and <http://www.courts.state.wi.us/wscqa>.
- Records not open to public inspection by statute are not contained on this website.

By viewing this document, you have read the above and agree to the use of the Reports of Decisions subject to the above terms, and that you understand the limitations of this on-line database.

Correcting information on the DRL website: An individual who believes that information on the website is inaccurate may contact the webmaster at web@drl.state.wi.gov

FILE COPY

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY
PROCEEDINGS AGAINST

FINAL DECISION AND ORDER

HEALTH PHARMACIES, INC.,
RESPONDENT

95 PHM 22

The parties to this action for the purposes of §227.53, Wis. Stats., are:

Health Pharmacies, Inc.
4233 West Beltline Highway
Madison, WI 53711

Wisconsin Pharmacy Examining Board
P.O. Box 8935
Madison, WI 53708-8935

Department of Regulation and Licensing
Division of Enforcement
P.O. Box 8935
Madison, WI 53708-8935

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final decision of this matter, subject to the approval of the Board. The Board has reviewed this Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following:

FINDINGS OF FACT

1. Respondent Health Pharmacies, Inc., is and was at all times relevant to the facts set forth herein a community pharmacy licensed in the State of Wisconsin pursuant to license #7387.

2. Respondent is under investigation for exceeding the legal limits for compounding and thus being a manufacturer, of making certain recordkeeping errors with respect to controlled substances dispensed by it and its staff, and dispensing in a manner inconsistent with state law and the Food Drug & Cosmetic Act. Respondent denies that it engaged in the conduct for which it is being investigated, but desires to settle this matter solely to avoid the expenses and uncertainties of litigation.

3. Respondent did, in 1992 and 1993, receive several thousand capsules of estrogen and progesterone which had been prepared by another pharmacy, which respondent dispensed to patients in its own containers. The use of respondent's containers incorrectly represented that respondent's own staff had compounded the medications. Respondent discontinued such actions voluntarily in 1993.

4. Respondent did, on or about April 20, 1994, apply to the Board to change the location of the pharmacy. Prior to May 5, 1994, the Board requested additional information from respondent, which was received by the Board on May 5, 1994. On September 22, 1994, by letter from the Board, respondent was again advised that such location change was not approved and

- C. No compounded drug product shall be delivered, dispensed, or otherwise transferred to another pharmacy for dispensing to a patient unless respondent has informed that pharmacy that the portion of the medication container label showing the name, address and telephone number of Health Pharmacies, Inc. must appear on the medication container dispensed to the patient, and Health Pharmacies, Inc. makes and documents direct telephone contact with each patient to provide a consultation.
- D. No substance shall be delivered, dispensed, or otherwise transferred to a practitioner's office more than once unless the practitioner certifies in writing that in-office administration of the substance to the practitioner's patients is medically necessary, and the quantities of such substance are reasonable under the circumstances to provide only that amount of product which will carry the patient from the time the practitioner administers the drug until a prescription can be presented to, and dispensed by, a pharmacy for that patient. In the absence of other evidence, such a period of time shall be presumed to be ten calendar days. The form of such certification shall be approved by the Board or its designee, which approval shall not be unreasonably withheld. The amount, if any, to be charged by respondent for the above permitted transfer of office supplies is within respondent's discretion. Except as permitted above, respondent shall not provide any "office samples" or other free or reduced-price products to practitioners. Records of office supplies provided to practitioners shall be clearly distinguishable from prescription dispensing records, and shall be readily retrievable and verifiable.
- E. Respondent shall compound only the number or quantity of medication called for by the initial-fill quantities stated on the prescriptions respondents have actually received at the time the compounding is commenced, or on the basis of prescriptions respondent has received in the past 30 days. Respondent may, in the case of capsules, round that number up to the number of capsules held by the pharmacy's equipment. Respondent shall not accept, compound or dispense two or more prescriptions for the same formula to the same patient at the same time, in an effort to evade the limitations of this paragraph. All drug products shall be dispensed and labeled with "beyond use" dates of six months from the date of compounding or 25% of the time before the expiration date of any component used in the compounding, whichever is nearer; any medication which will not be so used shall be discarded. Respondent may use any other beyond-use date which can be supported by reasonable stability testing.
- F. Respondent shall not provide reprints, articles or other printed materials purporting to state that the active ingredients in respondents' products, or formulae similar to those used by respondent, are safe or effective unless those articles were published in refereed journals. Respondent shall not promote directly or through another, any particular formula or dosage of any drug or drug product which they compound. Upon request, respondent shall submit all promotional and informational materials in use at that time (and for the year preceding the request) to the Board for review by the Board or its designee. Such submission is for informational purposes only. All material intended to be sent to practitioners or patients shall bear the date of printing. All reprints of articles or similar materials shall bear the disclaimer: "Reprinted for promotional purposes by Health Pharmacies, Inc." or similar wording.
- G. Respondent shall provide to any requesting licensed pharmacy (or pharmacist) which a patient desires to use with respondents' complete ingredient list and formula for any prescription which it has compounded for that patient, and shall make no statement concerning price, difficulty, or other issue which could reasonably be interpreted as an attempt to discourage the patient-selected pharmacy or pharmacist from compounding the prescription. If, in the course of transmitting all information necessary to truthfully describe

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY
PROCEEDINGS AGAINST

STIPULATION

HEALTH PHARMACIES, INC.,
RESPONDENT

95 PHM 22

It is hereby stipulated between the above Respondent and the undersigned prosecuting attorney for the Division of Enforcement of the Department of Regulation and Licensing, as follows:

1. This Stipulation is entered into as a result of a pending investigation of licensure of Respondent by the Division of Enforcement. The parties consent to the resolution of the 95 PHM 22 investigation by agreement and without a hearing on the a formal complaint which has been issued in this matter.
2. Respondent understands that by signing this Stipulation, respondent waives the following rights with respect to disciplinary proceedings: the right to a statement of the allegations against respondent; a right to a hearing at which time the State has the burden of proving those allegations; the right to confront and cross-examine the witnesses against respondent; the right to call witnesses on respondent's behalf and to compel attendance of witnesses by subpoena; the right to testify personally; the right to file objections to any proposed decision and to present briefs or oral arguments to the officials who are to render the final decision; the right to petition for rehearing; and all other applicable rights afforded to respondent under the United States Constitution, the Wisconsin Constitution, the Wisconsin Statutes, and the Wisconsin Administrative Code.
3. Respondent is aware of respondent's right to seek legal representation and obtained legal advice before signing this Stipulation.
4. Respondent assures the Board that it has at all times complied with ¶A of the Order with respect to its use of ingredients, and has actually compounded all medications dispensed as compounded medications since before January 1, 1994. Respondent also denies and does not agree that any violations have been committed intentionally or otherwise, but agrees to the adoption of the attached Final Decision and Order by the Board. The parties consent to the entry of the attached Final Decision and Order without further notice, pleading, appearance or consent of the parties. Respondent waives all rights to any appeal of the Board's order, if adopted in the form as attached.
5. If the terms of this Stipulation are not acceptable to the Board, the parties shall not be bound by the contents of this Stipulation or the proposed Final Decision and Order, and the matter shall be returned to the Division of Enforcement for further proceedings. In the event that this Stipulation is not accepted by the Board, the parties agree not to contend that the Board has been prejudiced or biased in any manner by the consideration of this attempted resolution.
6. The parties agree that an attorney for the Division of Enforcement may appear before the Board, in open or closed session, without the presence of Respondent or Respondent's attorney, for the purposes of speaking in support of this agreement and answering questions that the members of the Board and its staff may have in connection with their deliberations on the case. Respondent has the option of appearing with he prosecuting attorney at all open or closed sessions, and any appearance shall be preceded by timely notice.
7. The Board Advisor in this matter may participate freely in any deliberations of the Board regarding acceptance of this Stipulation and the proposed Final Order, and may relate to the Board any knowledge and views of the case acquired during the investigation.

Department of Regulation & Licensing

State of Wisconsin

P.O. Box 8935, Madison, WI 53708-8935

(608)

TTY# (608) 267-2416, hearing or speech
TRS# 1-800-947-3529, impaired only

GUIDELINES FOR PAYMENT OF COSTS AND/OR FORFEITURES

On December 10, 1996, the Pharmacy Examining Board
took disciplinary action against your license. Part of the discipline was an assessment of costs and/or a
forfeiture.

The amount of the costs assessed is: \$400.00 Case #: LS961011PHM 95PHM22

The amount of the forfeiture is: _____ Case # _____

Please submit a check or a money order in the amount of \$ 400.00

The costs and/or forfeitures are due: January 9, 1997

NAME: Health Pharmacies, Inc. LICENSE NUMBER: 7387

STREET ADDRESS: 4233 West Beltline Highway

CITY: Madison STATE: WI ZIP CODE: 53711

Check whether the payment is for costs or for a forfeiture or both:

X COSTS _____ FORFEITURE

Check whether the payment is for an individual license or an establishment license:

_____ INDIVIDUAL X ESTABLISHMENT

If a payment plan has been established, the amount due monthly is:

Make checks payable to:

**DEPARTMENT OF REGULATION AND LICENSING
1400 E. WASHINGTON AVE., ROOM 141
P.O. BOX 8935
MADISON, WI 53708-8935**

#2145 (Rev. 9/96)
Ch. 440.22, Stats.
G:\BDLS\FM2145.DOC

For Receiving Use Only

NOTICE OF APPEAL INFORMATION

Notice Of Rights For Rehearing Or Judicial Review, The Times Allowed For Each. And The Identification Of The Party To Be Named As Respondent.

Serve Petition for Rehearing or Judicial Review on:

STATE OF WISCONSIN PHARMACY EXAMINING BOARD

1400 East Washington Avenue

P.O. Box 8935

Madison, WI 53708.

The Date of Mailing this Decision is:

December 16, 1996

1. REHEARING

Any person aggrieved by this order may file a written petition for rehearing within 20 days after service of this order, as provided in sec. 227.49 of the *Wisconsin Statutes*, a copy of which is reprinted on side two of this sheet. The 20 day period commences the day of personal service or mailing of this decision. (The date of mailing this decision is shown above.)

A petition for rehearing should name as respondent and be filed with the party identified in the box above.

A petition for rehearing is not a prerequisite for appeal or review.

2. JUDICIAL REVIEW.

Any person aggrieved by this decision may petition for judicial review as specified in sec. 227.53, *Wisconsin Statutes* a copy of which is reprinted on side two of this sheet. By law, a petition for review must be filed in circuit court and should name as the respondent the party listed in the box above. A copy of the petition for judicial review should be served upon the party listed in the box above.

A petition must be filed within 30 days after service of this decision if there is no petition for rehearing, or within 30 days after service of the order finally disposing of a petition for rehearing, or within 30 days after the final disposition by operation of law of any petition for rehearing.

The 30-day period for serving and filing a petition commences on the day after personal service or mailing of the decision by the agency, or the day after the final disposition by operation of the law of any petition for rehearing. (The date of mailing this decision is shown above.)