

2009 DRAFTING REQUEST

Bill

Received: **09/02/2008**

Received By: **csundber**

Wanted: **As time permits**

Identical to LRB:

For: **Gary Sherman (608) 266-7690**

By/Representing: **Eleanora Tribys**

This file may be shown to any legislator: **NO**

Drafter: **csundber**

May Contact:

Addl. Drafters:

Subject: **Occupational Reg. - misc**

Extra Copies:

Submit via email: **YES**

Requester's email: **Rep.Sherman@legis.wisconsin.gov**

Carbon copy (CC:) to: **christopher.sundberg@legis.wisconsin.gov**

Pre Topic:

No specific pre topic given

Topic:

Prescription drug monitoring

Instructions:

See Attached

Drafting History:

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for Assembly per Joe via phone

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Received: 09/02/2008

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Wanted: As time permits

Identical to LRB:

For: John Townsend (608) 266-3156

By/Representing:

This file may be shown to any legislator: NO

Drafter: csundber

May Contact:

Addl. Drafters:

Subject: Occupational Reg. - misc

Extra Copies:

Submit via email: YES

Requester's email: Rep.Townsend@legis.wisconsin.gov

Carbon copy (CC:) to: christopher.sundberg@legis.wisconsin.gov
judy.kelly@legis.wisconsin.gov
gary.sherman@legis.wisconsin.gov

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Topic:

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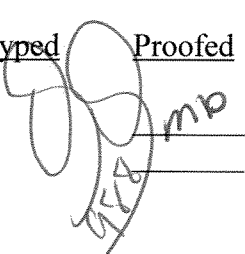
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FE Sent For:

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7/22/08

Townsend / Sherman

Prescription drug monitoring: direct DOA to promulgate rules implementing a program to monitor Schedule II/III drugs and other drugs identified by PEB by rule.

- Prescribing practitioner
- Pharmacy
- Patient

Should create electronic record containing data elements req'd by rule, for physicians/other prescribers, etc.

Contingent on obtaining federal grant \$. Available to persons in neighboring states. Out-of-state pharms lic'd by WI must participate.

Add req't to comply w/ rules to phys/ pharmacy chapters

OK to talk to Bill Black/ DRL

Ⓟ P-draft by 9/9

States with Prescription Monitoring Programs

State	Electronic / Paper ?	Drugs Included	Data / Elements to Report	Penalties for Failure to Report	Individuals with Access to Reports	Funding
Illinois IL ST CH 720 § 570/316 & 321; 720 § 570/318; 77 Ill. Adm. Code 2080.10 et. seq.	Electronic	C-II-V (Note – monitoring of C-III-V substances contingent upon receipt of federal grant money.)	Patient name; patient address; NDC number; date dispensed; quantity dispensed; dispenser's DEA number; prescriber's DEA number Information must be transmitted within 7 days of dispensing	N/A	IL Dept of Human Services may release info to... licensing boards investigating a specific practitioner; individuals from Attorney General's office involved in investigation, adjudication or prosecution; any investigating or prosecuting law enforcement officer from Dept. of State Police; office of a county sheriff, or State's Attorney or municipal police department of IL; prescription monitoring entities in other states A prescriber and dispenser inquiry system is to be developed. Inquirer will have read-only access to a stand-alone database which will contain records of previous 6 months, dispensers may make inquiry on a patient or customer solely for a medical purpose, Dept will provide a 1-to-1 secure link and encrypted software necessary for establishing links between Dept and inquirer, written inquiries are acceptable with fee and inquirers DEA #, data may not be stored for more than 24 months, tracking analysis will also be established. Prescriber & Dispenser NOT required to check patient info inquiry system – use <u>optional</u> . No fee will be charged for access to info. by a prescriber or dispenser.	Federal funding for C-III-V and for prescriber/ dispenser inquiry system

States with Prescription Monitoring Programs

State	Electronic / Paper ?	Drugs Included	Data / Elements to Report	Penalties for Failure to Report	Individuals with Access to Reports	Funding
Iowa I.C.A. § 124.551-124.558; I.C.A. § 124.553 Implementing rules to be promulgated by BoP	Electronic In secure format specified by BoP unless waiver is granted and an alternate secure format approved.		Pharmacy ID; patient ID; prescriber ID; date rx issued; date dispensed; indication of whether rx is new vs. refill; ID of drug dispensed; quantity dispensed; number of days' supply; serial or rx number; type of payment; other info identified by BoP and advisory council in rule. Timeframe for delivery of info to be determined in BoP issued rule	N/A	Info collected to be used by prescribing practitioners and pharmacists on a need-to-know basis to facilitate early ID of patients who may be at risk for addiction or are abusing / diverting drugs; BoP may provide info to treating pharmacist or prescriber for purposes of providing care to a patient; an individual requesting access to own info in program; pursuant to an order, subpoena, or other means of legal compulsion based upon a determination of probable cause in course of specific investigation Prescriber & pharmacist NOT required to check program and is immune from liability for seeking or not seeking info from program.	BoP may not charge fee to a pharmacy, pharmacist or prescriber for establishing, maintaining or administering the program

States with Prescription Monitoring Programs

State	Electronic / Paper ?	Drugs Included	Data / Elements to Report	Penalties for Failure to Report	Individuals with Access to Reports	Funding
<p>Michigan</p> <p>MI ST 333.73333a; MI ST 333.16315</p> <p>MI Regs R 338.3102; R 338.3162b -- e</p>	<p>Electronic (conforming to ASAP standards via on-line transmission, computer disk, CD, or other</p> <p>approved medium; report twice monthly on the 1st & 15th following month rx dispensed, or on other set days w/ approval); dispensers unable to report electronically may submit data using MAPS claim form or transmitting data via an internet web portal if waiver granted</p>	<p>C-II, III, IV, V</p>	<p>Patient identifier (patient identifier includes full name, address + zip, birthday, and any of the 3: SSI #, DL # or state issued ID #; for patients under 16, DL # is not required -- instead, zeros must be entered as the ID number; if the patient is a animal, the positive ID of the owner, i.e. patient identifier, must be recorded); drug name; quantity dispensed; NDC #; date rx issued; date dispensed; estimated days supply; rx #; prescriber DEA #; dispenser DEA #; MI pharmacy license #</p> <p>Exemptions to reporting: when CDS administered directly to patient or when dispensed in less than 48 hour supply</p> <p>Note – pharmacist, dispensing prescriber or vet may presume the info provided by the patient is correct.</p> <p>Info must be reported at least every 30 days and no later than the 15th calendar day of the month following the month in which the prescription is dispensed</p>	<p>N/A</p>	<p>Reports made to Department of Consumer and Industry Affairs or to the Department's contractor</p>	<p>Pain Management Education and Controlled Substances Electronic Monitoring and Antidiversion Fund (designates \$20 from each licensing fee to be deposited into fund); Notes that prescribers and pharmacists shall not be required to pay a new fee dedicated to the operation of the electronic monitoring system and shall not incur any additional costs solely related to the transmission of data to the department</p>

States with Prescription Monitoring Programs

State	Electronic / Paper ?	Drugs Included	Data / Elements to Report	Penalties for Failure to Report	Individuals with Access to Reports	Funding
Minnesota MN Statutes sec. 152.126; M.S.A. § 152.126	Electronic	C II & III, and any other drug deemed by the BoP as having the potential for abuse	Name of prescriber, NPI of the prescriber, name of the dispenser, NPI of the patient's date of birth, date prescription was written and filled, name and strength of controlled substance, quantity of controlled substance prescribed and dispensed Dispenser must provide patient with a conspicuous notice of these reporting requirements.	A dispenser who knowingly fails to submit data to the board is subject to disciplinary action by the appropriate health-related licensing board. A prescriber or dispenser authorized to access the data who knowingly discloses the data in violation of state or federal health care data privacy laws will be subject to disciplinary action by the appropriate health-related licensing board.	PMP data is private and not subject to public disclosure. Those allowed access to PMP information are: a prescriber if the info relates specifically to a current patient to whom the practitioner is prescribing or considering prescribing any controlled substance, dispenser if the info relates specifically to current patient the dispenser is dispensing or considering dispensing a controlled substance, patient's accessing info regarding themselves, personnel of board specifically assigned to conduct a bona fide investigation of a specific licensee, personnel of board engaged in collection of controlled substances info as part of assigned duties and responsibilities, authorized personnel of a vendor under contract with the board who are engaged in design, implementation, and maintenance of electronic reporting system as part of assigned duties and responsibilities, federal, state, and local law enforcement pursuant to a valid search warrant, personnel of the medical assistance program assigned to use the data collected to identify recipients whose usage of controlled substances may warrant restriction to a single primary care physician, a single outpatient pharmacy, or a single hospital.	BoP must apply for applicable federal grants or non-state funds to implement program. If the BoP does not secure non-state funds, the program will not be implemented without an appropriation from the legislature. The BoP may not increase license fees of pharmacists or pharmacies to adequately fund implementation of program.

22 W

**NATIONAL ALLIANCE FOR MODEL STATE DRUG LAWS
MODEL PRESCRIPTION MONITORING ACT
AUGUST 2002**

SECTION 1. SHORT TITLE.

This Act shall be known and may be cited as the "Model Prescription Monitoring Act".

SECTION 2. LEGISLATIVE FINDINGS.

[insert state-appropriate findings]

SECTION 3. PURPOSE.

[insert state-appropriate mission/purposes]

SECTION 4. DEFINITIONS.

(a) "Board" means the advisory board established under Section 6 of this Act.

(b) "Dispenser" means a person authorized in this state to distribute to the ultimate user a substance monitored by the prescription monitoring program, but does not include:

(I) a licensed hospital pharmacy that distributes such substances for the purposes of inpatient hospital care or the dispensing of prescriptions for controlled substances at the time of discharge from such a facility;

(II) a licensed nurse or medication aide who administers such a substance at the direction of a licensed physician; or

(III) a wholesale distributor of a substance monitored by the prescription monitoring program.

(c) "Prescriber" means a licensed health care professional with prescriptive authority

(d) "Prescription monitoring information" means information submitted to and maintained by the Prescription Monitoring Program.

(e) "Prescription Monitoring Program (PMP)" means a program established under Section 5 of this Act.

SECTION 5. ESTABLISHMENT OF A PRESCRIPTION MONITORING PROGRAM.

(a) The [designated state agency or entity] shall establish and maintain, with the consultation of the Board, an electronic system for monitoring the following substances dispensed in the state: [insert all or any combination of the following: federally controlled substances, additional state specified controlled substances, and drugs of concern documented to demonstrate a potential for abuse, particularly those identified by law enforcement and addiction treatment professionals.]

(b) The [designated state agency or entity] may contract with a vendor to establish and maintain the electronic monitoring system pursuant to guidelines which the [designated state agency or entity] shall promulgate.

SECTION 6. ADVISORY BOARD.

(a) The Advisory Board shall have the following members:

(I) [insert appropriate designees of state health, law enforcement and prosecutorial agencies]

(II) [insert appropriate designees of occupational licensing, certification and regulatory entities]

(III) [insert appropriate designees of impaired professionals programs]

(IV) [insert appropriate pain management and addiction treatment representatives]

(V) [insert appropriate patient rights advocates]

(VI) [insert appropriate recovering community advocates]

(VII) [insert appropriate community leaders]

(b) The [designated state agency or entity] shall seek and the Board shall provide input and advice regarding the development and operation of the electronic monitoring system, including but not limited to:

(I) which state controlled substances should be monitored,

(II) which drugs of concern demonstrate a potential for abuse and should be monitored,

(III) design and implementation of educational courses identified in Section 9,

(IV) proper analysis and interpretation of prescription monitoring information,

(V) design and implementation of an evaluation component, and

(VI) potential nominees to the Board.

SECTION 7. REPORTING OF PRESCRIPTION MONITORING INFORMATION.

(a) Each dispenser shall submit to the [designated state agency or entity], by electronic means, or other format specified in a waiver granted by the [designated state agency or entity], information specified by the [designated state agency or entity], including:

(I) A patient identifier,

(II) The drug dispensed,

(III) The date of the dispensing,

(IV) The quantity dispensed,

(V) The prescriber, and

(VI) The dispenser.

(b) Each dispenser shall submit the required information as frequently as specified by the [designated state agency]

(c) The [designated state agency or entity] may grant a waiver of electronic submission to any dispenser for good cause, including financial hardship, as determined by the [designated state agency or entity]. The waiver shall state the format and frequency with which the dispenser shall submit the required information.

SECTION 8. ACCESS TO THE PRESCRIPTION MONITORING INFORMATION/CONFIDENTIALITY.

(a) Except as indicated in paragraphs (b), (c), and (d), prescription monitoring information submitted to the [designated state agency or entity] shall be confidential and not subject to public or open records laws.

(b) The [designated state agency or entity] shall review the prescription monitoring information. If there is reasonable cause to believe a violation of law [or breach of occupational standards] may have occurred, the [designated state agency or entity] shall notify the appropriate law enforcement and occupational licensing, certification or regulatory agency or entity, and provide prescription monitoring information required for an investigation.

(c) The [designated state agency or entity] may provide prescription monitoring information for public research, policy or education purposes, to the extent all information reasonably likely to reveal the patient or other person who is the subject of the information has been removed.

(d) The following persons, after successful completion of the educational courses identified in Section 9(a), may access the prescription monitoring information in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential information under federal and state law and regulation.

(I) [insert prescribers]

(II) [insert dispensers]

(III) [insert all appropriate law enforcement personnel]

(IV) [insert all appropriate occupational licensing, certification and regulatory personnel]

(V) [insert all appropriate judicial authorities]

(VI) [insert all appropriate personnel of the designated state agency or vendor/contractor establishing and maintaining the prescription monitoring program]

NOTE: Patients have several traditional means other than a prescription monitoring program to access their medical information. However, some states' existing laws will require that patients have access to their prescription information which is maintained by a monitoring program. Those states will therefore need to include patients as a category of individuals able to access the prescription monitoring information under this section.

(e) The [designated state agency or entity] shall be immune from civil liability arising from inaccuracy of any of the information submitted to the [designated state agency or entity] pursuant to this Act.

SECTION 9. EDUCATION AND TREATMENT

(a) The [designated state agency or entity] shall, in consultation with the Board, implement the following education courses:

(I) An orientation course during the implementation phase of the PMP.

(II) A course for persons who are authorized to access the prescription monitoring information but who did not participate in the orientation course.

(III) A course for persons who are authorized to access the prescription monitoring information but who have violated laws or breached occupational standards involving dispensing, prescribing and use of substances monitored by the PMP.

(IV) A continuing education course for health care professionals developed by the American Society of Addiction Medicine and the state medical society on prescribing practices, pharmacology and identification, treatment and referral of patients addicted to or abusing substances monitored by the PMP.

When appropriate, the [designated state agency or entity], in consultation with the Board, shall develop the content of the education courses described in paragraphs (I) - (III).

(b) The [designated state agency or entity], in consultation with the Board, shall strongly recommend the application of a course to inform the public about use, diversion and abuse of, and addiction to, substances monitored by the PMP.

(c) The [designated state agency or entity], in consultation with the Board, shall, when appropriate:

- (I) work with associations for impaired professionals to ensure intervention, treatment and ongoing monitoring and follow-up; and
- (II) ensure that individual patients who are identified and who have become addicted to substances monitored by the PMP receive addiction treatment.

SECTION 10. UNLAWFUL ACTS AND PENALTIES

(a) A dispenser who knowingly fails to submit prescription monitoring information to the [designated state agency or entity] as required by this Act shall be subject to [insert appropriate administrative, civil or criminal penalty].

(b) A person authorized to have prescription monitoring information pursuant to this Act who knowingly discloses such information in violation of this Act shall be subject to [insert appropriate administrative, civil or criminal penalty.]

(c) A person authorized to have prescription monitoring information pursuant to this Act who uses such information in a manner or for a purpose in violation of this Act shall be subject to [insert appropriate administrative, civil or criminal penalty.]

SECTION 11. EVALUATION, DATA ANALYSIS AND REPORTING.

(a) The [designated state agency] shall, in consultation with the Board, design and implement an evaluation component to identify cost-benefits of the prescription monitoring program, and other information relevant to policy, research and education involving substances monitored by the PMP.

(b) The [designated state agency] shall report to the [insert appropriate state decisionmakers, e.g. legislature] on a periodic basis, no less than annually, about the costbenefits and other information noted in paragraph (a).

SECTION 12. RULES AND REGULATIONS.

The [designated state agency] shall promulgate rules and regulations necessary to implement the provisions of this Act.

SECTION 13. SEVERABILITY.

If any provision of this Act or application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the Act which can be given effect without the invalid provisions or applications, and to this end the provisions of this Act are severable.

SECTION 14. EFFECTIVE DATE.

This Act shall be effective on [insert specific date or reference to normal state method of determination of the effective date].

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In: 9/3 wanted: 9/10

State of Wisconsin
2009 - 2010 LEGISLATURE

LRB-0063

CTS:.....

ple
Lbjk

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION ✓

LPS - Please check spelling.

Insert

SA ✓
X-ref. ✓

and requiring the exercise
of rule-making authority

gen. cat.

monitor

1 AN ACT ...; relating to: creating a program to monotor the prescription

2 distribution, and use of prescription drugs.
and dispensing

Analysis by the Legislative Reference Bureau

This is a preliminary draft. An analysis will be provided in a later version. ✓

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

3 SECTION 1. 16.28 of the statutes is created to read:

4 ✓ 16.28 Prescription drug monitoring program. ✓ (1) In this section, ✓
5 "Prescription drug" means a substance identified in s. 961.16 or s. 961.18 or a drug ✓
6 identified by the pharmacy examining board by rule as having a substantial ✓
7 potential for abuse.

8 (2) The department shall designate an agency to establish by rule a program ✓
9 for electronically monitoring the prescription, distribution, and use of prescription ✓
10 drugs. The program shall do all of the following:

and dispensing

INS
2-1

- 1 (a) Identify specific data elements to be contained, in electronic form, in a
- 2 record documenting the prescription or distribution of a prescription drug. In
- 3 identifying specific data elements, the agency shall consider data elements identified
- 4 by similar programs in other states that border this state and shall ensure, to the
- 5 extent possible, that records generated by the program are easily shared with the
- 6 other states.
- 7 (b) Specify the persons to whom a record may be disclosed and the
- 8 circumstances under which such a disclosure may occur. The rule promulgated
- 9 under this paragraph shall permit the agency to share a record generated by the
- 10 program with relevant agencies of other states that border this state.
- 11 (c) Specify an electronic format for a record generated under the program.
- 12 (d) Specify a deadline for the delivery of a record to the agency responsible for
- 13 collecting the record.
- 14 (e) Specify a penalty for failure to comply with rules establishing the program.
- 15 (f) Maximize the potential for funding the operation of the program with
- 16 available federal funding sources.

SECTION 2. 441.07 (1) (e) of the statutes is amended to read:

441.07 (1) (e) A violation of any state or federal law that regulates prescribing or dispensing drugs or devices or of a rule promulgated under s. 16.28 (2), if the person has a certificate to prescribe drugs or devices under s. 441.16.

History: 1977 c. 418; 1979 c. 317, 337; 1981 c. 162; 1983 a. 273 s. 8; 1985 a. 29, 340; 1987 a. 264; 1993 a. 38; 1995 a. 309; 1997 a. 237; 1999 a. 22.

SECTION 3. 448.02 (3) (a) of the statutes is amended to read:

448.02 (3) (a) The board shall investigate allegations of unprofessional conduct and negligence in treatment by persons holding a license, certificate, or limited permit granted by the board. An allegation that a physician has violated s. 253.10

or a rule promulgated
under s. 16.28 (2)

1 (3), 448.30, or 450.13 (2) or has failed to mail or present a medical certification
 2 required under s. 69.18 (2) within 21 days after the pronouncement of death of the
 3 person who is the subject of the required certificate or that a physician has violated
 4 a rule promulgated under s. 16.28 (2) or that a physician has failed at least 6 times
 5 within a 6-month period to mail or present a medical certificate required under s.
 6 69.18 (2) within 6 days after the pronouncement of death of the person who is the
 7 subject of the required certificate is an allegation of unprofessional conduct.
 8 Information contained in reports filed with the board under s. 49.45 (2) (a) 12r., 50.36
 9 (3) (b), 609.17, or 632.715, or under 42 CFR 1001.2005, shall be investigated by the
 10 board. Information contained in a report filed with the board under s. 655.045 (1),
 11 as created by 1985 Wisconsin Act 29, which is not a finding of negligence or in a report
 12 filed with the board under s. 50.36 (3) (c) may, within the discretion of the board, be
 13 used as the basis of an investigation of a person named in the report. The board may
 14 require a person holding a license, certificate, or limited permit to undergo and may
 15 consider the results of one or more physical, mental, or professional competency
 16 examinations if the board believes that the results of any such examinations may be
 17 useful to the board in conducting its investigation.

History: 1975 c. 383, 421; 1977 c. 418; 1981 c. 185, 375, 391; 1983 a. 188 s. 10; 1983 a. 189 s. 329 (5); 1983 a. 253, 538; 1985 a. 29; 1985 a. 146 s. 8; 1985 a. 315, 332, 340; 1987 a. 27, 399, 403; 1989 a. 229; 1991 a. 186; 1993 a. 105, 107; 1995 a. 309; 1997 a. 67, 175, 191, 311; 1999 a. 32, 180; 2001 a. 89.

18 SECTION 4. 448.21 (3) of the statutes is amended to read:

19 ✓ 448.21 (3) PRESCRIPTIVE AUTHORITY. A physician assistant may issue a
 20 prescription order for a drug or device in accordance with guidelines established by
 21 a supervising physician and the physician assistant and, with rules promulgated by
 22 the board, and with rules promulgated under s. 16.28 (2). If any conflict exists
 23 between the guidelines and the rules, the rules shall control.

History: 1975 c. 383, 421; 1983 a. 524; 1989 a. 31; 1993 a. 105; 1997 a. 67, 175.

24 SECTION 5. 450.10 (1) (a) 9. of the statutes is created to read:

1 ✓ 450.10 (1) (a) 9. Violating a rule promulgated under s. 16.28 (2). ✓

2 (END) ✓

2009-2010 DRAFTING INSERT
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-0063/P1ins

CTS:.....

l bjk

1
2
3
4
5

Insert 2-1:

(a) Require a practitioner authorized to prescribe a prescription drug and a pharmacist authorized to dispense a prescription drug to generate an electronic record documenting each prescription or dispensing of a prescription drug and to deliver the electronic record to the agency designated by the department.

end of insert

Sundberg, Christopher

From: Pulda, Matt
Sent: Tuesday, December 09, 2008 2:35 PM
To: Sundberg, Christopher
Subject: LRB 09-0063

Chris,

Rep. Townsend and Rep. Sherman have agreed that Rep. Sherman will be the primary author for the prescription drug monitoring bill.

Thanks!

Matt Pulda
Legislative Assistant
Office of State Rep. John Townsend
(608) 266-3156

Sundberg, Christopher

From: Kelly, Judy
Sent: Friday, January 02, 2009 1:36 PM
To: Sundberg, Christopher
Cc: Tribys, Eleanora; Hoey, Joseph
Subject: Prescription Drug Monitoring LRB 0063/P1

Chris,

We would like to make the following changes on this bill:

Page 2 line 1. Rather than have Administration designate an agency, we would like the agency to be Regulation & Licensing so the bill should reflect that.

On Page 2, line 4, under (a) remove "a practitioner authorized to prescribe a prescription drug and"

On page 2, line 11, remove "that border this state".

On page 2, line 17, remove "that border this state".

Today is my last day in the capitol. Please direct any questions you may have to Eleanora Tribys.
Thank you.

Judy Kelly
Legislative Aide to
Rep. Gary Sherman