Report From Agency

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULEMAKING	**:**	
PROCEEDINGS BEFORE THE	**:**	**REPORT TO THE LEGISLATURE**
CONTROLLED SUBSTANCES BOARD	**:**	**CR 17-028**

I. THE PROPOSED RULE:

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

II. REFERENCE TO APPLICABLE FORMS: N/A

III. FISCAL ESTIMATE AND EIA:

The Fiscal Estimate and EIA is 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 statutes directs the Controlled Substances Board to establish by rule a prescription drug monitoring program and lists several requirements for the program 2015 Acts 266, 267 and 268 amended these requirements , specifically the requirements related to reporting, disclosure, and practitioner review. This rule amends the rule to implement these Acts and make other necessary changes resulting from the implementation.

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

The Controlled Substances Board held a public hearing on May 12, 2017. The following people either testified at the hearing, or submitted written comments:

Mark Grapentine, representing Wisconsin Medical Society
Matthew Stanford, representing Wisconsin Hospital Association
Joe Kachelski, representing Wisconsin Statewide Health Information Network
Brad Bekkum, representing Marshfield Clinic Health System
David Rushlow and Donn Dexter, representing Mayo Clinic Health System
Michael Richards, representing Gundersen Health System

The Controlled Substances Board summarizes the comments received either by hearing testimony or by written submission as follows:

Everyone who testified at the hearing or submitted comments were overall supportive of the rule. Multiple people providing comments made the following recommendations:

- Amend the language to explicitly recognize the medical principle of agency and delegation applies to the mandated physician review of the record.
- Designate the data elements which must be contained in a record to satisfy the practitioner's review obligation.
- Maintain the prohibition on a vendor simply providing a summary of PDMP data or a snapshot of PDMP data as a means for practitioners to meet the PDMP review mandate. However, amend the language to allow for integration efforts with third party vendors.
- Require registration with the ePDMP for receipt of notifications and law enforcement alerts if contracting with a third party vendor.
- Create language to authorize access to the PDMP by a practitioner's vendor provided the vendor enters into a data use agreement approved by the Department of Safety and Professional Services.
- Amend the language in CSB 4.105 (3) to clarify that mere non-compliance with the practitioner review mandate cannot be referred to the law enforcement.

In addition to the above recommendations, the following comments were made:

- Gundersen Health Systems requested practitioners working at skilled nursing facilities to be exempt from the required practitioner PDMP review.
- Marshfield Clinic Health System requested the requirement for a practitioner notify the Board when the practitioner is unable to review a patient record because the PDMP system is not operational or due to other technological failures.
- Marshfield Clinic Health System also recommended the rule allow PDMP integration access through Appriss, a third party vendor.

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

The Controlled Substances Board modified the rule to allow practitioners to delegate review following standards of practice and clarified language regarding referrals to law enforcement by limiting such reports to situations in which dangerous practice or criminal activity may have occurred.

The Controlled Substances Board recognizes the value of PDMP being integrated into a patient's electronic health record and is working to better facilitate health system and prescriber adoption of the ePDMP integration. However, the Controlled Substances Board believes it would be in the interest of public safety to provide the data directly through the PDMP system itself without using a third party vendor entity. This relieves significant concerns a third party vendor would receive the confidential patient health information, remove the encryption, manipulate the data and then transmit to the electronic health record. The Controlled Substances Board would have no control over what the third party does with sensitive patient health information nor be able to protect the confidentiality of patient health information. In addition, a practitioner would not receive any of the notifications or law enforcement alerts which are required features of the PDMP and valuable information to the decision making process of a practitioner prior to prescribing a controlled substance.

The Controlled Substances Board declined to define practitioner review beyond what is currently defined in s. CSB 4.02 (12m). Section 961.385 (2) (cs), Stats. requires the program to require a practitioner to review a patient's records under the program before the practitioner issues a prescription order for the patient. The statute does not limit the monitored prescription drug history report of a patient to a subset of patient information and the Controlled Substances Board's position is the entire patient record has pertinent data for the practitioner to review prior to prescribing a controlled substance.

The Controlled Substances Board declined to exempt practitioners working at skilled nursing facilities to be exempt from the required practitioner PDMP review. Section 961.385 (2) (cs) 2., Stats recreates exemptions to the practitioner review requirement and practitioner working in a skilled nursing facility does not fall under one of those exemptions, therefore, the Controlled Substances Board does not have the authority to make that exemption.

The Controlled Substances Board declined to remove the requirement for a practitioner to report to the Board when the practitioner is unable to review the patient's records because the PDMP system is not operational or due to other technological failure. The program is required to have this requirement in place per s. 961.385 (2) (cs) 2. e., Stats.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment 2b: In the rule summary's explanation of agency authority, consider providing a brief plain language description of the authority, rather than repeating the statutory text. Likewise, in the plain language analysis, consider providing a brief description of the changes effected by the enactment of the cited Acts, rather than simply citing the Acts.

Response: The Controlled Substances Board chose to keep the statutory language in the explanation of agency authority. While the statutory authority is lengthy it does list all of the items which are required to be a part of the prescription drug monitoring program.

Comment 2e: In s. CSB 4.02 (15g) and (17), the amended definitions for "pharmacist" and "practitioner" are phrased in a substantive rather than descriptive manner, and are unnecessary because the cited definitions under current law already include pharmacists and practitioners licensed in another state. Consider removing those changes.

Response: The amended definitions clarify that those licensed in another state but are working in Wisconsin (under another state's license) are included in the definition. This is a clarification for those working in federal facilities or working under the nurse licensure compact.

All of the remaining recommendations suggested in the Clearinghouse Report have been accepted in whole.

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

This rule does not have an impact on small business.