STATEMENT OF SCOPE

CONTROLLED SUBSTANCES BOARD

Rule No.: CSB 4

Relating to: Prescription Drug Monitoring Program

Rule Type: Both Permanent and Emergency

1. Finding/nature of emergency (Emergency Rule only):

2015 Act 266 authorizes emergency rules without a finding of emergency.

2. Detailed description of the objective of the proposed rule:

The objective of the rule is to update CSB 4 to implement Acts 266, 267 and 268.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:

The proposed rule will implement Acts 266, 267 and 268 and make other necessary changes resulting from the implementation of Acts 266, 267 and 268 to CSB 4 relating to the prescription drug monitoring program.

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):

961.385 (2) The board shall establish by rule a program for monitoring the dispensing of monitored prescription drugs. The program shall do all of the following:

(a) Require a pharmacy or a practitioner to generate a record documenting each dispensing of a monitored prescription drug at the pharmacy or, if the monitored prescription drug is not dispensed at a pharmacy, by the practitioner and to submit the record to the board no later than 11:59 p.m. of the next business day after the monitored prescription drug is dispensed, except that the program may not require the generation of a record in any of the following circumstances:

1. A monitored prescription drug is administered directly to a patient.

2. A monitored prescription drug is compounded, packaged, or labeled in preparation for delivery but is not delivered.

3. The prescription order is for a monitored prescription drug that is a substance listed in the schedule in s. 961.22 and is not a narcotic drug, and the prescription order is for a number of doses that is intended to last the patient 7 days or less.

(b) Identify specific data elements to be contained in a record documenting the dispensing of a monitored prescription drug, including the method of payment and, subject to sub. (2m), the name recorded under s. 450.11 (1b) (bm). In identifying specific data elements, the board shall consider data elements identified by similar programs in other states and shall ensure, to the extent possible, that records generated by the program are easily shared with other states.

(c) Specify the persons to whom a record may be disclosed and the circumstances under which the disclosure may occur. Except as otherwise provided under this section, the rule promulgated under this paragraph shall comply with s. 146.82.

(cm) Permit the board to disclose a record generated by the program to any of the following:

1. A practitioner, pharmacist, registered nurse licensed under s. 441.06, substance abuse counselor, as defined in s. 440.88 (1) (b), or individual authorized under s. 457.02 (5m) to treat alcohol or substance dependency or abuse as a specialty if any of the following is applicable:

a. The practitioner, pharmacist, registered nurse, substance abuse counselor, or individual is directly treating or rendering assistance to the patient.

b. The practitioner, pharmacist, registered nurse, substance abuse counselor, or individual is being consulted regarding the health of the patient by an individual who is directly treating or rendering assistance to the patient.

2. A person who medically coordinates, directs, or supervises, or establishes standard operating procedures for, a practitioner, pharmacist, registered nurse, substance abuse counselor, or individual authorized under s. 457.02 (5m) to treat alcohol or substance dependency or abuse as a specialty to whom records may be disclosed under subd. 1., if the person is evaluating the job performance of the practitioner, pharmacist, registered nurse, substance abuse counselor, or individual, or is performing quality assessment and improvement activities, including outcomes evaluation or development of clinical guidelines, and if the disclosure does not contain personally identifiable information, as defined in s. 19.62 (5), of a patient and is limited to only those records about the practitioner, pharmacist, registered nurse, substance abuse counselor, or individual the person medically coordinates, directs, or supervises, or for whom the person establishes standard operating procedures.

3. Relevant state boards and agencies, relevant agencies of other states, relevant law enforcement agencies, as defined in s. 165.77 (1) (b), and relevant prosecutorial units, as defined in s. 978.001 (2), if any of the following is true:

a. The state board or agency, agency of another state, law enforcement agency, or prosecutorial unit makes a written request for the record and is engaged in an active and specific investigation or prosecution of a violation of any state or federal law involving a monitored prescription drug, and the record being requested is reasonably related to that investigation or prosecution.

b. The state board or agency, agency of another state, law enforcement agency, or prosecutorial unit makes a written request for the record and is monitoring the patient as part of a drug court, as defined in s. 165.955 (1).

c. The circumstances indicate suspicious or critically dangerous conduct or practices of a pharmacy, pharmacist, practitioner, or patient. The board shall define what constitutes suspicious or critically dangerous conduct or practices for purposes of this subd. 3. c.

4. An agent of a practitioner or pharmacist if disclosure to the practitioner or pharmacist is authorized subject to subd. 1.

(cs) 1. Require a practitioner to review a patient's records under the program before the practitioner issues a prescription order for the patient. This subdivision does not apply after April 1, 2020 or 3 years after the 30th day after the date of publication in the Wisconsin Administrative Register of the notice under 2015 Wisconsin Act 266, section 17 (2g), whichever is later.

2. The requirement under subd. 1. that a practitioner review a patient's records under the program before the practitioner issues a prescription order for the patient does not apply if any of the following is true:

a. The patient is receiving hospice care, as defined in s. 50.94 (1) (a).

b. The prescription order is for a number of doses that is intended to last the patient 3 days or less and is not subject to refill.

c. The monitored prescription drug is lawfully administered to the patient.

d. Due to emergency, it is not possible for the practitioner to review the patient's records under the program before the practitioner issues a prescription order for the patient.

e. The practitioner is unable to review the patient's records under the program because the digital platform for the program is not operational or due to other technological failure if the practitioner reports that failure to the board.

(d) Specify a secure electronic format for submittal of a record generated under the program and authorize the board to grant a pharmacy or practitioner a waiver of the specified format.

(e) Specify a deadline for the submittal of a record to the board.

(f) Permit the board to refer to the appropriate licensing or regulatory board for discipline, or the appropriate law enforcement agency for investigation and possible prosecution, a pharmacist, pharmacy, or practitioner that fails to comply with rules promulgated under this subsection, including by failure to generate a record that is required by the program.

(g) Maximize the potential for funding the operation of the program with available federal funding sources.

(h) Ensure that the program complies with s. 146.82, except as otherwise provided in this section, and 45 CFR part 164, subpart E.

(i) Disclose information submitted to the program by a law enforcement agency under s. 961.37 (3) (a) to relevant practitioners, pharmacists, and others to whom the board may make disclosures under par. (c).

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:

300 hours

6. List with description of all entities that may be affected by the proposed rule:

Licensees who are authorized to prescribe and dispense controlled substances (Advanced Practice Nurse Prescribers, Anesthesiologist Assistants, Dentists, Optometrists, Pharmacies, Pharmacists, Physicians, Physician Assistants, and Podiatrists), law enforcement, and Department of Safety and Professional Services staff.

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:

None

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):

None to minimal. The rule is not likely to have a significant economic impact on small businesses.

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Authorized Signature

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Date Submitted