



State of Wisconsin
2015 - 2016 LEGISLATURE

LRB-2855/2
MPG:ahe

2015 ASSEMBLY BILL 364

September 25, 2015 - Introduced by Representatives NYGREN, PETRYK, NOVAK, TAUCHEN, SWEARINGEN, SPIROS, JAGLER, A. OTT, RIPP, KOLSTE, KERKMAN, SCHRAA, OHNSTAD, HORLACHER, SINICKI, MURTHA, EDMING, LOUDENBECK, VANDERMEER, GENRICH, MEYERS, ALLEN, BARCA, PETERSEN, KUGLITSCH, KNODL, MURSAU, MACCO, SANFELIPPO, BORN, SKOWRONSKI, J. OTT and SUBECK, cosponsored by Senators HARSDORF, GUDEx, COWLES, MARKLEIN, OLSEN, PETROWSKI, HANSEN and DARLING. Referred to Committee on Health.

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

Analysis by the Legislative Reference Bureau

This bill makes a number of changes to the Prescription Drug Monitoring Program (PDMP) administered by the Controlled Substances Board (board).

Under the bill, a pharmacy or practitioner generating a record under the PDMP when a monitored prescription drug is dispensed is required 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. Currently, there is no specific time frame required for the submission to the board of a record generated under the PDMP.

Under current law, the rules promulgated by the board implementing the PDMP must specify the persons to whom a record may be disclosed and the

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circumstances under which the disclosure may occur, including disclosure to relevant state boards and agencies, relevant agencies of other states, and relevant law enforcement agencies under circumstances indicating suspicious or critically dangerous conduct or practices of a pharmacy, pharmacist, practitioner, or patient. The bill adds disclosure to relevant prosecutorial units, and the bill specifies that disclosure of a record generated under the PDMP is authorized under the following additional circumstances:

1. 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.

2. 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.

The bill further permits disclosure to a practitioner, pharmacist, registered nurse, or substance abuse counselor who is treating or rendering assistance to the patient for whom the record was generated and under other specific circumstances.

Finally, the bill authorizes disclosure of a record generated under the PDMP to a person who medically coordinates, directs, or supervises, or establishes standard operating procedures for, a practitioner, pharmacist, registered nurse, or substance abuse counselor to whom records may otherwise be disclosed, if the person is evaluating the job performance of the practitioner, pharmacist, registered nurse, or substance abuse counselor, or is performing quality assessment and improvement activities, including outcomes evaluation or development of clinical guidelines, and if the disclosure is limited to only those records about the practitioner, pharmacist, registered nurse, or substance abuse counselor.

For further information see the *state* fiscal estimate, which will be printed as an appendix to this bill.

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

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

3 961.385 (1) (a) (intro.) “Administer” ~~has the meaning given in s. 450.01 (1).~~
4 means the direct application of a monitored prescription drug, whether by injection,
5 ingestion, or any other means, to the body of a patient by any of the following:

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

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

2 2. A patient at the direction of a practitioner.

3 3. A pharmacist.

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

5 961.385 (1) (ab) “Agent” means an authorized person who acts on behalf of or
6 at the direction of another person.

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

8 961.385 (1) (ad) “Business day” means any day on which the offices of the
9 department of safety and professional services are open.

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

11 961.385 (1) (ae) “Deliver” or “delivery” means the actual, constructive, or
12 attempted transfer of a monitored prescription drug from one person to another.

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

14 961.385 (1) (af) “Dispense” means to deliver a monitored prescription drug
15 pursuant to the lawful prescription order of a practitioner, including the
16 compounding, packaging, or labeling necessary to prepare the monitored
17 prescription drug for delivery.

18 **SECTION 7.** 961.385 (1) (aj) of the statutes, as created by 2015 Wisconsin Act
19 55, is amended to read:

20 961.385 (1) (aj) “Patient” means an individual or animal for whom a monitored
21 prescription drug is prescribed or to whom a monitored prescription drug is
22 dispensed or administered.

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

ASSEMBLY BILL 364**SECTION 8**

1 961.385 (2) (a) (intro.) Require a pharmacy or a practitioner to generate a
2 record documenting each dispensing of a monitored prescription drug at the
3 pharmacy or, if the monitored prescription drug is not dispensed at a pharmacy, by
4 the practitioner and to submit the record to the board no later than 11:59 p.m. of the
5 next business day after the monitored prescription drug is dispensed, except that the
6 program may not require the generation of a record in any of the following
7 circumstances:

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

10 961.385 (2) (c) Specify the persons to whom a record may be disclosed and the
11 circumstances under which the disclosure may occur. The Except as otherwise
12 provided under this section, the rule promulgated under this paragraph shall comply
13 with s. 146.82, except that the rule shall permit.

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

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

20 c. The circumstances ~~indicating~~ indicate suspicious or critically dangerous
21 conduct or practices of a pharmacy, pharmacist, practitioner, or patient. The board
22 shall define what constitutes suspicious or critically dangerous conduct or practices
23 for purposes of the rule promulgated under this paragraph this subd. 3. c.

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

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1 961.385 (2) (cm) 1. A practitioner, pharmacist, registered nurse licensed under
2 s. 441.06, or substance abuse counselor, as defined in s. 440.88 (1) (b) if any of the
3 following is applicable:

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

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

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

10 961.385 (2) (cm) 2. A person who medically coordinates, directs, or supervises,
11 or establishes standard operating procedures for, a practitioner, pharmacist,
12 registered nurse, or substance abuse counselor to whom records may be disclosed
13 under subd. 1., if the person is evaluating the job performance of the practitioner,
14 pharmacist, registered nurse, or substance abuse counselor, or is performing quality
15 assessment and improvement activities, including outcomes evaluation or
16 development of clinical guidelines, and if the disclosure is limited to only those
17 records about the practitioner, pharmacist, registered nurse, or substance abuse
18 counselor the person medically coordinates, directs, or supervises, or for whom the
19 person establishes standard operating procedures.

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

21 961.385 (2) (cm) 3. a. The state board or agency, agency of another state, law
22 enforcement agency, or prosecutorial unit makes a written request for the record and
23 is engaged in an active and specific investigation or prosecution of a violation of any
24 state or federal law involving a monitored prescription drug, and the record being
25 requested is reasonably related to that investigation or prosecution.

ASSEMBLY BILL 364**SECTION 12**

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

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

5 961.385 (2) (cm) 4. An agent of a practitioner or pharmacist if disclosure to the
6 practitioner or pharmacist is authorized subject to subd. 1.

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

8 961.385 (2) (cs) Require a practitioner to review a patient's records under the
9 program before the practitioner issues a prescription order for the patient.

10 **SECTION 15.** 961.385 (2) (h) of the statutes, as affected by 2015 Wisconsin Act
11 55, is amended to read:

12 961.385 (2) (h) Ensure that the program complies with s. 146.82, except as
13 otherwise provided in this section, and 45 CFR part 164, subpart E.

14 **SECTION 16.** 961.385 (3) (b) of the statutes, as affected by 2015 Wisconsin Act
15 55, is amended to read:

16 961.385 (3) (b) Nothing in this section may be construed to require a pharmacy,
17 or pharmacist, or practitioner to obtain, before ~~prescribing or~~ dispensing a monitored
18 prescription drug to a patient, information about the patient that has been collected
19 pursuant to the program established under sub. (2).

20 **SECTION 17. Nonstatutory provisions.**

21 (1) EMERGENCY RULES. The controlled substances board may promulgate
22 emergency rules under section 227.24 of the statutes implementing section 961.385
23 of the statutes, as amended by this act. Notwithstanding section 227.24 (1) (c) and
24 (2) of the statutes, emergency rules promulgated under this subsection remain in
25 effect until January 1, 2018, or the date on which permanent rules take effect,

