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 (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

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