**Section 390.1316 Unnecessary, Psychotropic, and Antipsychotic Drugs**

a) For the purposes of this Section the following definitions shall apply:

1) "Adverse consequence" – unwanted, uncomfortable, or dangerous effects that a medication may have, such as impairment or decline in an individual’s mental or physical condition or functional or psychosocial status. It may include, but is not limited to, various types of adverse medication reactions and interactions (e.g., medication-medication, medication-food, and medication-disease).

2) "Antipsychotic medication" – a medication that is used to treat symptoms of psychosis such as delusions, hearing voices, hallucinations, paranoia, or confused thoughts. Antipsychotic medications are used in the treatment of schizophrenia, severe depression, and severe anxiety. Older antipsychotic medications tend to be called typical antipsychotics. Those developed more recently are called atypical antipsychotics.

3) "Dose" – the total amount/strength/concentration of a medication given at one time or over a period of time. The individual dose is the amount/strength/concentration received at each administration. The amount received over a 24-hour period may be referred to as the daily dose.

4) "Duplicative therapy" – multiple medications of the same pharmacological class or category or any medication therapy that substantially duplicates a particular effect of another medication that the individual is taking.

5) "Emergency" – has the same meaning as in Section 1-112 of the Act and Section 390.330. (Section 2-106.1(b) of the Act)

6) "Excessive dose" – the total amount of any medication (including duplicative therapy) given at one time or over a period of time that is greater than the amount recommended by the manufacturer's label, package or insert, and the accepted standards of practice for a resident's age and condition.

7) "Gradual dose reduction" – the stepwise tapering of a dose to determine if symptoms, conditions, or risks can be managed by a lower dose or if the dose or medication can be discontinued.

8) "Informed consent" – documented, written permission for specific medications, given freely, without coercion or deceit, by a capable resident, or by a resident's authorized representative, after the resident, or the resident's authorized representative, has been fully informed of, and had an opportunity to consider, the nature of the medications, the likely benefits and most common risks to the resident of receiving the medications, any other likely and most common consequences of receiving or not receiving the medications, and possible alternatives to the proposed medications.

9) "Licensed nurse" – an advanced practice registered nurse or a registered professional nurse, as defined in the Nurse Practice Act.

10) "*Psychotropic medication"* – *medication that is used for or listed as used for psychotropic, antidepressant, antimanic or antianxiety behavior modification or behavior management purposes in the* Prescribers Digital Reference database, the Lexicomp-online database, or the American Society of Health-System Pharmacists database. Psychotropic medication also includes any medication listed in 42 CFR 483.45(c)(3). (Section 2-106.1(b) of the Act)

b) *A resident shall not be given unnecessary* medications. An *unnecessary* medication *is any* medication *used:*

1) *In an excessive dose, including in duplicative therapy;*

2) *For excessive duration;*

3) *Without adequate monitoring;*

4) *Without adequate indications for its use;*

5) *In the presence of adverse consequences that indicate the medications should be reduced or discontinued* (Section 2-106.1(a) of the Act); or

6) Any combination of the circumstances listed in subsections (b)(1) through (5).

c) Residents shall not be given antipsychotic drugs unless antipsychotic medication therapy is ordered by a physician or an authorized prescribing professional, as documented in the resident's comprehensive assessment, to treat a specific symptom or suspected condition as diagnosed and documented in the clinical record or to rule out the possibility of one of the conditions in accordance with Appendix C.

d) Residents who use antipsychotic medications shall receive gradual dose reductions and behavior interventions, unless clinically contraindicated, in an effort to discontinue these drugs in accordance with Appendix C. In compliance with subsection 2-106.1(b) of the Act and this Section, the facility shall obtain informed consent for each dose reduction.

e) *Psychotropic medication shall not be administered without the informed consent of the resident, the resident's guardian, or other authorized representative.* (Section 2-106.1(b) of the Act) Additional informed consent is not required for reductions in dosage level or deletion of a specific medication, pursuant to subsection (f). Informed consent is required for a medication administration program of sequentially increased doses or combination of medications to establish the lowest effective dose that will achieve the desired therapeutic outcome, pursuant to subsection (f). The most common side effects of medications shall be described.

f) Protocol for Securing Informed Consent for Psychotropic Medication

1) Pursuant to Section 2-106.1(b) of the Act, no resident shall be administered psychotropic medication prior to *a discussion between the resident or the resident's authorized representative,* or both, *and the resident's physician* or a physician the resident was referred to, *a registered pharmacist who is not a dispensing pharmacist for the facility where the resident lives, or a licensed nurse about the most common possible risks and benefits of a recommended medication, and the use of standardized consent forms designated by the Department.* (Section 2-106.1(b) of the Act)

2) Prior to initiating any detailed discussion designed to secure informed consent, a licensed health care professional shall inform the resident or the resident's authorized representative that:

A) The resident's physician has prescribed a psychotropic medication for the resident, and that informed consent is required from the resident or the resident's authorized representative before the resident may be given the medication;

B) The resident's informed consent may be withdrawn at any time; and

C) The resident may refuse to take the medication, even if informed consent was previously given.

3) The discussion shall include information about:

A) The name of the medication;

B) The condition or symptoms that the medication is intended to treat, and how the medication is expected to treat those symptoms;

C) How the medication is intended to affect those symptoms;

D) Other common effects or side effects of the medication, and any reasons (e.g., age, health status, other medications) that the resident is more or less likely to experience side effects;

E) Dosage information, including how much medication would be administered, how often, and the method of administration (e.g., orally or by injection; with, before, or after food);

F) Any tests and related procedures that are required for the safe and effective administration of the medication;

G) Any food or activities the resident should avoid while taking the medication;

H) Any possible alternatives to taking the medication that could accomplish the same purpose; and

I) Any possible consequences to the resident of not taking the medication.

4) Pursuant to Section 2-105 of the Act, the discussion designed to secure informed consent shall be private, between the resident or the resident's authorized representative, or both, and the resident's physician, or a physician the resident was referred to, or a registered pharmacist who is not a dispensing pharmacist for the facility where the resident lives, or an advanced practice or registered professional nurse.

5) In addition to the oral discussion, the resident or the resident's authorized representative shall be given the information in subsection (f)(3) in writing. The information shall be in plain language, understandable to the resident or the resident's authorized representative. If the written information is in a language not understood by the resident or the resident's authorized representative, the facility shall provide an interpreter capable of communicating with the resident or the resident's authorized representative and the authorized prescribing professional conducting the discussion. The authorized prescribing professional shall guide the resident through the written information. The written information shall include a place for the resident or the resident's authorized representative to give, or to refuse to give, informed consent. The written information shall be placed in the resident's record. Informed consent is not secured until the resident or the resident's representative has given written informed consent.

6) Regardless of the availability of the resident's authorized representative, the resident shall be notified and present at any discussion required by this Section. The resident shall be given, at a minimum, written information about the medication and an oral explanation of common side effects of the medication to facilitate the resident in identifying the medication and in communicating the existence of side effects to the direct care staff.

7) The maximum possible time period for informed consent shall be one year.

8) A resident or the resident's authorized representative shall not be asked to consent to the administration of a new psychotropic medication in a dosage or frequency that exceeds the maximum recommended daily dosage as found in the Prescribers Digital Reference database, the Lexicomp-online database, or the American Society of Health-System Pharmacists database unless the reason for exceeding the recommended daily dosage is explained to the resident or the resident's authorized representative by the resident's physician, or a physician the resident was referred to, or a registered pharmacist who is not a dispensing pharmacist for the facility where the resident lives, or an advanced practice or registered professional nurse, and the reason for exceeding the recommended daily dosage is justified by the prescribing prescriber in the clinical record. The dosage and frequency shall be reviewed and re-justified by the licensed prescriber on a weekly basis and reviewed by a consulting pharmacist. The justification for exceeding the recommended daily dosage shall be recorded in the resident's record and shall be approved within seven calendar days after obtaining informed consent, in writing, by the medical director of the facility.

9) The facility shall obtain informed consent using forms provided by the Department on its official website, or on forms approved by the Department, pursuant to subsection 2-106.1(b) of the Act. The facility shall document on the consent form whether the resident is capable of giving informed consent for medication therapy, including for receiving psychotropic medications. If the resident is not capable of giving informed consent, the identity of the resident's authorized representative shall be placed in the resident's record.

g) *In addition to any other requirement prescribed by* the Act or this Part, *a facility that is found to have violated this* Section *or the federal certification requirement that informed consent be obtained before administering a psychotropic medication shall for* three *years after the notice of violation be required to*:

1) *Obtain the signatures of* two *licensed health care professionals on every form purporting to give informed consent for the administration of a psychotropic medication, certifying the personal knowledge of each health care professional that the consent was obtained in compliance with the requirements of this subsection, or*

2) *Videotape or make a digital video record of the procedures followed by the facility to comply with the requirements of this subsection*. (Section 2-106.1(b) of the Act)

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