

2005 DRAFTING REQUEST

Bill

Received: **03/13/2006**

Received By: **csundber**

Wanted: **As time permits**

Identical to LRB:

For: **Terry Musser (608) 266-7461**

By/Representing:

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

Drafter: **csundber**

May Contact:

Addl. Drafters: **pkahler**

Subject: **Occupational Reg. - misc**

Extra Copies:

Submit via email: **YES**

Requester's email: **Rep.Musser@legis.state.wi.us**

Carbon copy (CC:) to: **christopher.sundberg@legis.state.wi.us**
pam.kahler@legis.state.wi.us

Pre Topic:

No specific pre topic given

Topic:

Prohibit epilepsy drug substitutions; prohibit penalty against provider who prescribes or dispenses a specific epilepsy drug

Instructions:

See Attached

Drafting History:

<u>Vers.</u>	<u>Drafted</u>	<u>Reviewed</u>	<u>Typed</u>	<u>Proofed</u>	<u>Submitted</u>	<u>Jacketed</u>	<u>Required</u>
/?	csundber 03/15/2006	kfollett 03/28/2006		_____			S&L
/1			pgreensl 03/28/2006	_____	mbarman 03/28/2006	lnorthro 04/11/2006	
				_____	mbarman 04/11/2006		

FE Sent For:

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<END>

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e-mail only

FE Sent For:

<END>

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Received: 03/13/2006

Received By: **csundber**

Wanted: **As time permits**

Identical to LRB:

For: **Michael Huebsch (608) 266-2401**

By/Representing: **Jodi Jensen**

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

Drafter: **csundber**

May Contact:

Addl. Drafters: **pkahler**

Subject: **Occupational Reg. - misc**

Extra Copies:

Submit via email: **YES**

Requester's email: **Rep.Huebsch@legis.state.wi.us**

Carbon copy (CC:) to: **christopher.sundberg@legis.state.wi.us**
pam.kahler@legis.state.wi.us

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May Contact:

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Subject: **Occupational Reg. - misc**

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/?	csundber	11 lzfz		3/28			
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3/28	by			pkahler			
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FE Sent For:

<END>

Kennedy, Debora

From: Jensen, Jodi
Sent: Friday, March 10, 2006 11:00 AM
To: Kennedy, Debora
Subject: Drafting request
Attachments: Epilepsy Patient Prescription Drug Safety Act.pdf

Hi Debora - Rep. Huebsch would like the attached language drafted into a bill. You can omit the policy declaration section.

Let me know if you have any questions.

Thanks!

MODEL LEGISLATION

EPILEPSY PATIENT PRESCRIPTION DRUG SAFETY ACT

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF XXXXX;

Section 1: Short title. This Act may be cited as the Epilepsy Patient Prescription Drug Safety Act.

Section 5: Policy Declaration. The General Assembly finds epilepsy is a devastating health condition that afflicts 2,300,000 United States citizens, over XXX,XXX of whom reside in XXXX. The General Assembly also finds epilepsy afflicts its victims at all ages, but is particularly devastating to children and the elderly.

The General Assembly further finds there are a number of widely used anti-epileptic drugs available to person with epilepsy, however there may be significant differences between the characteristics of anti-epileptic medications. The fact these differences exist could result in adverse effects, including loss of seizure control and development of toxic side effects. The General Assembly finds, changing from one formulation of anti-epileptic drug to another can usually be accomplished and risks minimized if physicians and patients properly maintain the right to determine their pharmaceutical course of therapy.

It is the intent of the General Assembly through implementation of this Act to protect citizens of the state of XXXX who are living with epilepsy by receiving safe and effective prescription drugs.

Section 10. Section XXX of the XXXX State Pharmacy Act is amended to read as follows:

(X) (a) Except as provided by this subsection, drug product selection authorized under this section does not apply to the refill of a prescription for any anti-epileptic drug for the treatment of epilepsy.

* (X) (b) A pharmacist shall not interchange an equivalent anti-epileptic drug for the treatment of epilepsy, as defined in paragraph (c) of this subsection without notification and the documented consent of the practitioner and patient.

(c.) For purposes of this subsection, epilepsy means a disorder of brain function that may or may not be associated with damage to brain structures. Anti-epileptic drug means (1) any drug prescribed for the treatment of epilepsy or (2) a drug used to treat or prevent convulsions that may pose a health risk to a patient if interchanged with another pharmaceutical manufacturer's product.

Section 15: (a) A participating provider shall determine the appropriate drug therapy for an enrollee. A prescription for any anti-epileptic drug the treatment of epilepsy shall be refilled using the same drug product by the same manufacturer, whether brand name or generic, that the pharmacist last dispensed under such prescription unless, prior to the dispensing of another pharmaceutical manufacturer's product, the pharmacist so notifies the participating provider and the participating provider gives documented consent thereto. A carrier shall not penalize the participating provider, the dispensing pharmacist or the enrollee, financially or otherwise, for prescribing, dispensing, or requesting a specific drug for the treatment of epilepsy.

(b) For purposes of this subsection, refill includes a new prescription written at the expiration of the then current issued prescription that continues the patient's therapy on the particular epilepsy drug.

Section 20. The general assembly hereby finds, determines and declares this act is necessary for the immediate preservation of the public peace, health and safety.

Section 25. Effective date. This act shall take effect upon becoming law.



State of Wisconsin
2005 - 2006 LEGISLATURE

LRB-4827/9
CTS:.....kjf
+ PJK
"Kay"
//
RNNR

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

D-note
SOON
(i 3-15)

and requirements for
health care plans
regarding drug therapy and
epilepsy drugs

gen

1 AN ACT ...; relating to: substitutions by pharmacists dispensing epilepsy drugs

Analysis by the Legislative Reference Bureau

X

Under current law, a pharmacist is required to dispense a prescription using the drug prescribed or, if the price is lower, a drug product that the federal food and drug administration has designated the therapeutic equivalent of the drug prescribed (drug product equivalent). Currently, a pharmacist may not substitute a drug product equivalent if a prescription indicates that no such substitution may be made.

This bill prohibits a pharmacist from substituting a drug product equivalent if the drug prescribed is a drug for treating epilepsy or for treating convulsions, unless the pharmacist obtains and documents the consent of the prescribing practitioner and the patient. Also, if a pharmacist is dispensing a refill of an epilepsy drug, the bill requires the pharmacist to dispense the same drug product, from the same manufacturer, that was previously dispensed, unless the pharmacist obtains and documents the consent of the prescribing practitioner.

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

Insert
A

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

2 SECTION 1. 448.02 (3) (a) of the statutes is amended to read:

SECTION 1

1 448.02 (3) (a) The board shall investigate allegations of unprofessional conduct
 2 and negligence in treatment by persons holding a license, certificate or limited
 3 permit granted by the board. An allegation that a physician has violated s. 253.10
 4 (3), 448.30 or 450.13 (2) (a) or has failed to mail or present a medical certification
 5 required under s. 69.18 (2) within 21 days after the pronouncement of death of the
 6 person who is the subject of the required certificate or that a physician has failed at
 7 least 6 times within a 6-month period to mail or present a medical certificate
 8 required under s. 69.18 (2) within 6 days after the pronouncement of death of the
 9 person who is the subject of the required certificate is an allegation of unprofessional
 10 conduct. Information contained in reports filed with the board under s. 49.45 (2) (a)
 11 12r., 50.36 (3) (b), 609.17 or 632.715, or under 42 CFR 1001.2005, shall be
 12 investigated by the board. Information contained in a report filed with the board
 13 under s. 655.045 (1), as created by 1985 Wisconsin Act 29, which is not a finding of
 14 negligence or in a report filed with the board under s. 50.36 (3) (c) may, within the
 15 discretion of the board, be used as the basis of an investigation of a person named in
 16 the report. The board may require a person holding a license, certificate or limited
 17 permit to undergo and may consider the results of one or more physical, mental or
 18 professional competency examinations if the board believes that the results of any
 19 such examinations may be useful to the board in conducting its investigation.

SECTION #. 450.13 (2) (title) is repealed and recreated to read: ~~FF~~

History: 1975 c. 383, 421; 1977 c. 418; 1981 c. 135, 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.

Change component →

SECTION 2. 450.13 (2) of the statutes is amended to read: ~~renumbered~~
 450.13 (2) (a).

21 450.13 (2) EXCEPTION. EXCEPTIONS. (a) A prescriber may indicate, by writing
 22 on the face of the prescription order or, with respect to a prescription order
 23 transmitted electronically, by designating in electronic format the phrase "No
 24 substitutions" or words of similar meaning or the initials "N.S.," that no substitution

450.13 (2) (title) as Exceptions.

1 of the drug product prescribed may be made under sub. (1). If such indication is
2 made, the pharmacist shall dispense the prescription with the specific drug product
3 prescribed. No preprinted statement regarding drug product substitution may
4 appear on the face of the prescription order.

History: 1985 a. 146; 1991 a. 114; 1997 a. 27.

5 SECTION 3. 450.13 (2) (b) of the statutes is created to read:

6 450.13 (2) (b) 1. In this paragraph, "epilepsy drug" means any of the following:

- 7 a. A prescribed drug product for the treatment of epilepsy.
- 8 b. A prescribed drug product for the treatment of prevention of convulsions, if
9 substitution of a drug product equivalent poses a risk to the health of the patient.

10 2. If a pharmacist dispenses an epilepsy drug, the pharmacist may not dispense
11 the drug product equivalent to the epilepsy drug that is prescribed unless the
12 pharmacist obtains and documents the consent of the practitioner who issued the
13 prescription order and the patient for whom the drug product is prescribed.

14 3. If a pharmacist dispenses a refill of a prescription for an epilepsy drug for
15 a patient or fills a new prescription order for an epilepsy drug for a patient upon the
16 expiration of a prescription order for the same epilepsy drug, the pharmacist shall
17 dispense the same drug product, from the same manufacturer, that was last
18 dispensed, unless the pharmacist obtains and documents the consent of the
19 practitioner who issued the prescription order.

20

(END)

Insert 3-19

D. - wto

2005-2006 DRAFTING INSERT
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-4827/ins
PI
PJK:.....

INSERT A

4 Under current law, a participating provider is a health care professional, a health care facility, or a health care service or organization that is under contract with a defined network plan, preferred provider plan, or limited service health organization to provide services, items, or supplies to enrollees of the plan or organization. This bill provides that a participating provider determines the appropriate drug therapy for an enrollee. The bill prohibits an insurer offering a defined network plan, preferred provider plan, or limited service health organization from penalizing, financially or otherwise, a participating provider for prescribing, a pharmacist for dispensing, or an enrollee for requesting a specific drug for the treatment of epilepsy.

(END OF INSERT A)

INSERT 3-19

1

2

SECTION 1. 609.31 of the statutes is created to read:

3

609.31 Drug therapy. (1) PROVIDER DETERMINES. A participating provider shall determine the appropriate drug therapy for an enrollee.

4

5

(2) PENALTIES PROHIBITED FOR EPILEPSY DRUGS. An insurer offering a defined network plan, preferred provider plan, or limited service health organization may not penalize, financially or otherwise, a participating provider for prescribing, a

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pharmacist for dispensing, or an enrollee for requesting a specific drug for the treatment of epilepsy.

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SECTION 2. Initial applicability.

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(1) DRUG THERAPY. If a contract between an insurer and a participating provider, or between an insurer and a pharmacist, or between an insurer and an

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enrollee, that is in effect on the effective date of this subsection contains a provision

14

that is inconsistent with the treatment of section 609.31 of the statutes, the

1 treatment of section 609.31[✓] of the statutes first applies to that contract on the date
2 on which it is renewed.

(END OF INSERT 3-19)

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-48277dn
CTS&PJK.....

#1
-
kgf

Rep. Huebsch:

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

1. The drafting instructions indicate that "epilepsy drug" includes a drug for the treatment of convulsions, if substitution with another manufacturer's product "may pose a health risk." Who should decide whether a substitution poses a health risk?
2. This draft preserves a cross-reference in current law indicating that it is professional misconduct for a physician to violate s. 450.13(2). Under current s. 450.13(2), a prescribing practitioner may indicate that a pharmacist may not dispense the drug product equivalent of the drug product that is prescribed. It is not clear how a physician could violate s. 450.13(2), since it neither prohibits nor requires conduct by a physician. Should the draft address this anomaly?

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



1. In the language of the model legislation, a "*participating* provider" determines an enrollee's drug therapy. Therefore, I limited the provision to defined network plans, preferred provider plans, and limited service health organizations in ch. 609. Is this

what you want? Should the “participating provider” who determines the drug therapy be limited to the one that is actually treating the enrollee for the condition for which the drugs are being prescribed? Who would determine an enrollee’s drug therapy if not a provider, the plan? If the plan covers only certain drugs, is the plan in violation of the provision if the drugs that are covered are not the ones that the participating provider would prescribe? Since the draft relates to drugs for the treatment of epilepsy, should this provision [proposed s. 609.31 (1)] be limited to drug therapy for the treatment of epilepsy?

2. “Penalize” is a pretty vague term. What does it mean to “penalize” an enrollee for requesting a specific drug for the treatment of epilepsy? Could it be interpreted to mean that not covering a drug that is requested by an enrollee is penalizing the enrollee? Could it be interpreted to mean that requiring a higher copay for a brand name drug requested by an enrollee is penalizing the enrollee?

Perhaps there is a good reason, but it seems strange to treat drugs prescribed, dispensed, or requested for the treatment of epilepsy differently from drugs prescribed, dispensed, or requested for the treatment of other conditions. Does prohibiting penalties for prescribing, dispensing, or requesting a specific drug for the treatment of epilepsy imply that an insurer *may* impose a penalty for prescribing, dispensing, or requesting a specific drug for the treatment of another condition?

Pamela J. Kahler
Senior Legislative Attorney
Phone: (608) 266-2682
E-mail: pam.kahler@legis.state.wi.us

if it is a brand name drug

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-4827/1dn
CTS&PJK:kjf:pg

March 28, 2006

Rep. Huebsch:

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

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Pamela J. Kahler
Senior Legislative Attorney
Phone: (608) 266-2682
E-mail: pam.kahler@legis.state.wi.us

Kraft, Becky

From: Jensen, Jodi
Sent: Monday, April 10, 2006 3:20 PM
To: LRB.Legal; Sundberg, Christopher
Subject: Draft Review: LRB 05-4827/1 Topic: Prohibit epilepsy drug substitutions; prohibit penalty against provider who prescribes or dispenses a specific epilepsy drug

Rep. Huebsch has given this bill to Rep. Musser to introduce. He has Rep. Huebsch's permission to make changes to the draft and/or request a jacket.

Thanks.

Jodi Jensen

Northrop, Lori

From: Rep.Musser
Sent: Tuesday, April 11, 2006 1:03 PM
To: LRB.Legal
Subject: Draft Review: LRB 05-4827/1 Topic: Prohibit epilepsy drug substitutions; prohibit penalty against provider who prescribes or dispenses a specific epilepsy drug

Please Jacket LRB 05-4827/1 for the ASSEMBLY.