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STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	**FINAL DECISION AND ORDER**
HEALTH PHARMACIES, INC., RESPONDENT.	:	LS0401071PHM

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

Health Pharmacies, Inc.
2809 Fish Hatchery Rd.
Madison, WI 53713

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 #7887, originally granted on 1/9/90 as #7039. On 12/10/96, respondent was disciplined in file 95 PHM 22 for misrepresenting the source of dispensed prescription drugs and changing the pharmacy location without first obtaining a license for the new location, and its license was limited.

2. On 9/19/00, the department obtained samples of five different prescription medications which respondent's staff had prepared for dispensing to patients. Analysis of these samples by a US FDA laboratory showed that two of them contained less than 75% by weight of an active ingredient, as shown on the label.

3. The 12/10/96 order provided, among other things, the following:

> 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 shal be presumed to be ten calendar days.

4. Respondent has, for some time, provided a form to physicians who desired an office supply to dispense to patients. The form includes the following language, and does not include the ten-day presumption language:

> I have requested that Health Pharmacies, Inc. send to me for my office supply, certain medications.
>
> I believe that in-office administration of these medication to my patients is medically necessary.
>
> I believe that I have requested the medications in amounts which are reasonable and calculated to supply my patients with a quantity that will last only until the time that they can receive a quantity dispensed by a pharmacy pursuant to my prescription.

5. Respondent has routinely shipped substantial office supplies of varying formulae to a Dr. C., a Hawaii physician who signed respondent's form, and from the quantities shipped and the physician's statement to a department investigator, the Board infers that the physician is supplying patients with a thirty day supply of the formula selected, on a trial basis.

CONCLUSIONS OF LAW

A. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter pursuant to §450.10, Wis. Stats. and is authorized to enter into the attached Stipulation pursuant to §227.44(5), Wis. Stats.

B. The conduct described in paragraph 2, above, violated §450.10(1)(a)6., Wis. Stats., and § Phar 10.03(2), Wis. Adm. Code. Such conduct constitutes unprofessional conduct within the meaning of the Code and statutes.

C. The conduct described in paragraph 5, above, violated §450.10(1)(a)8., Wis. Stats. Such conduct constitutes unprofessional conduct within the meaning of the statutes.

ORDER

NOW, THEREFORE, IT IS HEREBY ORDERED, that the attached Stipulation is accepted.

IT IS FURTHER ORDERED, that, Health Pharmacies, Inc., is REPRIMANDED for its unprofessional conduct in this matter.

IT IS FURTHER ORDERED, that respondent shall adhere to the following procedures designed to improve the compounding of prescriptions:

Respondent shall adopt and follow all good compounding practices as outlined by the United States Pharmacopeia, and maintain all records necessary to demonstrate such compliance.

Respondent shall provide adequate supplies of samples of its lots produced during a calendar month, to an independent testing laboratory acceptable to the Board, on a monthly basis for one year, and semiannually thereafter. The method of selecting the lots to be tested is set forth in Appendix A.

IT IS FURTHER ORDERED, that if independent testing reveals samples deviating more than the USP standard from expected value, respondent shall immediately take the following steps:

Immediately cease dispensing or transferring medication from the affected lot;

Immediately test a new sample from the affected lot, if available, and if these samples also deviate more than the USP standard from expected value (or if there is an insufficient quantity for testing), the remainder of the lot shall be destroyed and all medication from the lot shall be recalled from any pharmacy or practitioner who received it (failure to have adequate records permitting such recall is a violation of this Order);

When the same formula is next compounded, that lot shall also be immediately tested, and this shall be in addition to the random samples set forth above;

Respondent shall assess all results of independent testing, and make appropriate changes to its compounding practices, documenting the assessment and change, in an effort to continuously improve the quality of the pharmacy's products.

IT IS FURTHER ORDERED, that respondent shall report to the Board within six months of the date of this Order, then quarterly for one year, and thereafter semiannually, regarding its implementation of the above measures. The reports shall include specific descriptions of all deviations from the above standards, together with a statement of how such deviations will be prevented in the future. The report shall also include all the results of independent testing described above. Respondent may petition for less frequent reporting, or for other changes in this Order, after three years of reporting. The Board shall grant a petition to terminate reporting upon being satisfied that respondent has maintained good compounding practices for a substantia period of time, and will continue to do so, consistent with the health, safety and welfare of patient and public.

IT IS FURTHER ORDERED, that respondent shall not package any office supply container with a supply greater than fo ten days, based on customary prescribing practices, and shall include the ten-day presumption language in the forms it sends to physicians to sign. Respondent shall notify all physicians who have previously signed the office supply forms of the ten day presumption, with their next orders, if any.

IT IS FURTHER ORDERED, that respondent shall pay COSTS in this matter in the amount of $3,000, within 30 days o this order.

IT IS FURTHER ORDERED, that pursuant to §227.51(3), Wis. Stats., and ch. RL 6, Wis. Adm. Code, if the Board determines that there is probable cause to believe that respondent has violated any term of this Final Decision and Order, the Board may order that the license of respondent be summarily suspended pending investigation of the alleged violation.

Dated this June 24th, 2004.

WISCONSIN PHARMACY EXAMINING BOARD

Michael Bettiga
A Member of the board

APPENDIX A

A. The method of selecting samples to be tested for the first year is that for each calendar month:

1. Respondent shall select the largest lot of oral dosage units produced, based on the number of capsules, tablets, or liquid dosage units, if more than one lot meets this test, e.g. three lots of 1440 capsules were produced, then any of the three may be selected; and

2. Respondent shall select the largest lot of cream, ointment, lotion, topical gel, or other product intended to be applied to the skin (based upon volume in the lot), if two or more lots are the "largest lot" then respondent may select any such lot; and

3. Respondent shall select one other lot of oral dosage unit which shall not be the same formula as the largest lot for that month, or have the same principal ingredient (e.g. if the principal ingredient of the largest lot is testosterone, then the other lot selected shall not have testosterone as its principal ingredient, but it may have testosterone as a secondary ingredient).

B. The method of selecting samples to be tested after the first year is that at the end of the calendar month (six months after the last round of sampling for testing), respondent shall select one of the five largest lots of oral dosage units produced that month, based on the number of capsules, tablets, or liquid dosage units. If respondent has produced more than 200 batches in the month in which sampling is performed, or in either of the two previous months, then respondent shall also select a second lot (of any size: it need not be one of the largest 5 lots) of oral dosage units, which shall not be the same formula as the largest lot for that month, or have the same principal ingredient (e.g. if the principal ingredient of the largest lot is progesterone, then the other lot selected shall not have progesterone as its principal ingredient, but it may have progesterone as a minor ingredient).

C. These processes are based upon the representation of respondent that it has furnished an accurate listing of its products produced in December, 2003, and that such production is typical of its production throughout the year. If respondent's production materially changes in size, method, or product mix, while this Order is in effect, it shall notify the Board and the parties shall consider whether a different sampling and testing process would be more appropriate to adequately protect the public. Respondent is not obligated to change the process without a clear mandate from the Board, and the Board shall not order a change the process without first attempting to negotiate a reasonable approach with respondent. However, the Board reserves the right to change this process, including by increasing the number of lots to be sampled, upon material change in circumstances.