MODEL LEGISLATION: STANDARDIZED PROTOCOL FOR OBTAINING INFORMED CONSENT WHEN PRESCRIBING AN ANTIPSYCHOTIC MEDICATION

NOTE: The Long Term Care Community Coalition (LTCCC) has drafted the following model legislation to facilitate federal and state policy makers in the development of informed consent protections for the use of antipsychotic drugs. We believe that this language will also be useful to stakeholders in implementing good practices under current laws and regulations. It is based on the federal bill, the *Improving Dementia Care Treatment in Older Adults Act*, which was introduced by Senators Kohl (D-WI), Grassley (R-IA), and Blumenthal (D-CT) in the fall of 2012. That bill did not pass in the 112th Congress.

This model bill includes important language relating to form of consent, duration of consent and other issues that LTCCC deemed crucial following our study of states' informed consent laws and known, widespread issues with nursing home residents and their representatives being afforded the longstanding residents' rights to: be fully informed in advance about planned care or treatment, participate in planning for their care and treatment and refuse treatment (regardless of whether doing so may be detrimental). These problems were most recently (2012) documented by the Office of the Inspector General which found that, in a review of 375 randomly selected nursing facility records, 91 percent did not contain evidence that the resident, the resident's family or the resident's legal representative participated in the care planning process. Every resident in this study was administered an antipsychotic drug.

For more information on these issues, including LTCCC's 2013 national report on states' informed consent laws, the Inspector General's analysis and other resources on antipsychotic drug use, visit our dedicated website page, "Antipsychotic Drugs & Dementia Care: Resources and Information," at www.nursinghome411.org.

LTCCC is a non-profit organization dedicated to protecting the rights and welfare of long term care consumers in all settings, including nursing homes, assisted living facilities and the community, through policy research, systemic advocacy and public education. For more information on this and other long term care issues, visit our homepage: www.ltccc.org.

MODEL LEGISLATION: STANDARDIZED PROTOCOL FOR OBTAINING INFORMED CONSENT WHEN PRESCRIBING AN ANTIPSYCHOTIC MEDICATION

(a) Standardized Protocol-

(1) SKILLED NURSING FACILITIES- Section 1819(b) of the Social Security Act (42 U.S.C. 1395i-3(b)), as amended by section 4, is amended by adding at the end the following new paragraph: '(10) STANDARDIZED PROTOCOL FOR OBTAINING INFORMED CONSENT FROM AN OLDER ADULT WITH DEMENTIA PRIOR TO PRESCRIBING AN ANTIPSYCHOTIC FOR A USE NOT APPROVED BY THE FOOD AND DRUG ADMINISTRATION-

(A) PROTOCOL- The Secretary shall develop a standardized protocol for skilled nursing facilities to obtain informed consent from an older adult with dementia (or, if applicable, the older adult's designated health care agent or other surrogate under State law or regulation) prior to prescribing an antipsychotic to the older adult for a use not approved by the Food and Drug Administration. **The protocol shall require, at a minimum, a discussion between (i) the resident or the resident's authorized representative and (ii) the resident's physician, a registered pharmacist (who is not a dispensing pharmacist for the facility where the resident lives), or a licensed nurse on the possible risks and benefits of a recommended medication and the use of standardized consent forms designated by the Department.**

(B) Accessibility- The department shall make available on its Website and by mail a drug-specific form for obtaining informed consent under par. (a) for the administration of psychotropic medication. This form (i) shall be written in plain language, (ii) shall be able to be downloaded from the Department's official website, (iii) shall include information specific to the psychotropic medication for which consent is being sought, and (iv) shall be used for every resident for whom psychotropic drugs are prescribed and 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 period for which the informed consent is effective, which shall be no longer than six (6) 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, including outside advice, concerning the medication.**
8. **A space for the signature of the resident or the person acting on behalf of the resident.**

(C) REQUIREMENTS- The standardized protocol developed under subparagraph (A) shall include the following:

(i) A requirement, with respect to an older adult with dementia, that--

'(I) the facility, with the **direct** involvement of the prescriber, inform the older adult (or, if applicable, the older adult's designated health care agent or other surrogate under State law or regulation) of--

(aa) possible side effects and risks associated with the antipsychotic, including the mention of any 'black box warning';

(bb) treatment modalities that were attempted prior to the use of the antipsychotic;

(cc)an explanation of the patient's diagnosis and prognosis, or their predominant symptoms, with and without the medication;

(dd) information about the proposed medication, its purpose, the method of its administration, the recommended ranges of dosages, possible side effects and benefits, ways to treat side effects, and risks of other conditions, such as tardive dyskinesia;

(ee) a review of the patient's history, including medication history and previous side effects from medication;

(ff) an explanation of interactions with other drugs, including over-the-counter drugs, street drugs, and alcohol;

(gg) information about alternative treatments and their risks, side effects, and benefits, including the risks of nontreatment;

(hh) a statement describing the patient's right to give or withhold consent to the administration of psychotropic medications in nonemergency situations, the procedure for withdrawing consent, and notification that a court may override the patient's refusal and

(ii) any other information the Secretary determines appropriate;

(II) the older adult (or, if applicable, the older adult's designated health care agent or other surrogate under State law or regulation) **has been given all information that is material to the decision to give or withhold consent**

(III) the older adult (or, if applicable, the older adult's designated health care agent or other surrogate under State law or regulation) provide consent to the administration of the antipsychotic;

- **(i) Consent in writing meets the requirements of this section if it:**
  1. **On the form informed consent form for the use of antipsychotic drugs published by the Secretary.**
  2. **Acknowledges that the disclosure of that information has been made and that all questions asked about the procedure or procedures have been answered in a satisfactory manner.**
  3. **Is signed by the patient for whom the procedure is to be performed, or if the patient for any reason lacks legal capacity to consent, is signed by a person who**

has legal authority to consent on behalf of that patient in those circumstances.

and ‘

(IV) the administration of the antipsychotic is in accordance with any plan of care that the older adult has in place, including non-pharmacological interventions as appropriate that can effectively address underlying medical and environmental causes of behavioral disorders.

(ii) An alternative protocol for obtaining such informed consent--

(I) in the case of emergencies; and ‘(II) in the absence of a clearly identified designated health care agent or other surrogate under State law or regulation.

(iii) Other items determined appropriate by the Secretary.

(iv) (iv) **There shall be no violation for initiating treatment without informed consent if there is documentation within the patient's health record that an emergency exists where there is an unanticipated condition in which immediate action is necessary for preservation of life or the prevention of serious bodily harm to the patient or others or to alleviate severe physical pain, and it is impracticable to obtain the required consent, and provided that the action taken is within the customary practice of licensed healthcare practitioners of good standing acting within the scope of their professional licensure in similar circumstances**

(D) TIMING OF INFORMED CONSENT- Under the standardized protocol, a skilled nursing facility shall obtain informed consent--

(i) prior to the initial prescribing of antipsychotics; or ‘(ii) in the case of an individual already prescribed antipsychotics when admitted to a facility, the facility shall obtain informed consent if the facility maintains antipsychotic treatment after the first drug regimen review conducted with respect to the individual.

(E) RESPONSIBILITY OF INFORMED CONSENT- The disclosure of the material information and obtaining informed consent shall be the responsibility of the licensed healthcare practitioner who, acting within the scope of his or her professional licensure, performs or orders the procedure or treatment for which informed consent is required

(F) REFUSAL OF CONSENT- If a person has capacity, they have the right to refuse consent for health care, treatment or procedures. A refusal is valid if the person making it has been informed of the need, nature and significant risks the care offered in order to insure that refusal is being made after being reasonably informed. Any consent given for treatment may be revoked orally or in writing before or during the treatment period by the patient or by a person who is legally authorized to make health care decisions on behalf of the patient

(i) A facility cannot use the refusal of treatment as a basis for discharging a resident.

(G) COMPLIANCE- Effective beginning on the date that is 18 months after the date of enactment of the Improving Dementia Care Treatment for Older Adults Act of 2012, a skilled nursing facility shall comply with the standardized protocol developed under subparagraph (A).

(H) NO PREEMPTION- Nothing in this paragraph shall preempt any provision of State or Federal law that provides broader rights with respect to informed consent for residents of facilities.’.