STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING	:	FINAL REGULATORY FLEXIBILITY
PROCEEDINGS BEFORE THE	:	ANALYSIS
PHARMACY EXAMINING BOARD	:	(CLEARINGHOUSE RULE 12-009)

PROPOSED RULE

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 Wis. Act 362, the legislature directed the Wisconsin Pharmacy Examining Board (Board) to create a prescription drug monitoring program (PDMP) by rule. The proposed rule fulfills the legislative directive by establishing a PDMP to collect and maintain information 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 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 information about each time they dispense a monitored prescription drug. The information must be submitted to the Board within 7 days of the dispensing of the monitored prescription drug. The proposed rule also requires dispensers to submit a zero report 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 grant a waiver of the 7-day reporting requirements to a dispenser who only dispenses monitored prescription drugs to non-human animal patients. Instead, these dispensers would be required to submit the required information or zero report indicating that they have not dispensed a monitored prescription drug every 90 days.

The proposed rule requires a dispenser to electronically submit the information to the Board using the data standards established by the American Society for Automation in Pharmacy's Implementation Guide for Prescription Monitoring Programs or other electronic format identified by the Board.

Under the proposed rule, the Board may grant a waiver to a dispenser who is unable to comply with the electronic data submission requirement described above. Further, the Board may grant an emergency waiver to a dispenser who is unable to submit information within 7 days of dispensing a monitored prescription drug.

The proposed rule also requires the Board to develop and maintain a database to store the information submitted to the Board as part of the PDMP. Practitioners and dispensers will be able create accounts with the Board to access the database and view information that will be helpful in determining whether a patient is using monitored 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 information from the Board in accordance with s. 146.82, Stats.

METHODS TO REDUCE THE IMPACT ON SMALL BUSINESSES

In accordance with s. 227.114 (2), Stats., the Board considered the methods to reduce the impact on small businesses identified in the statute and incorporated three of them into the proposed rule. Specifically, the Board incorporated the methods indentified in ss. 227.114 (2) (a) to (c), Stats., into the proposed rule because they are feasible and consistent with the statutory objective of s. 450.19, Stats. The Board did not incorporate the method identified in s. 227.114 (2) (d), Stats., because it is inapplicable to the proposed rule. The Board did not incorporate the method identified in s. 227.114 (2) (e), Stats., because the Board lacks statutory authority to do so.

In accordance with s. 227.114 (2) (a), Stats., the Board incorporated "less stringent compliance or reporting requirements for small businesses" into the proposed rule to reduce the impact on small businesses. In general, the proposed rule requires dispensers to electronically submit information about monitored prescription drugs dispensed in a specified format to the Board every 7 days. The Board incorporated a waiver of the electronic reporting requirements to reduce the impact of the proposed rule on small businesses.

The waiver of the electronic reporting requirements reduces the proposed rule's impact on small businesses by giving dispensers options to submit information to the Board. Importantly, health care practitioners and pharmacists without the means to electronically submit information to the Board would not have to invest in hardware and software improvements to comply with the proposed rule. Instead, these dispensers may submit information to the Board on paper. The waiver is available to all dispensers and is especially beneficial to those who practice in small business settings.

The Board incorporated the waiver for less stringent compliance and reporting requirements, to give dispensers options to comply with the proposed rule. Because "dispensers" under the proposed rule consist of many types of health care practitioners and pharmacies whose practices vary significantly, the most practical way for a dispenser to comply with the proposed rule will also vary significantly. For example, a dispenser in a small business setting may not have suitable computer access or choose not to electronically submit information to the Board and want a waiver of the electronic reporting requirement. Conversely, another dispenser in a similar situation may choose to improve his or her electronic health records system (EHR) and to comply with the electronic reporting requirements of the proposed rule and submit information electronically.

Further, the Board incorporated less stringent reporting requirements to reduce the impact on small businesses by including the phrase "or other electronic method identified by the board" in

its description of the electronic reporting requirements. In the original text of the proposed rule submitted to the Legislative Clearinghouse, all dispensers would have been required to electronically submit information in the format identified in the American Society for Automation in Pharmacy (ASAP) Implementation Guide for Prescription Monitoring Programs. The Board received several comments stating that requiring all dispensers to comply with the ASAP format would significantly increase the compliance costs incurred by small businesses and non-pharmacy dispensers. The addition of "or other electronic method identified by the board" enables the Board to work with all dispensers to identify appropriate and cost-effective electronic methods through which dispensers unable to comply with the ASAP format can electronically submit information as required by the proposed rule.

Next, the Board incorporated less stringent compliance requirements by allowing health care practitioners and pharmacies who do not dispense monitored prescription drugs to apply for a complete exemption from the reporting requirements of the proposed rule. The Board correlated the application and expiration of the exemption to the licensure renewal process by making the exemption effective until licensure renewal or until the dispenser dispenses a monitored prescription drug. Therefore, the Board minimized the administrative burden that applying for and renewing an exemption may have created. Besides renewing the exemption, an exempt practitioner or dispenser would not be subject to any ongoing compliance or reporting requirements under the proposed rule.

In accordance with s. 227.114 (2) (b), Stats., the Board incorporated "less stringent schedules or deadlines for compliance or reporting requirements for small businesses." By default, the proposed rule requires dispensers to submit information about monitored prescription drugs dispensed to the Board every 7 days. The Board reduced the impact of the proposed rule on small businesses by enabling a dispenser who solely dispenses monitored prescription drugs to animal patients to apply for a waiver from the 7-day reporting requirement and to report information to the Board every 90 days. The waiver is limited to veterinarian dispensers for several reasons. First, a large majority of veterinarians practice in a small business setting and dispense from their clinics. Second, the use of EHR is less prevalent among veterinarians than it is among other health care practitioners. Third, the prolonged reporting period lessens the usefulness of the information stored by the PDMP database.

Similar to the waiver of the electronic reporting requirements, each veterinary dispenser has a choice in determining the most practical way for him or her to comply with the proposed rule. An individual dispenser is able to determine what reporting timeline is most practical based on his or her business processes and circumstances. For example, a veterinary dispenser in a small business setting may already rely on suitable electronic health records and choose to electronically submit information to the Board every 7 days. Similarly, a veterinary dispenser who dispenses higher volumes of monitored prescription drug may choose to report every 7 days. Conversely, a veterinary dispenser who dispenses monitored prescription drugs infrequently may decide that he or she will apply for the waiver to report information every 90 days.

In accordance with s. 227.114 (2) (c), Stats., the Board consolidated and simplified the compliance or reporting requirements for small businesses. Based on public comments, many of

which were from or on behalf of small businesses, the Board consolidated two of the originally separate data fields required to be submitted to the Board. Specifically, the proposed rule requires dispensers to submit either the National Drug Code (NDC) number or the name and strength of the monitored prescription drug. This consolidation gives dispensers more choice in how they report information to the Board. Pharmacies and other large volume dispensers with suitable EHR systems are able to submit the NDC number without having to manually enter the name and strength of the monitored prescription drug. Small volume dispensers who manually submit information to the Board may submit information to the Board without searching for the NDC number of every monitored prescription drug dispensed during a reporting period.

While the consolidation of reporting requirements benefits dispensers who practice in small businesses, the change is not limited to those dispensers. Any significant modifications to the required data fields must affect all dispensers. Otherwise, the varied data fields would reduce the potential benefits of the PDMP. The primary purpose of the PDMP is to correlate information in the database to identify patients exhibiting activities of prescription drug abuse. Therefore, the data must be cleansed and standardized among all dispensers. If the data fields and information are not standardized across all dispensers, queries for information would not return all relevant information and hinder the ability of the PDMP to effectively serve its purpose.

ISSUES RAISED BY SMALL BUSINESSES AND RESULTING CHANGES

The Board solicited feedback from businesses, associations representing businesses and interested members of the public throughout the development of the proposed rule. Several of the comments submitted to the Board were from small businesses, as defined in s. 227.114 (1), Stats., or from associations representing small businesses in Wisconsin.

The issues raised by or on behalf of small businesses primarily comprise three categories. The first category regards the requirement to report small dose and post-procedure dispensing of monitored prescription drugs. The second category regards the requirement of a dispenser to submit "zero reports" to the Board. Finally, the third category regards the effect of the proposed rule on veterinarians. The Board considered all issues raised in the comments and made substantive modifications to the proposed rule, where possible, in an effort to minimize the burden on small businesses.

Small Dose and Post-Operative Dispensing

Under the proposed rule, dispensers are required to submit information to the Board about each dispensing of a monitored prescription drug. There is no differentiation between dosage forms or amounts or reasons for the dispensing. The Board received several comments regarding health care practitioners who dispense small doses of a monitored prescription drug to a patient following surgery or other procedure. The comments suggest exempting the dispensing of small doses from the reporting requirements of the proposed rule. In general, the amount of drugs dispensed post-procedure is generally very small, 1-10 doses on average. Further, the comments state that because the dispensing is directly related to a medical procedure, it is unlikely that the patient underwent the procedure for the monitored prescription drugs or intends to use them illicitly.

Due to a lack of statutory authority, the Board made no changes to the proposed rule in response to the comments. Under s. 450.19 (2) (a), Stats., the Board shall create a PDMP that requires dispensers to "generate a record documenting each dispensing of a prescription drug and to deliver the record to the board, except that the program may not require the generation of a record when a drug is administered directly to a patient." The statute does not authorize the Board to create more exceptions to the requirement to report dispensing information to the Board.

Zero Reports

Under the proposed rule, dispensers are required to submit a "zero report" to the Board during a reporting period in which the dispenser did not dispense a monitored prescription drug. A reporting period is 7 days unless the dispenser is a veterinarian dispenser who has been granted a waiver of the 7-day reporting period and has a 90-day reporting period. The Board received several comments suggesting that the Board eliminate the zero report requirements.

The Board rejects the comments asking the Board to eliminate the zero report requirements to ensure the usefulness of the PDMP. The sole purpose of the zero report is to ensure that the Board has information from all dispensers at all times. Without complete information, the information stored as part of the PDMP is of limited value because the Board would have no way to determine whether a dispenser who failed to submit information during a reporting period simply forgot or did not dispense a monitored prescription drug during that time.

Further, the zero report is designed not to be a burden to a dispenser. In fact, a dispenser should be able to complete a zero report in seconds. As described by other state prescription monitoring programs, a dispenser can submit a zero report by entering the dates of the report and confirming that he or she did not dispense a monitored prescription drug during that time. Therefore, zero reports contain significantly less information than the reports with dispensing information and require no data compilation.

Veterinary Dispensers

Under the proposed rule, veterinary dispensers are required to report information to the Board just as all other dispensers. The Board received several comments suggesting that the Board exempt veterinary dispensers from the requirements of the proposed rule. However, the Board lacks statutory authority to exempt veterinary dispensers. Under s. 450.19 (2) (a), Stats., the Board is directed create a PDMP that shall require practitioners and dispensers to "generate a record documenting each dispensing of a prescription drug and to deliver the record to the board, except that the program may not require the generation of a record when a drug is administered directly to a patient." The statute does not authorize the Board to create any exemptions or more exceptions to the requirement to report dispensing information to the Board.

In response to comments submitted by veterinary dispensers, the Board modified the language describing the electronic submission requirements to clarify that the phrase "electronically submit" is not intended to define a software or hardware platform through which a dispenser

must submit information to the Board. The Board changed the language "the format identified in the American society for automation in pharmacy (ASAP) implementation guide for prescription monitoring programs" to "the data standards in the version and release of the American society for automation in pharmacy (ASAP) implementation guide for prescription monitoring programs identified by the board or other electronic format identified by the board." The modification is intended to clarify that the Board does not limit electronic submission to a virtual interface between a dispenser and the Board through which databases can send and receive information. Based on the practices of operational prescription monitoring programs in other states, the Board would accept information entered through a secure website, sent in a secure e-mail, included on mailed CD-ROMs and included on mailed diskettes as "electronically submitted" information under the proposed rule. The Board also added the phrase "or other electronic format identified by the board" in response to comments suggesting that the Board adopt an electronic format suitable to the practice of veterinary medicine.

Further, the Board consolidated data fields to reduce the burden on veterinary dispensers, among the reasons already discussed. Specifically, the proposed rule requires a dispenser to submit either the National Drug Code (NDC) number or the name and strength of the monitored prescription drug. The consolidation gives veterinary dispensers more choice in how they choose to report information. The data field is also now relevant for veterinary drugs that may not have an NDC number.

Finally, under the proposed rule, disciplinary authority over each of the licensed health care practitioners, pharmacies and pharmacists affected by the rule is with the board that issued him, her or it the license authorizing the dispensing or prescribing of monitored prescription drugs. The Board received comments suggesting that the Board specifically give the disciplinary authority of veterinarians affected by the rule to the Veterinary Examining Board. In response to the public comments and the Clearinghouse Report, the Board modified the language describing the disciplinary authority of other licensing boards for violations of the proposed rule.

NATURE OF REPORTS REQUIRED AND THEIR ESTIMATED COSTS

In general, the proposed rule requires dispensers to submit two types of reports to the Board: reports containing dispensing information and zero reports. Dispensers must submit the reports containing dispensing information within 7 days, or 90 days for veterinary dispensers granted a waiver, of dispensing a monitored prescription drug to a patient. The reports contain specific information about the prescriber, dispenser, patient and monitored prescription drug.

The estimated cost of an individual report with dispensing information would range from *de minimis* to less than one hundred dollars. The range would not likely be static for dispensers and would depend on several variables. While there is no exhaustive list of variables, several variables have the most significant affect on the estimated cost of a report with dispensing information.

A significant variable that affects the cost of a report with dispensing information is whether the dispenser currently utilizes compatible EHR that can compile and submit information to the Board. For example, the cost of an individual report to a dispenser who already utilizes

compatible EHR software and reports similar information to another state's prescription monitoring program would be less than a dispenser who decides to invest in retrofitting his or her EHR software to be compatible with the PDMP. Either way, the costs of an individual report will decrease over time for dispensers utilizing EHR.

The potential up-front costs of utilizing EHR to compile and submit information to the Board is not required. In fact, a dispenser may not use EHR at all and submit information to the Board through other electronic methods or by submitting the information on paper. In that case, a significant variable is whether the dispenser is required to report every 7 days or every 90 days. A dispenser submitting a report with dispensing information to the Board every 90 days would incur less frequent personnel costs to compile the reports to the Board than a dispenser who submits information to the Board every 7 days.

A related variable is the frequency a dispenser dispenses monitored prescription drugs. A dispenser who dispenses monitored prescription drugs numerous times per day would have more information to compile and submit that a dispenser who dispenses monitored prescription drugs infrequently. An individual report that contains information regarding numerous dispensing events that is compiled and submitted manually, either electronically or on paper, would likely cost more to compile and submit than a report that contains less information.

The estimated cost to complete a zero report is *de minimis*. The zero report contains very little information, much less information than the reports with dispensing information. In fact, a dispenser can complete a zero report in seconds by simply logging into their account and completing a brief form online. The zero reports require no data compilation and are only intended to ensure that the PDMP has complete information from all non-exempt dispensers at all times.

Finally, under the proposed rule, a dispenser that does not dispense 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 dispenser 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 further reporting requirements or associated costs incurred by dispensers.

NATURE OF OTHER MEASURES OR INVESTMENTS REQUIRED

Besides the costs associated with the required compiling and submitting of information relating to the dispensing of monitored prescription drugs, there are no other investments required by the proposed rule. Large-volume dispensers, such as pharmacies and physicians in large practices, may invest in modifying their current EHR software to automatically compile the required information. However, the investment is not required by the proposed rule, because the proposed rule is flexible in the methods through which dispensers can submit information to the Board.

COSTS TO THE AGENCY OF ADMINISTERING THE PROPOSED RULE

Based on the operating costs incurred by similar prescription monitoring programs, the Department estimates that it will cost approximately $210,000 annually to operate the PDMP created by the proposed rule. The annual costs are primarily comprised of a full-time program and planning analyst to monitor the program and work with the vendor and others to manage the PDMP and the contractual costs for a vendor to host and maintain the PDMP database, website and other related IT components of the PDMP.

IMPACT ON HEALTH, WELFARE AND SAFETY

The PDMP created by the proposed rule will have a significant impact on the health, welfare and safety of the people of Wisconsin. It creates an effective tool that will enable the approximately 50,000 pharmacies; pharmacists; health care practitioners, including physicians, dentists and veterinarians; law enforcement agencies and public health officials to obtain invaluable information to assist in the effort to curb prescription drug abuse in Wisconsin.

Currently, "prescription drug abuse is America's fastest growing drug problem" (Controlled Substances Workgroup of the Wisconsin State Council on Alcohol and Other Drug Abuse (SCAODA), "Reducing Wisconsin's Prescription Drug Abuse: A Call to Action," 8, Jan. 2012, citing CDC, "Public Health Grand Round Presentation," 10, Feb. 2011). In fact, one person died every 19 minutes in the United States in 2007 because of an "unintentional drug overdose" (CDC, "Grand Rounds: Prescription Drug Overdoses — a U.S. Epidemic," Jan. 13, 2012). Unintentional drug overdoses have become the second leading cause of accidental death in the United States (Susan Okie, A "Flood of Opioids, a Rising Tide of Deaths," New England Journal of Medicine, Nov. 18, 2010).

The prescription drug problem in Wisconsin is similar to the national problem (see SCAODA, 5-9). Wisconsin's prescription drug abuse rate is slightly higher than the national average of approximately 5%, with 5.83% of Wisconsin residents age 12 and older reporting using pain relievers for non-medical purposes in 2005-06 (Wisconsin Department of Health Services (DHS), "Wisconsin Epidemiological Profile on Alcohol and Other Drug Use," 2008; SCAODA, 6). According to the Controlled Substances Workgroup of the Wisconsin State Council on Alcohol and Other Drug Abuse, the prescription drug abuse problem is exacerbated in Wisconsin because the State does not have a PDMP (SCAODA, 8). In its January 2012 report "Reducing Wisconsin's Prescription Drug Abuse: A Call to Action," SCAODA states that:

> [a] well designed PDMP will provide an early warning system for emerging drug abuse trends, assist in enhancing patient care, and serve as a vehicle for communication with other states subsequently reducing doctor shopping across state lines. In addition, with appropriate confidentiality protections built into the Wisconsin PDMP for patient-identifiable health information, a PDMP will enhance the ability of law enforcement to conduct investigations of the illegal diversion of prescription medications. (*id.*)

Further, a Cost-Benefit Analysis conducted by the LaFollette School of Public Affairs states that "[p]rescription drug abuse has a significant impact on society. Drug abuse causes decreased productivity and absences from work, increased health care costs, and increased law enforcement costs" and that "[s]tates with PDMPs realize health care benefits through the reduction in excess hospital admissions including both in- and out-patient, reduction in addiction treatment, and reduction of prescription drug costs associated with prescription drug abuse" (Christine Durkin, et al., "Cost-Benefit Analysis of a Prescription Drug Monitoring Program in Wisconsin," LaFollette School of Public Affairs (LaFollette), 6, Dec. 20, 2010).

Finally, while the PDMP created by the proposed rule will improve the health, welfare and safety of Wisconsin citizens, the effectiveness of the PDMP is lessened by the modifications made to allow veterinarian dispensers to submit information every 90-days as opposed to every 7-days. The usefulness of the PDMP to identify cases of "doctor shopping," forged prescriptions and other activities at the time of providing a patient services is decreased because of the 90-day lapse in some of the information in the PMDP. In fact, the Board received comments suggesting the 7-day reporting requirement is too long and should be decreased as much as possible to increase the usefulness of the PDMP.