State of Misconsin



2015 Assembly Bill 364

Date of enactment: March 17, 2016 Date of publication*: March 18, 2016

2015 WISCONSIN ACT 266

AN ACT to renumber and amend 961.385 (1) (a); to amend 961.385 (1) (aj), 961.385 (1) (b), 961.385 (2) (a) (intro.), 961.385 (2) (c), 961.385 (2) (h) and 961.385 (3) (b); and to create 961.385 (1) (a) 1. to 3., 961.385 (1) (ab), 961.385 (1) (ad), 961.385 (1) (ae), 961.385 (1) (af), 961.385 (2) (cm) 1., 961.385 (2) (cm) 2., 961.385 (2) (cm) 3. a. and b., 961.385 (2) (cm) 4. and 961.385 (2) (cs) of the statutes; relating to: reporting, disclosure, and practitioner review requirements under the prescription drug monitoring program; providing an exemption from emergency rule procedures; and granting rule—making authority.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 961.385 (1) (a) of the statutes, as created by 2015 Wisconsin Act 55, is renumbered 961.385 (1) (a) (intro.) and amended to read:

961.385 (1) (a) (intro.) "Administer" has the meaning given in s. 450.01 (1). means the direct application of a monitored prescription drug, whether by injection, ingestion, or any other means, to the body of a patient by any of the following:

SECTION 2. 961.385(1)(a) 1. to 3. of the statutes are created to read:

961.385 (1) (a) 1. A practitioner or his or her agent.

- 2. A patient at the direction of a practitioner.
- 3. A pharmacist.

SECTION 3. 961.385 (1) (ab) of the statutes is created to read:

961.385 (1) (ab) "Agent" means an authorized person who acts on behalf of or at the direction of another person.

SECTION 4. 961.385 (1) (ad) of the statutes is created to read:

961.385 (1) (ad) "Business day" means any day on which the offices of the department of safety and professional services are open.

SECTION 5. 961.385 (1) (ae) of the statutes is created to read:

961.385 (1) (ae) "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a monitored prescription drug from one person to another.

SECTION 6. 961.385 (1) (af) of the statutes is created to read:

961.385 (1) (af) "Dispense" means to deliver a monitored prescription drug pursuant to the lawful prescription order of a practitioner, including the compounding, packaging, or labeling necessary to prepare the monitored prescription drug for delivery.

SECTION 7. 961.385 (1) (aj) of the statutes, as created by 2015 Wisconsin Act 55, is amended to read:

961.385 (1) (aj) "Patient" means an individual <u>or animal</u> for whom a monitored prescription drug is prescribed or to whom a monitored prescription drug is dispensed or administered.

SECTION 7m. 961.385 (1) (b) of the statutes, as created by 2015 Wisconsin Act 55, is amended to read:

^{*} Section 991.11, WISCONSIN STATUTES: Effective date of acts. "Every act and every portion of an act enacted by the legislature over the governor's partial veto which does not expressly prescribe the time when it takes effect shall take effect on the day after its date of publication."

961.385 (1) (b) "Prescription order" means an order transmitted orally, electronically, or in writing by a practitioner or a veterinarian licensed under ch. 89 for a monitored prescription drug for a particular patient.

SECTION 8. 961.385 (2) (a) (intro.) of the statutes, as affected by 2015 Wisconsin Act 55, is amended to read:

961.385 (2) (a) (intro.) 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:

SECTION 9. 961.385 (2) (c) of the statutes, as affected by 2015 Wisconsin Act 55, is amended to read:

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

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

- 3. Relevant state boards and agencies, relevant agencies of other states, and relevant law enforcement agencies, as defined in s. 165.77 (1) (b), including under and relevant prosecutorial units, as defined in s. 978.001 (2), if any of the following is true:
- c. The circumstances indicating 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 the rule promulgated under this paragraph this subd. 3. c.

SECTION 10. 961.385 (2) (cm) 1. of the statutes is created to read:

961.385 (2) (cm) 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.

SECTION 11. 961.385 (2) (cm) 2. of the statutes is created to read:

961.385 (2) (cm) 2. A person who medically coordinates, directs, or supervises, or establishes standard oper-

ating 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.

SECTION 12. 961.385 (2) (cm) 3. a. and b. of the statutes are created to read:

961.385 (2) (cm) 3. 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).

SECTION 13. 961.385 (2) (cm) 4. of the statutes is created to read:

961.385 (2) (cm) 4. An agent of a practitioner or pharmacist if disclosure to the practitioner or pharmacist is authorized subject to subd. 1.

SECTION 14. 961.385 (2) (cs) of the statutes is created to read:

961.385 (2) (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 3 years after the effective date of this subdivision [LRB inserts date].

- 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.

SECTION 15. 961.385 (2) (h) of the statutes, as affected by 2015 Wisconsin Act 55, is amended to read: 961.385 (2) (h) Ensure that the program complies with s. 146.82, except as otherwise provided in this section, and 45 CFR part 164, subpart E.

SECTION 16. 961.385 (3) (b) of the statutes, as affected by 2015 Wisconsin Act 55, is amended to read: 961.385 (3) (b) Nothing in this section may be construed to require a pharmacy, or pharmacist, or practitioner to obtain, before prescribing or dispensing a monitored prescription drug to a patient, information about the patient that has been collected pursuant to the program established under sub. (2).

SECTION 17. Nonstatutory provisions.

(1) EMERGENCY RULES. The controlled substances board may promulgate emergency rules under section 227.24 of the statutes implementing section 961.385 of the statutes, as amended by this act. Notwithstanding section 227.24 (1) (c) and (2) of the statutes, emergency rules promulgated under this subsection remain in effect until January 1, 2018, or the date on which permanent rules take effect, whichever is sooner. Notwithstanding section 227.24 (1) (a) and (3) of the statutes, the board is not required to provide evidence that promulgating a rule under this subsection as an emergency rule is necessary

for the preservation of the public peace, health, safety, or welfare and is not required to provide a finding of emergency for a rule promulgated under this subsection.

(2g) Notice to legislative reference bureau. For purposes of the requirement to review patient records under section 961.385 (2) (cs) of the statutes, as created by this act, the secretary of safety and professional services, in consultation with the controlled substances board, shall determine the date the prescription drug monitoring program under section 961.385 of the statutes, as affected by this act, will be operational and capable of electronically transmitting such records to a practitioner in accordance with standards determined by the secretary. Upon making that determination, the secretary of safety and professional services shall provide a notice to the legislative reference bureau stating that determination, and the legislative reference bureau shall promptly publish the notice in the Wisconsin Administrative Register

SECTION 18s. Effective dates. This act takes effect on April 1, 2017, except as follows:

- (1) REQUIREMENT TO REVIEW PATIENT RECORDS. The creation of section 961.385 (2) (cs) of the statutes takes effect on the 30th day after the date of publication in the Wisconsin Administrative Register of the notice under SECTION 17 (2g) of this act, or on April 1, 2017, whichever is later.
- (2) NOTICE TO LEGISLATIVE REFERENCE BUREAU. SECTION 17 (2g) of this act takes effect on the day after publication.
- (3) EMERGENCY RULES. SECTION 17 (1) of this act takes effect on the day after publication.