

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING :
PROCEEDINGS BEFORE THE : REPORT TO THE LEGISLATURE
PHARMACY EXAMINING BOARD : (CLEARINGHOUSE RULE 12-009)

I. THE PROPOSED RULE:

The proposed rule, including the analysis and text, is attached.

II. REFERENCE TO APPLICABLE FORMS:

Based on the forms required by other state prescription monitoring programs, the Pharmacy Examining Board (Board) anticipates that the proposed rule would require the Board to create approximately seven forms to operate the Prescription Drug Monitoring Program (PDMP) created by the proposed rule. The forms that would need to be created are: (1) an application for an account; (2) an application for a waiver from electronic reporting requirements; (3) an application for an emergency waiver of the 7-day reporting requirement; (4) an application for a waiver for veterinary dispensers; (5) an application for an exemption for health care practitioners and pharmacists who do not dispense monitored prescription drugs; (6) a form to request for information from the PDMP; and, (7) a form for law enforcement personnel to request information from the PDMP. The Board must also develop or identify a form upon which dispensers who submit information to the Board on paper may do so. The exact number of forms required by the proposed rule is unknown because some of the forms may be combined together, while others may need to be separated to operate the PDMP efficiently.

The Board would work with staff at the Department of Safety and Professional Services (Department) and a vendor to identify and create the required forms prior to the effective date of the proposed rules. All forms would be available on the Department's website, www.dsps.wi.gov, and at the Department, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

III. FISCAL ESTIMATE AND ECONOMIC IMPACT ANALYSIS:

The Fiscal Estimate and Economic Impact Analysis are attached.

IV. DETAILED STATEMENT EXPLAINING THE BASIS AND PURPOSE OF THE PROPOSED RULE, INCLUDING HOW THE PROPOSED RULE ADVANCES RELEVANT STATUTORY GOALS OR PURPOSES:

The Pharmacy Examining Board is directed to create a PDMP by 2009 Wis. Act 362, which created s. 450.19, Stats. The proposed rule of the Board creates ch. Phar 18 and satisfies the statutory directive to create a PDMP.

V. SUMMARY OF PUBLIC COMMENTS AND THE SECTION’S RESPONSES, EXPLANATION OF MODIFICATIONS TO PROPOSED RULES PROMPTED BY PUBLIC COMMENTS:

The Board worked with stakeholders and interested members of the public throughout the development of the proposed rule. To ensure abundant opportunity to comment on the proposed rule, the Board accepted written comments throughout the rule development process, held a roundtable discussion with stakeholders and interested individuals and held a public hearing on February 27, 2012. The Board considered all written comments, oral comments made during the roundtable discussion and testimony at the public hearing.

The following people submitted written comments, made oral comments at the roundtable discussion or testified at the public hearing:

Paul Baum	Zachery Janssen	Michael Ochowski
William Black	Twila Johnson	Sandra Osborn
Robert Block	Eric Knox	Robert Phillips
K.C. Brooks	Robert Klosterman	Gary Plank
Mara Brooks	Kimberly Kratt	Chris Rasch
Kim Brown-Pokorny	Dale Kressin	Pedro Luis Rivera
James Cardinal	Joel Kurzman	Dan Ross
Melissa Cheeks	Jordan Lamb	Emily Sallows
John Chisholm	Ken Lambrecht	Amy Schlotthauer
Dorothy Chaney	Gina Laur	Guy Shepardson
Tim Conway	Amy Lawrynk	Kristin Smith
Rachel Currans-Henry	William Lockwood, Jr.	Robert Spencer
Patricia Daugherty	Lisa McCalpine-	Arthur Thexton
Mary Lynn Driscoll	Witten	Edward Wall
Wesley Elfrod	Kelly McDowell	Judy Warmuth
Tom Engels	Michael McNett	Denise Webb
Tomson George	Michael Miller	Michael Wolf
Mark Grapentine	Gene Musser	Amy Zosel
Paula Hensel	Dan Oberschlake	

The Board summarizes the public comments received as follows:

The Board received comments regarding the definition of “dispense” and how it relates to the statutory definition of “delivery.” Specifically, the comments identified situations in which a monitored prescription drug may be dispensed, as in prepared and packaged, but never delivered to the patient. The comments stated concerns about the relationship between dispensed but undelivered drugs and the requirement for a dispenser to notify the Board of an error or omission within three business days.

The Board received comments regarding the definition of “dispenser.” Specifically, the public comments indicated that it was unclear whether the definition of “dispenser” referred to individual pharmacists or pharmacies.

The Board received a comment suggesting the addition of “federal” to the definition of “DEA registration number” to avoid confusion with agencies in other states that issue similar registration numbers.

The Board received comments regarding the definition of “prescription drug.” Specifically, the comments indicate unease with the term because it is already defined several different ways in the law. The comments suggest that the use of the term “prescription drug” adds needless confusion for practitioners, pharmacists and the public.

The Board received comments regarding where and how it will identify other drugs as having a substantial potential for abuse.

The Board also received comments regarding its identification of Tramadol as a drug that has a substantial potential for abuse. The comments state that because Tramadol is not a controlled substance, its inclusion in the list of monitored prescription drugs would cause reporting complications for practitioners and dispensers.

The Board received comments regarding the funding and long-term sustainability of the PDMP. The comments state that licensing fees should not be increased or diverted to pay for the operation of the PDMP and that the Board should secure another governmental funding source.

The Board received comments about access to the information stored as part of the PDMP (PDMP information). Specifically, comments asked the Board to clarify the language in the proposed rule regarding access to PDMP information, accounts to request PDMP information and the request process to obtain PDMP information. The comments asked the Board to clarify who would have direct access to PDMP information and who would need to submit a request to obtain PDMP information.

Further, the Board received comments regarding the Department of Health Services Medicaid Program’s access to PDMP information. Specifically, the comments state that the Medicaid Program should have direct access to PDMP information about Medicaid recipients to monitor fraud, abuse and care coordination.

Similarly, the Board received differing comments regarding law enforcement authorities’ access to PDMP information. Comments from law enforcement authorities state that they should not be required to get a court order to obtain PDMP information. They suggest a less stringent process through which a supervisor within the law enforcement authority monitors and approves requests for PDMP information. Conversely, the Board received comments from health care practitioners and dispensers stating that law enforcement authorities should be required to get a court order to access PDMP information because PDMP information should be protected as any other confidential health care record.

The Board received comments about the required data fields and the format identified in the American Society for Automation in Pharmacy (ASAP)

Implementation Guide for Prescription Monitoring Programs. The comments indicate that some of the fields are not applicable to veterinarian dispensers, are not able to be automatically populated by electronic health records systems, are not identical to fields used by other state prescription monitoring programs and are not necessarily supported by ASAP.

The Board received comments that suggest the Board require methadone clinics and other opioid treatment centers to submit data to the PDMP. As most methadone clinics and opioid treatment centers administer most of the drugs in the clinics, the comments also suggest the Board seek legislative change to require dispensers to report drugs that they administer to a patient.

The Board received comments regarding the relationship between a dispenser correcting dispensing data under the section entitled “[c]orrection of dispensing data” and potential disciplinary actions against the dispenser for submitting false information under other sections.

The Board received comments suggesting that the Board exempt all reporting requirements for small doses of drugs dispensed following a surgery or other medical procedure.

The Board received comments suggesting changes to the language in the section entitled “[e]xchange of PDMP information.” Specifically, the comments indicate that the term “state” and “jurisdiction” are used inconsistently in the section.

The Board received comments regarding the requirements of the proposed rule that apply to veterinarians. Specifically, the comments suggest exempting veterinarians from all requirements of the proposed rule. Alternatively, the comments suggest less stringent electronic reporting requirements and more lenient reporting standards for veterinarians.

The Board explains the modifications to its rule-making proposal prompted by public comments as follows:

The Board modified the definition of controlled substance to include all five federal and state schedules. The modified definition of “controlled substance” only identifies controlled substances and no longer substantively narrows the definition for use in the proposed rule. Further, the Board added the language “as changed and updated by 21 CFR 1308” to identify where the federal controlled substance schedules are updated. The modifications, together with the modifications to the definition of “monitored prescription drug” and creation of the section entitled “[d]rugs that have a substantial potential for abuse,” clarify what drugs are monitored and how the Board will update the list of monitored prescription drugs.

The Board added the word “federal” before “department of justice” in definition of “DEA registration number.”

The Board modified the definition of “dispenser” to clarify that pharmacies and practitioners are dispensers under the proposed rule. The Board also added a note regarding remote dispensing sites and their relation to pharmacies under the proposed rule. Last, the Board modified the definition of “dispenser delegate” because the modification to the definition of “dispenser” made the definition of “dispenser delegate” awkward.

The Board changed the term “prescription drug” to “monitored prescription drug.” Further, the Board modified the definition of “monitored prescription drug” to reference the created section that identifies drugs as having a substantial potential for abuse. Specifically, the Board no longer specifically lists “drug[s] identified by the board as having a substantial potential for abuse” or identifies controlled substances other than those in s. 450.19(1), Stats., in the definition.

The Board modified the definition of “NDC number” by removing the word “human” to clarify that monitored prescription drugs may also be intended for non-human animals.

The Board modified the definition of “pharmacy” by adding a reference to s. 450.065, Stats. to clarify that out-of-state pharmacies licensed in Wisconsin must comply with the requirements of the proposed rule.

The Board created s. 18.03 to specify exactly where the Board will identify drugs that have a substantial potential for abuse.

The Board combined the data field requirement of NDC number and name and strength of the monitored prescription drug. The purpose of the modification is to lessen the burden of including fields that may not be automatically populated by electronic health records systems while allowing dispensers to submit the name and strength of the prescription drug, if they choose to do so.

The Board modified the section entitled “submission of dispensing data” by separating it into three sections on electronic submissions, the frequency of submissions and veterinary dispensers.

The first section is entitled “electronic submission of dispensing data.” It describes the electronic submission requirements and waiver of those requirements. Further, the Board modified the language to clarify that dispensers are required to create an account to electronically submit data to the Board.

The Board modified the description of “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.” The modification is intended to clarify what the ASAP standards are and how the Board intends to utilize them.

The Board further modified the description of the electronic submission requirements of the proposed rule by adding the phrase “or other electronic format identified by the board.”

The Board modified the waiver of the electronic submission requirements by deleting the references to dispensers with and without electronic recordkeeping systems. There is now one subsection that describes the waiver of the electronic submissions requirements for all dispensers. Last, the Board deleted the substantial hardship requirement that dispensers with electronic recordkeeping systems would have had to demonstrate to get a waiver under the original language.

The second section created by the modifications to the section on “submission of dispensing data” is entitled “frequency of submissions.” It describes the frequency and time period requirements and waiver of those requirements.

The Board modified the language describing the “waiver” by terming it an “emergency waiver” to differentiate it from the waiver of the electronic submission requirements. Further, the Board modified the language to clarify that the waiver is intended for short-term emergencies and not a long-term waiver of the frequency requirements.

The Board included the language regarding zero reports in this section. The Board did not delete the language regarding zero reports because the zero report is an integral mechanism to ensure that the Board receives complete information during each reporting period. Every state prescription monitoring program with information available online requires zero reports when a dispenser does not dispense a monitored prescription drug during a reporting period.

The third section created by the modification to the section on “submission of dispensing data” is entitled “veterinary dispensers.” It describes the waiver from the frequency requirements available to dispensers who solely dispense monitored prescription drugs to non-human animals. Further, by separating the waiver for veterinary dispensers from other waivers, it clarifies specifically what requirements of the proposed rule the waiver affects.

The Board modified the timeframe within which a dispenser must inform the Board and correct inaccurate or omitted data from 3 business days to 7 days. The Board also deleted the definition of “business day” because it is no longer referenced by the proposed rule.

The Board modified the section entitled “access to and disclosure of PDMP information” by separating it into two sections on direct access to PDMP information and methods to obtain PDMP information.

The first section is entitled “direct access to PDMP information” and describes how dispensers, dispenser delegates, practitioners and practitioner delegates can access PDMP information through their accounts. Further, the section specifies

what dispensers, dispenser delegates, practitioners and practitioner delegates must do to create accounts with the PDMP to access the PDMP information.

Further, the Board deleted the section entitled “limiting access to PDMP information” and moved the language into the section on “direct access to PDMP information.” The language is only relevant to persons with direct access to PDMP information.

Finally, the Board modified the reasons for which it may deny, suspend, revoke or otherwise restrict or limit a dispenser’s, dispenser delegate’s, practitioner’s or practitioner delegate’s direct access to PDMP information by including adverse actions taken by the federal drug enforcement administration and criminal convictions of offenses substantially related to the prescribing or dispensing of a monitored prescription drug.

The second section created by the modification to the section on “access to and disclosure of PDMP information” is entitled “methods of obtaining PDMP information.” It identifies the persons to whom the Board shall disclose PDMP information upon request and sufficient evidence. The Board modified the language to clarify that persons who must request PDMP information may still create accounts and submit requests through them. Further, the Board modified the language to specify the steps that each category of persons must satisfy to enable the Board to disclose PDMP information to them.

The Board also modified the language to better reflect that PDMP information is protected in the same manner as other health care records. Specifically, the Board added the language: “the minimum amount of PDMP information necessary to designated staff of a relevant agency in another state in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 450.19, Stats., this chapter and other state or federal laws and regulations relating to the privacy of patient health care records” in each paragraph describing persons able to obtain PDMP information.

The Board modified the requirements for a patient and patient delegate to obtain PDMP information. The Board modified “[a]ppears in person at the department with two forms of valid government-issued proof of identity, one of which is photographic” to “[a]ppears in person at the department with two forms of valid proof of identity, one of which is valid government-issued photographic identification.”

The Board also deleted the reference to “public health officials” because it added unnecessary confusion. The Board also modified the language to include specific references to “a prisoner's health care provider, the medical staff of a prison or jail in which a prisoner is confined, the receiving institution intake staff at a prison or jail to which a prisoner is being transferred or a person designated by a jailer to maintain prisoner medical records or designated staff of the department of corrections” to clarify their ability to obtain PDMP information under the law.

The Board modified the language in the section entitled “[u]se of PDMP information by the board and department.” Specifically, the Board changed the language to clarify that only Board or Department staff “assigned administrative duties over the PDMP” shall have access to PDMP information under this section. The intent is to clarify that Board or Department staff charged with investigating licensees cannot access information under this section of the proposed rule. Further, the Board modified the list of purposes for which Board and Department staff, vendors and other agents may access PDMP information to include “[e]valuating and responding to legitimate requests for PDMP information.” The intent is to further clarify that Board and Department staff will access the PDMP information under this section for purposes of operating the PDMP.

The Board removed the language regarding “the electronic reporting system” in the section entitled “[u]se of PDMP information by the board and department.” The language does not appear elsewhere in the proposed rule and adds unnecessary confusion.

The Board modified the language in the section entitled “[c]onfidentiality of PDMP information” to be consistent with other sections of the proposed rule that use the language “laws or regulations relating to the privacy of patient health care records.” Further, the Board modified the language to include “criminal” in the list of possible actions against someone who uses PDMP information in violation of the law.

The Board modified the language in the section entitled “[e]xchange of PDMP information” to clarify that the prescription monitoring program in another jurisdiction must be run by a relevant agency in that jurisdiction. The Board modified the language to use the term “jurisdiction” and deleted the term “state” where it appeared in the original language.

In all places it appears in the proposed rule, the Board modified the term “is” in the phrase “is subject to disciplinary action by the appropriate licensing board” to “may be.”

The Board acknowledges the concerns expressed by low volume dispensers who suggest various exemptions from the reporting requirements of the proposed rule. However, the Board does not have the statutory authority to exempt any dispensing of a monitored prescription drug.

The Board also acknowledges the funding concerns of practitioners, dispensers and other potential users of the PDMP. However, securing ongoing funding for the program is outside of the scope of the Board’s rule-making authority.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment 4 c: In s. Phar 18.02 (7), (14), and (15), the acronyms that are used should be defined. In addition, citations to the federal laws or regulations that are mentioned should be provided.

Response: The Board accepts the comment, except the Board finds that the definition of “DEA registration number” in s. Phar 18.02 (6) is sufficiently clear.

Comment 4 d: Section Phar 18.02 (10) should indicate how it may be determined that a person licensed in another state is recognized by this state as a person authorized to dispense drugs. This material could be included in a Note.

Response: The comment is no longer applicable to the proposed rule. The initial definition of “dispenser” was modeled on the statutory definition of “practitioner” in s. 450.02 (17), Stats. However, the Board modified the definition of “dispenser” based on public comments received to clarify whether a “pharmacy” or a “pharmacist” is a “dispenser” under the proposed rule.

Comment 4 e: In s. Phar 18.03 (2) (p), is there a method for a dispenser to determine a patient’s gender other than by visual observation? Is this a concern for instances in which a prescription may be picked up by another person or at a drive-through location, when it may not be possible to determine which passenger in a car is the patient? Is a dispenser obligated to inquire as to gender if the dispenser is not sure?

Response: The Board considered the comment and finds that no changes to the proposed rule are necessary, because a patient’s gender is an integral part of every patient’s medical record kept by practitioners and pharmacies. Therefore, there is no need to describe methods by which a dispenser can ascertain a patient’s gender.

Comment 5 a: In s. Phar 18.02 (11), “it” should be changed to “the dispenser”. Likewise, in s. Phar 18.02 (21), “it” should be changed to “the practitioner”.

Response: The Board accepts the comment as it relates to s. Phar 18.02 (21), practitioner delegates. However, the changes to the definition of “dispenser” discussed above created problems with the original definition of “dispenser delegate” because a pharmacy itself cannot delegate tasks. To rectify the problem, the Board modified the definition of “dispenser delegate.” Therefore, the comment is no longer applicable to the definition of “dispenser delegate.”

Comment 5 d: In s. Phar 18.03 (2), it appears that it would be more precise to state that the data shall “consist of” rather than “contain” the specified data.

Response: The Board rejects the comment because it used the term “contain” to allow dispensers to submit more data, if they so choose. The specific data elements described in the proposed rule constitute the minimum amount of data required and is not intended to limit data to just the elements identified in the proposed rule.

Comment 5 e: In s. Phar 18.03 (2) (h), the phrase “provided by the amount of drug dispensed” or similar language, should be added.

Response: The Board rejects the comment because the language in the proposed rule is clearly understood by health care professionals. Further, the Board finds that the addition

of the phrase “provided by the amount of drug dispensed” would add unnecessary confusion.

Comment 5 h: It appears that the intent of s. Phar 18.04 (4) (intro) would be more accurately conveyed if it were written as follows: “The board may grant a waiver from the requirements of subs. (1) and (6) to a dispenser who does not dispense prescription drugs to humans if the dispenser does all of the following:”.

Response: The Board partially accepts the comment. The Board accepts that there are better ways to describe veterinary dispensers. However, the Board believes it is important to maintain the reference to “animals” in the description. Therefore, the Board developed more succinct language to describe veterinary dispensers.

Comment 5 i: In s. Phar 18.04 (5) (b) 1., the phrase “Compliance would result in” should be inserted before “A substantial hardship”.

Response: The Board removed the substantial hardship requirement under s. Phar 18.04 (5) (b) 1. based on public comments received. Therefore, the comment is no longer applicable to the proposed rule.

Comment 5 j: In s. Phar 18.04 (6), “a prescription drug” should be replaced with “any prescription drugs”.

Response: The Board rejects the comment. The Board changed the term “prescription drug” to “monitored prescription drug” based on public comments received. The Board finds “any monitored prescription drugs” to be unnecessarily confusing.

Comment 5 k: May a dispenser provide the information required in s. Phar 18.05 electronically?

Response: Yes. The Board developed a note explaining the ways, including electronic mail, through which a dispenser may send notice to the Board.

Comment 5 l: The rule should explain what is meant by “health care facility staff committee” and “accreditation or health care services review organization”, referred to in s. Phar 18.08 (4) (c). This comment also applies to “public health official”, referred to in s. Phar 18.08 (4) (d).

Response: The enabling statute, s. 450.19, Stats., requires the proposed rule to comply with the requirements of s. 146.82, Stats., which govern the confidentiality of patient health care records. The terms used in the proposed rule are from s. 146.82, Stats., and the Board does not describe them further to ensure that PDMP information created pursuant to the proposed rule is treated as any other confidential health care record under the law. The Board deleted the reference to “public health official” because it added unnecessary confusion.

Comment 5 m: Should the rule, in s. Phar 18.09, impose a requirement that an individual notify the board if they are no longer appropriately licensed to dispense prescription

drugs? Is there a procedure in place by which the board will be notified of: (1) disciplinary actions taken against Wisconsin dispensers by agencies in other states; or (2) revocation of delegations by practitioners?

Response: Under the practice acts governing health professions, a licensee is required to notify the board that issued him or her the license in the event of an adverse action taken by another state. Therefore, the Board does not find it necessary to add a requirement to notify it of adverse actions taken in other states.

The Board accepts in whole all other recommendations suggested in the Clearinghouse Report. Further, the Board modified the language throughout the proposed rule to be consistent with the comments in the Clearinghouse Report, even if specific references to each instance of identical or similar language was not included in the Clearinghouse Report.

VII. OTHER MODIFICATIONS:

The Board added a reference to s. 961.31, Stats., in the section entitled “[a]uthority and scope.”

The Board modified the rule by renumbering sections, subsections and paragraphs as required by the modifications made based on comments from the public and the Legislative Clearinghouse. Similarly, the Board modified the internal references in the proposed rule to reflect the modified sections, subsections and paragraphs.

VIII. REPORT FROM THE SBRRB AND FINAL REGULATORY FLEXIBILITY ANALYSIS:

The SBRRB met on March 7, 2012 and the Board has not yet received a report from the SBRRB regarding the proposed rule. Therefore, only the Final Regulatory Flexibility Analysis is attached.