

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENT

- 1) Heading of the Part: Illinois Veterans' Homes Code
- 2) Code Citation: 77 Ill. Adm. Code 340
- 3) Section Number: 340.1615 Proposed Action:
New
- 4) Statutory Authority: Nursing Home Care Act [210 ILCS 45]
- 5) A Complete Description of the Subjects and Issues Involved: The Illinois Veterans' Homes Code regulates the administration of medications to residents, including psychotropic medication.

Public Act 96-1372, passed by the General Assembly in 2010, overhauled many elements of care in the Nursing Home Care Act [210 ILCS 45]. Among the changes was a new requirement that the Department "adopt, by rule, a protocol specifying how informed consent for psychotropic medication may be obtained or refused."

The addition of new Section 340.1615 (Administration of Psychotropic Medications) implements this portion of PA 96-1372.

The economic effect of this proposed rulemaking is unknown. Therefore, the Department requests any information that would assist in calculating this effect.

The Department anticipates adoption of this rulemaking approximately six to nine months after publication of the Notice in the *Illinois Register*.

- 6) Published studies or reports, and sources of underlying data, used to compose this rulemaking: None
- 7) Will this rulemaking replace any emergency rulemaking currently in effect? No
- 8) Does this rulemaking contain an automatic repeal date? No
- 9) Does this rulemaking contain incorporations by reference? No
- 10) Are there any other proposed rulemakings pending on this Part? Yes

Section Numbers: Proposed Action: Illinois Register Citation:

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340.1000	Amend	34 Ill. Reg. 18286; November 29, 2010
340.1120	Amend	34 Ill. Reg. 18286; November 29, 2010
340.1130	Amend	34 Ill. Reg. 18286; November 29, 2010
340.1150	Amend	34 Ill. Reg. 18286; November 29, 2010
340.1220	Amend	34 Ill. Reg. 18286; November 29, 2010
340.1225	New	34 Ill. Reg. 18286; November 29, 2010
340.1230	Amend	34 Ill. Reg. 18286; November 29, 2010
340.1240	Repeal	34 Ill. Reg. 18286; November 29, 2010
340.1245	Amend	34 Ill. Reg. 18286; November 29, 2010
340.1305	Amend	34 Ill. Reg. 18286; November 29, 2010
340.1314	Repeal	34 Ill. Reg. 18286; November 29, 2010
340.1315	Amend	34 Ill. Reg. 18286; November 29, 2010
340.1316	Amend	34 Ill. Reg. 18286; November 29, 2010
340.1317	Amend	34 Ill. Reg. 18286; November 29, 2010
340.1351	New	34 Ill. Reg. 18286; November 29, 2010
340.1470	Amend	34 Ill. Reg. 18286; November 29, 2010
340.1505	Amend	34 Ill. Reg. 18286; November 29, 2010
340.1575	New	34 Ill. Reg. 18286; November 29, 2010

11) Statement of Statewide Policy Objectives: This rulemaking may create a State mandate.

12) Time, Place, and Manner in which interested persons may comment on this proposed rulemaking: Interested persons may present their comments concerning this rulemaking within 45 days after this issue of the *Illinois Register* to:

Susan Meister
Division of Legal Services
Illinois Department of Public Health
535 West Jefferson St., 5th Floor
Springfield, Illinois 62761

217/782-2043
e-mail: dph.rules@illinois.gov

13) Initial Regulatory Flexibility Analysis:

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- A) Type of small businesses, small municipalities and not-for-profit corporations affected: Veterans' homes
 - B) Reporting, bookkeeping or other procedures required for compliance: Yes
 - C) Types of professional skills necessary for compliance: Nursing, medical
- 14) Regulatory Agenda on which this rulemaking was summarized: July 2010

The full text of the Proposed Amendment begins on the next page:

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TITLE 77: PUBLIC HEALTH
CHAPTER I: DEPARTMENT OF PUBLIC HEALTH
SUBCHAPTER c: LONG-TERM CARE FACILITIESPART 340
ILLINOIS VETERANS' HOMES CODE

SUBPART A: GENERAL PROVISIONS

Section

340.1000	Definitions
340.1010	Incorporated and Referenced Materials
340.1110	General Requirements
340.1115	Federal Veterans' Regulations
340.1120	Application for License
340.1125	Alzheimer's Special Care Disclosure
340.1130	Criteria for Adverse Licensure Actions
340.1140	Denial of Initial License
340.1150	Revocation or Denial of Renewal of License
340.1160	Inspections, Surveys, Evaluations, and Consultations
340.1170	Presentation of Findings by the Department
340.1190	Ownership Disclosure
340.1200	Monitor and Receivership
340.1210	Determination of a Violation
340.1220	Determination of the Level of a Violation
340.1230	Plans of Correction and Reports of Correction
340.1240	Calculation of Penalties
340.1245	Conditions for Assessment of Penalties
340.1250	Reduction or Waiver of Penalties
340.1255	Supported Congregate Living Arrangement Demonstration
340.1260	Waivers

SUBPART B: POLICIES AND FACILITY RECORDS

Section

340.1300	Facility Policies
340.1305	Request for Resident Criminal History Record Information
340.1310	Admission, Retention and Discharge Policies
340.1314	Criminal History Background Checks for Persons Who Were Residents on May

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340.1315	Identified Offenders
340.1316	Discharge Planning for Identified Offenders
340.1317	Transfer of an Identified Offender
340.1320	Disaster Preparedness
340.1330	Incidents and Accidents
340.1335	Infection Control
340.1340	Facility Record Requirements
340.1350	Personnel Policies
340.1360	Initial Health Evaluation for Employees
340.1370	Administrator
340.1375	Personnel Requirements
340.1376	Registry of Certified Nursing Assistants
340.1377	Health Care Worker Background Check
340.1378	Resident Attendants
340.1380	Contacting Local Law Enforcement

SUBPART C: RESIDENT RIGHTS

Section	
340.1400	Implementation of Resident Rights and Facility Responsibilities
340.1410	General
340.1420	Contract Between Resident and Facility
340.1430	Residents' Advisory Council
340.1440	Abuse and Neglect
340.1450	Communication and Visitation
340.1460	Resident's Funds
340.1470	Transfer or Discharge
340.1480	Complaint Procedures
340.1490	Private Right of Action

SUBPART D: HEALTH SERVICES

Section	
340.1500	Medical Care Policies
340.1505	Medical, Nursing and Restorative Services
340.1510	Communicable Disease Policies
340.1520	Tuberculin Skin Test Procedures
340.1530	Physician Services

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340.1535	Dental Programs
340.1540	Life-Sustaining Treatments
340.1550	Obstetrical and Gynecological Care
340.1560	Nursing Personnel
340.1570	Personal Care
340.1580	Restraints
340.1590	Nonemergency Use of Physical Restraints
340.1600	Emergency Use of Physical Restraints
340.1610	Unnecessary, Psychotropic, and Antipsychotic Drugs
340.1615	Administration of Psychotropic Medications
340.1620	Medication Administration (Repealed)
340.1630	Self-Administration of Medication (Renumbered)
340.1640	Vaccinations
340.1645	Language Assistance Services

SUBPART E: MEDICATIONS

Section

340.1650	Medication Policies and Procedures
340.1655	Compliance with Licensed Prescriber's Orders
340.1660	Administration of Medication
340.1665	Control of Medication
340.1670	Labeling and Storage of Medication
340.1675	Self-Administration of Medication

SUBPART F: RESIDENT LIVING SERVICES

Section

340.1700	Recreational and Activity Programs
340.1710	Social Services
340.1720	Work Programs
340.1730	Volunteer Program

SUBPART G: RESIDENT RECORDS

Section

340.1800	Resident Record Requirements
340.1810	Content of Medical Records
340.1820	Records Pertaining to Resident's Property

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- 340.1830 Retention, Transfer, and Inspection of Records
340.1840 Confidentiality of Resident's Records

SUBPART H: FOOD SERVICE

Section

- 340.1900 Food Service Staff
340.1910 Diet Orders
340.1920 Meal Planning
340.1930 Therapeutic Diets (Repealed)
340.1940 Menus and Food Records
340.1950 Food Preparation and Service
340.1960 Kitchen Equipment, Utensils and Supplies

SUBPART I: PHYSICAL PLANT SERVICES,
FURNISHINGS, EQUIPMENT AND SUPPLIES

Section

- 340.2000 Maintenance
340.2010 Water Supply, Sewage Disposal and Plumbing
340.2020 Housekeeping
340.2030 Laundry Services
340.2040 Furnishings
340.2050 Equipment and Supplies

- 340.TABLE A Heat Index Table/Apparent Temperature
340.TABLE B Guidelines for the Use of Various Drugs

AUTHORITY: Implementing and authorized by the Nursing Home Care Act [210 ILCS 45].

SOURCE: Emergency rule adopted at 18 Ill. Reg. 10391, effective June 21, 1994, for a maximum of 150 days; emergency rule expired November 18, 1994; adopted at 19 Ill. Reg. 5679, effective April 3, 1995; emergency amendment at 20 Ill. Reg. 496, effective January 1, 1996, for a maximum of 150 days; emergency expired May 29, 1996; amended at 20 Ill. Reg. 10045, effective July 15, 1996; amended at 20 Ill. Reg. 12013, effective September 10, 1996; amended at 22 Ill. Reg. 3959, effective February 13, 1998; amended at 22 Ill. Reg. 7162, effective April 15, 1998; amended at 23 Ill. Reg. 1038, effective January 15, 1999; amended at 23 Ill. Reg. 7931, effective July 15, 1999; amended at 24 Ill. Reg. 17225, effective November 1, 2000; amended at 25 Ill. Reg. 4869, effective April 1, 2001; amended at 26 Ill. Reg. 4870,

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effective April 1, 2002; amended at 26 Ill. Reg. 10589, effective July 1, 2002; emergency amendment at 27 Ill. Reg. 2222, effective February 1, 2003, for a maximum of 150 days; emergency expired June 30, 2003; amended at 27 Ill. Reg. 5903, effective April 1, 2003; emergency amendment at 27 Ill. Reg. 14230, effective August 15, 2003, for a maximum of 150 days; emergency expired January 11, 2004; amended at 27 Ill. Reg. 15904, effective September 25, 2003; amended at 27 Ill. Reg. 18148, effective November 15, 2003; amended at 28 Ill. Reg. 11209, effective July 22, 2004; emergency amendment at 29 Ill. Reg. 11931, effective July 12, 2005, for a maximum of 150 days; emergency rule modified in response to JCAR Recommendation at 29 Ill. Reg. 15208, effective September 23, 2005, for the remainder of the maximum 150 days; emergency amendment expired December 8, 2005; amended at 29 Ill. Reg. 12924, effective August 2, 2005; amended at 30 Ill. Reg. 1452, effective January 23, 2006; amended at 30 Ill. Reg. 5303, effective March 2, 2006; amended at 31 Ill. Reg. 6098, effective April 3, 2007; amended at 31 Ill. Reg. 8841, effective June 6, 2007; amended at 33 Ill. Reg. 9384, effective June 17, 2009; amended at 34 Ill. Reg. 19214, effective November 23, 2010; amended at 35 Ill. Reg. 3442, effective February 14, 2011; amended at 35 Ill. Reg. _____, effective _____.

SUBPART D: HEALTH SERVICES

Section 340.1615 Administration of Psychotropic Medications

This Section addresses the use of psychotropic medications in the treatment of residents.

- a) For the purpose of this Section, the following definitions shall apply:

Code – the Mental Health and Developmental Disabilities Code [405 ILCS 5].

Guardianship – the legal relationship between a resident or ward and a court-appointed guardian, including a public guardian such as the Office of State Guardian. Illinois guardians may make legally binding decisions on behalf of wards in personal or financial affairs, or both. For the purposes of this Part, the guardian must have court authority to make personal decisions for the ward. Guardians with personal decision-making authority will typically act under a plenary guardianship. A plenary guardian is one who has full decision-making authority over the person as provided under Section 11(a)-17 of the Illinois Probate Act of 1975 [755 ILCS 5/11a-17]. However, a guardian may also legitimately act under a temporary or a limited guardianship in which the guardian has clearly defined medical decision-making authority. A parent or an adult child of an adult resident without guardianship is not legally authorized to make

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binding decisions on behalf of a resident. When doubt exists as to the decision-making authority of a guardian, the guardian shall supply either letters of office or a copy of a court order documenting legal authority to act on behalf of the ward.

Informed consent – the voluntary and knowing choice by a resident or his/her legal guardian.

Lack of competency – the inability, due to diagnosed and documented mental impairment, to make reasoned decisions regarding treatment/habilitation alternatives, including the taking of psychotropic medication, by evaluating, among other factors, information about the likelihood of therapeutic benefits and the risk of side effects.

Legally and clinically competent resident – an individual who is not under guardianship and has the capacity to make reasoned decisions and give informed consent.

Legally and clinically incompetent resident – an individual under guardianship or who lacks the capacity to make reasoned decisions and give informed consent.

Long-acting psychotropic medication – psychotropic medications, including but not limited to Haldol Decanoate and Prolixin Decanoate, that are designed so that a single dose will have an intended clinical effect for a period of at least 48 hours. [Section 1-113.5 of the Code]

Psychotropic medication – medication that is used for or listed as used for antipsychotic, antidepressant, antimanic, or antianxiety behavior modification or behavior management purposes in the latest editions of the AMA Drug Evaluations or the Physician's Desk Reference. (Section 2-106.1(b) of the Act)

Substitute decision maker – a person who possesses the authority to make decisions under the Powers of Attorney for Health Care Law [755 ILCS 45/Art. IV] or under the Mental Health Treatment Preference Declaration Act [755 ILCS 43]. [Section 1-110.5 of the Code]

b) Drug Treatment

1) A resident shall not be given unnecessary drugs. An unnecessary drug is any drug used in an excessive dose, including in duplicative therapy; for

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excessive duration; without adequate monitoring; without adequate indications for its use; or in the presence of adverse consequences that indicate the drugs should be reduced or discontinued. (Section 2-106.1(a) of the Act)

2) Facilities shall comply with Table B in the use of psychotropic medication.

c) Evaluation

1) No new psychotropic medication shall be prescribed for a resident unless examinations have been conducted in accordance with Section 340.1310 or Section 340.1500. A physician shall conduct the examinations personally within the 30 days prior to the resident being given the psychotropic medication. The prescribing physician shall record, sign, and date the prescription. The prescribing physician shall also document appropriate clinical information related to the need for the psychotropic medication in the resident's medical record at the time of the prescription. This subsection (c)(1) does not apply to a dosage adjustment of existing psychotropic medications.

2) When psychotropic medication is administered in an emergency (see subsection (e)), the requirements of subsection (c)(1) need not be met if the prescribing physician has determined, either by personal observation or with information supplied by the attending physician, facility medical director, nurse practitioner, physician assistant or registered nurse with thorough knowledge of the resident's current clinical condition, that the resident is in need of immediate psychotropic medication to prevent the resident from causing serious and imminent physical harm to self or others.

d) Informed Consent

Psychotropic medication shall not be prescribed without the informed consent of the resident, the resident's guardian, or other legally authorized representative. (Section 2-106.1(b) of the Act) Prior to the first treatment review, the multidisciplinary team shall assess the resident's ongoing capability to give informed consent. This assessment process shall also include providing information to the resident to improve the resident's understanding of all

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psychotropic medications prescribed, including written information that describes risks, potential benefits, and alternatives, if alternatives are available. At the time of the first treatment review, the clinical team shall make a determination of the resident's apparent competency or lack of competency to give informed consent, and this determination shall be entered into the treatment plan. If a guardian is needed and if no guardian is known to be appointed, the facility shall initiate the process of application for guardianship by contacting the resident's family or, if no family member is able to serve as guardian or initiate guardianship proceedings, the State Guardianship and Advocacy Commission. Psychotropic medications may continue to be prescribed to a non-objecting resident until a court hearing can be held to make a formal determination of competency, and a guardian can be appointed.

1) Legally and Clinically Competent Residents

A) If the resident is able to give informed consent, the physician, a registered pharmacist, or a licensed nurse shall communicate the following information to the resident:

- i) The nature and purpose of the proposed treatment;
- ii) Whether the proposed treatment requires periodic testing/procedures to ensure safety/efficacy;
- iii) Side effects, risks, and benefits of the proposed treatment;
- iv) Prognosis and risks without the proposed treatment;
- v) Complementary treatments not previously tried and their risks, side effects, benefits and efficacy;
- vi) The right to refuse the proposed treatment; and
- vii) A copy of the written informed consent for each psychotropic medication currently prescribed or newly proposed to be prescribed or, if the resident refuses to sign but gives verbal consent, signed documentation by two licensed professionals who witnessed the verbal consent. The form used for documentation shall be a duplicate of the

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signed written informed consent. When possible, in accordance with State and federal law concerning release of medical information, and with the resident's permission, the resident's family or resident's representative should also be provided a copy of the written informed consent form for each psychotropic medication.

- B) The required information shall be given to the resident in a manner consistent with Section 340.1645 and with his or her ability to understand, including the regular use of sign language for any deaf or hard of hearing individual for whom sign language is a primary mode of communication.
- C) Informed written consent shall be obtained from the resident for all new psychotropic medication no later than the initial care planning meeting.
- D) If the resident has previously executed a declaration for mental health treatment under the Mental Health Treatment Preference Declaration Act or a health care power of attorney under the Powers of Attorney for Health Care Law, the facility shall act in accordance with that declaration or power of attorney.
- E) Residents newly admitted from home or hospital and those returned to the facility from an acute hospital stay may continue psychotropic medications previously prescribed to them until the multidisciplinary team can complete a competency assessment.

2) Legally and Clinically Incompetent Residents

- A) Prior to prescribing new psychotropic medications in non-emergency situations, a physician or licensed nurse shall discuss the following information with the resident and the resident's guardian or substitute decision maker:
 - i) The nature and purpose of the proposed treatment;
 - ii) Whether the proposed treatment requires periodic testing/procedures to ensure safety/efficacy;

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- iii) Side effects and risks of the proposed treatment;
 - iv) Prognosis and risks without the proposed treatment;
 - v) Complementary treatments not previously tried and their risks, side effects, benefits and efficacy; and
 - vi) The right to refuse the proposed treatment.
- B) A copy of the written informed consent form for each psychotropic medication currently prescribed or newly proposed to be prescribed shall be given to the resident and guardian or substitute decision maker. This form is a duplicate of the signed written informed consent, which is to be kept in the resident's medical record.
- C) Adequate time for the resident and the guardian or substitute decision maker to review the written information shall be allowed and any questions answered prior to signing the written informed consent. Consent forms for psychotropic medication shall be provided to guardians or substitute decision makers for review prior to the initial care planning meeting.
- D) The required information shall be given to the resident and the resident's guardian or substitute decision maker in a manner consistent with Section 340.1645 and with his or her ability to understand, including the regular use of sign language for any deaf or hard of hearing individual for whom sign language is a primary mode of communication.
- E) The resident shall be asked if he/she agrees to receive the proposed treatment. If the resident does not object, written informed consent shall be obtained from the resident's guardian or substitute decision maker and shall be documented in the resident's medical record. If the resident has no guardian or substitute decision maker or if the guardian or substitute decision maker does not provide written informed consent, any treatment shall proceed in accordance with subsection (e) (Treatment in Emergencies).

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- F) If the resident objects to the proposed treatment, any treatment shall proceed in accordance with subsection (e) (Treatment in Emergencies).
- G) If the resident has previously executed a declaration for mental health treatment under the Mental Health Treatment Preference Declaration Act or a health care power of attorney under the Powers of Attorney for Health Care Law, the facility shall to act in accordance with that declaration or power of attorney.
- H) If a court orders the involuntary administration of psychotropic medication, the psychotropic medication shall be administered in accordance with both the order and accepted clinical practice.

e) Treatment in Emergencies

- 1) In an emergency when treatment is necessary to prevent a resident from causing serious and imminent physical harm to self or others, a member of the treatment/habilitation team shall document, in the resident's medical record, the complementary treatments that the staff implemented that were unsuccessful in addressing the emergency. The documentation shall include a written explanation of the reasons why complementary treatments were not successful.
- 2) For administration of psychotropic medications, the prescribing physician, or a nurse in consultation with a physician, shall document his or her determination that an emergency exists based on a personal examination of the individual. Administration of the psychotropic medication shall be accompanied by a physician's order.
- 3) In prescribing psychotropic medication in an emergency, the prescribing physician, or a nurse with the consultation of a physician, shall examine the resident and document his/her determination of the initial emergency and response, including the circumstances leading up to the need for emergency treatment, in the resident's medical record as soon as possible, but within 24 hours after the emergency. Psychotropic medication shall not be continued unless the need for the psychotropic medication is predetermined at least every 24 hours and the circumstances

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demonstrating that need are set forth in the resident's medical record. A redetermination is based on a personal examination of the resident by a physician or by a nurse with the consultation of a physician.

- 4) Psychotropic medication shall not be administered over a resident's refusal under Section 2-107 of the Code for a period in excess of 72 hours, excluding Saturdays, Sundays and holidays, unless the treating physician, with the support of the treatment/habilitation team, files a petition for a court order under Section 2-107.1 of the Code and the administration of psychotropic medication continues to be necessary to prevent the resident from causing serious and imminent physical harm to self or others. If no petition is filed, administration of psychotropic medication shall be discontinued.
- 5) A restriction of rights form shall be completed for each emergency administration of psychotropic medication.
- 6) *Upon commencement of services, or as soon thereafter as the condition of the resident permits and the guardian or substitute decision maker consents, the facility shall advise the resident as to the circumstances under which the use of emergency forced psychotropic medication is permitted under Section 2-107(a) of the Code [Section 2-200(d) of the Code]. This information shall be provided no later than 72 hours after the determination to administer emergency forced psychotropic medication is made. The facility shall ask the resident which form of intervention he or she would prefer if any of the circumstances set forth in Section 2-107(a) of the Code arises. The resident's preference shall be documented in the medical record and communicated by the facility to the resident's guardian or substitute decision maker, if any. If any circumstances set forth in Section 2-107(a) of the Code arise, the facility shall consider the preferences of the resident regarding which form of intervention to use as communicated to the facility by the resident or as stated in the resident's advance directive.*
- 7) Long-acting psychotropic medications shall not be administered under Section 2-107 of the Code under any circumstances.

f) Treatment Monitoring

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1) Documentation

- A) The attending physician, or a nurse in consultation with a physician, shall examine and document the status of the resident's condition in the resident's medical record as often as the resident's clinical condition warrants, but not less than every 30 calendar days. Documentation of the rationale for administration of psychotropic medication, including type, dosage or frequency of administration of the proposed psychotropic medication as applicable, shall be included. Beneficial effects and significant side effects, as well as their treatment and management or the absence of treatment and management, shall also be noted.
- B) Facility staff shall document in the resident's medical record additional clinical information, such as assessments, evaluations or laboratory results, as it becomes available.

2) Treatment Review

- A) If a resident has been receiving psychotropic medication continuously or regularly for a period of three months and the treatment is continued, every three months thereafter for as long as the treatment continues the facility medical director or other physician designated by the facility director shall, along with the facility's pharmaceutical advisory committee, review the psychotropic treatment regimen.
- B) At least seven days prior to the treatment review meeting, the resident, guardian or substitute decision maker, if any, and any person designated under Section 2-200(b) of the Code shall be given written notification of the time and place of the treatment review meeting. The notice shall also advise the resident of his/her right to designate a person to attend the meeting and assist the resident in accordance with Section 2-107.2 of the Code.
- C) A written recommendation concerning the suitability of continued treatment with psychotropic medication shall be prepared after each meeting.

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- D) If, during the course of the treatment review meeting, the resident advises the committee that he/she no longer agrees to continue receiving psychotropic medication, or if the resident's guardian or substitute decision maker refuses psychotropic medication for the resident, the treatment shall be discontinued, except when the resident is receiving treatment pursuant to subsections (d)(1) and (d)(2) of this Section.
- i) If the resident is determined to be receiving appropriate treatment and the benefit to the resident outweighs the risk of harm to the resident, treatment shall be continued, provided that the resident does not object and the guardian or substitute decision maker, if any, does not refuse. (See Section 2-107.2 of the Code.)
- ii) If the findings of the treatment review meeting are not in agreement with the current treatment plan, the treatment/habilitation team shall consider and implement a revision to the plan.
- iii) If there is disagreement on the implementation of the recommendations, the facility medical director or lead physician (designated by the facility director) shall review the case and make a final decision. The facility medical director (or lead physician) may seek medical consultation from others prior to making a final determination. The basis shall be documented in the medical record.
- E) The participation of the resident and guardian or substitute decision maker, if any, and the recommendations from the treatment review meeting shall be recorded in the resident's medical record.

(Source: Added at 35 Ill. Reg. _____, effective _____)