



2009 ASSEMBLY BILL 526

October 27, 2009 - Introduced by Representatives MEYER, TOWNSEND, PASCH, GUNDERSON, A. OTT, NERISON and WOOD, cosponsored by Senator HOLPERIN. Referred to Committee on Aging and Long-Term Care.

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

Analysis by the Legislative Reference Bureau

Current law prescribes the situations and procedures under which a guardian may 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

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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 puts others at significant risk of physical harm; if time and distance preclude obtaining written informed consent; and if a physician has determined that the resident or others 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. If the nursing home is unable to contact a person acting on behalf of an incapacitated resident to obtain oral consent but has made a good faith effort to contact such a 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.

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:

1 **SECTION 1.** 50.08 of the statutes is created to read:

2 **50.08 Informed consent for psychotropic medications.** (1) In this
3 section:

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

5 (b) “Incapacitated” has the meaning given in s. 50.06 (1).

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

8 (d) “Psychotropic medication” means an antipsychotic, an antidepressant,
9 lithium carbonate, or a tranquilizer.

10 (2) A physician who prescribes a psychotropic medication to a nursing home
11 resident who has degenerative brain disorder shall notify the nursing home if the
12 prescribed medication has a boxed warning under 21 CFR 201.57.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23 2. There is an emergency in which a resident is at significant risk of physical
24 or emotional harm or the resident puts others at significant risk of physical harm and

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1 in which time and distance preclude obtaining written informed consent before
2 administering psychotropic medication.

3 3. A physician has determined that the resident or others will be harmed if the
4 psychotropic medication is not administered before written informed consent is
5 obtained.

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

13 (c) If par. (a) applies, the resident is incapacitated, and the nursing home has
14 made a good faith effort to obtain oral consent, under par. (b), of a person acting on
15 behalf of the resident but has been unable to contact such a person, the nursing home
16 may administer the psychotropic medication to the resident for up to 24 hours before
17 obtaining consent under par. (a) or sub. (3).

18

(END)