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(FORM UPDATED: 08/11/2010)

WISCONSIN STATE LEGISLATURE ...
PUBLIC HEARING - COMMITTEE RECORDS

2011-12
(session year)

Assembly
(Assembly, Senate or Joint)

Committee on Health...

COMMITTEE NOTICES ...

- Committee Reports ... **CR**
- Executive Sessions ... **ES**
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INFORMATION COLLECTED BY COMMITTEE FOR AND AGAINST PROPOSAL

- Appointments ... **Appt** (w/Record of Comm. Proceedings)
- Clearinghouse Rules ... **CRule** (w/Record of Comm. Proceedings)
- Hearing Records ... bills and resolutions (w/Record of Comm. Proceedings)
  (**ab** = Assembly Bill) (**ar** = Assembly Resolution) (**ajr** = Assembly Joint Resolution)
  (**sb** = Senate Bill) (**sr** = Senate Resolution) (**sjr** = Senate Joint Resolution)
- Miscellaneous ... **Misc**

* Contents organized for archiving by: Stefanie Rose (LRB) (October 2013)

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

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 though 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.

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING	:	PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE	:	PHARMACY EXAMINING BOARD
PHARMACY EXAMINING BOARD	:	(CLEARINGHOUSE RULE 12-009)

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.

This rule is not subject to ss. 227.135 (2) or 227.185, Stats., as affected by 2011 Wis. Act 21. The scope statement for this rule, published in Register No. 660, on December 14, 2010, was sent to LRB prior to June 8, 2011 (the effective date of 2011 Wisconsin Act 21).

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted:

Subchapter II of s. 961 and ss. 19.35, 146.82, 450.01 to 065, 09 and 19 and 453.02, Stats.

Statutory authority:

Sections 15.08 (5) (b), 227.11 (2) (a), 450.19 (2) and (5), 961.31, Stats.

Explanation of agency authority:

In s. 450.19 (2), Stats., the legislature directs the Pharmacy Examining Board (Board) to establish by rule a prescription drug monitoring program. In s. 961.31, Stats., the legislature authorizes the Board to promulgate rules relating to the dispensing of controlled substances. Finally, in ss. 15.08 (5) (b), and 227.11 (2) (a), Stats., the legislature confers to the Board the powers to promulgate rules for the guidance of the profession and to interpret the provisions of statutes it enforces.

Related statute or rule:

Section 146.82, chs. 450 and 961, Stats., and chs. Phar 1 and 8 and CSB 2.

Plain language analysis:

The proposed rule creates 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, as changed

by 21 CFR 1308, 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. For each dispensing of a monitored prescription drug, dispensers must compile and submit the following data to the Board:

- dispenser's full name;
- dispenser's NPI number or DEA registration number;
- date dispensed;
- prescription number;
- NDC number or the name and strength of the monitored prescription drug;.
- 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.

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 create accounts with the Board and electronically submit the data to the Board in the format established by the version and release of the American Society for Automation in Pharmacy's Implementation Guide for Prescription Monitoring Programs identified by the Board or other electronic format identified by the Board.

Under the proposed rule, the Board may grant a waiver to a dispenser who is not able to comply with the electronic data submission requirements. The Board may also grant an emergency waiver to a dispenser who is unable to submit data to the Board within 7 days of dispensing a monitored prescription drug. Therefore, dispensers who are not able to comply with one or both of the reporting or submission requirements may submit to the Board applications for a waiver or an emergency 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, dispensers and their delegates are able create

accounts with the Board to access the database and view information that may be helpful in determining whether a patient is using monitored prescription drugs illicitly. The Board may limit a practitioner's, dispenser's or their delegate's access to the information based upon wrongful use of the information, issued disciplinary action or other adverse action taken against a practitioner, dispenser or their delegates.

Further, under the proposed rule, other entities, such as law enforcement authorities, patients and staff of the Department of Safety and Professional Services, may obtain data from the Board as permitted under s. 146.82, Stats.

Dispensers, practitioners and their delegates are able to request that the Board review a denial of a request for a waiver, emergency waiver or limitation imposed upon their access to information. The Board will conduct the review at a regularly scheduled meeting and allow the practitioner, dispenser or delegate to address the Board.

The proposed rule states that the data compiled and stored by the Board under the proposed rules is confidential and not subject to inspection or copying under the state's open records laws.

Under the proposed rule, the Board may exchange data obtained through the PDMP with relevant agencies and prescription monitoring programs in other states.

Summary of, and comparison with, existing or proposed federal legislation:

There is no existing or proposed federal regulation.

Comparison with rules in adjacent states:

Illinois: The statutes and administrative rules governing the Illinois Prescription Monitoring Program require dispensers to submit to a database similar information regarding the prescribing and dispensing of controlled substances (Schedules II-V) within 7 days of the dispensing. *See* 720 Illinois Compiled Statutes 570/316-21 and Illinois Administrative Code Title 77, Chapter X, Subchapter e, Part 2080.

Iowa: The statutes and administrative rules governing the Iowa Prescription Monitoring Program require dispensers to submit to a database similar information regarding the prescribing and dispensing of controlled substances (Schedules II-IV) two times per month. *See* Iowa Code § 124.551-58 and Iowa Administrative Code Title 657, Chapter 37.

Michigan: The statutes and administrative rules governing the Michigan Automated Prescription System require dispensers to submit to a database similar information regarding the prescribing and dispensing of controlled substances (Schedules II-V) two times per month. *See* Michigan Public Health Code § 333.7333a and Michigan Administrative Code R. 338.471.

Minnesota: The statutes governing the Minnesota Prescription Monitoring Program require dispensers to submit to a database similar information regarding the prescribing and dispensing of controlled substances (Schedules II-IV) on a daily basis. *See* Minnesota Statute 152.126.

Summary of factual data and analytical methodologies:

The Board created a Work Group to develop the proposed rule. The Work Group analyzed information from national non-profit organizations that compiled information about other states' prescription monitoring programs. Further, the organizations provided analysis regarding the effectiveness of differing prescription drug monitoring models and processes.

The Board also solicited feedback from approximately fifty stakeholders that represent health care practitioners, pharmacists, pharmacies, hospitals, public health agencies and law enforcement agencies. The Board solicited comments from the stakeholders throughout the development of the proposed rule and many stakeholders submitted comments to the Board. The Board will consult with the stakeholders and other interested individuals as implementation of the PDMP continues.

Further, as of February 2012, there are forty operational state prescription monitoring programs in the United States, including programs in all four states neighboring Wisconsin. The Work Group solicited and compiled information from states' operational prescription monitoring programs regarding best practices and techniques to minimize the burden on practitioners and dispensers. Importantly, the Work Group used the information to ensure the compatibility of the PDMP with prescription monitoring programs in other states and better situate itself for future federal grant funding as required by 2009 Wis. Act 362. The Work Group also identified criteria required to apply for other grants in an effort to maximize the possibility of obtaining future federal grant funding for the PDMP.

Finally, the Work Group relied on the requirements and guidelines of the Harold Rogers Prescription Drug Monitoring Implementation Grant that the federal Department of Justice awarded to the Department to implement the PDMP. The federal grant requirements provide relevant information because they are based on best practices of operational PDMP and the previous experiences of grantees implementing prescription monitoring programs.

Analysis and supporting documents used to determine effect on small business or in preparation of Economic Impact Analysis:

To prepare the Economic Impact Analysis and regulatory flexibility reports for the proposed rule, the Department actively solicited comments from the public and stakeholders representing pharmacies; pharmacists; health care practitioners, including physicians, dentists and veterinarians; hospitals; clinics and law enforcement officials since November 2011. Further, the Department posted notice to solicit comments on the economic impact of the proposed rule on its website for more than 30 days, from December 16, 2011 to January 19, 2012. The Department also held a roundtable discussion about the proposed rule on January 17, 2012 to solicit feedback about the proposed rule from stakeholders and members of the public who expressed interest in the PDMP.

During the solicitation period for comments regarding the economic impact of the proposed rule, the Department received four comments that referred to the economic impact or funding of the

PDMP. Of the four comments, two provide specific estimates regarding the economic impact of the proposed rule on veterinarians in Wisconsin and two present general concerns regarding the ongoing funding of the PDMP beyond the federal grant.

For a complete analysis of the received comments, see the Fiscal Estimate, Economic Impact Analysis and Final Regulatory Flexibility Analysis.

Anticipated costs incurred by the private sector:

As described in the Economic Impact Analysis and Final Regulatory Flexibility Analysis, the Department anticipates that specific segments of the private sector may incur moderate costs to comply with the requirements of the proposed rule. However, while the health care sector may incur moderate costs to comply with the requirements of the proposed rule, the Department does not find that the proposed rule would adversely affect in any material way the economy, any sector of the economy, productivity, jobs or the overall economic competitiveness of this state. Similarly, the Department does not find that the proposed rule will have any economic effect on public utilities or their rate payers.

Fiscal Estimate:

The Fiscal Estimate and Economic Impact Analysis are attached.

Effect on small business:

The Final Regulatory Flexibility Analysis is attached.

Changes to the analysis prepared under s. 227.14 (2), Stats.:

The statutes interpreted are more specific per the Clearinghouse Report.

In the explanation of agency authority, the language "as amended by 2009 Act 362" has been deleted per the Clearinghouse Report.

The plain language analysis has been changed to reflect modifications made to the text of the proposed rule.

Copies of the Proposed Rule, Fiscal Estimate, Economic Impact Analysis or Final Regulatory Flexibility Analysis:

Copies are available upon request to Chad Zadrazil, Department of Safety and Professional Services, Division of Board Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, Wisconsin 53708 or by email at chad.zadrazil@wisconsin.gov.

Agency contact person:

Chad Zadrazil, Program and Policy Analyst – Advanced, Department of Safety and Professional Services, Division of Board Services, 1400 East Washington Avenue, Room 151, P.O. Box 8935, Madison, Wisconsin 53708; telephone 608-266-0011; email at chad.zadrazil@wisconsin.gov.

TEXT OF RULE

SECTION 1. Ch. Phar 18 is created to read:

CHAPTER PHAR 18

PRESCRIPTION DRUG MONITORING PROGRAM

Phar 18.01 Authority and scope. The rules in this chapter are adopted under authority in ss. 15.08 (5) (b), 227.11 (2) (a), 961.31, 450.02 (3) (a) and 450.19, Stats., for the purpose of creating a prescription drug monitoring program to collect and maintain information relating to the prescribing and dispensing of prescription drugs.

Phar 18.02 Definitions. As used in this chapter:

(1) "Access" means to have the ability to view PDMP information through an account established with the board.

(2) "Administer" has the meaning given in s. 450.01 (1), Stats.

(3) "Animal" has the meaning given in s. 453.02 (1m), Stats.

(4) "Board" has the meaning given in s. 450.01 (2), Stats.

(5) "Controlled substance" means a drug, substance, analog or precursor described in any of the following:

(a) Schedule I, II, III, IV or V in the federal controlled substances act, 21 USC 812 (b) (1) to (b) (5) and (c), as changed and updated by 21 CFR 1308.

(b) Schedule I, II, III, IV or V in subch. II. of s. 961, Stats., as amended by ch. CSB 2.

(6) "DEA registration number" means the registration number issued to a pharmacy or practitioner by the federal department of justice, drug enforcement administration.

(7) "Department" means the department of safety and professional services.

(8) "Dispense" has the meaning given in s. 450.01 (7), Stats.

(9) "Dispenser" means all of the following:

(a) a pharmacy from where a pharmacist dispenses a monitored prescription drug.

Note: A site of remote dispensing authorized under s. 450.062, Stats., and s. Phar 7.095 is under the supervision of a pharmacy.

(b) a practitioner who dispenses a monitored prescription drug.

(10) "Dispenser delegate" means an agent or employee of a dispenser to whom the task of inputting or accessing PDMP information has been delegated.

(11) "Dispensing data" means data compiled pursuant to s. Phar 18.04.

(12) "Drug" has the meaning given in s. 450.01 (10), Stats.

(13) "Monitored prescription drug" (a) means all of the following:

1. A controlled substance included in s. 450.19 (1), Stats.

2. A drug identified by the board as having a substantial potential for abuse in s. Phar 18.03.

(b) It does not mean a controlled substance that by law may be dispensed without a prescription order.

(14) "NDC number" means national drug code number, the universal product identifier used in the U.S. to identify a specific drug product.

(15) "NPI number" means national provider identifier number, the registration number issued to a practitioner or pharmacy by the national provider identifier registry.

(16) "Patient" has the meaning given in s. 450.01 (14), Stats.

(17) "Person authorized by the patient" means person authorized by the patient in s. 146.81 (5), Stats., and includes persons with delegated authority under s. 48.979, Stats.

(18) "PDMP information" means all of the following:

(a) The data compiled and stored by the board from dispensing data submitted to it by dispensers.

(b) The information created by the board to satisfy the requirements in s. Phar 18.13.

(19) "Pharmacy" means any place of practice licensed by the board under ss. 450.06 or 450.065, Stats.

(20) "Practitioner" has the meaning given in s. 450.01 (17), Stats.

(21) "Practitioner delegate" means an agent or employee of a practitioner to whom the practitioner has delegated the task of accessing PDMP information.

(22) "Prescription" has the meaning given in s. 450.01 (19), Stats.

(23) "Prescription order" has the meaning given in s. 450.01 (21), Stats.

(24) "Program" means the prescription drug monitoring program established under this chapter.

(25) "Zero report" means a report that indicates that a dispenser has not dispensed a monitored prescription drug since the previous submission of dispensing data or a zero report.

Phar 18.03 Drugs that have a substantial potential for abuse. Pursuant to s. 450.19 (1), Stats., the board has identified all of the following drugs as having a substantial potential for abuse:

(1) A controlled substance identified in schedule II, III, IV or V in the federal controlled substances act, 21 USC 812 (b) (2) to (b) (5) and (c), as changed and updated by 21 CFR 1308.

(2) A controlled substance identified in schedule IV or V in subch. II. of s. 961, Stats., as amended by ch. CSB 2.

(3) Tramadol.

Phar 18.04 Dispensing data. (1) Subject to s. Phar 18.09, a dispenser shall compile dispensing data that contains information about each time he or she dispenses a monitored prescription drug to a patient.

(2) The dispensing data shall contain all of the following information:

(a) The dispenser's full name.

(b) The dispenser's NPI number or DEA registration number.

(c) The date dispensed.

(d) The prescription number.

(e) The NDC number or the name and strength of the monitored prescription drug.

(f) The quantity dispensed.

(g) The estimated number of days of drug therapy.

(h) The practitioner's full name.

(i) The practitioner's NPI number or DEA registration number, if applicable.

(j) The date prescribed.

(k) The quantity prescribed.

(L) The patient's full name.

(m) The patient's address, including street address, city, state and ZIP code.

(n) The patient's date of birth.

(o) The patient's gender.

(3) A dispenser who fails to compile dispensing data as required by subs. (1) and (2) may be subject to disciplinary action by the licensing board that issued the license under which the dispenser is authorized to dispense monitored prescription drugs.

Phar 18.05 Electronic submission of dispensing data. (1) A dispenser shall create an account with the board through which the dispenser shall submit dispensing data to the board.

Note: The application to create an account may be completed online at www.dsps.wi.gov or obtained at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

(2) The dispensing data shall be submitted to the board in compliance with 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.

Note: The guide for dispensers which specifies the data standards in the version and release of the ASAP implementation guide for prescription monitoring programs identified by the board and other electronic formats identified by the board may be obtained online at www.dsps.wi.gov or at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

(3) If a dispenser is not able to create an account or submit dispensing data as required by subs. (1) and (2), the board may grant a waiver to a dispenser who satisfies all of the following conditions:

(a) The dispenser agrees to begin filing dispensing data on a paper form identified by the board for each monitored prescription drug dispensed.

(b) The dispenser files with the board a written application for a waiver on a form provided by the board.

Note: The application for a waiver may be obtained online at www.dsps.wi.gov or at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

(4) A dispenser who fails to create an account with the board and submit dispensing data as required by subs. (1) and (2) or be granted a waiver under sub. (3) may be subject to disciplinary action by the licensing board that issued the license under which the dispenser is authorized to dispense monitored prescription drugs.

Phar 18.06 Frequency of submissions. (1) A dispenser shall submit dispensing data to the board within 7 days of dispensing a monitored prescription drug.

(2) If a dispenser does not dispense a monitored prescription drug for 7 days, the dispenser shall submit a zero report to the board.

(3) If a dispenser is not able to submit dispensing data within 7 days of dispensing a monitored prescription drug as required by sub. (1), the board may grant an emergency waiver to a dispenser who satisfies all of the following conditions:

(a) The dispenser is not able to submit dispensing data because of circumstances beyond its control.

(b) The dispenser files with the board a written application for an emergency waiver on a form provided by the board prior to the required submission of dispensing data.

Note: The application for an emergency waiver may be obtained online at www.dsps.wi.gov or at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

(4) Unless otherwise specified by the board, an emergency waiver shall only be effective for 7 days.

(5) A dispenser who fails to submit dispensing data or a zero report as required by subs. (1) and (2), be granted a waiver under sub. (3), or submits false information to the board may be subject to disciplinary action by the licensing board that issued the license under which the dispenser is authorized to dispense monitored prescription drugs.

Phar 18.07 Veterinary dispensers. (1) The board may grant a waiver from the requirements of s. Phar 18.06 to a dispenser who solely dispenses monitored prescription drugs to animal patients if the dispenser satisfies all of the following conditions:

(a) The dispenser submits dispensing data in accordance with the electronic reporting requirements of s. Phar 18.05, unless they have been separately waived by the board.

(b) The dispenser submits dispensing data compiled under s. Phar 18.04 to the board every 90 days.

(c) The dispenser submits a zero report to the board if he or she does not dispense a monitored prescription drug for 90 days.

(d) The dispenser files with the board a written application for a waiver on a form provided by the board.

Note: The application for a waiver may be obtained online at www.dsps.wi.gov or at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

(2) A dispenser granted a waiver under sub. (1) who fails to submit dispensing data as required by sub. (1) or submits false information to the board may be subject to disciplinary action by the licensing board that issued the license under which the dispenser is authorized to dispense monitored prescription drugs.

Phar 18.08 Correction of dispensing data. If a dispenser discovers omissions or inaccuracies in previously submitted dispensing data or other PDMP information, the dispenser shall notify the board in writing within 7 days and submit documentation that identifies the erroneous information and includes the correct information.

Note: The written notice to the board may be submitted through an account with the board, sent by electronic mail or sent by U.S. mail to the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

Phar 18.09 Exemptions from compiling and submitting dispensing data. (1) The board shall exempt a dispenser from compiling and submitting dispensing data and from submitting a zero report as required under this chapter until the dispenser is required to renew his or her license, or until the dispenser dispenses a monitored prescription drug, if the dispenser satisfies all of the following conditions:

(a) The dispenser provides evidence sufficient to the board that he or she does not dispense monitored prescription drugs.

(b) The dispenser files with the board a written request for exemption on a form provided by the board.

Note: The application for an exemption may be obtained online at www.dsps.wi.gov or at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708. A dispenser who is already exempt can renew his or her exemption as part of the licensure renewal process.

(2) A dispenser is not required to compile or submit dispensing data when the prescription drug is administered directly to a patient.

Phar 18.10 Direct access to PDMP information. (1) Dispensers, practitioners, dispenser delegates and practitioner delegates may access PDMP information 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.

(2) To obtain access to PDMP information, dispensers, practitioners, dispenser delegates and practitioner delegates shall create an account with the board on a form provided by the board.

Note: The application to create an account may be completed online at www.dsps.wi.gov or obtained at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

(3) The board 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 for any of the following reasons:

(a) The dispenser, dispenser delegate, practitioner or practitioner delegate uses PDMP information in violation of ss. 146.82, 450.19, Stats., this chapter or other state or federal laws or regulations relating to the privacy of patient health care records.

(b) The dispenser, dispenser delegate, practitioner or practitioner delegate is no longer licensed in this state or another state and recognized by this state as a person authorized to prescribe or dispense monitored prescription drugs.

(c) The board, other licensing board or regulatory agency takes adverse action against the dispenser, dispenser delegate, practitioner or practitioner delegate.

(d) A licensing board or equivalent regulatory agency in another jurisdiction takes adverse action against the dispenser, dispenser delegate, practitioner or practitioner delegate.

(e) The federal department of justice, drug enforcement administration takes adverse action against the dispenser, dispenser delegate, practitioner or practitioner delegate.

(f) The dispenser, dispenser delegate, practitioner or practitioner delegate is convicted of a crime substantially related to the prescribing or dispensing of a monitored prescription drug.

(g) The dispenser delegate or practitioner delegate is no longer delegated the task of inputting or accessing PDMP information.

Phar 18.11 Requests for review. (1) A dispenser, dispenser delegate, practitioner or practitioner delegate may request that the board review any of the following:

(a) The denial of a waiver requested pursuant to s. Phar 18.05 (3).

(b) The denial of an emergency waiver requested pursuant to s. Phar 18.06 (3).

(c) The denial of a waiver requested pursuant to s. Phar 18.07 (1).

(d) The denial, suspension, revocation or other restriction or limitation imposed on the dispenser's, dispenser delegate's, practitioner's or practitioner delegate's account pursuant 18.10 (3).

(2) To request a review, the dispenser, dispenser delegate, practitioner or practitioner delegate shall file a written request with the board within 20 days after the mailing of the notice of the action in sub. (1). The request shall be in writing and include all of the following:

(a) The dispenser's, dispenser delegate's, practitioner's or practitioner delegate's name and address, including street address, city, state and ZIP code.

(b) The reason for requesting a review.

(3) The board shall conduct the review at its next regularly scheduled meeting and notify the dispenser, dispenser delegate, practitioner or practitioner delegate of the time and place of the review.

(4) No discovery is permitted.

(5) The board shall preside over the review. The review shall be recorded by audio tape unless otherwise specified by the board.

(6) The board shall provide the dispenser, dispenser delegate, practitioner or practitioner delegate with an opportunity to submit written documentation, make a personal appearance before the board and present a statement. The board may establish a time limit for making a presentation. Unless otherwise determined by the board, the time for making a personal appearance shall be 20 minutes.

(7) If the dispenser, dispenser delegate, practitioner or practitioner delegate fails to appear for a review, or withdraws the request for a review, the board may note the failure to appear in the minutes and affirm its original decision without further action.

Phar 18.12 Methods of obtaining PDMP information. (1)The board shall disclose PDMP information about a patient to the patient if he or she does all of the following:

(a) Appears in person at the department with two forms of valid proof of identity, one of which is valid government-issued photographic identification.

(b) Makes a request for the PDMP information on a form provided by the board.

(2) The board shall disclose PDMP information about a patient to a person authorized by the patient if the person authorized by the patient does all of the following:

(a) Appears in person at the department with two forms of valid proof of identity, one of which is valid government-issued photographic identification.

(b) Provides proof sufficient to the board of the authorization or delegation from the patient.

(c) Makes a request for the PDMP information on a form provided by the board.

(3) The board shall disclose 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 if the designated staff does all of the following:

(a) Creates an account with the board on a form provided by the board.

(b) Provides proof sufficient to the board that the relevant agency in another state is entitled to the information under ss. 146.82 and 450.19 (2) (c), Stats.

(c) Makes a request for the PDMP information through its account with the board.

(4) The board shall disclose the minimum amount of PDMP information necessary to a health care facility staff committee, or accreditation or health care services review organization 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 if the designated staff does all of the following:

(a) Creates an account with the board on a form provided by the board.

(b) Provides proof sufficient to the board that the health care facility staff committee, or accreditation or health care services review organization is entitled to the information under s. 146.82 (2) (a) 1., Stats.

(c) Makes a request for the PDMP information through its account with the board.

(5) The board shall disclose the minimum amount of PDMP information necessary to designated staff of a federal or state governmental agency 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 if the designated staff does all of the following:

(a) Creates an account with the board on a form provided by the board.

(b) Provides proof sufficient to the board that the federal or state governmental agency is entitled to the information under s. 146.82 (2) (a) 5., Stats.

(c) Makes a request for the PDMP information through its account with the board.

(6) The board shall disclose the minimum amount of PDMP information necessary to designated staff of the department who is charged with investigating dispensers, dispenser delegates, practitioners and practitioner delegates 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 if the designated staff does all of the following:

(a) Creates an account with the board on a form provided by the board.

(b) Provides proof sufficient to the board that the department is entitled to the information under s. 146.82 (2) (a) 5., Stats.

(c) Makes a request for the PDMP information through its account with the board.

(7) The board shall disclose the minimum amount of PDMP information necessary 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 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 if the person does all of the following:

(a) Creates an account with the board on a form provided by the board.

(b) Provides proof sufficient to the board that the person is entitled to the information under s. s. 146.82 (2) (a) 21., Stats.

(c) Makes a request for the PDMP information through its account with the board.

(8) The board shall disclose the minimum amount of PDMP information necessary to a coroner, deputy coroner, medical examiner or medical examiner's assistant following the death of a patient 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 if the person does all of the following:

(a) Creates an account with the board on a form provided by the board.

(b) Provides proof sufficient to the board that the person is entitled to the information under s. 146.82 (2) (a) 18., Stats.

(c) Makes a request for the PDMP information through its account with the board.

(9) The board shall disclose the minimum amount of PDMP information necessary to a researcher 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 if the person does all of the following:

(a) Creates an account with the board on a form provided by the board.

(b) Provides proof sufficient to the board that the person is entitled to the information under s. ss. 146.82 (2) (a) 6. or 20., Stats.

(c) Makes a request for the PDMP information through its account with the board.

(10) The board shall disclose the minimum amount of PDMP information to designated staff of a law enforcement authority in the same or similar manner, and 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 if the designated staff does all of the following:

(a) Creates an account with the board on a form provided by the board.

(b) Provides a lawful order of a court of record under s. 146.82 (2) (a) 4., Stats., or provides evidence satisfactory to the board that the law enforcement agency is entitled to the information under s. 146.82 (a) 11., Stats.

(c) Makes a request for PDMP information through its account with the board.

Note: The application to create an account and form to request PDMP information may be completed online at www.dsps.wi.gov or obtained at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

Phar 18.13 Use of PDMP information by the board and department. (1) The board shall develop and maintain a PDMP database to store PDMP information.

(2) The PDMP database shall store PDMP information in an encrypted format.

(3) The board shall maintain a log of persons to whom the board grants access to PDMP information.

(4) The board shall maintain a log of information submitted and accessed by each dispenser, dispenser delegate, practitioner and practitioner delegate.

(5) The board shall maintain a log of requests for PDMP information.

(6) Board and department staff assigned administrative duties over the PDMP, vendors and other agents of the board shall only have access to the minimum amount of PDMP information necessary for all of the following purposes:

(a) The design, implementation, operation, and maintenance of the program, including the PDMP database, as part of the assigned duties and responsibilities of their employment.

(b) The collection of prescription drug information as part of the assigned duties and responsibilities under s. 450.19, Stats., and this chapter.

(c) Evaluating and responding to legitimate requests for PDMP information.

(d) Other legally authorized purposes.

Phar 18.14 Confidentiality of PDMP information. (1) The PDMP information maintained by the board, department or a vendor contracting with the department which is submitted to, maintained, or stored as a part of the program is not subject to inspection or copying under s. 19.35, Stats.

(2) A person who discloses PDMP information in violation of ss. 146.82, 450.19, Stats., this chapter or other state or federal laws or regulations relating to the privacy of patient health care records, may be subject to disciplinary action by the licensing board that issued the license under which the person is authorized to prescribe or dispense monitored prescription drugs and all appropriate civil and criminal penalties.

Phar 18.15 Exchange of PDMP information. (1) The board may exchange PDMP information with a prescription monitoring program operated by a relevant agency in another jurisdiction if the prescription monitoring program satisfies all of the following conditions:

(a) The prescription monitoring program is compatible with the program.

(b) The relevant agency operating the prescription monitoring program agrees to exchange similar information with the program.

(2) In determining the compatibility of a prescription drug monitoring program to the program, the board may consider any of the following:

(a) The safeguards for privacy of patient records and the prescription monitoring program's success in protecting patient privacy.

(b) The persons authorized to access the information stored by the prescription drug monitoring program.

(c) The schedules of controlled substances monitored by the prescription monitoring program.

(d) The information required by the agency to be submitted regarding the dispensing of a prescription drug.

(e) The costs and benefits to the board of sharing information.

(3) The board may assess a prescription drug monitoring program's continued compatibility with the program at any time.

(END OF TEXT OF RULE)

The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.22 (2) (intro.), Stats.

Dated _____ Agency _____

Chairperson
Pharmacy Examining Board

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA 2049 (R 07/2011)

ADMINISTRATIVE RULES
FISCAL ESTIMATE AND ECONOMIC IMPACT ANALYSIS

Type of Estimate and Analysis

☐ Original ☒ Updated ☐ Corrected

Administrative Rule Chapter, Title and Number

Wis. Admin. Code Ch. Phar 18

Subject

Prescription drug monitoring program

Fund Sources Affected	Chapter 20, Stats. Appropriations Affected
☐ GPR ☐ FED ☒ PRO ☐ PRS ☐ SEG SEG-S	20.165(1)(g) and 20.165(1)(h)(g)

Fiscal Effect of Implementing the Rule

☐ No Fiscal Effect ☐ Indeterminate	☐ Increase Existing Revenues ☐ Decrease Existing Revenues	☒ Increase Costs ☐ Could Absorb Within Agency's Budget ☐ Decrease Costs

The Rule Will Impact the Following (Check All That Apply)

☐ State's Economy ☐ Local Government Units	☒ Specific Businesses/Sectors ☐ Public Utility Rate Payers

Would Implementation and Compliance Costs Be Greater Than $20 million?

☐ Yes ☒ No

Policy Problem Addressed by the Rule

The proposed rule implements the legislative mandate in 2009 Wisconsin Act 362, which directs the Pharmacy Examining Board to establish through rule a prescription drug monitoring program (PDMP). The primary purpose of the PDMP is to decrease the illicit use of prescription drugs and the resulting health care, social and law enforcement costs.

The U.S. Centers for Disease Control and Prevention (CDC) has stated that "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). Between 1999 and 2007, deaths related to opioid overdoses increased by 296%, from 2,901 to 11,499 (SCAODA, 5). According to the CDC, one person died every 19 minutes in 2007 because of an "unintentional drug overdose" (CDC, "Grand Rounds: Prescription Drug Overdoses — a U.S. Epidemic," Jan. 13, 2012). In fact, 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).

In 2001, the cost to society of pain reliever abuse alone was estimated to be $8.6 billion (SCAODA, 30, *citing* Angela Baldesare, "Cost of Prescription Drug Abuse: A Literature Review," Jan. 6, 2011). Since 2001, there has been an approximately 58% increase in the number of Americans who have abused prescription pain relievers, from 22 million in 2001 to approximately 35 million in 2009 (SCAODA, 30). While more recent data on the costs associated with prescription drug abuse is not available, the associated costs have likely risen as well (*id.*).

The prescription drug abuse problem involves diversion of those drugs. According to the National Survey on Drug Use and Health, nearly one-third of people age 12 and over who used drugs for the first time in 2009 began by using a prescription drug non-medically (Substance Abuse and Mental Health Services

Administration (SAMHSA), "Results from the 2009 National Survey on Drug Use and Health, Vol. 1, Summary of National Findings," 2010). The SAMHSA survey also states that over 70% of people abusing prescription pain relievers got those drugs from friends or relatives (*id.*).

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). Between 2007-08, 15% of adults in Wisconsin reported using pain relievers for non-medical purposes (SCAODA, 5). Based on current trends, the misuse of prescription drugs will soon surpass marijuana as the most used illegal drug in Wisconsin (*id.*).

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.*)

Finally, 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).

Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)

In September 2011, the United States Department of Justice awarded a Harold Rogers Prescription Drug Monitoring Program- Implementation Grant to the Department of Safety and Professional Services, of which the Pharmacy Examining Board is part. The grant is in the amount of $399,284 and is scheduled to end in September 2013. However, the grant may end earlier if all of the grant funds are exhausted. The sole purpose of the grant is to fund the development and implementation of the PDMP. The Department anticipates that the grant will fully fund the development and implementation of the PDMP.

Once grant funds are exhausted, there will be ongoing operational costs to the Department. The operational costs include staff costs related to monitoring and administering the PDMP. Specifically, the Department will need a full-time program and planning analyst to monitor the program and work with the vendor and others to manage the PDMP. Further, there will be ongoing costs for a vendor to host and maintain the PDMP database, website and other related IT components of the PDMP. Based on the annual costs incurred by similar prescription monitoring programs in other states, the Department's fiscal estimate is approximately $210,000 for annual operational costs.

The proposed rule will affect health care practitioners; including physicians, advanced practice nurses, dentists, optometrists and veterinarians; pharmacies and pharmacists. While individuals and businesses in the health care sector will incur minimal to moderate costs to comply with the requirements of the proposed rule, the Department does not find that the proposed rule would adversely affect in any material way the economy, any sector of the economy, productivity, jobs or the overall economic competitiveness of this state. Similarly, the Department does not find that the proposed rule will have any economic effect on public utilities or their rate

payers.

The Department solicited written comments from businesses, associations representing businesses, local governmental units and the public for over 30-days by posting a notice and the text of the proposed rule on the Department's website and the Administrative Rules website. Further, the Department emailed the proposed rule and notice of the comment period to businesses, associations representing businesses and individuals who had indicated an interest in the proposed rule or who would be directly affected by it. On several occasions, the Department reminded the businesses, associations representing businesses and individuals about the solicitation period.

In addition to the solicitation period for written comments, the Department held a roundtable discussion about the rule with identified businesses, associations representing businesses and individuals who had expressed an interest in or who would be directly affected by the proposed rule. Seventeen people, representing businesses, associations and other governmental agencies, attended the roundtable discussion. At the roundtable, representatives from the Pharmacy Society of Wisconsin (PSW) and the National Association of Chain Drug Stores (NACDS) expressed concern regarding the ongoing operational funding of the PDMP.

The Department received four written comments that referred to the economic impact or funding of the PDMP during the solicitation period for written comments. The comments were from Dr. Richard Spencer, the Chairperson of the Wisconsin Veterinary Examining Board, the Wisconsin Veterinary Medical Association (WVMA), PSW and NACDS. The comments from PSW and NACDS reiterate concerns expressed at the roundtable discussion about the ongoing funding of the PDMP. The comments from PSW and NACDS do not offer specific estimates regarding the economic impact of the proposed rule. The comments from Dr. Spencer and WVMA concern the economic impact of the proposed rule on veterinarians in Wisconsin and include specific estimates. No other individual, business or association submitted estimates of the proposed rule's economic impact.

The comments from Dr. Spencer and the WVMA specifically regard the estimated economic impact of the proposed rule on veterinarians. In his comments, Dr. Spencer estimates that it would take a staff person in his clinic one to two hours to compile and submit the required information to the PDMP and cost between $30 and $60 per submission. Dr. Spencer states that he would likely cease dispensing monitored prescription drugs and merely prescribe them to be dispensed by a pharmacist.

In its comments, the WVMA estimates that the yearly costs to veterinarians in Wisconsin would be $7,953,816, or approximately $11,000 of direct personnel costs and lost revenue per year for each of the 719 veterinarian clinics in Wisconsin. The WVMA based its estimate on the assumption that it would take approximately 4.5 hours per week to comply with the requirements of the proposed rule for a clinic with some electronic health records (EHR) and 6.5 hours per week to comply for clinics without EHR. The WVMA did not provide or describe its calculations or underlying assumptions it used to calculate its estimate.

To better estimate the economic impact of the proposed rule on veterinarians and other health care practitioners without EHR, the Department asked the WVMA to provide more information about its estimate. Specifically, the Department asked for more information regarding:

- the estimated number of times per week, on average, that veterinarians dispense a monitored prescription drug from their clinic and how it estimated the number;
- the basis for assuming that it will take a clinic 4.5 hours per week, on average, for clinics with some type of EHR to comply with the requirements in the proposed rule; and
- the basis for assuming that it will take a clinic 6.5 hours per week, on average, for clinics without EHR to comply with the requirements in the proposed rule.

After the submission of the original Economic Impact Analysis, the WVMA provided the following information in response to the Department's request:

- There is no software to track the average number of times per week that veterinarians dispense monitored prescription drugs.

- Most veterinarians do not utilize EHR and "will have to, therefore, re-type the information requested in the rule to get it into a reportable form to send to DSPS."
- The WVMA has not been able to find "software that would pull the requested fields into one report"
- The average number of veterinarians per clinic is 4.17. Therefore, to estimate the number of hours it would take a veterinarian at a clinic with EHR to comply with the reporting requirements, the WVMA interviewed a representative from a clinic with six veterinarians and a representative from a clinic with three veterinarians. The clinics utilized different EHR software. The WVMA asked the representatives to compile the information required under the proposed rule. The representatives reported their total time to the WVMA. The WVMA averaged the two times reported by the representatives to get its estimate of 4.5 hours per week to comply with the requirements of the proposed rule for clinics with EHR.
- The WVMA estimated the number of hours it would take a veterinarian at a clinic without EHR to comply with the reporting requirements in much the same way, "but with the realization that a person would need to manually go through paper records and pull the information."
- The WVMA states that its estimates were based "on pulling the information for the entire clinic – not by each individual dispensing veterinarian." It notes that "[a]t the informational meeting we learned that DSPS would like the information to be pulled by veterinarian, which most likely will increase the time."
- Finally, the WVMA notes that:
    - "[V]eterinary clinics are unable to pull all the fields that are currently being proposed."
    - "Some fields are not used or are irrelevant for veterinary medicine."
    - "[T]hese estimates do not include the time or costs associated with securing the state vendor's platform software or any additional software purchase."
    - The hourly wage used to calculate the estimated cost is low and that the clinics that were consulted pay more than the wage the WVMA used in its estimates.
    - The estimate includes lost revenue. If an "individual is pulling information for mandatory reporting, they are not providing service for clients, thus losing revenue potential [for the clinic]." The WVMA also notes that the wage it used to calculate lost revenue was also "very low."

Despite the comments from the WVMA, the Department does not find that health care practitioners, pharmacies or pharmacists will incur significant costs to comply with the reporting requirements of the proposed rule.

The professions most affected by the requirements of the proposed rule would likely only incur the minimal programming costs described above because of their existing reliance on EHR. According to the Wisconsin Department of Health Services (DHS), approximately 74% of physicians are in large group practice and utilize EHR. Therefore, approximately 18,500 of the approximately 25,000 licensed physicians in Wisconsin practice in a large group setting and utilize EHR. Further, according to DHS, only 17 pharmacies in Wisconsin are not capable of receiving electronic prescription orders. Therefore, just over 1% of the approximately 1,274 pharmacies licensed in Wisconsin are not able to receive electronic prescription orders.

For health care professionals who already utilize EHR; including physicians, other health care practitioners in large group practices, pharmacies and pharmacists; there would likely be minimal up-front cost associated with the computer programming required to compile and electronically submit the data to the PDMP. The up-front costs would vary from a few hundred dollars to a few thousand dollars depending on the size of the practice, the sophistication of the EHR software and whether the practitioner, pharmacy or pharmacist currently reports to an operational prescription monitoring program in another state. Once the initial up-front programming is complete, there would not be any significant ongoing costs required to maintain compliance with the proposed rule.

However, as the comments from the WVMA state, the use of EHR is not as prevalent among veterinarians. In fact, according to the WVMA, only 273 of the 719 veterinary clinics in Wisconsin, approximately 38%, are able to access prescription information electronically.

In estimating the economic impact on veterinarians and other health care practitioners, pharmacies and

pharmacists without EHR, the Department analyzed the comments submitted by Dr. Spencer and the WVMA. The Department believes the estimate provided by the WVMA is significantly higher than the costs health care practitioners, pharmacies and pharmacists would reasonably incur under the proposed rule for a number of reasons. The Department estimates that health care practitioners, pharmacies and pharmacists without EHR would likely incur ongoing personnel costs involved in the manual inputting and submitting of information to the PDMP that vary from a few hundred dollars per 90-day period to a few hundred dollars per week. The variance depends on whether the dispenser dispenses the monitored prescription drugs solely to non-human animals, the frequency of dispensing monitored prescription drugs and the business process chosen to collect and submit the information to the PDMP.

The methodology through which the WVMA calculated the amount of time it would take veterinarians with EHR and veterinarians without EHR to comply with the requirements of the proposed rule resulted in an excessively high estimated yearly cost. Specifically, the data collection method used by the WVMA involved staff persons at the two chosen veterinary clinics retroactively searching an unspecified number of records to collect the data required by the proposed rule. While the proposed rule purposefully does not regulate the business process through which health care practitioners, pharmacies and pharmacists could comply with the reporting requirements, affected individuals and business will have advance notice of all requirements of the proposed rule. Therefore, they will be able to collect the required information in a proactive manner as opposed to combing through healthcare records for the information at a later date. With advance notice and a proactive business practice to collect the required information, the time required to comply with the requirements for veterinary clinics and other health care practitioners without EHR would be significantly less. Consequently, the cost to the practitioners, including direct staffing costs and lost revenue, would be much less than the amount estimated by the WVMA.

Another issue with the estimated economic impact submitted by the WVMA is that it is based on an assumption that the proposed rule requires weekly submissions of data to the PDMP. Despite the fact that veterinarians dispense the same, human-grade monitored prescription drugs as other health care practitioners, the proposed rule explicitly includes less stringent reporting requirements for veterinary dispensers. Specifically, the proposed rule enables dispensers who solely dispense to non-human, animal patients to apply for a waiver of the 7-day reporting requirement and instead be required to submit data to the PDMP every 90-days. Therefore, the personnel costs associated with collecting and submitting data to the PDMP would be incurred every 90-days and not on a weekly basis for veterinarian dispensers.

Next, the estimated economic impact and follow-up information submitted by the WVMA did not provide information concerning the frequency that veterinarians dispense the monitored prescription drugs. Further, there is no indication of the number of monitored prescription drugs that were dispensed by the two representative clinics or how their dispensing practices relate to the dispensing practices at other veterinary clinics. The estimate submitted by the WVMA also assumes that all veterinary clinics dispense monitored prescription drugs from their clinic without providing any evidence of such.

The Department understands that there is no software available to track the frequency of veterinary dispensing of monitored prescription drugs. However, the Department has no information regarding the frequency of dispensing or how the two sample clinics relate to the average frequency. Significantly, there are great variances among veterinary and other health care clinics that dispense monitored prescription drugs. Some clinics may dispense a monitored prescription drug quite frequently, while others may dispense a monitored prescription drug infrequently or not at all.

Further, there is variety in the practice of veterinary medicine, from practices that specialize in large animals to practices that specialize in treating companion animals. Considering the variances in practice scopes and settings, it is reasonable that some veterinarians dispense monitored prescription drugs regularly and others do not.

In its follow-up explanation of its estimated economic impact, the WVMA also notes that its estimate does not include "the time or costs associated with securing the state vendor's platform software or any additional software purchase." The Department is not aware of any direct cost to health care practitioners, pharmacies or pharmacists to secure the "state vendor's platform software or any additional software." In fact, all health care

practitioners, pharmacies and pharmacists would be able to comply with the reporting requirements of the proposed rule without incurring any software costs. The PDMP will allow direct data entry through a secure web page that is accessible through a standard web browser. Further, if a health care practitioner, pharmacy or pharmacist does not have computer access, the proposed rule allows him, her or it to apply for a waiver of the electronic reporting requirements and submit data to the PDMP on paper.

Finally, the proposed rule includes an exemption from all compliance requirements of the rule for health care practitioners, pharmacies and pharmacists that do not dispense any of the monitored prescription drugs. To make the administrative burden as small as possible, the proposed rule relates the application for an exemption to licensure renewal. Therefore, health care practitioners, pharmacies and pharmacists that do not dispense monitored prescription drugs will not have any additional filing requirements or costs related to the PDMP.

Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule

The benefit of implementing the proposed rule is to ultimately lessen the occurrences of prescription drug diversion, the illicit use of prescription drugs in Wisconsin and resulting health care, social and law enforcement costs. The proposed rule is also in conformity with legislative directive in 2009 Wisconsin Act 362. While an alternative to implementing the rule is to not comply with the legislative directive in 2009 Wisconsin Act 362 and not to monitor the dispensing of monitored prescription drugs across the state, the State would not experience the significant benefits of having a PDMP.

The proposed rule 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 their efforts to curb prescription drug abuse in Wisconsin. Based on independent evaluations and studies of operational prescription monitoring programs in other states, the Prescription Monitoring Program Center of Excellence of Brandeis University, states that:

> P[D]MPs are important tools in the effort to curb major sources of prescription drug diversion: prescription fraud, forgeries, doctor shopping and illicit, medically unwarranted prescribing on the part of some practitioners and pharmacists. P[D]MPs therefore serve an essential function in combating the prescription drug abuse epidemic (Prescription Monitoring Program Center of Excellence, "Briefing on PMP Effectiveness," *Brandeis University*, 2, Feb. 2011).

While exact costs of prescription drug abuse are unknown, SCAODA has "no doubt ... that the costs [of prescription drug abuse] are substantial, when one includes health care, criminal justice and societal costs in the equation" (SCAODA, 30).

Excessive healthcare costs in Wisconsin would decrease with the implementation of the PDMP. According to the LaFollette Analysis, "prescription drug abusers have 12 times as many hospital stays, and 63 times as many out-patient visits compared to non-abusers" (LaFollette, 6, *citing* Alan White, et al., *Direct Costs of Opioid Abuse in an Uninsured Population in the United States*, Journal of Managed Care Pharmacy, Vol. 11, No. 6, Jul./Aug. 2005). Further, "excess health care costs due to opioid abuse are estimated to be $9,446 for privately insured individuals and $12,394 for publicly insured individuals" (LaFollette, 7 and App. G). Operational PDMPs result in reductions in excess hospital admissions and addiction treatment and a reduction in the costs of prescription drugs associated with prescription drug abuse (*id.*). Therefore, the LaFollette Analysis predicts a health care savings of $113,000,000 during the first ten years of having an operational PDMP in Wisconsin (*id.*).

The proposed rule and resulting PDMP would substantially decrease the social costs of prescription drug abuse. As described in the LaFollette Analysis, "[t]he deterred abuse that could result from a PDMP in Wisconsin would significantly reduce the productivity loss associated with prescription drug abuse" (LaFollette, 7 and App. H). In the United States, prescription opioid abuse results in $4,545,900,000 workplace productivity loss every year (*id.*). Therefore, the Analysis conservatively estimates the PDMP will result in $9,290,000 annual avoided productivity loss associated with prescription opioid drug abuse in Wisconsin (*id.*).

The proposed rule would also reduce law enforcement costs associated with investigating suspected prescription drug abuse. According to the LaFollette Analysis, a PDMP would reduce the costs of investigating crimes associated with suspected prescription drug abuse by $112,077 per year (LaFollette, 7-8 and App. I). Further, the Department anticipates that the PDMP will reduce its costs associated with investigating licensees suspected of diverting prescription drugs.

Finally, the proposed rule would be effective in addressing the prescription drug abuse epidemic in Wisconsin. A 2009 study analyzed the effectiveness of the 32 then-operational PDMPs and concluded that "PDMPs can successfully deter prescription opioid diversion and abuse" (Richard Reisman, et al., "Prescription Opioid Usage and Abuse Relationships: An Evaluation of State Prescription Drug Monitoring Program Efficacy," *Journal of Substance Abuse: Research and Treatment*, 2009). Further, the results of the study "support[] the efficacy of PDMPs and provides statistical support for establishing PDMPs in all states" (*id.*). With such significant estimated benefits of having a PDMP, SCAODA recommends that "first and foremost, Wisconsin [] continue its efforts to implement a well designed PDMP, which will be an effective tool across a number of priority areas including health care, surveillance and law enforcement" (SCAODA, 31).

Long Range Implications of Implementing the Rule

The anticipated long range results of implementing the proposed rule are a reduction in the non-medical use of controlled substances and other prescription drugs that have a substantial potential for abuse and reduction in related health care, social and law enforcement costs.

Compare With Approaches Being Used by Federal Government

There is no existing or proposed federal regulation comparable to the proposed rule.

Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

The proposed rule is similar to the approaches being used by Illinois, Iowa, Michigan and Minnesota, who currently have operational prescription monitoring programs. Further, as of February 1, 2012, 41 states have operational prescription monitoring programs similar to the one established by the proposed rule.

Name and Phone Number of Contact Person

Chad Zadrazil, Program and Policy Analyst – Advanced, 608-266-0011

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA 2049 (R 07/2011)

ADMINISTRATIVE RULES
FISCAL ESTIMATE AND ECONOMIC IMPACT ANALYSIS

Type of Estimate and Analysis

☒ Original ☐ Updated ☐ Corrected

Administrative Rule Chapter, Title and Number

Wis. Admin. Code Ch. Phar 18

Subject

Prescription drug monitoring program

Fund Sources Affected	Chapter 20 , Stats. Appropriations Affected
☐ GPR ☐ FED ☒ PRO ☐ PRS ☐ SEG SEG-S	20.165(1)(g) and 20.165(1)(h)(g)

Fiscal Effect of Implementing the Rule

☐ No Fiscal Effect	☐ Increase Existing Revenues	☒ Increase Costs
☐ Indeterminate	☐ Decrease Existing Revenues	☐ Could Absorb Within Agency's Budget
		☐ Decrease Costs

The Rule Will Impact the Following (Check All That Apply)

☐ State's Economy	☒ Specific Businesses/Sectors
☐ Local Government Units	☐ Public Utility Rate Payers

Would Implementation and Compliance Costs Be Greater Than $20 million?

☐ Yes ☒ No

Policy Problem Addressed by the Rule

The proposed rule implements the legislative mandate in 2009 Wisconsin Act 362, which directs the Pharmacy Examining Board to establish through rule a prescription drug monitoring program. The primary purpose of the prescription drug monitoring program is to decrease the illicit use of prescription drugs and the resulting social, health care and law enforcement costs. As noted in a 2011 report issued by the Executive Office of the President of the United States, "Epidemic: Responding to America's Prescription Drug Abuse Crisis," prescription drug abuse is the country's fastest-growing drug problem.

According to the National Survey on Drug Use and Health (NSDUH), nearly one-third of people age 12 and over who used drugs for the first time in 2009 began by using a prescription drug non-medically ("Results from the 2009 National Survey on Drug Use and Health: National Findings," SAMHSA, 2010). The same survey also states that the vast majority of people abusing prescription pain relievers (over 70%) got those drugs from friends or relatives. The "Monitoring the Future" study—which surveys drug use among young people—showed that prescription drugs are the second most-abused category of drugs after marijuana ("Monitoring the Future: A Synopsis of the 2009 Results of Trends in Teen Use of Illicit Drugs and Alcohol," University of Michigan).

Given the recent report from the President's office and other sources of data, it is clear that prescription drug abuse is a serious problem in America and it is a problem that has grown over the last decade. Wisconsin's problems mirror the nation's, with prescription drug abuse encompassing such activities as "doctor shopping" to obtain multiple prescriptions, illegal sales of prescription drugs by prescribers, and prescription forgery. Wisconsin's prescription drug abuse rate is on par with the national average, with 5.83% of state residents age 12 and older reporting use of pain relievers for non-medical purposes in 2005-06 (SAMHSA 2007; WIDHS 2008).

It has been estimated that, in 2010, there were roughly 297,331 abusers in Wisconsin. The social costs of drug abuse include decreased productivity and absence from work, increased health care costs, and increased law

enforcement costs (Birnbaum, H., et al., 2006, "Estimated Costs of Prescription Opioid Analgesic Abuse in the United States in 2001," Clinical Journal of Pain. 22(1): 667-676).

Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)

There will be ongoing staff costs related to monitoring and administering the program. DSPS will have the need for a full-time program and planning analyst to monitor the program and work with the vendor and others to manage the program. Further, there will be ongoing costs for a vendor to host and maintain the PDMP database, website and other related IT components of the PDMP. Based on the annual costs incurred by similar prescription monitoring programs in other states, we anticipate annual costs of approximately $210,000.

While the health care sector will incur moderate costs to comply with the requirements of the proposed rule, the Department does not find that the proposed rule would adversely affect in any material way the economy, any sector of the economy, productivity, jobs or the overall economic competitiveness of this state. Similarly, the Department does not find that the proposed rule will have any economic effect on public utilities or their rate payers.

During the solicitation period for comments regarding the economic impact of the proposed rule, the Department received four comments that referred to the economic impact or funding of the PDMP. The comments are attached. Of the four comments, two provide specific estimates regarding the economic impact of the proposed rule on veterinarians in Wisconsin and two present general concerns regarding the ongoing funding of the PDMP.

The two comments about the economic impact on veterinarians present differing estimates on the impact to the profession. The first comment, from Dr. Richard Spencer, the Chairperson of the Wisconsin Veterinary Examining Board, estimates that it would take a staff person one to two hours to compile and submit the required information to the PDMP and cost between $30 and $60 per submission. Dr. Spencer also states that he would likely cease dispensing monitored prescription drugs and merely prescribe them to be dispensed by a pharmacist.

The other comments regarding the economic impact of the proposed rules on the veterinary profession are from the Wisconsin Veterinary Medical Association (WVMA). The WVMA estimates that the yearly impact on veterinarians would be $7,953,816, or approximately $11,000 of direct personnel costs and lost revenue for each of the 719 veterinarian clinics in Wisconsin as of December 2011. The estimate is based on the assumption that it would take approximately 4.5 hours per week to comply with the requirements of the proposed rule for a clinic with some electronic health records and 6.5 hours per week to comply for clinics without any electronic health records.

The Department sought further information regarding the WVMA's assumptions in their analysis. The Department has yet to receive any further information. Specifically, the Department asked for further information regarding:

- the estimated number of times per week, on average, that veterinarians dispense a monitored prescription drug from their clinic and how it estimated the number;
- the basis for assuming that that it will take a clinic 4.5 hours per week, on average, for clinics with some type of electronic records to comply with the requirements in the draft rules; and
- the basis for assuming that it will take a clinic 6.5 hours per week, on average, for clinics without any electronic records to comply with the requirements in the draft rules.

The Department believes the information is required to estimate the proposed rule's economic impact on the veterinary profession and will continue to search for it. Without having information regarding the number of times veterinarians dispense the monitored prescription drugs, the Department has no way to validate or calculate Dr. Spencer's or the WVMA's estimate economic impact.

Further, the proposed rule already includes a less stringent compliance and reporting requirements for veterinarians, including less stringent schedules for compliance reporting requirements. Specifically, the

proposed rule enables the Board to waive the 7-day reporting requirements for dispensers who solely dispense to non-human animal patients. Under the terms of the waiver, veterinarian dispensers would be required to submit data to the PDMP every 90-days.

Finally, the proposed rule includes an exemption from all compliance requirements of the rule for pharmacies, pharmacists and health care practitioners that do not dispense any of the monitored prescription drugs. To make the administrative burden as small as possible, the proposed rule relates the application for an exemption to licensure renewal. Therefore, the pharmacies, pharmacists and health care practitioners that do not dispense any of the monitored prescription drugs will not have any additional filing requirements or deadlines.

Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule

The benefit of implementing the proposed rule is to ultimately lessen the occurrences of prescription drug diversion, the illicit use of prescription drugs in Wisconsin and resulting social, health care and law enforcement costs. The proposed rule creates a tool that will enable the approximately 50,000 pharmacies; pharmacists; practitioners, including physicians, dentists and veterinarians; law enforcement agencies and public health officials to obtain invaluable information to assist in their efforts to curb prescription drug abuse in Wisconsin. Further, the proposed rules are in conformity with legislative directive in 2009 Wisconsin Act 362. An alternative to implementing the rule is to not comply with legislative directive in 2009 Wisconsin Act 362 and to not monitor the dispensing of controlled substances across the state.

Long Range Implications of Implementing the Rule

The anticipated long range results of implementing the proposed rule are a reduction in the non-medical use of controlled substances and other prescription drugs that have a substantial potential for abuse and reduction in related social, health care and enforcement costs. The reductions will be due to the ability of practitioners and dispensers to ensure that their patients are not "doctor shopping" or undertaking other activities associated with the non-medical use of prescription drugs.

Compare With Approaches Being Used by Federal Government

There is no existing or proposed federal regulation comparable to the proposed rule.

Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

The proposed rule is similar to the approaches being used by Illinois, Iowa, Michigan and Minnesota, who currently have operational prescription monitoring programs. In addition, 36 other states currently have operational prescription monitoring programs similar to the one established by the proposed rule.

Name and Phone Number of Contact Person

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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.

LCRC
FORM 2

WISCONSIN LEGISLATIVE COUNCIL
RULES CLEARINGHOUSE

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CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

CLEARINGHOUSE RULE **12-009**

AN ORDER to create ch. Phar 18, relating to the prescription drug monitoring program and affecting small business.

Submitted by **DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES**

01-27-2012 RECEIVED BY LEGISLATIVE COUNCIL.

02-21-2012 REPORT SENT TO AGENCY.

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LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]

   Comment Attached YES ☐ NO ☑

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]

   Comment Attached YES ☑ NO ☐

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]

   Comment Attached YES ☐ NO ☑

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS [s. 227.15 (2) (e)]

   Comment Attached YES ☑ NO ☐

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]

   Comment Attached YES ☑ NO ☐

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL REGULATIONS [s. 227.15 (2) (g)]

   Comment Attached YES ☐ NO ☑

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]

   Comment Attached YES ☐ NO ☑

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CLEARINGHOUSE RULE 12-009

Comments

[NOTE: All citations to "Manual" in the comments below are to the Administrative Rules Procedures Manual, prepared by the Legislative Reference Bureau and the Legislative Council Staff, dated November 2011.]

2. Form, Style and Placement in Administrative Code

The entire rule should be reviewed and redrafted as necessary to conform to proper drafting style of introductory material and punctuation at the end of subunits. In particular, introductory material should end with a colon and contain words like "all of the following" or "any of the following". Each subunit following the introduction should form a complete sentence when read with the introduction. Subunits of a rule should not end with "and" or "or". [See s. 1.03 (3) and (4) of the Manual.] Many provisions of the rule need to be redrafted in this regard. Section Phar 18.02 (23) is in particular need of editing.

4. Adequacy of References to Related Statutes, Rules and Forms

a. In the Statutes Interpreted section of the analysis, more specific citations than "Chapters 961 and 450, Stats." should be provided.

b. In the Explanation of Agency Authority for the rule, the phrase "as amended by 2009 Act 362" is not necessary because all amendments to the statutes that were made by Acts of 2009 have been incorporated in the current version of the Wisconsin statutes.

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.

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. [s. 1.09 (1) and (2), Manual.]

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?

f. In several instances, notes should be created to disclose where or how particular information, including forms, may be obtained. For example, a note should be inserted following s. Phar 18.04 (2) to explain where the ASAP implementation guide may be obtained, and all provisions of the rule that refer to forms, such as a form for an extension of time to file data in s. Phar 18.04 (3) (b), should include a note explaining how the required form may be obtained. [See s. 1.09 (1) of the Manual.]

g. In s. Phar 18.04 (4) (a), "requirements of this section" should be changed to "requirements of sub. (2)."

5. Clarity, Grammar, Punctuation and Use of Plain Language

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".

b. In s. Phar 18.02 (18), the phrase "and other information pertaining to the program" is vague. Could it be made more specific?

c. It appears that it is unnecessary to define "submit", which is done in s. Phar 18.02 (26), because the text of the rule sets forth the requirement that data be delivered electronically. In any event, the definition is not properly drafted, since it defines a noun, while the word "submit" is a verb.

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.

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

f. Section Phar 18.03 (3) states that a dispenser is subject to disciplinary action by the "appropriate licensing board". Would it be more informative to state that a dispenser is subject to disciplinary action by the board that issued the license under which the dispenser is authorized to dispense prescription drugs?

g. In all provisions of the rule that create a right to request a waiver or extension of any requirement, the rule should set forth a timeframe for submission of the request and for action by the board, as well as a description of the process by which a person may appeal a denial of the request. Likewise, the rule should set forth a process for appeal of a suspension, revocation, or

restriction imposed by the board under s. Phar 18.09 (intro). In addition, consistent terminology should be used when referring to "waivers" and "extensions". It appears that s. Phar 18.04 (3) refers to a waiver, while sub. (3) (b) refers to the same item as an "extension".

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:".

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

j. In s. Phar 18.04 (6), "a prescription drug" should be replaced with "any prescription drugs".

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

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).

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?