

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING : INITIAL REGULATORY FLEXIBILITY
PROCEEDINGS BEFORE THE : ANALYSIS
PHARMACY EXAMINING BOARD : (CLEARINGHOUSE RULE 12 -)

PROPOSED ORDER

An order of the Pharmacy Examining Board to create ch. Phar 18, relating to the prescription drug monitoring program and affecting small business.

BACKGROUND

Under 2009 Act 362, the legislature directed the Wisconsin Pharmacy Examining Board (Board) to create through rule a prescription monitoring program. The proposed rule fulfills the legislative directive by establishing a prescription drug monitoring program (PDMP) to collect and maintain data regarding the prescribing and dispensing of monitored prescription drugs. The monitored prescription drugs are federally controlled substances in Schedules II-V, state controlled substances in Schedules II-V, as amended by the Controlled Substances Board, and Tramadol, a drug identified by the Board as having a substantial potential for abuse. A controlled substance that can be legally dispensed without a prescription order is not a monitored prescription drug under the proposed rule.

In general, the proposed rule requires dispensers to compile and submit to the Board data about each time they dispense a monitored prescription drug within 7 days. The proposed rule also requires dispensers to submit reports to the Board for each 7-day period during which he or she does not dispense a monitored prescription drug.

Under the proposed rule, the Board may waive the 7-day reporting requirements for dispensers who only dispense monitored prescription drugs to non-human animal patients. Instead, the dispensers would be required to submit the required data or report indicating that they have not dispensed a monitored prescription drug every 90 days.

The proposed rule requires dispensers to submit the data to the Board electronically, in the standard established by the American Society for Automation in Pharmacy's Implementation Guide for Prescription Monitoring Programs.

Under the proposed rule, the Board may grant waivers to dispensers who are not able to comply with the 7-day reporting or the electronic data submission requirements. Therefore, dispensers who are not able to comply with one or both of the reporting or submission requirements may submit to the Board an application for a waiver.

The proposed rule requires the Board to develop and maintain a database to store all of the data submitted to it as part of the PDMP. Practitioners and dispensers will be able create accounts

with the Board to access the database and view information that may be helpful in determining whether a patient is using any of the specific prescription drugs illicitly. Further, under the proposed rule, other entities, such as law enforcement authorities, patients and staff of the Department of Safety and Professional Services, may create accounts to request data from the Board as permitted under s. 146.82, Stats.

TYPES OF SMALL BUSINESSES AFFECTED BY THE RULE

The proposed rule will affect small businesses, as defined in s. 227.114 (1), Stats., that dispense monitored prescription drugs. As pharmacies dispense most of the monitored prescription drugs in Wisconsin, pharmacies and pharmacists would be most affected by the rule. Still, as the proposed rule also requires health care practitioners that dispense monitored prescription drugs to submit information regarding each dispensing of a monitored prescription drug to the PDMP, some health care practitioners will also be affected. Health care practitioners are physicians, advanced practice nurses, dentists, optometrists and veterinarians. Therefore, the proposed rule will affect community pharmacies, other small pharmacies and pharmacists and practitioners that practice medicine within a small business.

PROPOSED REPORTING, BOOKKEEPING, AND OTHER PROCEDURES REQUIRED FOR COMPLIANCE WITH THE RULE

The proposed rule requires pharmacies, pharmacists and health care practitioners that dispense monitored prescription drugs to submit information regarding each dispensing of a monitored prescription drug to the PDMP in the electronic format identified by the American Society for Automation in Pharmacy's (ASAP) Implementation Guide for Prescription Monitoring Program. The format identified by ASAP is the standard used by all operational state prescription monitoring programs. It defines the required data elements and acceptable inputs, which enables state prescription monitoring programs to share data with one another more easily.

The data elements identified in the proposed rule comply with the ASAP format. Therefore, to comply with the proposed rule, pharmacies, pharmacists and health care practitioners are required to compile and submit the following information to the PDMP within seven days of dispensing a monitored prescription drug:

- dispenser's full name;
- dispenser's NPI number or DEA registration number;
- date dispensed;
- prescription number;
- name and strength of the prescription drug;
- NDC number;
- quantity dispensed;
- estimated number of days of drug therapy;
- practitioner's full name;
- practitioner's NPI number or DEA registration number, if applicable;
- date prescribed;
- quantity prescribed;

- patient's full name;
- patient's address, including street address, city, state and ZIP code;
- patient's date of birth; and
- patient's gender.

As of December 5, 2011, there are 1,279 licensed pharmacies in Wisconsin according to the Department of Safety and Professional Services' database. According to the Department of Health Services (DHS), only 17 pharmacies in the state of Wisconsin are not capable of receiving electronic prescription orders. Therefore, the type of business most affected by the compliance requirements of the proposed rule is not expected to incur significant costs to comply with the proposed rule.

The use of EHR is also prevalent among physicians and other health care practitioners in large group practice. According to DHS, approximately 74% of physicians are in large group practice and almost all of them utilize electronic health records (EHR).

Conversely, the use of EHR is not as prevalent among veterinarians. According to the Wisconsin Veterinary Medical Association, approximately 273 of the 719 veterinary clinics in Wisconsin are able to access prescription information electronically.

Understanding that the use of EHR varies among types of businesses and health care practitioners, the Board developed the proposed rule to allow the submission of data to the PDMP in multiple ways.

If a pharmacy, pharmacist or health care practitioner currently utilizes EHR, they can comply with the requirement to submit data electronically in the proposed rule by programming their current prescription dispensing software to automatically collect and submit the data to the PDMP. Likely, there would be an up-front cost associated with the computer programming as it may require hiring a computer programmer or software vendor to make the necessary changes. However, there would not be any significant ongoing personnel costs required to maintain compliance with the proposed rule.

A pharmacy, pharmacist or health care practitioner who does not currently utilize EHR can comply with the requirement to submit data electronically in the proposed rule by manually submitting the data to the PDMP. Manual submission can still be accomplished electronically through an online account established with the Board, through secure email or mailing of compact disks that contain the data.

Further, if a pharmacy, pharmacist or health care practitioner does not have access to a computer or is otherwise unable to compile or submit data by any electronic means, they may apply for a waiver from the Board. Once waived, the pharmacy, pharmacist or health care practitioner would be able to submit data on paper to the PDMP.

By choosing a method that does not require computer programming and software development, there are no up-front compliance costs to retrofit computer software. However in order to maintain compliance, a pharmacy, pharmacist health care practitioner or a delegate must

manually submit data regarding each dispensing of a monitored prescription drug within seven days of dispensing it. Therefore, the pharmacy, pharmacist or health care practitioner would incur personnel costs associated with compiling and submitting data to the PDMP.

By default, the proposed rule requires the submission of data within seven days of dispensing a monitored prescription drug or, if no monitored prescription drugs were dispensed in a seven-day period, seven days from the previous data submission. Therefore, most pharmacies, pharmacists and health care practitioners that dispense a monitored prescription drug would be submitting data at least every seven days.

The proposed rule lessens the reporting burden on veterinarians who solely dispense monitored prescription drugs to non-human animal patients by allowing them to apply for a waiver from the seven-day reporting requirements. Instead, the veterinarian would be required to submit data to the PDMP every 90 days.

Under the proposed rule, a pharmacy, pharmacist or health care practitioner that does not dispense the monitored prescription drugs may apply for a complete exemption from the reporting requirements. The proposed rule associates the expiration of the exemption to licensure renewal to eliminate the administrative burden that applying for an exemption may have created. Under the proposed rule, the exemption would last until licensure renewal or until the pharmacy, pharmacist or health care practitioner dispenses a monitored prescription drug. Therefore, a pharmacy, pharmacist or health care practitioner applying for the exemption can indicate so as part of the licensure renewal process. There would be no compliance requirements or associated costs incurred by exempt pharmacies, pharmacists and health care practitioners.

TYPES OF PROFESSIONAL SKILLS NECESSARY FOR COMPLIANCE WITH THE RULE

The proposed rule would not require a pharmacy, pharmacist or health care practitioner to obtain any professional skills beyond those common among the professions.