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DQA Memo 10-037

**To:** Nursing Homes

NH 17

**From:** Paul Peshek  
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**Via:** Otis Woods, Administrator  
Division of Quality Assurance

**Informed Consent for Psychotropic Medications**

The purpose of this memo is to inform nursing homes regulated by the Division of Quality Assurance (DQA) about the new requirements for informed consents for psychotropic medications. Included in this memo is a link to a DQA website with other information including answers to questions that may arise regarding the statutory changes.

**Background**

On May 11, 2010 Governor Doyle signed 2009 [Act 281](#). This act created WI Stats. 50.08 requiring informed consent before administration of a psychotropic medication to a nursing home resident who has degenerative brain disorder. This act will take effect on December 1, 2010 and is intended to expand/clarify informed consent requirements for residents in nursing homes with degenerative brain disorder.

**Main Provisions**

- 1) An individual who prescribes a psychotropic medication with a label containing a boxed warning must inform the nursing home of the warning. (A “boxed warning”, also known as a “black box warning”, or a “black label warning” is named for the black border surrounding the text of the warning that appears on the package insert, label, and other literature describing the medication (e.g., magazine advertising). It is the most serious medication warning required by the Food and Drug Administration (FDA).
- 2) Before administering a psychotropic medication with a boxed label warning to a resident with a degenerative brain disorder, the facility must obtain written informed consent.  
**Exceptions:** 2009 Act 281, at ss. 50.08 (3m) and (4a)-(4c), Wis. Stats., provides the following exceptions to the obtaining of written informed consent:
  - a) A nursing home is not required to obtain written informed consent before administering a psychotropic medication to a resident with a degenerative brain

disorder if the prescription for the psychotropic medication is written or reauthorized while the resident is off of the nursing home's premises.

b) A nursing home is not required to obtain written informed consent before administering a psychotropic medication to a resident with a degenerative brain disorder if all of the following apply:

- i) The resident is not the subject of a court order to administer psychotropic medications under s. 55.14, Wis. Stats.
- ii) There is an emergency in which a resident is at significant risk of physical or emotional harm or the resident puts others at significant risk of physical harm and in which time and distance preclude obtaining written informed consent before administering psychotropic medication.
- iii) A physician has determined that the resident or others will be harmed if the psychotropic medication is not administered before written informed consent is obtained.

c) If par. b) above 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, except as provided in par. d) below. 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.

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

- 3) The statute allows for emergencies where oral consent can be used prior to obtaining written consent, as outlined in 2) above.
- 4) The Department is to make forms available for facilities to use to obtain written consent required under this law.

The Division of Quality Assurance has created a website that contains links to the following: informed consent forms, instructions for the forms, statutory language, and question and answers (Q&A). The Q&A document will be updated periodically to reflect questions received and answers provided. The web site can be accessed at [http://www.dhs.wisconsin.gov/rl\\_dsl/NHs/NHprovs.htm](http://www.dhs.wisconsin.gov/rl_dsl/NHs/NHprovs.htm)

If you have further questions or comments please contact Doug Englebert, Pharmacy Practice Consultant at (608) 266-5388 or [douglas.Englebert@wisconsin.gov](mailto:douglas.Englebert@wisconsin.gov).