**Section 300.686 Unnecessary, Psychotropic, and Antipsychotic Medications**

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 300.330 of this Part. (Section 2-106.1(b-3) 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 surrogate decision maker, after the resident, or the resident's surrogate decision maker, 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, a registered nurse, or a licensed practical nurse*, as defined in the Nurse Practice Act. (Section 2-106.1(d) of the 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-3) of the Act)

11) *"Surrogate decision maker" – an individual representing the resident's interests* in regard to consent to receive psychotropic medications, *as permitted by* Section 2-106.1(b-3) of the Actand this Section. (Section 2-106.1(b-3) of the Act)

b) *State laws, regulations, and policies related to psychotropic medication are intended to ensure psychotropic medications are used only when the medication is appropriate to treat a resident's specific, diagnosed, and documented condition and the medication is beneficial to the resident, as demonstrated by monitoring and documentation of the resident's response to the medication.* (Section 2-106.1(b) of the Act)

c) *Psychotropic medication shall only be given in both emergency and nonemergency situations if the diagnosis of the resident supports the benefit of the medication and clinical documentation in the resident's medical record supports the benefit of the medication over the contraindications related to other prescribed medications.* (Section 2-106.1(b-3) of the Act)

d) *A resident shall not be given unnecessary drugs*. An *unnecessary drug is any drug 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 stated in subsections (d)(1) through (5).

e) Residents shall not be given antipsychotic medications 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 F.

f) Residents who use antipsychotic medications shall receive gradual dose reductions and behavior interventions, unless clinically contraindicated, in an effort to discontinue these medications in accordance with Appendix F. In compliance with subsection 2-106.1(b-3) of the Act and this Section, the facility shall obtain informed consent for each dose reduction.

g) *Except in the case of an emergency, psychotropic medication shall not be administered* *without the informed consent of the resident or the resident's surrogate decision maker.* (Section 2-106.1(b-3) of the Act) Additional informed consent is not required for changes in the prescription so long as those changes are described in the original written informed consent form, as required by subsection (h)(12)(A). The informed consent may provide for a medication administration program of sequentially increased doses or a combination of medications to establish the lowest effective dose that will achieve the desired therapeutic outcome, pursuant to subsection (h)(12)(A). The most common side effects of the medications shall be described. In an emergency, a facility shall:

1) *Document the alleged emergency in detail, including the facts surrounding the medication's need,* pursuant to the requirements of Section 300.1820; *and*

2) *Present this documentation to the resident and the resident's representative* or other surrogate decision maker no later than 24 hours after the administration of emergency psychotropic medication. (Section 2-106.1(b-3) of the Act)

h) Protocol for Securing Informed Consent for Psychotropic Medication

1) Except in the case of an emergency as described in subsection (g), *a facility* shall *obtain voluntary informed consent, in writing, from a resident or the resident's surrogate decision maker before administering or dispensing a psychotropic medication to that resident*. *When informed consent is not required for a change in dosage* as described in subsection (h)(12)(A)*, the facility shall note in the resident's file that the resident was informed of the dosage change prior to the administration of the medication or that verbal, written, or electronic notice has been communicated to the resident's surrogate decision maker that a change in dosage has occurred*. (Section 2-106.1(b-3) of the Act)

2) No resident shall be administered psychotropic medication prior to *a discussion between the resident or the resident's surrogate decision maker*, or both, *and the resident's physician* or a physician the resident was referred to, *a registered pharmacist, 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-3) of the Act)

3) Prior to initiating any detailed discussion designed to secure informed consent, a licensed health care professional shall inform the resident or the resident's surrogate decision maker that 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 surrogate decision maker before the resident may be given the medication.

4) 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.

5) 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 surrogate decision maker and the resident's physician, or a physician the resident was referred to, or a registered pharmacist, or a licensed nurse.

6) In addition to the oral discussion, the resident or his or her surrogate decision maker shall be given the information in subsection (h)(4) in writing, in a *form designated or developed by the Department. Each form shall* *be written in plain language* understandable to the resident or the resident's surrogate decision maker, *be able to be downloaded from the Department's official website or another website designated by the Department*, *shall* *include information specific to the psychotropic medication for which consent is being sought, and* will *be used for every resident for whom psychotropic drugs are prescribed*. (Section 2-106.1(b-3) of the Act)

7) If the written information is in a language not understood by the resident or his or her surrogate decision maker, the facility, in compliance with the Language Assistance Services Act and the Language Assistance Services Code, shall provide, at no cost to the resident or the resident's surrogate decision maker, an interpreter capable of communicating with the resident or his or her surrogate decision maker and the authorized prescribing professional conducting the discussion.

8) The authorized prescribing professional shall guide the resident through the written information. The written information shall include a place for the resident or his or her surrogate decision maker 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 surrogate decision maker has given written informed consent. If the resident has dementia and the facility is unable to contact the resident's surrogate decision maker, the facility shall not administer psychotropic medication to the resident except in an emergency as provided by subsection (g).

9) *Informed consent shall be sought* first from a resident, then froma surrogate decision maker, in the following order or priority:

A) *The resident's guardian of the person if one has been named by a court of competent jurisdiction.*

B) *In the absence of a court-ordered guardian, informed consent shall be sought from a health care agent under the Illinois Power of Attorney Act* *who has authority to give consent*.

C) *If neither a court-ordered guardian of the person, nor a health care agent under the Power of Attorney Act, is available, and the attending physician determines that the resident lacks capacity to make decisions, informed consent shall be sought from the resident's attorney-in-fact designated under the Mental Health Treatment Preference Declaration Act, if applicable, or the resident's representative*. (Section 2-106.1(b-3) of the Act)

10) Regardless of the availability of a surrogate decision maker, the resident may be notified and present at any discussion required by this Section. Upon request, the resident or the resident's surrogate decision maker 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.

11) The facility shall inform *the resident, surrogate decision maker, or both of the existence of a copy of:*

A) *The resident's care plan;*

B) *The facility policies and procedures adopted in compliance with Section 2-106.1(b-15) of the Act*, and this Section; *and*

C) *A notification that the most recent of the resident's care plans and the facility's policies are available to the resident or surrogate decision maker upon request*.

12) *The maximum possible period for informed consent shall be until*:

A) *A change in the prescription occurs, either as to type of psychotropic medication or an increase or decrease in dosage, dosage range, or titration schedule of the prescribed medication that was not included in the original informed consent; or*

B) *A resident's care plan changes* in a way that affects the prescription or dosage of the psychotropic medication. (Section 2-106.1(b-3) of the Act).

13) A resident or their surrogate decision maker 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 their surrogate decision maker by a licensed medical professional, and the reason for exceeding the recommended daily dosage is justified by the prescribing professional 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.

14) Pursuant to Section 2-104(c) of the Act, the resident or the resident's surrogate decision maker shall be informed, at the time of the discussion required by subsection (h)(2), that their informed consent may be withdrawn at any time, and that, even with informed consent, the resident may refuse to take the medication.

15) 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 Section 2-106.1(b-3) 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 surrogate decision maker shall be placed in the resident's record.

16) *No facility shall deny continued residency to a person on the basis of the person's or resident's, or the person's or resident's surrogate decision maker's, refusal of the administration of psychotropic medication, unless the facility can demonstrate that the resident's refusal would place the health and safety of the resident, the facility staff, other residents, or visitors at risk*. *A facility that alleges that the resident's refusal to consent to the administration of psychotropic medication will place the health and safety of the resident, the facility staff, other residents, or visitors at risk shall*:

A) *Document the alleged risk in detail*, along with *a description of all nonpharmacological or alternative care options attempted and why they were unsuccessful*;

B) *Present this documentation to the resident or the resident's surrogate decision maker, to the Department, and to the Office of the State Long Term Care Ombudsman; and*

C) *Inform the resident or* their *surrogate decision maker of* their *right to appeal* an involuntary transfer or discharge *to the Department* as provided in the Act and this Part*.* (Section 2-106.1(b-10) of the Act)

i) All *facilities shall implement written policies and procedures for compliance with Section 2-106.1 of the Act* and thisSection*. A facility's failure to* make available to the Department *the documentation required under this subsection is sufficient to demonstrate its intent to not comply with Section 2-106.1 of the Act* andthis Section *and shall be grounds for review by the Department*. (Section 2-106.1(b-15) of the Act)

j) *Upon the receipt of a report of any violation of Section 2-106.1 of the Act* and this Section, *the Department will investigate and, upon finding sufficient evidence of a violation of Section 2-106.1 of the Act* and this Section, *may proceed with disciplinary action against the licensee of the facility. In any administrative disciplinary action under this subsection, the Department will have the discretion to determine the gravity of the violation and, taking into account mitigating and aggravating circumstances and facts, may adjust the disciplinary action accordingly*. (Section 2-106.1(b-20) of the Act)

k) *A violation of informed consent that, for an individual resident, lasts for seven days or more under this Section is, at a minimum, a Type "B" violation. A second violation of informed consent within a year from a previous violation in the same facility regardless of the duration of the second violation is, at a minimum, a Type "B" violation*. (Section 2-106.1(b-25) of the Act)

l) *Any violation of Section 2-106.1 of the Act* and this Section *by a facility may be enforced by an action brought by the Department in the name of the People of Illinois for injunctive relief, civil penalties, or both injunctive relief and civil penalties. The Department may initiate the action upon its own complaint or the complaint of any other interested party*. (Section 2-106.1(b-30) of the Act)

m) *Any resident who has been administered a psychotropic medication in violation of* *Section 2-106.1 of the Act* and this Section *may bring an action for injunctive relief, civil damages, and costs and attorney's fees against any facility responsible for the violation*. (Section 2-106.1(b-35) of the Act)

n) *An action under this Section shall be filed within two years after either the date of discovery of the violation that gave rise to the claim or the last date of an instance of a noncompliant administration of psychotropic medication to the resident, whichever is later*. (Section 2-106.1(b-40) of the Act)

o) *A facility subject to action under Section 2-106.1 of the Act* and this Section *shall be liable for damages of up to $500 for each day, after discovery of a violation, that the facility violates the requirements of Section 2-106.1 of the Act* and this Section. (Section 2-106.1(b-45) of the Act)

p) *The rights provided for in Section 2-106.1 of the Act* and this Section *are cumulative to existing resident rights. No part of this Section shall be interpreted as abridging, abrogating, or otherwise diminishing existing resident rights or causes of action at law or equity*. (Section 2-106.1(b-55) of the Act)

q) *In addition to* the penalties described in this Section and *any other penalty prescribed by law, a facility that is found to have violated Section 2-106.1 of the Act* and this Section, *or the federal certification requirement that informed consent be obtained before administering a psychotropic medication, shall thereafter be required to 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* Section 2-106.1 of the Act and this Section. (Section 2-106.1(b-3) of the Act)

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