2009 DRAFTING REQUEST

Bill

Received: **01/21/2009**

Received By: **rryan**

Wanted: **As time permits**

Identical to LRB:

For: **Dan Meyer (608) 266-7141**

By/Representing: **Jennifer Western**

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

Drafter: **tdodge**

May Contact:

Addl. Drafters:

Subject: **Health - miscellaneous**

Extra Copies:

Submit via email: **YES**

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

Carbon copy (CC:) to:

Pre Topic:

No specific pre topic given

Topic:

Informed consent for psychotropic medications in nursing homes and CBRFs

---

Instructions:

See attached

Drafting History:

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
/?	rryan 02/13/2009 tdodge 03/13/2009	csicilia 03/23/2009		_____ _____ _____ _____			
/P1	tdodge 04/22/2009	csicilia 05/01/2009	rschluet 03/24/2009	_____ _____	lparisi 03/24/2009		S&L
/1	tdodge 07/15/2009	csicilia 07/22/2009	rschluet 05/01/2009	_____ _____	mbarman 05/01/2009		S&L

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
/2	tdodge 09/08/2009	csicilia 09/10/2009	jfrantze 07/22/2009	_____ _____	mbarman 07/22/2009		S&L
/3			jfrantze 09/10/2009	_____ _____	cduerst 09/10/2009	mbarman 10/14/2009	

FE Sent For: at intro
10/28

<END>

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FE Sent For: 1/3 gjs 9/10 01 9/10 **<END>**

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/2 gs 7/22/09 7/22 7/22

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/?	rryan 02/13/2009 tdodge						

FE Sent For:

<END>

Dodge, Tamara

From: Western, Jennifer
Sent: Thursday, February 19, 2009 5:01 PM
To: Dodge, Tamara
Subject: FW: Drafting Instructions

Categories: Informed Consent Antipsychotic Req

Hi Tami,

I just wanted to follow up on the email I sent you yesterday and our phone conversation. You had asked whether there was a certain deadline or urgency for this bill draft. If it would expedite the process, a preliminary would be fine too.

I was thinking about it and technically, there isn't an urgency, but the constituent that we have been working with first contacted DHS in early 2008 and this has dragged on for her and her family since then. I know she hasn't always gotten timely responses from the department, and they weren't always that helpful.

I know you are busy and I am *very grateful* for your help on this draft. I just wanted to clarify why I may have sounded like I am hoping a draft may be available as soon as possible.

Thanks, again.

Jennifer

Dodge, Tamara

From: Western, Jennifer
Sent: Wednesday, February 18, 2009 4:22 PM
To: Dodge, Tamara
Subject: FW: Drafting Instructions

Categories: Informed Consent Antipsychotic Req

Hi Tami,

Here are the directions I sent to Robin on January 23rd, along with my follow up about the timeline. Please let me know if you have any questions. Dick Sweet also knows about this, as he has met with Rep. Meyer about this.

Thanks for your help.

Jennifer, 6-7141

From: Ryan, Robin
Sent: Friday, February 06, 2009 1:10 PM
To: Western, Jennifer
Subject: RE: Drafting Instructions

I'm sorry, I don't. We have been rather busy. I should be able to give you a better sense next week.

From: Western, Jennifer
Sent: Friday, February 06, 2009 12:58 PM
To: Ryan, Robin
Subject: RE: Drafting Instructions

Hi Robin,

I was just wondering whether you might have a sense for when this draft may be available?

Thanks,

Jennifer

From: Western, Jennifer
Sent: Friday, January 23, 2009 1:55 PM
To: Ryan, Robin
Cc: Sweet, Richard; Rep.Meyer
Subject: Drafting Instructions

Hi Robin. I am just following up on the request I sent on Wednesday for draft language requiring written informed consent for the administration of psychotropic medication to resdients of nursing homes or CBRF's who have been diagnosed with a degenerative brain disorder. I talked further with Dick Sweet about the specifics of the bill and in what chapter the provision may best fit. Rep. Meyer would like it drafted in Chapter 50, as this chapter extrapolates upon the rights of residents, specifically in Ch 50.09.

Please let me know if you have any questions about this request.

Thank you!!!

~Jennifer, 266-7141
Office of Dan Meyer
State Representative
34th Assembly District

General Purpose:
To require that for residents of nursing homes or CBRFs diagnosed with a (degenerative brain disorder) and to whom are prescribed a psychotropic medication for a reason other than an FDA approved reason, the facility must obtain written informed consent from either the patient, the legal guardian of the patient, or the health care agent under a power of attorney for health care.

Allow two exceptions, the same that are currently described in Ch 51 pertaining to written consent for patients with developmental disabilities or mental illness. (Both are described further in DHS 94.03 (2m), which was drafted to implement Ch 51.)

DHS 94.03 (2m) In emergency situations or where time and distance requirements preclude obtaining written consent before beginning treatment and a determination is made that harm will come to the patient if treatment is not initiated before written consent is obtained, informed consent for treatment may be temporarily obtained by telephone from the parent of a minor patient or the guardian of a patient. Oral consent shall be documented in the patient's record, along with details of the information verbally explained to the parent or guardian about the proposed treatment. Verbal consent shall be valid for a period of 10 days, during which time informed consent shall be obtained in writing.

Definition of Informed Consent: similar to DHS 94.02 (22)
"Informed consent" or "consent" means written consent voluntarily signed by a patient who is competent and who understands the terms of the consent, or by the patient's legal guardian or by the health care agent under a power of attorney for health care, without any form of coercion, or temporary oral consent obtained by telephone.

Content of Informed Consent: similar to DHS 94.03
Informed consent. (1) Any informed consent document required under this chapter shall declare that the patient or the person acting on the patient's behalf has been provided with specific, complete and accurate information and time to study the information or to seek additional information concerning the proposed treatment or services made necessary by and directly related to the person's degenerative brain disorder, including:

(a) The benefits of the proposed treatment and services;
(b) The way the treatment is to be administered and the services are to be provided;
(c) The expected treatment side effects or risks of side effects which are a reasonable possibility, including side effects or risks of side effects from medications;
(d) Alternative treatment modes and services;
(e) The probable consequences of not receiving the proposed treatment and services;
(f) The time period for which the informed consent is effective, which shall be no longer than 15 months from the time the consent is given; and
(g) The right to withdraw informed consent at any time, in writing.

(2) An informed consent document is not valid unless the subject patient who has signed it is competent, that is, is substantially able to understand all significant information which has been explained in easily understandable language, or the consent form has been signed by the legal guardian or by the health care agent under a power of attorney for health care of an incompetent patient.

(3) The patient, or the person acting on the patient's behalf, shall be given a copy of the completed informed consent form, upon request.

(4) When informed consent is refused or withdrawn, no retaliation may be threatened or carried out.

Department Requirement to Update Forms

DHS shall be responsible for providing access to updated informed consent for medication forms, which include accurate information about any FDA warnings.

Ryan, Robin

From: Dodge, Tamara
Sent: Wednesday, January 21, 2009 1:26 PM
To: Ryan, Robin
Subject: FW: Request for a preliminary draft

I can call since I talked to Jennifer about this request before.
- Tami

Tamara J. Dodge
Attorney
Wisconsin Legislative Reference Bureau
P.O. Box 2037
Madison, WI 53701-2037
(608) 267 - 7380
tamara.dodge@legis.wisconsin.gov

From: Western, Jennifer
Sent: Wednesday, January 21, 2009 1:22 PM
To: Ryan, Robin; Dodge, Tamara
Cc: Sweet, Richard
Subject: RE: Request for a preliminary draft

Robin or Tamara,

Could one of you please call Dick Sweet at 266-2982? It is just regarding where this request would best be placed... based on our meeting with DHS...

Thanks!

Jennifer

From: Ryan, Robin
Sent: Wednesday, January 21, 2009 1:13 PM
To: Western, Jennifer; Dodge, Tamara
Subject: RE: Request for a preliminary draft

Woops -- I 'm glad both of you are more observant than I. Jennifer, I will forward your request to Cathlene Hanaman who is drafting mental health.

Robin

From: Western, Jennifer
Sent: Wednesday, January 21, 2009 1:08 PM
To: Ryan, Robin; Dodge, Tamara
Subject: RE: Request for a preliminary draft

Hey Robin, I just didn't know if Tami got your email, since I didn't see her in the TO Field.

From: Ryan, Robin
Sent: Wednesday, January 21, 2009 1:05 PM
To: Western, Jennifer
Subject: RE: Request for a preliminary draft

Tami, is this a mental health draft?

From: Western, Jennifer

Sent: Wednesday, January 21, 2009 11:56 AM
To: Ryan, Robin; Dodge, Tamara
Cc: Sweet, Richard
Subject: Request for a preliminary draft

Hello, Robin & Tamara.

Representative Meyer would like to request legislative language. First I will start out by providing some background.

Background:
(A Milwaukee Journal Sentinel Article is attached.) A constituent of Representative Meyer's contacted him because her father was in a nursing home. The legal guardian was presented with an, "Informed Consent for Medication Form" for the administration of a psychotropic medication called Risperdal. The legal guardian signed the form. However the form, which had been downloaded from the DHS website, was outdated and did not list "black box" risk information that had been updated by the FDA in 2005. (The form was from 2001.) The black box warning lists that there is an increased risk of mortality in elderly patients with dementia and related psychosis. Obviously, the legal guardian was not presented this information on the outdated form. Unfortunately, the constituent's father did pass away.

After contacting DHS about the issue of the nursing home presenting the legal guardian with an outdated form, DHS' reply was that there could be no violation because there is no law requiring any (let alone updated) informed consent at all for patients with degenerative brain disorders. (According to DHS, an informed consent for medication form is required for patients with mental illness or developmental disabilities that are being administered psychotropic medication.)

The Request:
Representative Meyer would like to request language that would simply require the "Informed Consent for Medication Form" to be completed by a patient with a degenerative brain disorder (or their guardian) before psychotropic medications are administered. (He would like this proposal to keep any exceptions for temporary verbal agreement, court orders, or emergencies.)

Also, require the DHS to keep informed consent for medication forms that are available on their website updated.

Based on conversations with some nursing homes, many voluntarily present a form, much like this nursing home did. This proposal would make that a requirement, along with making sure the forms are updated.

You may have questions about this request. If you would like to call me, I can be reached at 266-7141. If you would like to talk to Legislative Council, I have been communicating with Dick Sweet about this issue and he attended a meeting we had with DHS about this.

Thank you,

Jennifer, 266-7141
Office of Dan Meyer
State Representative
34th Assembly District

<< File: MJS 11-22-2008.pdf >>

Ryan, Robin

From: Western, Jennifer
Sent: Wednesday, January 21, 2009 11:56 AM
To: Ryan, Robin; Dodge, Tamara
Cc: Sweet, Richard
Subject: Request for a preliminary draft

Attachments: MJS 11-22-2008.pdf

Hello, Robin & Tamara.

Representative Meyer would like to request legislative language. First I will start out by providing some background.

Background:
(A Milwaukee Journal Sentinel Article is attached.) A constituent of Representative Meyer's contacted him because her father was in a nursing home. The legal guardian was presented with an, "Informed Consent for Medication Form" for the administration of a psychotropic medication called Risperdal. The legal guardian signed the form. However the form, which had been downloaded from the DHS website, was outdated and did not list "black box" risk information that had been updated by the FDA in 2005. (The form was from 2001.) The black box warning lists that there is an increased risk of mortality in elderly patients with dementia and related psychosis. Obviously, the legal guardian was not presented this information on the outdated form. Unfortunately, the constituent's father did pass away.

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Thank you,

Jennifer, 266-7141
Office of Dan Meyer
State Representative
34th Assembly District

MJS
-22-2008.pdf (41 K

JOURNAL INTERACTIVE

Public Investigator
Bio | E-mail

Public Investigator | Taking tips, chasing leads, solving problems

Family didn't know of warning for anti-psychotic drug

By Ellen Gabler of the Journal Sentinel

Posted: Nov. 22, 2008

Bruce Bowman shouldn't have died the way he did, his children say.

His throat shouldn't have swelled up. His body shouldn't have gone rigid. He shouldn't have gotten pneumonia. The once strong former logger shouldn't have withered away. Two weeks before he died June 19, Bowman weighed 112 pounds.

The 71-year-old man had dementia and was a resident at Taylor Park Nursing and Rehabilitation Center in Rhinelander.

Six months before he died, Bowman started taking Risperdal, an anti-psychotic drug prescribed to control his "agitation" and "physical aggression," according to medical records.

Bowman's children believe the drug killed him.

They insist they were never told by the nursing home staff that Risperdal has a black-box warning that reads: "Increased mortality in elderly patients with dementia-related psychosis."

They didn't know that in clinical trials for Risperdal, most patient deaths occurred from cardiovascular or infectious complications, such as pneumonia. The drug's listed side effects also include vomiting, weight loss and muscle stiffness, among many others.

"I'd never give any kind of consent for any of that," said Martin Bowman, Bruce's son, who was the legal guardian of his father's care and needed to approve any changes in medication.

The black-box warning for Risperdal was issued by the Food and Drug Administration in 2005. The

drug is approved for use in people with schizophrenia, bipolar disorder and some irritability associated with autism.

But Martin Bowman never saw that warning because the nursing home was using nearly 7-year-old medication consent forms, Public Investigator found.

Before administering a drug to a patient, the nursing home had the patient's legal guardian sign a form that detailed a medication's risks.

But the old forms didn't have the paragraphs of warnings about Risperdal because the warnings hadn't been issued in 2001, when the forms apparently were printed.

A spokesman for Prestige Healthcare, the company that owns Taylor Park nursing home, declined to comment on Bowman's situation, the outdated consent forms or the nursing home's general procedures.

The nursing home could have downloaded an updated form from the state Department of Health Services Web site. But the forms - updated or not - aren't required in nursing homes, according to the department.

A patient, or his or her legal guardian, can be informed verbally about a drug's risks. Martin Bowman said he was not verbally informed about the risks and would never have given permission if he had known.

Bruce Bowman's family said they visited him at least once a week while he was at Taylor Park. They noticed his deterioration - the drooling; his rigid, claw-like hands; his trouble swallowing; and his weight loss - and asked the nurses what was wrong. No one had any answers, said Lisa MaKarrall, Bruce Bowman's daughter. It wasn't until May when Bruce's ex-wife, a former registered nurse, called a hospital psychiatry ward that they found out that Risperdal had a black-box warning, MaKarrall said.

No regulations violated

The state Bureau of Nursing Home Resident Care investigated Taylor Park this summer and again this fall after Bruce Bowman's daughter complained about how her father had been treated. The agency found Taylor Park and its staff did not violate any federal regulations in giving Risperdal to Bruce Bowman.

But his family still wants others to know the dangers of the drug.

Anti-psychotic drugs often are prescribed to elderly patients with dementia to control their agitation and outbursts. But some of the drugs, such as Risperdal, are not approved for elderly patients with dementia and have the black-box warning.

A handful of states have sued the company that makes and markets Risperdal, Janssen Pharmaceutica of Johnson & Johnson. The states contend the company failed to disclose many of the dangers of the drug. The lawsuits also claim the company marketed the drug to populations for which it had not been approved - such as elderly people. That is against the law.

Janssen spokeswoman Kara Russell said the company denies the allegations.

Many of the states also are suing Janssen to recoup millions of taxpayer dollars spent from Medicaid

programs for prescriptions for unapproved uses.

Some researches worry that the anti-psychotic drugs might be overprescribed to subdue nursing-home patients. The consequences can be deadly.

"If someone died from an anti-psychotic, you don't get a second chance," said Thomas E. Lackner, a doctor of pharmacy and professor at the University of Minnesota's College of Pharmacy.

Lackner said using an anti-psychotic drug on elderly patients with dementia is usually a last resort. But sometimes the drugs are helpful, doctors say.

Even though Risperdal and other anti-psychotic drugs aren't approved for treating patients with dementia-related psychosis, that doesn't mean doctors can't prescribe the drugs off-label, or for a purpose other than the drug's approved use.

This practice happens often for all sorts of drugs, doctors say.

"There sometimes aren't any other options," said Edmund H. Duthie, professor of medicine and chief of geriatrics at the Medical College of Wisconsin.

Archives

- Owners of towed cars feel they are victims of a city snow job
- For shoppers, staying alert at the register pays
- Parking con has few parallels
- Child support paid, not received
- Some parkers get tickets in error at automatic meters
- Web site's demise leaves people without payments
- Promised debt relief dissolves
- 'Spa Man' still elusive, even at home
- Spa dealer elusive in paying court-ordered debts
- Drain cleaner Blanton Brothers draws complaints
- Court to reverse foreclosure over parking-related fine
- State lags in checking restaurant cleanliness
- Foreclosure looms despite vow of aid
- City stands firm in foreclosure case
- Don't lose your identity when you sell your car
- Disability applicant caught in Social Security limbo
- Many choose court route to fight parking tickets
- Milwaukee man files petition to pay parking fine, keep house
- Coffee shops' poor pours short customers
- Bubble of waste bursts over kitchen

Ryan, Robin

From: Sweet, Richard
Sent: Wednesday, January 21, 2009 2:11 PM
To: Ryan, Robin; Hanaman, Cathlene
Cc: Western, Jennifer
Subject: Dementia

Robin/Cathlene,

I think the issue that Jenny brought to your attention is not a ch. 51 issue since the definition in that chapter of "developmental disability" explicitly excludes dementia. It may be a ch. 50 issue if it's limited to facilities regulated under that chapter, or a ch. 450 issue since it deals with consent for prescription drugs.

Dick Sweet

Senior Staff Attorney
Wisconsin Legislative Council
(608)266-2982
richard.sweet@legis.wisconsin.gov

State of Wisconsin
2009 - 2010 LEGISLATURE

LRB-1703/P1
TJD:.:....

In 3/13/09 soon

cjs RMNR

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

D-NJ

Gen Cat

AN ACT ...; **relating to:** requiring informed consent before administration of psychotropic medication to a nursing home or community-based residential facility resident who has degenerative brain disorder.

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. 50.08 of the statutes is created to read:

50.08 Informed consent for psychotropic medications. (1) DEFINITIONS. In this section:

(a) "Degenerative brain disorder" has the meaning given in s. 55.01 (1v).

(b) "Incapacitated" has the meaning given in s. 50.06 (1).

(c) "Off-label use" means use of a prescription or over-the-counter medication for a purpose other than a purpose approved by the federal food and drug administration.

(d) "Person acting on behalf of the resident" means a guardian of the person, as defined in s. 54.01 (12), or a health care agent, as defined in s. 155.01 (4).

****NOTE: Is it okay to include health care agents acting under a power of attorney for health care as a person who can provide informed consent? In some situations, I believe, residents would not have a guardian because they have a health care agent.

(e) "Psychotropic medication" means a prescription drug, as defined in s. 450.01 (20), that is used to treat or manage a psychiatric symptom or challenging behavior.

(B)

(2) A physician, as defined in s. 448.01 (5), or a psychiatrist, as defined in s. 457.01 (8e), who prescribes a psychotropic medication to a resident of a nursing home or community-based residential facility resident who has degenerative brain disorder shall notify the nursing home or community-based residential facility if the medication is prescribed for an off-label use.

****NOTE: I added this provision because I wondered how the staff of the facility would know that the medication was prescribed for an off-label use. Is that okay?

(B) Sub.

(3) (a) Except as provided in sub. (4) or (5), before administering a psychotropic medication prescribed for an off-label use to a resident who has degenerative brain disorder, a nursing home or a community-based residential facility shall obtain written informed consent from the resident or, if the resident is incapacitated, a person acting on behalf of the resident, on a form provided by the department under par. (b) or on a form that contains the same information as the form under par. (b).

(b) The department shall make available on its Internet website or by mail an informed consent form for administration of psychotropic medication that contains all of the following information:

****NOTE: I did not specify the type of person required to obtain informed consent from the patient. Is that okay?

resident

space for a

1. A description of the benefits of the proposed treatment and the way the medication will be administered.

federal

2. A description, using the most recently issued information from the U.S food and drug administration, of the side effects or risks of side effects of the medication and any warnings about the medication.

space for a

3. A description of any alternative treatment modes or medications.

space for a

4. A description of the probable consequenses of not receiving the medication.

A space for indicating the

5. The time period for which the informed consent is effective, which shall be no longer than 15 months from the time the consent is given.

6. A notification of the right to withdraw informed consent, in writing, at any time.

the nursing home or community-based residential facility

7. A declaration that the resident or the person acting on behalf of the resident has been provided with specific, complete, and accurate information, and time to study the information or to seek additional information concerning the medication.

c

(b) If the resident is incapacitated, the employee of the facility shall request from a person acting on behalf of the resident written informed consent under par. (a). Written informed consent provided by a guardian is subject to s. 54.25.

****NOTE: I refer to the guardianship statutes here because there are procedures specified for the guardian to follow regarding informed consent for psychotropic medications. I presume that you still want the guardian to follow those procedures.

d

(c) Upon request, the facility shall give the resident, or a person acting on behalf of the resident, a copy of the completed informed consent form.

e

(d) No person may retaliate against or threaten to retaliate against a resident or person acting on behalf of a resident for refusing to provide or withdrawing informed consent.

nursing home or community-based residential facility

f

(e) The facility shall use the most current informed written consent form available from the department or shall update its own form, containing all of the

9) 8. A space for the signature of the resident or the person acting on behalf of the resident.

information in par. (a) 1. to 7., with the most current information about the medication available from the department.

(4) (a) A nursing home or community-based residential facility is not required to obtain written informed consent before administering a psychotropic medication under sub. (3) if all of the following apply:

1. There is an emergency in which a resident is at significant risk of physical or emotional harm or where time and distance preclude obtaining written informed consent before administering psychotropic medication.

2. A physician, as defined in s. 448.01 (5), or a psychiatrist, as defined in s. 457.01 (8e), has determined that harm will come to the patient if treatment is not initiated before written informed consent is obtained.

(b) If par. (a) applies, the nursing home or community-based residential facility shall obtain temporary oral consent from a person acting on behalf of the resident before administering the psychotropic medication. The oral consent shall be entered in the resident's medical record. The oral consent shall be valid for 10 days, during which an employee of the nursing home or community-based residential facility shall obtain written informed consent under sub. (3).

(5) A nursing home or community-based residential facility is not required to obtain written informed consent before administering a psychotropic medication under sub. (3) if a court of competent jurisdiction has ordered the psychotropic medication to be administered.

****NOTE: In the instructions you mentioned a court order as an exception to the usual procedures to obtain informed consent. Is paragraph (b) what you had in mind?

(END)

D-N

4. 1. The resident is incapacitated and not able to provide consent and the resident is not the subject of a court order to administer psychotropic medications under s. 55.14.

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-1703/?dn P1
TJD:.../:...
gjs

Date

To Jennifer Western:

Please review this preliminary draft to make sure it complies with your intent. Do you want the informed consent required for only those facility residents with degenerative brain disorder or for all nursing home residents? Also, do you want to require informed consent only for off-label uses of psychotropic medications? I wanted to confirm this because, as it is drafted, the draft only requires that facilities obtain informed consent for off-label uses of psychotropic medications from residents with degenerative brain disorder.

Tamara J. Dodge
Legislative Attorney
Phone: (608) 267-7380
E-mail: tamara.dodge@legis.wisconsin.gov

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-1703/P1dn
TJD:cjs:rs

March 23, 2009

To Jennifer Western:

Please review this preliminary draft to make sure it complies with your intent. Do you want the informed consent required for only those facility residents with degenerative brain disorder or for all nursing home residents? Also, do you want to require informed consent only for off-label uses of psychotropic medications? I wanted to confirm this because, as it is drafted, the draft only requires that facilities obtain informed consent for off-label uses of psychotropic medications from residents with degenerative brain disorder.

Tamara J. Dodge
Legislative Attorney
Phone: (608) 267-7380
E-mail: tamara.dodge@legis.wisconsin.gov

Dodge, Tamara

From: Western, Jennifer
Sent: Wednesday, April 08, 2009 1:58 PM
To: Dodge, Tamara
Subject: RE: Request for /1 on LRB 1703 - Informed Consent

Yes, that is correct on the black box warning.

From: Dodge, Tamara
Sent: Wednesday, April 08, 2009 11:44 AM
To: Western, Jennifer
Subject: RE: Request for /1 on LRB 1703 - Informed Consent

Jennifer,

I just want to clarify something before I get into redrafting LRB-1703. The informed consent will be required for prescription of psychotropics (defined as antipsychotics, antidepressants, lithium, or tranquilizers) to those with degenerative brain disorder. As I understand from your email below, you want informed consent required only in the instance where the medication has a black box warning. Is that correct?

In other words, a nursing home resident with degenerative brain disorder who is prescribed a psychotropic drug that does not have a black box warning would not have to provide written informed consent for administration of the medication. But the same resident who is prescribed a psychotropic drug with a black box warning would have to provide written informed consent. I just want to make sure I am clear.

On your comment 7 regarding page 4, line 10: I did mean to say "all." I took the typical emergency exception and split it into steps. The idea would be that if the resident is at risk of harm and a physician certifies as such, then the emergency procedure would apply. The only time this would occur is if the resident is incapacitated because, if the resident is capable of giving informed consent, then the emergency procedure is not needed. I could rewrite this so that a resident himself or herself could give temporary oral consent (if not capable of signing). I can talk to you about this issue. I just wanted to get started on the "black box" issue first.

Tami

Tamara J. Dodge
Attorney
Wisconsin Legislative Reference Bureau
P.O. Box 2037
Madison, WI 53701-2037
(608) 267 - 7380
tamara.dodge@legis.wisconsin.gov

From: Western, Jennifer
Sent: Tuesday, March 31, 2009 3:11 PM
To: Dodge, Tamara
Cc: Sweet, Richard
Subject: Request for /1 on LRB 1703 - Informed Consent

Hello Tamara,

Representative Meyer would like to ask for a /1 to LRB 1703. The following are the answers to the drafter's notes in the bill and some other changes he is requesting to be made. Please feel free to let me or Dick Sweet from Leg Council know if you have any questions about these requested changes to the draft.

Thanks,

Jennifer, 6-7141
Office of Dan Meyer
State Representative

34th Assembly District

1. (Drafters Notes) Do you want the informed consent required for only those facility residents with degenerative brain disorder or for all nursing home residents?
Only for patients with degenerative brain disorder.

2. (Drafters Notes) Also, do you want to require informed consent only for off–label uses of psychotropic medications?
No because it is possible that a person may have a condition like dementia and be prescribed an antispychotic - not for their dementia - but for another approved reason for taking the drug like depression or weight. This person should still have a informed consent form presented to them. So, the mission of the bill in a nutshell is: Any patient residing in a nursing home or CBRF with degenerative brain disorder who is prescribed an antipsychotic must receive an informed consent form if that medicaiton includes black box warning issued by the FDA.

3. (Page 2, Line 5 Note) Is it okay to include health care agents acting under a power of attorney for health care as a person who can provide informed consent? In some situations, I believe, residents would not have a guardian because they have a health care agent.
Yes.

4. (Definition of psychotropic medication)
On page 2, line 6, psychotropic medication is defined. The draft uses the definition from Chap 55, but there are also definitions in Chap 50 and 51. Rep. Meyer would like the bill to define psychotropic medication as defined in Chap 50 & 51, rather than Chap 55. Chap 50 & 51 are more restrictive:

Chapter 50: UNIFORM LICENSURE
50.035(5)(a)2
"Psychotropic medication" means an antipsychotic, antidepressant, lithium carbonate or a tranquilizer.

50.04(2t)(a)2
"Psychotropic medication" means an antipsychotic, antidepressant, lithium carbonate or a tranquilizer.

Chapter 51: UNIFORM LICENSURE
51.64(1)(b)
"Psychotropic medication" means an antipsychotic, antidepressant, lithium carbonate or a tranquilizer.

5. (Page 2, Line 12 Note) I added this provision because I wondered how the staff of the facility would know that the medication was prescribed for an off–label use. Is that okay?
Yes. However, due to the changes implicit in #2 above, it needs to be reworded. So, "A physician, as defined in s. 448.01 (5), or a psychiatrist, as defined in s.457.01 (8e), who prescribes a psychotropic medication to a resident of a nursing home or community–based residential facility resident who has degenerative brain disorder shall notify the nursing home or community–based residential facility if the medication has been issued a black box warning by the federal food and drug administration."

5. (Page 3 top of page Note) I did not specify the type of person required to obtain informed consent from the resident. Is that okay?
Yes, that's fine.

6. (Page 3, line 18 Note) I refer to the guardianship statutes here because there are procedures specified for the guardian to follow regarding informed consent for psychotropic medications. I presume that you still want the guardian to follow those procedures.
Okay.

7. (Any instead of ALL)
On page 4, line 10 it should say if "any" of the following apply, rather than all with reference to exceptions.

[Code of Federal Regulations]
[Title 21, Volume 4]
[Revised as of April 1, 2008]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR201.57]

[Page 24-39]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 201_LABELING--Table of Contents

Subpart B_Labeling Requirements for Prescription Drugs and/or Insulin

Sec. 201.57 Specific requirements on content and format of labeling for human prescr

The requirements in this section apply only to prescription drug products described in Sec. 201.56(b)(1) and must be implemented according to the schedule specified in Sec. 201.56(c), except for the requirement in paragraph (c)(18) of this section to reprint any FDA-approved patient labeling at the end of prescription drug labeling or accompany the prescription drug labeling, which must be implemented no later than June 30, 2007.

[[Page 25]]

(a) Highlights of prescribing information. The following information must appear in all prescription drug labeling:

(1) Highlights limitation statement. The verbatim statement ``These highlights do not include all the information needed to use (insert name of drug product) safely and effectively. See full prescribing information for (insert name of drug product).''

(2) Drug names, dosage form, route of administration, and controlled substance symbol. The proprietary name and the established name of the drug, if any, as defined in section 502(e)(3) of the Federal Food, Drug, and Cosmetic Act (the act) or, for biological products, the proper name (as defined in Sec. 600.3 of this chapter) including any appropriate descriptors. This information must be followed by the drug's dosage form and route of administration. For controlled substances, the controlled substance symbol designating the schedule in which the controlled substance is listed must be included as required by Sec. 1302.04 of this chapter.

(3) Initial U.S. approval. The verbatim statement ``Initial U.S. Approval'' followed by the four-digit year in which FDA initially approved a new molecular entity, new biological product, or new combination of active ingredients. The statement must be placed on the line immediately beneath the established name or, for biological products, proper name of the product.

(4) Boxed warning. A concise summary of any boxed warning required by paragraph (c)(1) of this section, not to exceed a length of 20 lines. The summary must be preceded by a heading, in upper-case letters, containing the word ``WARNING'' and other words that are appropriate to identify the subject of the warning. The heading and the summary must be contained within a box and bolded. The following verbatim statement must be placed immediately following the heading of the boxed warning: ``See full prescribing information for complete boxed warning.''

(5) Recent major changes. A list of the section(s) of the full prescribing information, limited to the labeling sections described in

paragraphs (c)(1), (c)(2), (c)(3), (c)(5), and (c)(6) of this section, that contain(s) substantive labeling changes that have been approved by FDA or authorized under Sec. 314.70(c)(6) or (d)(2), or Sec. 601.12(f)(1) through (f)(3) of this chapter. The heading(s) and, if appropriate, the subheading(s) of the labeling section(s) affected by the change must be listed together with each section's identifying number and the date (month/year) on which the change was incorporated in labeling. These labeling sections must be listed in the order in which they appear in the full prescribing information. A changed section must be listed under this heading in Highlights for at least 1 year after the date of the labeling change and must be removed at the first printing subsequent to the 1 year period.

(6) Indications and usage. A concise statement of each of the product's indications, as required under paragraph (c)(2) of this section, with any appropriate subheadings. Major limitations of use (e.g., lack of effect in particular subsets of the population, or second line therapy status) must be briefly noted. If the product is a member of an established pharmacologic class, the concise statement under this heading in Highlights must identify the class in the following manner: ``(Drug) is a (name of class) indicated for (indication(s)).''

(7) Dosage and administration. A concise summary of the information required under paragraph (c)(3) of this section, with any appropriate subheadings, including the recommended dosage regimen, starting dose, dose range, critical differences among population subsets, monitoring recommendations, and other clinically significant clinical pharmacologic information.

(8) Dosage forms and strengths. A concise summary of the information required under paragraph (c)(4) of this section, with any appropriate subheadings (e.g., tablets, capsules, injectable, suspension), including the strength or potency of the dosage form in metric system (e.g., 10-milligram tablets) and whether the product is scored.

[[Page 26]]

(9) Contraindications. A concise statement of each of the product's contraindications, as required under paragraph (c)(5) of this section, with any appropriate subheadings.

(10) Warnings and precautions. A concise summary of the most clinically significant information required under paragraph (c)(6) of this section, with any appropriate subheadings, including information that would affect decisions about whether to prescribe a drug, recommendations for patient monitoring that are critical to safe use of the drug, and measures that can be taken to prevent or mitigate harm.

(11) Adverse reactions. (i) A list of the most frequently occurring adverse reactions, as described in paragraph (c)(7) of this section, along with the criteria used to determine inclusion (e.g., incidence rate). Adverse reactions important for other reasons (e.g., because they are serious or frequently lead to discontinuation or dosage adjustment) must not be repeated under this heading in Highlights if they are included elsewhere in Highlights (e.g., Warnings and Precautions, Contraindications).

(ii) For drug products other than vaccines, the verbatim statement ``To report SUSPECTED ADVERSE REACTIONS, contact (insert name of manufacturer) at (insert manufacturer's phone number) or FDA at (insert current FDA phone number and Web address for voluntary reporting of adverse reactions).''

(iii) For vaccines, the verbatim statement ``To report SUSPECTED ADVERSE REACTIONS, contact (insert name of manufacturer) at (insert manufacturer's phone number) or VAERS at (insert the current VAERS phone number and Web address for voluntary reporting of adverse reactions).''

(iv) For manufacturers with a Web site for voluntary reporting of

adverse reactions, the Web address of the direct link to the site.

(12) Drug interactions. A concise summary of the information required under paragraph (c)(8) of this section, with any appropriate subheadings.

(13) Use in specific populations. A concise summary of the information required under paragraph (c)(9) of this section, with any appropriate subheadings.

(14) Patient counseling information statement. The verbatim statement ``See 17 for Patient Counseling Information'' or, if the product has FDA-approved patient labeling, the verbatim statement ``See 17 for Patient Counseling Information and (insert either FDA-approved patient labeling or Medication Guide).''

(15) Revision date. The date of the most recent revision of the labeling, identified as such, placed at the end of Highlights.

(b) Full prescribing information: Contents. Contents must contain a list of each heading and subheading required in the full prescribing information under Sec. 201.56(d)(1), if not omitted under Sec. 201.56(d)(4), preceded by the identifying number required under Sec. 201.56(d)(1). Contents must also contain any additional subheading(s) included in the full prescribing information preceded by the identifying number assigned in accordance with Sec. 201.56(d)(2).

(c) Full prescribing information. The full prescribing information must contain the information in the order required under paragraphs (c)(1) through (c)(18) of this section, together with the headings, subheadings, and identifying numbers required under Sec. 201.56(d)(1), unless omitted under Sec. 201.56(d)(4). If additional subheadings are used within a labeling section, they must be preceded by the identifying number assigned in accordance with Sec. 201.56(d)(2).

(1) Boxed warning. Certain contraindications or serious warnings, particularly those that may lead to death or serious injury, may be required by the FDA to be presented in a box. The boxed warning ordinarily must be based on clinical data, but serious animal toxicity may also be the basis of a boxed warning in the absence of clinical data. The box must contain, in uppercase letters, a heading inside the box that includes the word ``WARNING'' and conveys the general focus of the information in the box. The box must briefly explain the risk and refer to more detailed information in the ``Contraindications'' or ``Warnings and Precautions'' section, accompanied by the identifying number for the section or subsection containing the detailed information.

[[Page 27]]

(2) 1 Indications and usage. This section must state that the drug is indicated for the treatment, prevention, mitigation, cure, or diagnosis of a recognized disease or condition, or of a manifestation of a recognized disease or condition, or for the relief of symptoms associated with a recognized disease or condition.

(i) This section must include the following information when the conditions listed are applicable:

(A) If the drug is used for an indication only in conjunction with a primary mode of therapy (e.g., diet, surgery, behavior changes, or some other drug), a statement that the drug is indicated as an adjunct to that mode of therapy.

(B) If evidence is available to support the safety and effectiveness of the drug or biological product only in selected subgroups of the larger population (e.g., patients with mild disease or patients in a special age group), or if the indication is approved based on a surrogate endpoint under Sec. 314.510 or Sec. 601.41 of this chapter, a succinct description of the limitations of usefulness of the drug and any uncertainty about anticipated clinical benefits, with reference to

State of Wisconsin
2009 - 2010 LEGISLATURE

LRB-1703/P1
TJD:cjs:rs

In: 4/22/09

RMNR

stays

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

Regen Cat

AN ACT *to create* 50.08 of the statutes; **relating to:** requiring informed consent before administration of psychotropic medication to a nursing home or community-based residential facility resident who has degenerative brain disorder.

Insert A

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. 50.08 of the statutes is created to read:

50.08 Informed consent for psychotropic medications. (1) In this section:

(a) "Degenerative brain disorder" has the meaning given in s. 55.01 (1v).

(b) "Incapacitated" has the meaning given in s. 50.06 (1).

(c) "Off-label use" means use of a prescription or over-the-counter medication for a purpose other than a purpose approved by the federal food and drug administration.

(c) (d) "Person acting on behalf of the resident" means a guardian of the person, as defined in s. 54.01 (12), or a health care agent, as defined in s. 155.01 (4).

****NOTE: Is it okay to include health care agents acting under a power of attorney for health care as a person who can provide informed consent? In some situations, I believe, residents would not have a guardian because they have a health care agent.

Ins 2-6

(d) (e) "Psychotropic medication" means a prescription drug, as defined in s. 450.01 (20), that is used to treat or manage a psychiatric symptom or challenging behavior.

(2) A physician, as defined in s. 448.01 (5), or a psychiatrist, as defined in s. 457.01 (8e), who prescribes a psychotropic medication to a resident of a nursing home or community-based residential facility resident who has degenerative brain disorder shall notify the nursing home or community-based residential facility if the medication prescribed for an off-label use has a boxed warning under 21 CFR 201.57

****NOTE: I added this provision because I wondered how the staff of the facility would know that the medication was prescribed for an off-label use. Is that okay?

that has a boxed warning under 21 CFR 201.57

(3) (a) Except as provided in sub. (4), before administering a psychotropic medication prescribed for an off-label use to a resident who has degenerative brain disorder, a nursing home or a community-based residential facility shall obtain written informed consent from the resident or, if the resident is incapacitated, a person acting on behalf of the resident, on a form provided by the department under par. (b) or on a form that contains the same information as the form under par. (b).

(b) The department shall make available on its Internet Web site or by mail an informed consent form for administration of psychotropic medication that contains all of the following:

multiple, drug-specific forms

Obtaining informed consent under par. (a) for the

****NOTE: I did not specify the type of person required to obtain informed consent from the resident. Is that okay?

1. A space for a description of the benefits of the proposed treatment and the way the medication will be administered.

2. A description, using the most recently issued information from the federal food and drug administration, of the side effects or risks of side effects of the medication and any warnings about the medication.

3. A space for a description of any alternative treatment modes or medications.

4. A space for a description of the probable consequences of not receiving the medication.

5. A space for indicating the time period for which the informed consent is effective, which shall be no longer than 15 months from the time the consent is given.

6. A notification of the right to withdraw informed consent, in writing, at any time. statement that the resident or a person acting on behalf of the resident may

7. A declaration that the resident or the person acting on behalf of the resident has been provided with specific, complete, and accurate information, and time to study the information or to seek additional information concerning the medication.

8. A space for the signature of the resident or the person acting on behalf of the resident.

(c) Written informed consent provided by a guardian is subject to s. 54.25.

****NOTE: I refer to the guardianship statutes here because there are procedures specified for the guardian to follow regarding informed consent for psychotropic medications. I presume that you still want the guardian to follow those procedures.

(d) Upon request, the nursing home or community-based residential facility shall give the resident, or a person acting on behalf of the resident, a copy of the completed informed consent form.

Insert 4-1

(g) (e) No person may retaliate against or threaten to retaliate against a resident or person acting on behalf of a resident for refusing to provide or withdrawing informed consent.

(h) (f) The nursing home or community-based residential facility shall use the most current informed written consent form available from the department or shall update its own form with the most current information about the medication available from the department.

(4) (a) A nursing home or community-based residential facility is not required to obtain written informed consent before administering a psychotropic medication under sub. (3) if all of the following apply:

1. The resident is incapacitated and not able to provide consent and the resident is not the subject of a court order to administer psychotropic medications under s. 55.14.

2. There is an emergency in which a resident is at significant risk of physical or emotional harm or where time and distance preclude obtaining written informed consent before administering psychotropic medication.

3. A physician, as defined in s. 448.01 (5), or a psychiatrist, as defined in s. 457.01 (8e), has determined that harm will come to the patient if treatment is not initiated before written informed consent is obtained.

(b) If par. (a) applies, the nursing home or community-based residential facility shall obtain temporary oral consent from a person acting on behalf of the resident before administering the psychotropic medication. The oral consent shall be entered in the resident's medical record. The oral consent shall be valid for 10 days, during

the resident or, if the resident is incapacitated,

after time
which the nursing home or community-based residential facility shall obtain written informed consent under sub. (3).

(END)

may not continue to administer the psychotropic medication unless it has obtained

INSERT A

Current law prescribes the situations and procedures under which a guardian may provide consent to voluntary or involuntary administration of psychotropic medications to his or her ward. This bill requires that a nursing home or community-based residential facility obtain written informed consent before administering a psychotropic medication that contains a boxed warning to any resident who has degenerative brain disorder. A psychotropic medication is defined in the bill as an antipsychotic, antidepressant, lithium carbonate, or tranquilizer. A boxed warning is a warning described in the federal regulations the text of which is contained in a black outlined box on the drug's label and in the full prescribing information.

Under the bill, the nursing home or community-based residential facility may obtain written informed consent using either a form created by the Department of Health Services or their own form that contains certain items, including: space for a description of the benefits of the proposed treatment and the way the medication will be administered; a description , using the most recently issued information from the federal food and drug administration, of the side effects or risks of side effects of the medication and any warnings about the medication; spaces for a description of alternative medications and probable consequences of not receiving the medication; and a declaration that the resident or a person acting on behalf of the resident has been provided with the information and time to study the information or seek additional information concerning the medication. Either the resident or, if the resident is incapacitated, a person acting on behalf of the resident, may provide written informed consent. A nursing home or community-based residential facility is not required to obtain written informed consent if there is an emergency in which a resident, who is not under a court order to administer psychotropic medication, is at significant risk of physician or emotional harm or time and distance preclude obtaining written informed consent and if a physician has determined that harm will come to the resident if treatment is not initiated. In that emergency situation, the nursing home or community-based residential facility must obtain temporary oral consent, enter the oral consent in the resident's medical record, and obtain written informed consent within 10 days.

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

INSERT 2-6

an antipsychotic, antidepressant, lithium carbonate, or tranquilizer.

Unless consent is withdrawn sooner, written

INSERT 4-1

informed consent

obtained

(e) An informed consent form under this subsection is valid for the time specified on the form but for not longer than 15 months from the date the resident, or a person acting on behalf of the resident, signed the form.

(END)

(9H) (f) A resident, or a person acting on behalf of the resident, may withdraw consent in writing, at any time.

7/10/09

Jen from Rep Meyer's office called.

Redraft informed consent bill to eliminate CBRFs from draft NH&CBRFs work differently.

State of Wisconsin
2009 - 2010 LEGISLATURE

LRB-1703/1
TJD:cjs:rs

In: 7/15/09

RMNR

S Fangs

2009 BILL

SA

Regan Cat

AN ACT *to create* 50.08 of the statutes; **relating to:** requiring informed consent before administration of psychotropic medication to a nursing home or community-based residential facility resident who has degenerative brain disorder.

Analysis by the Legislative Reference Bureau

Current law prescribes the situations and procedures under which a guardian may provide consent to the voluntary or involuntary administration of psychotropic medications to his or her ward. This bill requires that a nursing home or community-based residential facility obtain written informed consent before administering a psychotropic medication that contains a boxed warning to any resident who has degenerative brain disorder. A psychotropic medication is an antipsychotic, an antidepressant, lithium carbonate, or a tranquilizer. A boxed warning is a warning, described in the federal regulations, the text of which is contained in a black outlined box on the drug's label and in the full prescribing information.

Under the bill, the nursing home or community-based residential facility may obtain written informed consent using either a form created by the Department of Health Services or its own form that contains certain items, including: space for a description of the benefits of the proposed treatment and the way the medication will be administered; a description, using the most recently issued information from the federal Food and Drug Administration, of the side effects or risks of side effects of the medication and any warnings about the medication; spaces for a description of

alternative medications and probable consequences of not receiving the medication; and a declaration that the resident or a person acting on behalf of the resident has been provided with the information and time to study the information or seek additional information concerning the medication. Either the resident or, if the resident is incapacitated, a person acting on behalf of the resident, may provide written informed consent. A nursing home or community-based residential facility is not required to obtain written informed consent if there is an emergency in which a resident, who is not under a court order for administration of psychotropic medication, is at significant risk of physical or emotional harm or time and distance preclude obtaining written informed consent and if a physician has determined that the resident will be harmed if treatment is not initiated. In such an emergency situation, the nursing home or community-based residential facility must obtain oral consent, enter the oral consent in the resident's medical record, and obtain written informed consent within ten days.

For further information see the ***state and local*** 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. 50.08 of the statutes is created to read:

50.08 Informed consent for psychotropic medications. (1) In this section:

(a) "Degenerative brain disorder" has the meaning given in s. 55.01 (1v).

(b) "Incapacitated" has the meaning given in s. 50.06 (1).

(c) "Person acting on behalf of the resident" means a guardian of the person, as defined in s. 54.01 (12), or a health care agent, as defined in s. 155.01 (4).

(d) "Psychotropic medication" means an antipsychotic, an antidepressant, lithium carbonate, or a tranquilizer.

(2) A physician, as defined in s. 448.01 (5), or a psychiatrist, as defined in s. 457.01 (8e), who prescribes a psychotropic medication to a nursing home or community-based residential facility resident who has degenerative brain disorder

shall notify the nursing home or community-based residential facility if the prescribed medication has a boxed warning under 21 CFR 201.57.

(3) (a) Except as provided in sub. (4), before administering a psychotropic medication that has a boxed warning under 21 CFR 201.57 to a resident who has degenerative brain disorder, a nursing home or a community-based residential facility shall obtain written informed consent from the resident or, if the resident is incapacitated, a person acting on behalf of the resident, on a form provided by the department under par. (b) or on a form that contains the same information as the form under par. (b).

(b) The department shall make available on its Web site or by mail multiple, drug-specific forms for obtaining informed consent under par. (a) for the administration of psychotropic medication that contain all of the following:

1. A space for a description of the benefits of the proposed treatment and the way the medication will be administered.

2. A description, using the most recently issued information from the federal food and drug administration, of the side effects or risks of side effects of the medication and any warnings about the medication.

3. A space for a description of any alternative treatment modes or medications.

4. A space for a description of the probable consequences of not receiving the medication.

5. A space for indicating the time period for which the informed consent is effective, which shall be no longer than 15 months from the time the consent is given.

6. A statement that the resident or a person acting on behalf of the resident may withdraw informed consent, in writing, at any time.

7. A declaration that the resident or the person acting on behalf of the resident has been provided with specific, complete, and accurate information, and time to study the information or to seek additional information concerning the medication.

8. A space for the signature of the resident or the person acting on behalf of the resident.

(c) Written informed consent provided by a guardian is subject to s. 54.25.

(d) Upon request, the nursing home or community-based residential facility shall give the resident, or a person acting on behalf of the resident, a copy of the completed informed consent form.

(e) Unless consent is withdrawn sooner, written informed consent obtained under this subsection is valid for the time specified on the informed consent form but not for longer than 15 months from the date the resident, or a person acting on behalf of the resident, signed the form.

(f) A resident, or a person acting on behalf of the resident, may withdraw consent, in writing, at any time.

(g) No person may retaliate against or threaten to retaliate against a resident or person acting on behalf of a resident for refusing to provide or withdrawing consent.

(h) The nursing home or community-based residential facility shall use the most current written informed consent forms available from the department or shall update its own forms with the most current information about the medications available from the department.

(4) (a) A nursing home or community-based residential facility is not required to obtain written informed consent before administering a psychotropic medication under sub. (3) if all of the following apply:

1. The resident is not the subject of a court order to administer psychotropic medications under s. 55.14.

2. There is an emergency in which a resident is at significant risk of physical or emotional harm or in which time and distance preclude obtaining written informed consent before administering psychotropic medication.

3. A physician, as defined in s. 448.01 (5), or a psychiatrist, as defined in s. 457.01 (8e), has determined that the resident will be harmed if treatment is not initiated before written informed consent is obtained.

(b) If par. (a) applies, the nursing home or community-based residential facility shall obtain oral consent from the resident or, if the resident is incapacitated, a person acting on behalf of the resident, before administering the psychotropic medication. The oral consent shall be entered in the resident's medical record. The oral consent shall be valid for 10 days, after which time the nursing home or community-based residential facility may not continue to administer the psychotropic medication unless it has obtained written informed consent under sub. (3).

(END)

Dodge, Tamara

From: Western, Jennifer
Sent: Tuesday, September 01, 2009 12:50 PM
To: Dodge, Tamara
Cc: Sweet, Richard
Subject: FW: LRB 1703/2

Hello, Tami:

✓Rep. Meyer would like to ask for a revision to LRB 1703/2. He would like to ask for the change that Dick Sweet suggested below, which is to add language on page 5, line 3, that would say ", except that if the resident is incapacitated and the nursing home has made a good faith effort to obtain the consent of a person acting on behalf of the resident but has been unable to contact that person, the nursing home may administer the psychotropic medication for up to 24 hours before obtaining oral consent of that person".

✓He would also like to add the language Dick suggested on page 4, line 19-21, which is to substitute in, "significant risk of physical harm to self or others or emotional harm to self".

✓Also, on page 4, line 20: change the word "or" to "and."

✓ Last change on page 4, line 23: add "or others" after resident.

These changes are meant to address a concern that was recently brought up which is that there may be times when there is an emergency, but the nursing home can't get a hold of the guardian to obtain temporary oral consent.

Please feel free to let me know if you have any questions. Thanks for your help!

Jennifer, 266-7141
Office of Dan Meyer
State Representative
34th Assembly District

From: Sweet, Richard
Sent: Tuesday, August 25, 2009 12:54 PM
To: Western, Jennifer
Subject: RE: LRB 1703/2

Jenny,

Sorry I didn't get back to you sooner, but I was on vacation last week (probably in Dan's district--Hazelhurst).

I think their first concern is valid and, by addressing it, you might also partially be addressing their third concern. On page 5, line 3, before the period, you could add something along the following lines: ", except that if the resident is incapacitated and the nursing home has made a good faith effort to obtain the consent of a person acting on behalf of the resident but has been

unable to contact that person, the nursing home may administer the psychotropic medication for up to 24 hours before obtaining oral consent of that person".

You might also want to revise page 4, lines 19 to 21, to substitute in "significant risk of physical harm to self or others or emotional harm to self". Also, should the second "or" on line 20 be "and"? And on page 4, line 23, you want also want to add in "or others" after "the resident".

On the second point, there is a statute on court-ordered psychotropic medications. It's s. 55.14, Stats. (which is cited on page 4, line 18).

Let me know if you want to discuss this.

Dick Sweet

Senior Staff Attorney
Wisconsin Legislative Council
(608)266-2982
richard.sweet@legis.wisconsin.gov

From: Western, Jennifer
Sent: Thursday, August 20, 2009 12:51 PM
To: Sweet, Richard
Subject: LRB 1703/2

Hi Dick,

I am writing in regards to the antipsychotic legislation that Rep. Meyer is working on. I went to the Nursing Home Administrator Board Meeting that took place on August 6th at DRL. There are a few issues that were brought up, which I would like to ask you about.

1. An administrator wondered what would happen if they could not reach the family in order to get temporary oral consent. Specifically, that member was concerned that there may be an emergency situation (such as those described in 4(a)) where the patient is at a risk to themselves, other patients or staff. She suggested if there is an emergency like this, and they can't reach the family/guardian, that they have at least 24 hours to obtain the temporary oral consent. That seemed like a good idea. Do you have any easy recommended language for adding that?

2. The first question people asked is, "What if they say 'No?'" I replied by asking what happens currently when they voluntarily provide the form and someone declines to sign it. A similar question is what happens when the family/guardian of a patient with mental illness declines to sign the form? We decided it would probably invovle the courts. But I want to be prepared for this question, so if you have any info, I would appreciate it.

3. The concern that I think is behind the former question is that nursing homes have the responsibility to keep patients safe and they want to be able to deal with an emergency. Its not like they can decline to serve patients that are difficult or physically abusive. So they want to make sure they can keep everyone safe. This isn't a question, but if you have any thoughts on this (I assume it would be the same as patients with mental illness) I would appreciate them as well.

Thanks yet again.

Jennifer
Office of Dan Meyer
State Representative
34th Assembly District

State of Wisconsin
2009 - 2010 LEGISLATURE

LRB-1703/2 3
TJD:cjs:jf

In: 9/8/09

Stays RMNR

2009 BILL

AN ACT *to create* 50.08 of the statutes; **relating to:** requiring informed consent before administration of psychotropic medication to a nursing home resident who has degenerative brain disorder.

Analysis by the Legislative Reference Bureau

Current law prescribes the situations and procedures under which a guardian may provide consent to the voluntary or involuntary administration of psychotropic medications to his or her ward. This bill requires that a nursing home obtain written informed consent before administering a psychotropic medication that contains a boxed warning to any resident who has degenerative brain disorder. A psychotropic medication is an antipsychotic, an antidepressant, lithium carbonate, or a tranquilizer. A boxed warning is a warning, described in the federal regulations, the text of which is contained in a black outlined box on the drug's label and in the full prescribing information.

Under the bill, the nursing home may obtain written informed consent using either a form created by the Department of Health Services or its own form that contains certain items, including: space for a description of the benefits of the proposed treatment and the way the medication will be administered; a description, using the most recently issued information from the federal Food and Drug Administration, of the side effects or risks of side effects of the medication and any warnings about the medication; spaces for a description of alternative medications and probable consequences of not receiving the medication; and a declaration that the resident or a person acting on behalf of the resident has been provided with the

(d) Upon request, the nursing home shall give the resident, or a person acting on behalf of the resident, a copy of the completed informed consent form.

(e) Unless consent is withdrawn sooner, written informed consent obtained under this subsection is valid for the time specified on the informed consent form but not for longer than 15 months from the date the resident, or a person acting on behalf of the resident, signed the form.

(f) A resident, or a person acting on behalf of the resident, may withdraw consent, in writing, at any time.

(g) No person may retaliate against or threaten to retaliate against a resident or person acting on behalf of a resident for refusing to provide or withdrawing consent.

(h) The nursing home shall use the most current written informed consent forms available from the department or shall update its own forms with the most current information about the medications available from the department.

(4) (a) A nursing home is not required to obtain written informed consent before administering a psychotropic medication under sub. (3) if all of the following apply:

1. The resident is not the subject of a court order to administer psychotropic medications under s. 55.14.

2. There is an emergency in which a resident is at significant risk of physical or emotional harm or in which time and distance preclude obtaining written informed consent before administering psychotropic medication.

3. A physician, as defined in s. 448.01 (5), or a psychiatrist, as defined in s. 457.01 (8e), has determined that the resident will be harmed if treatment is not initiated before written informed consent is obtained.

or puts others at significant risk of physical harm

information and time to study the information or seek additional information concerning the medication. Either the resident or, if the resident is incapacitated, a person acting on behalf of the resident, may provide written informed consent. A nursing home is not required to obtain written informed consent if there is an emergency in which a resident, who is not under a court order for administration of psychotropic medication, is at significant risk of physical or emotional harm or time and distance preclude obtaining written informed consent, and if a physician has determined that the resident will be harmed if treatment is not initiated. In such an emergency situation, the nursing home must obtain oral consent, enter the oral consent in the resident's medical record, and obtain written informed consent within ten days. ← Insert A

if

or others

For further information see the ***state and local*** 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. 50.08 of the statutes is created to read:

50.08 Informed consent for psychotropic medications. (1) In this section:

(a) "Degenerative brain disorder" has the meaning given in s. 55.01 (1v).

(b) "Incapacitated" has the meaning given in s. 50.06 (1).

(c) "Person acting on behalf of the resident" means a guardian of the person, as defined in s. 54.01 (12), or a health care agent, as defined in s. 155.01 (4).

(d) "Psychotropic medication" means an antipsychotic, an antidepressant, lithium carbonate, or a tranquilizer.

(2) A physician, as defined in s. 448.01 (5), or a psychiatrist, as defined in s. 457.01 (8e), who prescribes a psychotropic medication to a nursing home resident who has degenerative brain disorder shall notify the nursing home if the prescribed medication has a boxed warning under 21 CFR 201.57.

(3) (a) Except as provided in sub. (4), before administering a psychotropic medication that has a boxed warning under 21 CFR 201.57 to a resident who has

degenerative brain disorder, a nursing home shall obtain written informed consent from the resident or, if the resident is incapacitated, a person acting on behalf of the resident, on a form provided by the department under par. (b) or on a form that contains the same information as the form under par. (b).

(b) The department shall make available on its Web site or by mail multiple, drug-specific forms for obtaining informed consent under par. (a) for the administration of psychotropic medication that contain all of the following:

1. A space for a description of the benefits of the proposed treatment and the way the medication will be administered.

2. A description, using the most recently issued information from the federal food and drug administration, of the side effects or risks of side effects of the medication and any warnings about the medication.

3. A space for a description of any alternative treatment modes or medications.

4. A space for a description of the probable consequences of not receiving the medication.

5. A space for indicating the time period for which the informed consent is effective, which shall be no longer than 15 months from the time the consent is given.

6. A statement that the resident or a person acting on behalf of the resident may withdraw informed consent, in writing, at any time.

7. A declaration that the resident or the person acting on behalf of the resident has been provided with specific, complete, and accurate information, and time to study the information or to seek additional information concerning the medication.

8. A space for the signature of the resident or the person acting on behalf of the resident.

(c) Written informed consent provided by a guardian is subject to s. 54.25.

except as provided in par. (c)

(b) If par. (a) applies, the nursing home shall obtain oral consent from the resident or, if the resident is incapacitated, a person acting on behalf of the resident, before administering the psychotropic medication. The oral consent shall be entered in the resident's medical record. The oral consent shall be valid for 10 days, after which time the nursing home may not continue to administer the psychotropic medication unless it has obtained written informed consent under sub. (3).

(END)

Insert 5-7

INSERT A

If the nursing home is unable to contact a person acting on behalf of the resident to obtain oral consent but has made a good faith effort to contact the person, the nursing home may administer the psychotropic medication to the resident for up to 24 hours before it must obtain oral consent from the resident or a person acting on behalf of the resident.

INSERT 5-7

(c) If the resident is incapacitated, and the nursing home has made a good faith effort to obtain the consent, under par. (b), of a person acting on behalf of the resident but has been unable to contact that person, the nursing home may administer a psychotropic medication to the resident for up to 24 hours before obtaining consent from the resident or a person acting on behalf of the resident.

(END)

Barman, Mike

From: Western, Jennifer

Sent: Wednesday, October 14, 2009 11:23 AM

To: LRB.Legal

Subject: Draft Review: LRB 09-1703/3 Topic: Informed consent for psychotropic medications in nursing homes and CBRFs

Please Jacket LRB 09-1703/3 for the ASSEMBLY.