



<b>Policy Title:</b>	<b>Psychotropic Medication and Informed Consent</b>
<b>Policy #:</b>	<b>05-002-0010</b>
<b>Effective Date:</b>	04/2/2025
<b>Approved by:</b>	Telly Delor, Chief Operating Officer
<b>Functional Area:</b>	Office of Recipient Rights
<b>Responsible Leader:</b>	Telly Delor, Chief Operating Officer
<b>Policy Owner:</b>	Sandy O'Neill, Recipient Rights Director
<b>Applies to:</b>	Contracted Network Providers, Direct Operated Programs, SCCCMH Staff

**Purpose:** To ensure informed consent is obtained prior to a recipient's use of psychotropic medications, and that the recipient is provided with the information regarding that medication.

### I. Policy Statement

In accordance with the Michigan Compiled Laws and the Michigan Department of Health and Human Services (MDHHS) Administrative Rules, St. Clair County Community Mental Health (SCCCMH) requires all qualified employees and volunteers of SCCCMH and its provider network to obtain the written *informed consent* of a *recipient*/recipient's legal representative prior to the recipient's use of a psychotropic medication.

### II. Standards

- A.** *Psychotropic medications* shall be prescribed only by a person licensed by the State of Michigan Department of Licensing and Regulatory Affairs.
- B.** The use of all psychotropic medications shall follow the Food and Drug Administration (FDA) safety guidelines noted in the "package insert" also known as "Full Prescription Information" unless there is clinical justification to exceed this safety guideline, which must be fully documented in the recipient's electronic health record.
- C.** Psychotropic medications shall not be administered unless:
  - 1. The recipient, or their guardian, gives informed consent, or
  - 2. Administration is necessary to prevent physical injury to the recipient or others, or

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3. It is Court ordered.

- D.** Initial administration of emergency psychotropic medications may not be extended beyond 48 hours unless there is consent. The duration of psychotropic medications shall be as short as possible and at the lowest possible dosage that is therapeutically effective. The emergency psychotropic medication shall be terminated as soon as there is little likelihood that the recipient poses a risk of harm to themselves or others.
- E.** Emergency psychotropic medications may be administered to prevent physical harm or injury after signed documentation of the physician is placed in the recipient's clinical record, and when the actions of a recipient or other criteria clearly demonstrate to a physician that the recipient poses a risk of harm to himself, or others.
- F.** Before initiating a course of psychotropic drug treatment for a recipient, the prescriber, or a licensed health professional acting under the delegated authority of the prescriber, shall do both of the following:

  - 1. Explain the specific risks and the most common adverse effects that have been associated with that drug.
  - 2. Provide the recipient with a written summary of the most common adverse effects associated with that drug.
- G.** Region 10 PIHP shall provide oversight of informed consent of psychotropic medications within the provider network in accordance with the terms of its MDHHS/PIHP contract. Region 10 PIHP shall consider informed consent of psychotropic medications as a program-level delegation. As such, SCCCMH and its provider network shall provide documentation of receipt of informed consent in accordance with this administrative policy and the Mental Health Code.
- H.** Region 10 PIHP shall monitor SCCCMH and its provider network to ensure recipients provide informed consent before receiving psychotropic medications. Informed consent will be monitored through Utilization Review of Case Records. As a result of its monitoring activities, Region 10 PIHP may make process improvement recommendations to SCCCMH and its provider network.
- I.** SCCCMH and its provider network shall have policies and procedures in place for obtaining informed consent from recipients/recipients' guardians for the use of psychotropic medications. The Informed Consent form must include a revocation statement and be maintained in the recipient's electronic health record.

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### III. Procedures, Definitions, and Other Resources

#### A. Procedures

##### Responsibilities

Position	Responsibilities
Prescriber	<ol style="list-style-type: none"> <li>1. Determine medications</li> <li>2. Explain risks and adverse effects associated with medications to recipients/guardians.</li> <li>3. Provide written summary of the most common adverse effects</li> </ol>
Program clerical/Nursing Staff	<ol style="list-style-type: none"> <li>1. Ensure the recipient/recipient's guardian provides informed consent for the use of the psychotropic medication(s) prescribed.</li> <li>2. Ensure the Consent for Psychotropic Medications is signed.</li> <li>3. Forward the signed Consent Form to Data Management for scanning into the record.</li> </ol>

##### Actions

Action Number	Responsible Stakeholder	Details
1.0	Prescriber	<ol style="list-style-type: none"> <li>1. Determine a psychotropic medication may benefit a recipient.</li> <li>2. Explain the specific risks and the most common adverse effects that have been associated with the medication to a recipient/recipient's guardian.</li> <li>3. Provide the recipient/recipient's guardian with a written summary of the most common adverse effects associated with the medication. If the recipient's guardian is not present for the recipient's clinical visit with their prescriber, prescriber forwards written summary to nursing staff for outreach to guardian.</li> </ol>
2.0	Program Clerical Staff/Nursing Staff	<ol style="list-style-type: none"> <li>4. Ensure the recipient/recipient's guardian provides informed consent for the use of the psychotropic medication(s) prescribed.</li> <li>5. Ensure the "Consent for the Use of Medication" is signed by the recipient/recipient's guardian and the prescriber.</li> <li>6. Forward the "Consent for the Use of Medication" to Data Management for scanning in the recipient's record.</li> </ol>

#### B. Related Policies

N/A

### C. Definitions

1. *Empowered Guardian*: For the purpose of this administrative policy, a person appointed by the Probate Court to exercise authority on behalf of a recipient.
2. *Informed Consent*: All of the following are elements of informed consent:
  - a. *Legal Competency*: An individual shall be presumed to be legally competent. This presumption may be rebutted only by a court appointment of a guardian or exercise by a court of guardianship powers and only to the extent of the scope and duration of the guardianship. An individual shall be presumed legally competent regarding matters that are not within the scope and authority of the guardianship.
  - b. *Knowledge*: To consent, a recipient or legal representative must have basic information about the procedures, risks, other related consequences, and other relevant information. The standard governing required disclosure by a doctor is what a reasonable patient needs to know in order to make an informed decision. Other relevant information includes all of the following:
    - i. The purpose of the procedures.
    - ii. A description of the attendant discomforts, risks, and benefits that can reasonably be expected.
    - iii. A disclosure of appropriate alternatives advantageous to the recipient.
    - iv. An offer to answer further inquiries.
  - c. *Comprehension*: An individual must be able to understand what the personal implications of providing consent will be based upon the information provided under item C.2.b. (Knowledge).
  - d. *Voluntariness*: There shall be free power of choice without the intervention of an element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion, including promises or assurances of privileges or freedom. There shall be an instruction that an individual is free to withdraw consent and to discontinue participation or activity at any time without prejudice to the recipient.
3. *Psychotropic Medications*: Drugs prescribed to control mood, mental status, or behaviors. Any new medication so approved by the Food and Drug Administration (FDA) shall be included in this administrative policy.
4. *Recipient*: Means an individual who receives mental health services from the Michigan Department of Health and Human Services (MDHHS), a community mental health services program, or a facility, or from a provider that is under contract with the MDHHS or a community mental health services program.

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5. *Service Staff*: Means those staff assigned to provide direct service (e.g., group home staff members, day program staff members, direct care staff members, outpatient staff members, clinicians, and case managers).

**D. Forms**

N/A

**E. Other Resources** (i.e., training, secondary contact information, exhibits, etc.)

N/A

**F. References**

1. Michigan Mental Health Code, Sections 330.1718 and 330.1719
2. MDHHS Administrative Rules 330.7158 and 330.7003

**IV. History**

- Initial Approval Date: 05/2008
- Last Revision Date: BY:
- Last Reviewed Date: 02/2025 BY: Sandy O'Neill
- Non-Substantive Revisions: N/A
- Key Words: Informed Consent Psychotropic, Psychotropic medications form, Signed consent for psychotropics