# *2009 DRAFTING REQUEST*

## Assembly Substitute Amendment (ASA-AB227)

Received: **07/30/2009**

Received By: **csundber**

Wanted: **As time permits**

Identical to LRB:

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

By/Representing: **Nora 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**

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**Pre Topic:**

No specific pre topic given

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**Topic:**

Fix funding contingency, open records exemption, add criminal and administrative immunity

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**Instructions:**

See attached

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**Drafting History:**

| Vers. | Drafted | Reviewed | Typed | Proofed | Submitted | Jacketed | Required |
|---|---|---|---|---|---|---|---|
| /? | csundber<br>07/30/2009 | bkraft<br>08/10/2009 | | _____<br>_____ | | | |
| /1 | csundber<br>08/13/2009 | bkraft<br>08/13/2009 | mduchek<br>08/10/2009 | _____<br>_____ | lparisi<br>08/10/2009 | lparisi<br>08/10/2009 | |
| /2 | | | jfrantze<br>08/14/2009 | _____<br>_____ | mbarman<br>08/14/2009 | mbarman<br>08/14/2009 | |

FE Sent For:

**<END>**

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| /1 | | /2 bjk 8/13 | mduchek 08/10/2009 8/13 | 8/14 | lparisi 08/10/2009 | lparisi 08/10/2009 | |

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|---|---|---|---|---|---|---|---|
| /? | csundber | /1 bjk 8/10 | 8/10 | MD/PH | | | |

FE Sent For:

**<END>**

**Sundberg, Christopher**

**From:** Sweet, Richard
**Sent:** Thursday, July 30, 2009 10:03 AM
**To:** Sundberg, Christopher; Tribys, Eleanora
**Subject:** RE: Rx Monitoring bill AB 227

Chris/Nora,

I think that most of the confidentiality concerns can be address by adding a new paragraph to s. 450.19(2), which is in the section created by the bill that specifies what the program must do. The new paragraph could be something like the following:
**"(h) Ensure that the program is operated in compliance with s. 146.82 and 45 CFR, part 164, subpart E."** This is something the program would have to do anyhow, but it highlights the confidentiality issue and should address concerns. This language would replace the s. 146.82 language in the amendment.

You might also want to add a subdivision in s. 146.82(2)(a) that would allow submission by pharmacists and prescribers, although this is probably already be covered by s. 146.82(2)(a)5., which provides an exception to confidentiality requirements in response to a written request by any federal or state governmental agency to perform a legally authorized function. Any new provision would be along the following lines: **"22. To the pharmacy examining board for purposes of the prescription drug monitoring program under s. 450.19."**

I think that the suggestion to provide that these records aren't subject to inspection or copying under the Open Records Law is a good suggestion.

Dick

---

**From:** Sundberg, Christopher
**Sent:** Thursday, July 30, 2009 9:34 AM
**To:** Sweet, Richard
**Cc:** Tribys, Eleanora
**Subject:** RE: Rx Monitoring bill AB 227

Dick, can you clarify the privacy issue a bit? Monitoring prescription data is, at some level, inconsistent with privacy, but perhaps the data should be exempt from open-records inspection?

---

**From:** Tribys, Eleanora
**Sent:** Wednesday, July 29, 2009 10:27 AM
**To:** Sundberg, Christopher
**Subject:** RE: Rx Monitoring bill AB 227

Here are the additional amendments that came out of the hearing:

1) need to add *criminal* and *administrative* liability to the immunity provision

2) Seems to be confusion that the National All Schedules Prescription Electronic Records Act of 2005 or NASPER is not included in the provision re: source of funding, even though it is, but by statute number. Perhaps we should include the name of the act to clarify.

3). Many think that the privacy protections are not strong enough. Apparently Dick Sweet was there (I'm in the district) and offered to work on appropriate language and I believe you said you were already working with him too. So please see what you can do to come up with adequate language to deal with the privacy/HIPAA issues, as you already indicated you planned to do.

I suspect at this point a sub would be more appropriate.

*Nora Tribys*
Office of Rep. Gary Sherman
74th Assembly District
715 774 3691

-----Original Message-----
**From:** Sundberg, Christopher
**Sent:** Monday, July 27, 2009 3:12 PM
**To:** Tribys, Eleanora
**Subject:** RE: Rx Monitoring bill AB 227

OK- no amendment yet, pending the hearing.

FYI, my recollection is that HIPAA permits disclosures of personal health information that are required by state law, but I'll confer with our HIPAA expert when she returns.

CS

---

**From:** Tribys, Eleanora
**Sent:** Monday, July 27, 2009 3:08 PM
**To:** Sundberg, Christopher
**Subject:** Rx Monitoring bill AB 227

It's been awfully hectic today and could not back to you sooner. Gary understands about the deadline for obtaining federal funding and that it needs to be statutory language, but still thinks that perhaps at this point we can wait till after the hearing tomorrow for any further amendments.

I also mentioned to him about the privacy concerns as it relates to HIPAA. He said nearly 40 other states have managed to make their monitoring program compliant with HIPAA and that whatever language in necessary to do that should be utilized.

Thanks ,

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

**Sundberg, Christopher**

**From:** Tribys, Eleanora
**Sent:** Thursday, July 30, 2009 12:34 PM
**To:** Sundberg, Christopher
**Subject:** Rx Monitoring bill AB 227

So, I think we are good to go?

-----Original Message-----
**From:** Sherman, Gary
**Sent:** Thursday, July 30, 2009 12:23 PM
**To:** Tribys, Eleanora
**Subject:** RE: Rx Monitoring bill AB 227

I agree about the open records law.

The other sounds ok, as long as it doesn't keep docs and pharmacists from access, since that is the whole point of the law.

G

---

**From:** Tribys, Eleanora
**Sent:** Thursday, July 30, 2009 12:15 PM
**To:** Sherman, Gary
**Subject:** FW: Rx Monitoring bill AB 227

So, what do you think?

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

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**To:** Sundberg, Christopher; Tribys, Eleanora
**Subject:** RE: Rx Monitoring bill AB 227

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Thanks ,

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

7/30/09 ASA to AB 227

1. Fix contingency: move to statutory material.
2. Exemption from open records copy/inspection.
3. Add paragraph requiring compliance w/ HIPAA and s. 146.82.
4. Add subd. to s. 146.82 authorizing records under monitoring program.
5. AA1: substitute "practitioner" for doctors, APNP, etc.

In: 7/30/09 Wanted: soon

# State of Wisconsin
## 2009 – 2010 LEGISLATURE

s0096/1
LRB-0003/2
CTS:bjk:ph
stays

ASA , to

# 2009 ASSEMBLY BILL 227

SA x-ref (Inserts) ← are out of order

April 23, 2009 – Introduced by Representatives SHERMAN, TOWNSEND, BENEDICT, BERCEAU and HEBL, cosponsored by Senators JAUCH, RISSER, OLSEN, DARLING, CARPENTER and TAYLOR. Referred to Committee on Public Health.

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, 2015, the bill is void.

**ASSEMBLY BILL 227**

INS 2-1

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.

or practitioner

(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.

INS 3-6A

(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.

Insert 3-6AA

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

**SECTION 2. Nonstatutory provisions.**

INS 3-6B

(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, 2015, section 450.19 of the statutes, as created by this act, is void.

Please Change component to text: treat

(END)

# State of Wisconsin
## 2009 – 2010 LEGISLATURE

LRBa0562/1
CTS:cjs:md

# ASSEMBLY AMENDMENT 1,

# TO 2009 ASSEMBLY BILL 227

INS 2-1

July 24, 2009 – Offered by Representative SHERMAN.

At the locations indicated, amend the bill as follows:

**1.** Page 2, line 1: delete that line and substitute:

"**SECTION 1g.** 146.82 (1) of the statutes is amended to read:

146.82 **(1)** CONFIDENTIALITY. All patient health care records shall remain confidential. Patient health care records may be released only to the persons designated in this section or to other persons with the informed consent of the patient or of a person authorized by the patient. This subsection does not prohibit reports made in compliance with s. 253.12 (2), 255.40, or 979.01; electronic records generated or disclosed pursuant to rules promulgated under s. 450.19; testimony authorized under s. 905.04 (4) (h); or releases made for purposes of health care operations, as defined in 45 CFR 164.501, and as authorized under 45 CFR 164, subpart E.

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

END INS 2-1

INS 3-6A

**2.** Page 2, line 7: delete the material beginning with "pharmacist" and ending with "dentist" on line 8 and substitute "pharmacist or practitioner".

**3.** Page 3, line 6: after that line insert:

"**(3)** (a) A practitioner or pharmacist is immune from civil liability arising from the practitioner's or pharmacist's compliance in good faith with this section or with rules promulgated under this section.

(b) Nothing in this section may be construed to require a pharmacist or practitioner to obtain, before prescribing or dispensing a prescription to a patient, information about the patient that has been collected pursuant to the program described under sub. (2).".

or professional discipline

or criminal

END INS 3-6A

(END)

Insert 3-6AA

**Insert 3-6B:**

(h) Ensure that the program complies with s. 146.82 and 45 CFR part 164, subpart E.

**(4)** Electronic records generated under the program under this section are not subject to inspection or copying under s. 19.35.

**Sundberg, Christopher**

**From:** Hoey, Joseph
**Sent:** Wednesday, August 12, 2009 2:16 PM
**To:** Sundberg, Christopher

submitted electronically in a secure format specified by the board unless the board has granted a waiver and approved an alternate secure format.

Redraft sub — "electronic record" has caused concern regarding compliance burden, so rephrase per Joe Hoey instruction above. Also allow BOP to grant waiver of electronic format.

In: 8/13/09 Wanted: Monday PM 8/17/09

# State of Wisconsin
## 2009 - 2010 LEGISLATURE

2 e

LRBs0096/1 PMNR
CTS:bjk:md
stays

## ASSEMBLY SUBSTITUTE AMENDMENT ,

## TO 2009 ASSEMBLY BILL 227

5A

regen.

AN ACT ***to amend*** 146.82 (1); and ***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.

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under s. 905.04 (4) (h); or releases made for purposes of health care operations, as defined in 45 CFR 164.501, and as authorized under 45 CFR 164, subpart E.

**SECTION 2.** 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:

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(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.

delivery of

secure electronic

and authorize the board to grant a pharmacist or practioner a waiver of the specified format

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

(h) Ensure that the program complies with s. 146.82 and 45 CFR part 164, subpart E.

**(3)** (a) A pharmacist or practitioner is immune from civil or criminal liability or professional discipline arising from the pharmacist's or practitioner's compliance in good faith with this section or with rules promulgated under this section.

(b) Nothing in this section may be construed to require a pharmacist or practitioner to obtain, before prescribing or dispensing a prescription to a patient, information about the patient that has been collected pursuant to the program described under sub. (2).

**(4)** Electronic records generated under the program under this section are not subject to inspection or copying under s. 19.35.

**(5)** The department 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 program under this section. If the department fails to obtain federal funding before January 1, 2015, this section is void.

**(END)**