State of Wisconsin
2009 - 2010 LEGISLATURE

LRB-0063/P1
CTS:bjk:rs

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

AN ACT ***to amend*** 441.07 (1) (e), 448.02 (3) (a) and 448.21 (3); and ***to create*** 16.28 and 450.10 (1) (a) 9. of the statutes; **relating to:** creating a program to monitor the prescription and dispensing of prescription drugs and requiring the exercise of rule-making authority.

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:

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

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

(2) The department shall designate an agency to establish by rule a program for monitoring the prescription and dispensing of prescription drugs. The program shall do all of the following:

(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.

(b) Identify specific data elements to be contained in an electronic record documenting the prescription or dispensing of a prescription drug. In identifying specific data elements, the agency shall consider data elements identified by similar programs in other states that border this state and shall ensure, to the extent possible, that electronic records generated by the program are easily shared with the other states.

(c) Specify the persons to whom an electronic record may be disclosed and the circumstances under which the disclosure may occur. The rule promulgated under this paragraph shall permit the agency to share an electronic record generated by the program with relevant agencies of other states that border this state.

(d) Specify a format for an electronic record generated under the program.

(e) Specify a deadline for the delivery of an electronic record to the agency responsible for collecting the record.

(f) Specify a penalty for failure to comply with rules promulgated under this subsection.

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

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

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

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

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

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

(END)

D-note

Insert A:

This bill directs the Department of Regulation and Licensing (department) to establish by rule a program for monitoring the prescription and dispensing of certain drugs (generally, controlled substances that current law permits certain licensed practitioners to prescribe). The program must do all of the following: (1) require a pharmacist to generate an electronic record documenting each prescription and dispensing of a covered prescription and to deliver the record to the department; (2) identify data elements to be contained in such a record; (3) specify to whom and under what circumstances such a record may be disclosed; (4) specify a format and a deadline for delivery of such a record to the department; and (5) specify a penalty for a failure to comply with program requirements.

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

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-0063/P2dn
CTS:...:...
Lbjk

Date

Representative Sherman:

This is a redraft of LRB-0063/P1. Please review it carefully to ensure it is consistent with your intent, and note the following:

1. In this draft, the program no longer requires that a prescribing practitioner generate an electronic record documenting the prescription of a covered drug. I have assumed, however, that you intend the program to require that an electronic record generated by a pharmacist dispensing a covered drug include information regarding the prescription. In other words, this draft no longer requires a physician or other prescribing practitioner to generate an electronic record documenting the prescription of a covered drug, but shifts responsibility for documenting such a prescription to the pharmacist who dispenses the prescription. Of course, the Department of Regulation and Licensing (DRL) must decide the specific data elements required to document such a prescription. Is this correct?

2. Please let me know how you wish to fund DRL's duties in this draft.

Christopher T. Sundberg
Legislative Attorney
Phone: (608) 266-9739
E-mail:
christopher.sundberg@legis.wisconsin.gov

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-0063/P2dn
CTS:bjk:rs

January 7, 2009

Representative Sherman:

This is a redraft of LRB-0063/P1. Please review it carefully to ensure it is consistent with your intent, and note the following:

1. In this draft, the program no longer requires that a prescribing practitioner generate an electronic record documenting the prescription of a covered drug. I have assumed, however, that you intend the program to require that an electronic record generated by a pharmacist dispensing a covered drug include information regarding the prescription. In other words, this draft no longer requires a physician or other prescribing practitioner to generate an electronic record documenting the prescription of a covered drug, but shifts responsibility for documenting such a prescription to the pharmacist who dispenses the prescription. Of course, the Department of Regulation and Licensing (DRL) must decide the specific data elements required to document such a prescription. Is this correct?

2. Please let me know how you wish to fund DRL's duties in this draft.

Christopher T. Sundberg
Legislative Attorney
Phone: (608) 266-9739
E-mail:
christopher.sundberg@legis.wisconsin.gov

2/27 G. Sherman

Redraft LRB-0063/P2:

1. Effect of bill is contingent on obtaining fed $.

2. Require dept to apply for grant specified in legislation from other states.

In: 1/28/09

State of Wisconsin
2009 - 2010 LEGISLATURE

P3
LRB-0063/~~P2~~ RNK
CTS:bjk:rs
stay

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

SAV

regen.

AN ACT ***to create*** 440.032 of the statutes; **relating to:** directing the Department of Regulation and Licensing to create a program to monitor the prescription and dispensing of prescription drugs and requiring the exercise of rule-making authority.

Analysis by the Legislative Reference Bureau

This bill directs the Department of Regulation and Licensing (department) to establish by rule a program for monitoring the prescription and dispensing of certain drugs (generally, controlled substances that current law permits certain licensed practitioners to prescribe). The program must do all of the following: (1) require a pharmacist to generate an electronic record documenting each prescription and dispensing of a covered prescription and to deliver the record to the department; (2) identify data elements to be contained in such a record; (3) specify to whom and under what circumstances such a record may be disclosed; (4) specify a format and a deadline for delivery of such a record to the department; and (5) specify a penalty for a failure to comply with program requirements.

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:

INS A

SECTION 1. 440.032 of the statutes is created to read:

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

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

(a) Require a pharmacist authorized to dispense a prescription drug to generate an electronic record documenting each prescription and dispensing of a prescription drug and to deliver the electronic record to the department.

(b) Identify specific data elements to be contained in an electronic record documenting the prescription or dispensing of a prescription drug. In identifying specific data elements, the department shall consider data elements identified by similar programs in other states and shall ensure, to the extent possible, that electronic records generated by the program are easily shared with other states.

(c) Specify the persons to whom an electronic record may be disclosed and the circumstances under which the disclosure may occur. The rule promulgated under this paragraph shall permit the department to share an electronic record generated by the program with relevant agencies of other states.

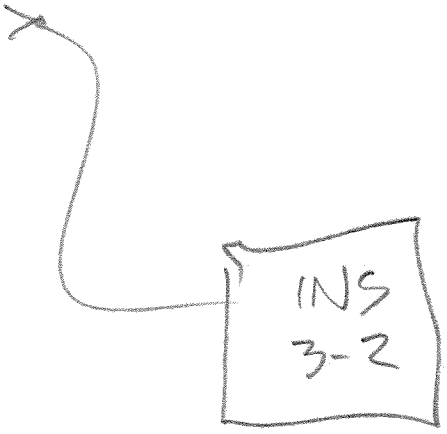
(d) Specify a format for an electronic record generated under the program.

(e) Specify a deadline for the delivery of an electronic record to the department responsible for collecting the record.

(f) Specify a penalty for failure to comply with rules promulgated under this subsection.

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

(END)



Insert A:

The bill requires the department to apply for certain federal grants to establish and operate the program. If the department fails to obtain federal funding before January 1, 2012, the bill is void.

Insert 3-2:

SECTION 1. Nonstatutory provisions.

(1) The department of regulation and licensing shall submit a timely application for a federal grant under 42 USC 280g-3 and under the Harold Rogers Prescription Drug Monitoring Program to fund the establishment and operation of the prescription drug monitoring program under section 440.032 of the statutes, as affected (created) by this act. If the department of regulation and licensing fails to obtain federal funding before January 1, 2012, section 440.032 of the statutes, as affected (created) by this act, is void.

STATE PRESCRIPTION MONITORING STATUTES & REGULATIONS CITATION LIST*

RELATED STATE PRESCRIPTION MONITORING STATUTES & REGULATIONS CITATION LIST **

1. HAW. REV. STAT. § 329-104 (2008) [confidentiality]

2. MICH. COMP. LAWS ANN. § 333.16204C (West 2008) [pain management]

3. MICH. COMP. LAWS. ANN. § 333.16135 (West 2008) [pain management education]

4. UTAH CODE ANN. § 26-1-36 (West 2008) [pain management]

* These citations reference those state statutes and regulations establishing prescription monitoring programs with emphasis on the maintenance of the database, identification of the agency which houses the program, information that the program gathers, who has access to the information once collected, and other related information. There are other state statutes and regulations related to the prescribing of controlled substances that are not cited here.

** These citations reference those state statutes and regulations that are related to the establishment of a prescription monitoring program with an emphasis on issues such as confidentiality and pain management. There are other issues that are related to the establishment of a prescription monitoring program as it relates to controlled substances that are not cited here.

Sundberg, Christopher

From: Tribys, Eleanora
Sent: Monday, February 23, 2009 2:44 PM
To: Sundberg, Christopher
Subject: RE: LRB 0063 Rx Drug Monitoring

I hope I am not too late with this additional request. I believe there are others besides doctors who are authorized to directly dispense prescription medications. If so, please include all so authorized under the reporting requirement.

Thanks!

Nora Tribys
Office of Rep. Gary Sherman
74th Assembly District

-----Original Message-----
From: Tribys, Eleanora
Sent: Friday, February 20, 2009 3:21 PM
To: Sundberg, Christopher
Subject: RE: LRB 0063 Rx Drug Monitoring

Hello again,

There was some confusion between prescribing and dispensing physicians and whether either or both should be included in the scope of those required to report. I am attaching correspondence from the PMP administrator in Ohio who offered some helpful information. We would like dispensing physicians to be included in this bill and go with her definitions. Perhaps you could look at the Kentucky statute she references and add appropriate language, including her definitions, if you think it would help avoid ambiguity. I'm also attaching a document that contains the Kentucky citation.

Nora Tribys
Office of Rep. Gary Sherman
74th Assembly District

<< File: Droz Danna WI PMP proposal.htm >> << File: State Stat Citations.pdf >>

-----Original Message-----
From: Sundberg, Christopher
Sent: Thursday, February 19, 2009 3:11 PM
To: Tribys, Eleanora
Subject: RE: LRB 0063 Rx Drug Monitoring

I think you're right on both items. Let me know when you're ready for another draft.

From: Tribys, Eleanora

Sent: Thursday, February 19, 2009 3:04 PM
To: Sundberg, Christopher
Subject: LRB 0063 Rx Drug Monitoring

Good Afternoon,

In reviewing the 3rd prelim draft on this, I have two questions:

1) In draft /P1, there was included on page 4, lines 6-7 the following language:

SECTION 5. 450.10 (1) (a) 9. of the statutes is created to read:
450.10 **(1)** (a) 9. Violating a rule promulgated under s. 16.28 (2).

I was wondering why that was deleted from the 2nd and 3rd drafts. Even though we decided to exclude prescribing practitioners from the scope of this bill and retained only pharmacists, should not that provision be retained, albeit with reference to 440.032(2) rather than 16.28?

2) On page 3, line 1-2 of /P3 it states:

(e) Specify a deadline for the delivery of an electronic record to the department responsible for collecting the record.

I am wondering why the highlighted is included. Is it not a leftover from the first draft where the responsible department was not specified? Now that it is DRL, should not those words be deleted?

Please let me know how you respond. If you do agree, there is no need to go ahead and prepare another draft at this time, as there is the possibility that we may have additional changes.

Thanks much,

Nora Tribys
Office of Rep. Gary Sherman
74th Assembly District

Sundberg, Christopher

From: Tribys, Eleanora
Sent: Friday, February 20, 2009 3:21 PM
To: Sundberg, Christopher
Subject: RE: LRB 0063 Rx Drug Monitoring

Attachments: Droz Danna WI PMP proposal.htm; State Stat Citations.pdf

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Nora Tribys
Office of Rep. Gary Sherman
74th Assembly District


Droz Danna WI PMP proposal.htm...


State Stat Citations.pdf (84 K...

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Thanks much,

Nora Tribys
Office of Rep. Gary Sherman
74th Assembly District

From: Danna Droz [OARRSAdmin@ohiopmp.gov]
Sent: Friday, February 20, 2009 10:12 AM
To: Tribys, Eleanora
Subject: RE: Wisconsin PMP proposal

Ms. Tribys,
Thank you for the feedback. I'm glad my comments were helpful.

From your discussion below, it is apparent that I was not clear enough in some of the wording I chose. There is a difference between practitioners submitting the prescriptions they authorize (which is what I was referring to) and drugs they may dispense from their office. I interpreted your previous bill to require practitioners to report the prescriptions they authorize.

First let me define some terms that often become confused in these discussions.

Prescribe – means to authorize a patient to obtain a drug. For example, a physician may write, call-in, or electronically send a "prescription" to a pharmacy.
Administer – means to give a drug to be immediately consumed by the patient. This includes injections or pills that the prescriber watches the patient swallow. The patient leaves the premises with empty hands.
Dispense – means to give a drug to be consumed at a later time. Pharmacies always dispense. A practitioner may also dispense if they provide drugs for the patient to take at a later time. The patient leaves with drugs in their hands.

Most people (including doctors) confuse these terms.

There are several states that require practitioners who dispense drugs to report to their monitoring program. Since these practitioners are choosing to act like a pharmacy, I believe they should be subject to the same reporting requirements as the pharmacies. Otherwise, it is a significant loophole. In my experience, I have noted that some of the practitioners who are trying to "fly under the radar" will dispense from their office(s) instead of writing prescriptions.

The software that is not compatible with reporting is prescribing software, not dispensing software. Typically, a dispensing practitioner uses different software for their dispensing records than for their prescribing. States have found ways for these practitioners to report, if difficulties arise. Also, some practitioners choose not to dispense the drugs that have to be reported. Most pharmacy software contracts include a clause to provide anything that is needed to comply with state or federal law. I presume that practitioner dispensing software contracts contain similar language. If not, it is still no excuse for not including dispensing practitioners in your monitoring program. When I worked in the Kentucky program, we required dispensing practitioners to dispense. It worked out without much headache.

I apologize for the confusion. Please feel free to call me if you want to discuss any of this further.

I will review the bill in the next few days and get back to you.

Danna

Danna E Droz, RPh, JD
Prescription Monitoring Program Administrator
Ohio State Board of Pharmacy
77 S High St. Room 1702
Columbus, OH 43215-6126
Phone: 614-466-4143
Fax: 614-644-8556
e-mail OARRSadmin@ohiopmp.gov

From: Tribys, Eleanora [mailto:Eleanora.Tribys@legis.wisconsin.gov]
Sent: Thursday, February 19, 2009 6:11 PM
To: Danna Droz
Subject: Wisconsin PMP proposal

Good Day Ms. Droz,

Last fall you commented on the initial draft of a proposal to institute a PMP in Wisconsin (see below). Your comments were appreciated and some changes were made in light of them.

Namely, 1) to avoid overload and duplication, we removed physicians and other authorized prescribers and limited it to pharmacists only who actually dispense the prescription.

2) We designated the Dept of Regulation & Licensing to oversee the program.

3) We included all states in information sharing rather than limiting it to bordering states.

I am attaching a current draft of the bill FYI.

Since the most recent draft, another objection has been raised, and that is that pharmacists are not the only dispensers of these substances and that doctors may dispense them occasionally directly from their clinics and that if a doctor dispenses a controlled substance it should be reported.

This would seem to present a significant problem, in light of your statements made previously, i.e.

c. Not all physicians are equipped to transmit prescription information in any electronic format.

d. No physician prescription software is capable of transmitting data in the format that pharmacies use to transmit PMP data to their state.

it would appear that including physician dispensers would not be workable.

Do you happen to know whether other states include doctors who dispense directly and how they get around the reporting difficulty you described?

Also, is there any evidence available that would indicate that physician dispensed prescriptions account for any significant percentage of questionable or abused prescriptions?

Any thoughts you may have on this issue would be most greatly appreciated.

,

Nora Tribys

Office of Rep. Gary Sherman

74th Assembly District

<<09-0063P3.pdf>>

-----Original Message-----
From: Danna Droz [mailto:OARRSAdmin@ohiopmp.gov]
Sent: Friday, November 28, 2008 10:15 AM
To: Richard Thomas
Subject: RE: LRB 09-0063/P1 Topic: Prescription drug monitoring

Chief Thomas,

I am sorry this has taken me so long.

This approach is very different to what other states have done.

1. The bill authorizes a department (it's not clear which one) to designate an agency (also unclear) to oversee the PMP program and write all the rules. Most bills state which department/agency will house the program. This may not be a problem in Wisconsin but I've never see it done. My experience is that if the department and agency are law enforcement, it will not pass. If the department and agency are health agencies or healthcare licensing agencies, the bill is more likely to pass.

2. The bill requires physicians to transmit the prescriptions they authorize to the state agency as well as requiring pharmacies to transmit what they dispense. No other PMP requires this because of the problems with this approach.

a. Not all prescriptions are dispensed. If a prescription is never dispensed, it cannot be abused, misused or diverted. So the program will be receiving a good deal of useless data. It is also common to "fix" prescription errors with a new prescription.

b. If the prescription IS dispensed, the program will receive duplicated data. No program in other states is designed to handle this type of duplication so there will be a problem with obtaining or developing software. These types of duplicate records are not the exact duplicates that a computer can recognize as duplicate.

c. Not all physicians are equipped to transmit prescription information in any electronic format.

d. No physician prescription software is capable of transmitting data in the format that pharmacies use to transmit PMP data to their state.

I recommend deleting this requirement. In my opinion, it will kill the entire bill.

I understand the thought behind this requirement and it has been discussed for many years. However, e-prescribing is not yet mature as a technology to allow this to happen in the next few years. There are some technological hurdles that

no one has addressed and few people even recognize at this point.

3. On page 2, Line 17, it refers to sharing data with bordering states. I recently studied 6 states that have a PMP. I found that ALL of them have data in their database from every state in the US. Therefore, I recommend removing this restriction ("that border this state") and allow sharing with all states.

Beyond that, I can't say much more because the bill leaves all the details to an unnamed agency. If someone has these details in mind, I will be happy to work with them in the future.

Thank you for this opportunity to comment. I would love to be informed as this bill progresses.

Danna Droz

Danna E Droz, RPh, JD

Prescription Monitoring Program Administrator

Ohio State Board of Pharmacy

77 S High St. Room 1702

Columbus, OH 43215-6126

Phone: 614-466-4143

Fax: 614-644-8556

e-mail OARRSadmin@ohiopmp.gov

STATE PRESCRIPTION MONITORING STATUTES & REGULATIONS CITATION LIST*

1. ALA. CODE §§ 20-2-210 to -220 (2008)

2. ALASKA STAT. § 17.30.200 (2008)

3. ARIZ. REV. STAT. ANN. §§ 36-2601 to -2611 (2008)

4. CAL. HEALTH & SAFETY CODE §§ 11165, 11165.1 (West 2008)
   CAL. CIV. CODE § 56.36 (West 2008)
   CAL. CODE REGS. tit. 16, § 1715.5 (2009)

5. COLO. REV. STAT. ANN. §§ 12-22-701 to -710, 2-3-1203, 24-34-104 (West 2008)

6. CONN. GEN. STAT. ANN. §§ 21a-254, 254a (West 2008)
   CONN. AGENCIES REGS. §§ 21a -254-2 to -7 (2008)

7. HAW. REV. STAT. §§ 329-1, 329-101 to -104 (2008)
   HAW. CODE R. §§ 23-200-2, -17 (Weil 2008)

8. IDAHO CODE ANN. §§ 37-2726, -2730A (2008)
   IDAHO ADMIN. CODE r. 27.01.01.469 (2008)

9. 720 ILL. COMP. STAT. ANN. 570/316 to 321 (West 2008)
   ILL. ADMIN. CODE tit. 77, §§ 2080.10 to -.30, -.50, -.70, -.90, -.100, -.190 (2009)
   26 Ill. Reg. 3975 (2002)

10. IND. CODE ANN. §§ 35-48-7-1, -3 to -7.5, -8.1, -10.1, -11.1, -12.1, -13.1, -14 (West 2008)
    858 IND. ADMIN. CODE 2-1-1 to -4 (2008)

11. IOWA CODE ANN. §§ 124.551 to -.558 (West 2008)

12. KAN. STAT. ANN. §§ 65-1681 to -1695 (2008)

13. KY. REV. STAT ANN. § 218A.202 (West 2008) – *Portions Held Unconstitutional*
    KY. REV. STAT. ANN. § 315.121 (West 2008)
    902 KY. ADMIN. REGS. 55:110 (2009)

14. LA. REV. STAT. ANN. §§ 40:975, 40:1001 to -1014 (2008)

15. ME. REV. STAT. ANN. tit. 22, §§ 7245 to 7252 (2008)
    14-118-11 ME. CODE R. § 1 to 9 (2008)

16. MASS. GEN. LAWS. ANN. ch. 94C, §§ 1 to -48 (West 2008)
    105 MASS. CODE REGS. 700.006 (2009)
    247 MASS. CODE REGS. 5.04 (2009)

17. MICH. COMP. LAWS. ANN. §§ 333.7112 to -.7113, -.7333a (West 2008)

18. MINN. STAT. ANN. § 152.126 (West 2008)

19. MISS. CODE ANN. § 41-29-101 et seq. (West 2008)
    MISS. CODE ANN. § 73-21-127 (West 2008)
    MISS. CODE ANN. § 73-21-97 (West 2008)
    MISS. CODE ANN. § 73-21-103 (West 2008)

20. NEV. REV. STAT. ANN. §§ 453.1545, 639.23507 (West 2008)
    NEV. ADMIN. CODE § 639.926 (2008)

21. N.J. STAT. ANN. §§ 45: 1-45 to 1-52 (West 2008) – Effective August 1, 2010

22. N.M. STAT. ANN. § 30-31-16 (West 2008)
    N.M. CODE R. §§ 16.19.29.1 to -.13 (2008)

23. N.Y. PUB. HEALTH LAW §§ 12-b, 3331 to 3333, 3338, 3343, 3370, 3371, 3372, 3385, 3396 (McKinney 2008)
    N.Y. COMP. CODES R. & REGS. tit. 10, §§ 80.67 to -.69, -.71 to -.73, -.108, -.123 (2009)

24. N.C. GEN. STAT. ANN. §§ 90-113.70 to -113.76 (West 2008)
    10A N.C. ADMIN. CODE 26E.0601 to -.0603 (2008)

25. N.D. CENT. CODE §§ 19-03.5-01 to -10 (2008)
    N.D. ADMIN. CODE 61-12-01-01 to -03 (2008)

26. OHIO REV. CODE ANN. §§ 4729.75 to -.84, -.99 (West 2008)
OHIO ADMIN. CODE §§ 4729-37-01 to -11 (2009)

27. OKLA. STAT. ANN. tit. 63, §§ 2-309 to -309H (West 2008)

28. 18 PA. CONS. STAT. ANN. § 9102 (West 2008)
28 PA. CODE § 25.131 (2009)

29. R.I. GEN. LAWS § 21-28-3.18 (2008)
14-060-020 R.I. CODE R. §1 to 4 (Weil 2008)

30. S.C. CODE ANN. §§ 44-53-1610 to -1680 (2008)

31. TENN. CODE ANN. §§ 53-10-301 to -309 (West 2008)

32. TEX. HEALTH & SAFETY CODE ANN. §§ 481.074 to -.0761, -.127, -.128 (Vernon 2007)
37 TEX. ADMIN. CODE §§ 13.71 to -.86 (2009)

33. UTAH CODE ANN. §§ 58-37-7.5, -7.7, 7.8 (West 2008)
UTAH ADMIN. CODE r. 156-37-609, -610 (2009)

34. VT. STAT. ANN. tit. 18, §§ 4281 to 4287 (2008)

35. VA. CODE ANN. §§ 54.1-2505, -2519 to -2525, 2.2-3705.5 (West 2008)
18 VA. ADMIN. CODE §§ 76-20-10 to -70 (2008)

36. WASH. REV. CODE ANN. §§ 70.225.010 to -.900 (West 2008)
WASH. ADMIN. CODE §§ 246-800-101 to -150 (2008)

37. W.VA. CODE ANN. §§ 60A-9-1 to -7 (West 2008)
W.VA. CODE R. §§ 15-8-1 to -7 (2008)

38. WYO. STAT. ANN. § 35-7-1060 (2008)
WY. Bd. Of Pharmacy, Rules and Regs., ch. 8 §§ 1-7 (2008)

Sundberg, Christopher

From: Tribys, Eleanora
Sent: Wednesday, March 11, 2009 10:13 AM
To: Sundberg, Christopher
Subject: RE: LRB 0063 Rx Drug Monitoring

Yes, I believe so,plus those two other items from way back when at the bottom of this stream.

Thank You!
Nora

-----Original Message-----
From: Sundberg, Christopher
Sent: Wed 3/11/2009 9:33 AM
To: Tribys, Eleanora
Subject: RE: LRB 0063 Rx Drug Monitoring

So are you ready for me to do a redraft that (1) adds a requirement that non-pharmacist dispensers comply with reporting requirements and (2) identifies the PEB as the entity that must promulgate the rules that establish the monitoring program?

CS

From: Tribys, Eleanora
Sent: Monday, March 09, 2009 3:23 PM
To: Sundberg, Christopher
Subject: RE: LRB 0063 Rx Drug Monitoring

We originally had prescribers, but took them out because it could cause a lot of duplication in reporting. We want only dispensers be required to report, as per the Danna Droz ' discussion of the issue sent to you previously.

Thanks,

Nora Tribys
Office of Rep. Gary Sherman
74th Assembly District

> -----Original Message-----
> From: Sundberg, Christopher
> Sent: Monday, March 09, 2009 1:41 PM
> To: Tribys, Eleanora
> Subject: RE: LRB 0063 Rx Drug Monitoring
>
> I think it work fine to redraft the bill to require the PEB, rather than DRL, to create the drug monitoring program. The only questions I'd have relate to the elements of the drug monitoring program that apply to drug prescribers. I recall that we discussed putting back into the bill a requirement that physicians and others authorized to prescribe drugs comply with the rules establishing the program. Will it be sufficient merely to require prescribers to comply with rules promulgated by the PEB to the extent they apply to prescribers? It seems to me that it ought to be sufficient, but I'd be more confident if we could consult with DRL on the question.
>
> CS
>
> ---
>
> From: Tribys, Eleanora
> Sent: Monday, March 02, 2009 2:04 PM
> To: Sundberg, Christopher
> Subject: RE: LRB 0063 Rx Drug Monitoring

Good Afternoon,

To address some of DRL's concerns, mostly wanting more details of the monitoring program and that the current draft designates that they specify all the details, Gary thinks that perhaps to assuage some of that, that wherever appropriate to designate the Pharmacy Examining Board specifically as the entity to establish the program rules. What do you think about that - would that work?

Gary's idea behind this bill is to specifically have the professionals who know about these things establish the rules, and have the flexibility for change that a rulemaking authority has, rather than legislating every detail of the program in the bill.

Nora Tribys
Office of Rep. Gary Sherman
74th Assembly District

-----Original Message-----
From: Sundberg, Christopher
Sent: Tuesday, February 24, 2009 8:50 AM
To: Tribys, Eleanora
Subject: RE: LRB 0063 Rx Drug Monitoring

OK. Let me know when you're ready for a redraft.

CS

From: Tribys, Eleanora
Sent: Monday, February 23, 2009 5:07 PM
To: Sundberg, Christopher
Subject: LRB 0063 Rx Drug Monitoring

We just received a memo from DRL raising some issues about our bill, so please do not complete your work on this until we have had the opportunity to review their concerns and see if there are yet additional issues we will need to address.

Thank You,

Nora Tribys
Office of Rep. Gary Sherman
74th Assembly District

-----Original Message-----
From: Tribys, Eleanora
Sent: Monday, February 23, 2009 2:44 PM
To: Sundberg, Christopher
Subject: RE: LRB 0063 Rx Drug Monitoring

I hope I am not too late with this additional request. I believe there are others besides doctors who are authorized to directly dispense prescription medications. If so, please include all so authorized under the reporting requirement.

Thanks!

Nora Tribys
Office of Rep. Gary Sherman
74th Assembly District

-----Original Message-----
From: Tribys, Eleanora
Sent: Friday, February 20, 2009 3:21 PM
To: Sundberg, Christopher
Subject: RE: LRB 0063 Rx Drug Monitoring

Hello again,

There was some confusion between prescribing and dispensing physicians and whether either or both should be included in the scope of those required to report. I am attaching correspondence from the PMP administrator in Ohio who offered some helpful information. We would like dispensing physicians to be included in this bill and go with her definitions. Perhaps you could look at the Kentucky statute she references and add appropriate language, including her definitions, if you think it would help avoid ambiguity. I'm also attaching a document that contains the Kentucky citation.

Nora Tribys
Office of Rep. Gary Sherman
74th Assembly District

<< File: Droz Danna WI PMP proposal.htm >> << File: State Stat Citations.pdf >>

-----Original Message-----
From: Sundberg, Christopher
Sent: Thursday, February 19, 2009 3:11 PM
To: Tribys, Eleanora
Subject: RE: LRB 0063 Rx Drug Monitoring

I think you're right on both items. Let me know when you're ready for another draft.

From: Tribys, Eleanora
Sent: Thursday, February 19, 2009 3:04 PM
To: Sundberg, Christopher
Subject: LRB 0063 Rx Drug Monitoring

Good Afternoon,

In reviewing the 3rd prelim draft on this, I have two questions:

1) In draft /P1, there was included on page 4, lines 6-7 the following language:

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

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

I was wondering why that was deleted from the 2nd and 3rd drafts. Even though we decided to exclude prescribing practitioners from the scope of this bill and retained only pharmacists, should not that provision be retained, albeit with reference to 440.032(2) rather than 16.28?

2) On page 3, line 1-2 of /P3 it states:

(e) Specify a deadline for the delivery of an electronic record to the department

responsible for collecting the record.

I am wondering why the highlighted is included. Is it not a leftover from the first draft where the responsible department was not specified? Now that it is DRL, should not those words be deleted?

Please let me know how you respond. If you do agree, there is no need to go ahead and prepare another draft at this time, as there is the possibility that we may have additional changes.

Thanks much,

Nora Tribys
Office of Rep. Gary Sherman
74th Assembly District

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-0063/1dn
CTS:...:...
bjk

Date

Representative Sherman:

> Please review this draft carefully to ensure it is consistent with your intent, and note the following:

1. I have altered the statutory material in the bill so that the Pharmacy Examining Board is tasked with creating the prescription drug monitoring program. I have not modified the nonstatutory provision that requires the Department of Regulation and Licensing to apply for federal grants to fund the establishment and operation of the program. Is this correct?

2. I have added physicians, advanced practice nurses, optometrists, and dentists to the professionals who must generate electronic records when dispensing covered prescription drugs, except when a covered drug is administered directly to a patient.

3. I have not added the violation of rules establishing the prescription drug monitoring program to the definition of "unprofessional conduct," which was included in an earlier version. For most dispensers, it seems reasonably clear that they would be bound by rules promulgated by the Pharmacy Examining Board. Under current s. 450.10 (1) (a) 2., "unprofessional conduct" include "[v]iolating ... any federal or state statute or rule which substantially relates to the practice of the [pharmacist]." Similarly, under current s. 448.015 (4), "unprofessional conduct" by a physician includes any act in violation of ch. 450; under current s. 441.07 (1) (e), an advance practice nurse may be disciplined for violating "any state or federal law that regulates prescribing or dispensing drugs or devices"; under current s. 447.07 (3) (L), a dentist may be disciplined for violating ch. 450. An optometrist's obligation to comply with ch. 450, however, is less clear. Should the draft be modified to create explicit statutory obligations to comply with the rules establishing the prescription drug monitoring program? If so, for which professionals?

Christopher T. Sundberg
Legislative Attorney
Phone: (608) 266-9739
E-mail:
christopher.sundberg@legis.wisconsin.gov

In: 3/12/09

State of Wisconsin
2009 - 2010 LEGISLATURE

LRB-0063/P3 1 e RMNR
CTS:bjk:rs
stays

2009 BILL

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

d-note

Insert SA X-ref

Pharmacy Examining Board

regen

AN ACT ***to create*** 440.032 of the statutes; **relating to:** directing the Department of Regulation and Licensing to create a program to monitor the prescription and dispensing of prescription drugs and requiring the exercise of rule-making authority.

INS A

Analysis by the Legislative Reference Bureau

This bill directs the Department of Regulation and Licensing (department) to establish by rule a program for monitoring the prescription and dispensing of certain drugs (generally, controlled substances that current law permits certain licensed practitioners to prescribe). The program must do all of the following: (1) require a pharmacist to generate an electronic record documenting each prescription and dispensing of a covered prescription and to deliver the record to the department; (2) identify data elements to be contained in such a record; (3) specify to whom and under what circumstances such a record may be disclosed; (4) specify a format and a deadline for delivery of such a record to the department; and (5) specify a penalty for a failure to comply with program requirements.

The bill requires the department to apply for certain federal grants to establish and operate the program. If the department fails to obtain federal funding before January 1, 2012, the bill is void.

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:

SECTION 1. 440.032 of the statutes is created to read:

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

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

(a) Require a pharmacist authorized to dispense a prescription drug to generate an electronic record documenting each prescription and dispensing of a prescription drug and to deliver the electronic record to the department.

(b) Identify specific data elements to be contained in an electronic record documenting the prescription or dispensing of a prescription drug. In identifying specific data elements, the department shall consider data elements identified by similar programs in other states and shall ensure, to the extent possible, that electronic records generated by the program are easily shared with other states.

(c) Specify the persons to whom an electronic record may be disclosed and the circumstances under which the disclosure may occur. The rule promulgated under this paragraph shall permit the department to share an electronic record generated by the program with relevant agencies of other states.

(d) Specify a format for an electronic record generated under the program.

(e) Specify a deadline for the delivery of an electronic record to the department responsible for collecting the record. board

(f) Specify a penalty for failure to comply with rules promulgated under this subsection.

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

SECTION 2. Nonstatutory provisions.

(1) The department of regulation and licensing shall submit a timely application for a federal grant under 42 USC 280g-3 and under the Harold Rogers Prescription Drug Monitoring Program to fund the establishment and operation of the prescription drug monitoring program under section 440.032 of the statutes, as 450.19 created by this act. If the department of regulation and licensing fails to obtain federal funding before January 1, 2012, section 440.032 of the statutes, as created 450.19 by this act, is void.

(END)

D-note

Insert A:

This bill directs the Pharmacy Examining Board (board) to establish by rule a program for monitoring the dispensing of certain drugs (generally, controlled substances that current law permits certain licensed practitioners to prescribe). The program must do all of the following: (1) require a pharmacist, physician, advanced practice nurse, dentist, or optometrist to generate an electronic record documenting each dispensing of a covered prescription and to deliver the record to the board, unless the prescription is administered directly to a patient; (2) identify data elements to be contained in such a record; (3) specify to whom and under what circumstances such a record may be disclosed; (4) specify a format and a deadline for delivery of such a record to the board; and (5) specify a penalty for a failure to comply with program requirements.

The bill requires the Department of Regulation and Licensing to apply for certain federal grants to establish and operate the program. If the department fails to obtain federal funding before January 1, 2012, the bill is void.

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-0063/1dn
CTS:bjk:md

March 13, 2009

Representative Sherman:

Please review this draft carefully to ensure it is consistent with your intent and note the following:

1. I have altered the statutory material in the draft so that the Pharmacy Examining Board is tasked with creating the prescription drug monitoring program. I have not modified the nonstatutory provision that requires the Department of Regulation and Licensing to apply for federal grants to fund the establishment and operation of the program. Is this correct?

2. I have added physicians, advanced practice nurses, optometrists, and dentists to the professionals who must generate electronic records when dispensing covered prescription drugs, except when a covered drug is administered directly to a patient.

3. I have not added the violation of rules establishing the prescription drug monitoring program to the definition of "unprofessional conduct," which was included in an earlier version. For most dispensers, it seems reasonably clear that they would be bound by rules promulgated by the Pharmacy Examining Board. Under current s. 450.10 (1) (a) 2., "unprofessional conduct" includes "[v]iolating ... any federal or state statute or rule which substantially relates to the practice of the [pharmacist]." Similarly: under current s. 448.015 (4), "unprofessional conduct" by a physician includes any act in violation of ch. 450; under current s. 441.07 (1) (e), an advance practice nurse may be disciplined for violating "any state or federal law that regulates prescribing or dispensing drugs or devices"; and under current s. 447.07 (3) (L), a dentist may be disciplined for violating ch. 450. An optometrist's obligation to comply with ch. 450, however, is less clear. Should the draft be modified to create explicit statutory obligations to comply with the rules establishing the prescription drug monitoring program? If so, for which professionals?

Christopher T. Sundberg
Legislative Attorney
Phone: (608) 266-9739
E-mail:
christopher.sundberg@legis.wisconsin.gov

Sundberg, Christopher

From: Sherman, Gary
Sent: Friday, March 13, 2009 2:48 PM
To: Sundberg, Christopher
Subject: RE: Submitted: LRB 09-0063/1 Topic: Prescription drug monitoring?body=

2015, please.

G

From: Sundberg, Christopher
Sent: Friday, March 13, 2009 2:35 PM
To: Sherman, Gary
Subject: RE: Submitted: LRB 09-0063/1 Topic: Prescription drug monitoring?body=

It appears that there is no sunset that applies to either of the grant programs referenced in the bill, but that the availability of future grants is subject to the appropriation of federal funds.

Should I redraft and advance the date on page 3, line 13 to 2014 or 2015?

From: Sherman, Gary
Sent: Friday, March 13, 2009 2:09 PM
To: Sundberg, Christopher
Subject: RE: Submitted: LRB 09-0063/1 Topic: Prescription drug monitoring?body=

Please check, but I think even a little more time would help.

Gary

From: Sundberg, Christopher
Sent: Friday, March 13, 2009 12:54 PM
To: Sherman, Gary
Subject: RE: Submitted: LRB 09-0063/1 Topic: Prescription drug monitoring?body=

If you want, I could try to find out if there is currently some deadline for the grants. Otherwise, I'll redraft. Let me know what you'd like to do.

CS

From: Sherman, Gary
Sent: Friday, March 13, 2009 12:48 PM
To: Sundberg, Christopher
Cc: Tribys, Eleanora; Hoey, Joseph
Subject: Submitted: LRB 09-0063/1 Topic: Prescription drug monitoring?body=

In the non-statutory provision, 2012 seems awfully short. We would have to enact legislation to redo the whole thing if we missed that date. Can we go a bit further out, like five years or so?

Otherwise, I think we are there.

Gary

No virus found in this incoming message.
Checked by AVG.
Version: 7.5.557 / Virus Database: 270.11.13/1999 - Release Date: 3/13/2009 5:59 AM

In: 3/13/09

State of Wisconsin
2009 - 2010 LEGISLATURE

LRB-0063/1 RMN R
CTS:bjk:md
stays

2009 BILL

regen

AN ACT *to create* 450.19 of the statutes; **relating to:** directing the Pharmacy Examining Board to create a program to monitor the dispensing of prescription drugs and requiring the exercise of rule-making authority.

Analysis by the Legislative Reference Bureau

This bill directs the Pharmacy Examining Board (board) to establish by rule a program for monitoring the dispensing of certain drugs (generally, controlled substances that current law permits certain licensed practitioners to prescribe). The program must do all of the following: 1) require a pharmacist, physician, advanced practice nurse, dentist, or optometrist to generate an electronic record documenting each dispensing of a covered prescription and to deliver the record to the board, unless the prescription is administered directly to a patient; 2) identify data elements to be contained in such a record; 3) specify to whom and under what circumstances such a record may be disclosed; 4) specify a format and a deadline for delivery of such a record to the board; and 5) specify a penalty for a failure to comply with program requirements.

The bill requires the Department of Regulation and Licensing to apply for certain federal grants to establish and operate the program. If the department fails to obtain federal funding before January 1, 2012, the bill is void.

5

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:

SECTION 1. 450.19 of the statutes is created to read:

450.19 Prescription drug monitoring program. (1) In this section, "prescription drug" means a substance identified in s. 961.16 or 961.18 or a drug identified by the board by rule as having a substantial potential for abuse.

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

(a) Require a pharmacist, physician, advanced practice nurse certified under s. 441.16 (2), optometrist, or dentist authorized to dispense a prescription drug to generate an electronic record documenting each dispensing of a prescription drug and to deliver the electronic record to the board, except that the program may not require the generation of an electronic record when a drug is administered directly to a patient.

(b) Identify specific data elements to be contained in an electronic record documenting the dispensing of a prescription drug. 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 electronic records generated by the program are easily shared with other states.

(c) Specify the persons to whom an electronic record may be disclosed and the circumstances under which the disclosure may occur. The rule promulgated under this paragraph shall permit the board to share an electronic record generated by the program with relevant agencies of other states.

(d) Specify a format for an electronic record generated under the program.

(e) Specify a deadline for the delivery of an electronic record to the board.

(f) Specify a penalty for failure to comply with rules promulgated under this subsection.

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

SECTION 2. Nonstatutory provisions.

(1) The department of regulation and licensing shall submit a timely application for a federal grant under 42 USC 280g–3 and under the Harold Rogers Prescription Drug Monitoring Program to fund the establishment and operation of the prescription drug monitoring program under section 450.19 of the statutes, as created by this act. If the department of regulation and licensing fails to obtain federal funding before January 1, 2012, section 450.19 of the statutes, as created by this act, is void.

(END)