

DMH POLICY

Title: Medication Education, Capacity Assessment, and Informed Consent For Psychiatric Medications	Policy #: 14-01 Date Issued: July 1, 2014 Effective Date: September 29, 2014
Approval by Commissioner:	
Signature: Marcia Fowler	Date:

I. PURPOSE

Informed Consent is integral to person and family-centered approaches and principles of recovery and resiliency. The purpose of this policy is to safeguard the rights of Adults and Minors who are prescribed Psychiatric Medications by establishing a process to obtain Informed Consent. This is accomplished by ensuring that Medication Education is done, individuals are assessed for Capacity, and Informed Consent or legal authorization for treatment is obtained in accordance with Massachusetts law and good clinical practice. This Policy repeals and replaces DMH Policies 83-50 and 96-3R.

II. SCOPE

This policy applies to all DMH-operated and contracted facilities and programs (e.g., partial hospitalization programs and Programs of Assertive Community Treatment) in which Psychiatric Medications are prescribed. This includes inpatient facilities, outpatient programs and Intensive Residential Treatment Programs (IRTPs) and the Clinically Intensive Residential Treatment Program (CIRT).

III. DEFINITIONS

Adult: An individual who is 18 years of age or older.

Capacity: A clinical judgment that an individual has the ability to provide Informed Consent to treatment with Psychiatric Medications.

Emancipated Minor: A person under the age of 18 years who has achieved independence from parental authority by operation of law in accordance with M.G.L. c. 112, §§ 12E or 12F.

Health Care Agent (HCA): An Adult with authority to make health care decisions for another Adult pursuant to a Health Care Proxy executed in accordance with M.G.L. c. 201D.

Health Care Proxy: A document delegating to a Health Care Agent the authority to make health care decisions in accordance with the requirements of M.G.L. c. 201D.

Incapacitated Person: A person who has been determined by a Probate or District Court to lack Capacity to give Informed Consent.

Informed Consent: A decision to accept or refuse recommended treatment which is: 1) based on adequate knowledge of the information relevant to the decision being made, 2) made voluntarily, and 3) made by an individual who has Capacity to make the decision.

Lamb Warning: A notification given to an individual by a Prescribing Clinician, prior to an evaluation, that the individual's participation is voluntary and may be terminated at any time, and that any communications made during the course of the evaluation will not be privileged and may be disclosed in court proceedings. A Lamb Warning is only valid if the individual knowingly and voluntarily agrees to waive the privilege upon receiving such notification.

Legally Authorized Representative (LAR): A guardian or other fiduciary granted applicable authority by a court of competent jurisdiction or, in the case of a Minor, the parent(s) or other individual or entity with legal custody of the Minor. For the purpose of this policy, the term "LAR" is limited to those LARs who are authorized to make health care decisions.

Mature Minor: A Minor who does not meet the criteria for emancipation, who is deemed capable of providing Informed Consent to treatment, and for whom a determination has been made that it would not be in the minor's best interest to notify the parent(s) of the medical treatment for which Informed Consent is being sought.

Medication Education: Education and information provided to an individual regarding Psychiatric Medications, their purpose, benefits, risks and alternatives, which is necessary for Informed Consent and which promotes the individual's full participation in the decision-making process.

Minor: An individual under the age of 18 years.

Prescribing Clinician: A licensed physician or other licensed clinician who is authorized under Massachusetts law to prescribe Psychiatric Medications.

Psychiatric Medications: Medications prescribed to treat symptoms of mental illness. Such medications include, but are not limited to, antipsychotic medications.

Rogers Monitor: An individual appointed by the court to monitor an individual's treatment with medication pursuant to a Substituted Judgment Treatment Order.

Substituted Judgment Treatment Order (commonly referred to as a Rogers Order or 8B): A Probate or District Court order which authorizes the administration of antipsychotic medications or other Psychiatric Medications in accordance with an approved treatment plan to an individual who has been adjudicated to lack Capacity to give Informed Consent.

IV. POLICY STATEMENT

DMH acknowledges and supports the desire of all individuals to be strong agents in determining the course of their own lives and control their own minds and bodies, including the Psychiatric Medication treatment choices they make. An individual's ability to meaningfully understand information about Psychiatric Medications, to process medication and treatment information, and to give Informed Consent may vary over time, including having the Capacity to make certain Psychiatric Medication treatment decisions while lacking Capacity to make other treatment decisions. DMH recognizes its obligation to afford all individuals, including Minors, regardless of their assessed Capacity status, the right to receive Medication Education pertaining to their Psychiatric Medication treatment and, to the extent possible, participate in all phases of the decision-making process concerning treatment with these medications.

This policy is governed by the following principles:

- Prescribing Clinicians should provide Medication Education on an ongoing basis throughout an individual's course of treatment regardless of Capacity in a manner that promotes an individual's participation in all aspects of the decision-making processes around Psychiatric Medications.
- An Adult is presumed to have Capacity to provide Informed Consent unless a court of competent jurisdiction determines otherwise.
- An individual's Capacity and ability to give Informed Consent may vary over time and the assessment of these areas should be dynamic throughout an individual's course of treatment.
- Prescribing Clinicians should work with individuals towards increasing their Capacity to give Informed Consent.
- Promoting an individual's participation in all aspects of the decision-making process concerning the use of Psychiatric Medication and negotiating Psychiatric Medication treatment will enhance treatment understanding, adherence, and health outcomes.
- All information related to Medication Education and Informed Consent must be provided in the person's preferred language for discussing healthcare and in terms that the individual, LAR or HCA can understand.

V. PRESCRIBING CLINICIAN'S RESPONSIBILITIES

The following process must be used when prescribing Psychiatric Medication:

- to the extent possible and consistent with the individual's ability to understand, provide Medication Education to the individual, LAR or HCA about options for treatment, the proposed treatment, treatment changes and address the development of any adverse reactions related to the use of Psychiatric Medication(s) in a manner that promotes an individual's participation in all aspects of the decision-making process;
- determine the Capacity of the individual to consent or refuse the proposed/recommended Psychiatric Medication(s);
- obtain Informed Consent for Psychiatric Medications;
- obtain consent from a HCA, where applicable;
- apply for Substituted Judgment Treatment Orders, if necessary;
- assess the need for further Medication Education, need for updated capacity assessment, and need for obtaining new/updated Informed Consent on an ongoing basis and, at a minimum, at each periodic review; and
- document in the individual's medical record, as applicable, the Medication Education provided, Capacity assessment, Informed Consent, persons involved and actions taken.

A. Providing Medication Education. The Prescribing Clinician is responsible for providing ongoing Medication Education to the individual for whom Psychiatric Medication(s) is being proposed, including Minors, and to an LAR or HCA, as applicable. Individuals (including LARs and HCAs, as applicable) shall be offered the opportunity to ask questions, discuss the information provided by the Prescribing Clinician, and negotiate implementation of treatment with Psychiatric Medications.

1. The information provided shall include the need for the Psychiatric Medication(s); the type of Psychiatric Medication(s) being recommended; the benefits, risks, and possible drug interactions of the proposed or alternative treatment with Psychiatric Medication(s); alternative treatments (including no Psychiatric Medications); and the likely clinical outcomes with and without treatment with Psychiatric Medications. The Prescribing Clinician must also provide access to additional reliable written information concerning the proposed and alternative Psychiatric Medications.
2. All forms of Medication Education must be sensitive to the developmental needs of individuals of different ages and capacities.
3. The Prescribing Clinician must inform the individual, if they have Capacity, or the individual's LAR or HCA, if any, of the right to consent to or refuse any or all

of the non-court authorized Psychiatric Medications, and if consent is given, of the right to withdraw it at a future time.

4. If an individual lacks the Capacity to give Informed Consent for their own Psychiatric Medications, the Prescribing Clinician still must provide the information outlined in V.A.1 to the individual, to the extent possible, and consistent with the person's age and ability to understand.

B. Determining Capacity

1. When a Prescribing Clinician has reason to believe that a formal assessment of an individual's Capacity to make decisions concerning Psychiatric Medications is needed, a Lamb Warning must be given at the start of the Capacity evaluation.
2. The Prescribing Clinician must make a determination regarding the individual's Capacity based on their best clinical judgment of the individual's ability to reasonably understand the information, to understand how information applies to them, to reason about information provided and to make and express choices.
3. The Prescribing Clinician must assess an individual's Capacity when first evaluating the individual for Psychiatric Medications and anytime when it appears that an individual's ability to understand and process information has changed.
4. Assessing the capacity of individuals taking Psychiatric Medications should also occur, at a minimum, at each periodic review for individuals at facilities (see 104 CMR 27.11) or annually for individuals treated in community based settings.
5. If the Prescribing Clinician believes that an Adult who has been adjudicated as an Incapacitated person has regained the Capacity to give Informed Consent, the Prescribing Clinician should consult with legal counsel.

C. Obtaining Informed Consent. After determining an individual has Capacity, the Prescribing Clinician must obtain verbal Informed Consent prior to prescribing Psychiatric Medications and, pursuant to Section V.F.6, written Informed Consent as soon as possible thereafter. If an individual deemed not to have Capacity to consent for prescribed Psychiatric Medications agrees to accept recommended treatment with Psychiatric Medications, the administration of Psychiatric Medications may occur, provided the Prescribing Clinician initiates the process to obtain a Substituted Judgment Treatment Order (See Addendum).

D. Pursuing a Substituted Judgment Treatment Order. If an individual is clinically determined not to have Capacity, the Prescribing Clinician must initiate the process to obtain a Guardianship or Substituted Judgment Treatment Order pursuant to existing DMH practice. A Prescribing Clinician who initiates the process to obtain a

Substituted Judgment Order is expected to cooperate with the requirements for completing a medical certificate and affidavit and for maintaining such orders in effect. Special considerations apply to Minors, see Section G.4.

E. Review of Informed Consent

1. If the care of an individual is transferred to a new Prescribing Clinician, the new Prescribing Clinician must review the written Informed Consent obtained by the prior Prescribing Clinician and assess the individual's Capacity.
2. If the Prescribing Clinician becomes aware that the individual has concerns about any aspect of the Psychiatric Medication(s) prescribed, these issues must be discussed with the individual and, if applicable, the individual's LAR or HCA by the Prescribing Clinician. The Prescribing Clinician should consult with the DMH legal office to determine whether these concerns need to be brought to the attention of the court, defense counsel, or Rogers Monitor, where applicable.
3. An individual deemed capable, or an LAR or HCA on behalf of the individual, can withdraw consent for a Psychiatric Medication(s) any time and such withdrawal must be documented pursuant to Section V.F, provided however that treatment authorized under a Substituted Judgment Treatment Order is not subject to the consent or withdrawal of consent by an Individual, LAR or HCA. If consent is withdrawn, the Prescribing Clinician should consult with the DMH legal office to determine appropriate next steps.

F. Documentation

1. The Prescribing Clinician must document the Medication Education provided to an individual or their LAR or HCA, including the issues discussed, and outcome of the discussion. The source of any written medication information given to an individual must also be documented.
2. The Prescribing Clinician must document in the individual's medical record that a Lamb Warning was provided to the individual at the start of each Capacity examination.
3. The Prescribing Clinician must document all evaluations of Capacity that they conduct and if the individual is deemed to lack Capacity, what actions, if any, the Prescribing Clinician has taken as a result of that determination.
4. The Prescribing Clinician must document the individual's, LAR's, or HCA's verbal agreement or refusal to accept Psychiatric Medication(s). With refusals, the expressed basis of the refusal should also be documented.

5. The Prescribing Clinician must document the occurrence of ongoing reviews conducted in accordance with Sections V.B and E., above.
6. The requirements outlined in V.F.1-5 must be documented on the DMH approved Medication Education/Capacity Assessment/Informed Consent progress note template and the individual must be asked to sign the progress note indicating review and agreement. The progress note with the individual's signature must be stored in the progress note section of the individual's medical record.
7. The reasons for any emergency treatment with Psychiatric Medications in accordance with V.G.5, below, must be documented in the individual's medical record.

G. Other Considerations

1. **Limited Authority of Guardians.** Since a guardianship decree may limit the powers of the guardian, it is important to review the decree to determine the scope of the guardian's authority. In most cases, a guardian will have authority to consent to service planning, routine and preventative care, and Psychiatric Medications such as antidepressants, anti-anxiety medication, or mood stabilizers. A guardian, however, does not have any authority to consent or withhold consent to the administration of antipsychotic medication. Only a court of competent jurisdiction can authorize such treatment pursuant to a Substituted Judgment Treatment Order.
2. **Health Care Proxy**
 - a. The application and utilization of Health Care Proxies is governed by M.G.L. c.201D.
 - b. A valid Health Care Proxy may be executed by an Adult who has not been adjudicated Incapacitated and who has the Capacity to delegate health care decisions to another person in accordance with M.G.L. c. 201D.
 - c. A Health Care Agent has the authority to make health care decisions only when a Prescribing Clinician determines in accordance with M.G.L. c. 201D that an individual lacks Capacity to make or communicate his or her own health care decisions. The extent of the HCA's authority may be limited by the express terms of the proxy.
 - d. Notice of a determination that an individual lacks Capacity to make health care decisions must be given orally and in writing to the individual, where there is any indication that the individual may comprehend such notice, to the HCA and, if the individual is in or transferred from a mental health facility, to the facility director.

- e. If an individual has a HCA and the Prescribing Clinician determines that the Adult does not have the Capacity to give Informed Consent, then the HCA must provide Informed Consent provided that the Health Care Proxy does not limit the HCA's authority to do so. If the individual does not have the Capacity to give Informed Consent and the HCA does not have the authority to consent to treatment with Psychiatric Medications, a guardianship or Substituted Judgment Treatment Order must be obtained (see Section V.D).
- f. The HCA can make all medical decisions the principal could make unless the authority is limited by the express terms of the Health Care Proxy.
- g. If the individual revokes the Health Care Proxy either in writing or verbally, the HCA immediately loses authority to provide consent on the individual's behalf. If the Prescribing Clinician determines that the individual continues to lack Capacity at the time he or she objects to the HCA's treatment decision or revokes the applicable Health Care Proxy, the Prescribing Clinician must initiate legal proceedings to affirm the Health Care Proxy or seek appointment of a guardian and Substituted Judgment Treatment Order.
- h. A HCA who has been delegated authority under a Health Care Proxy executed in accordance with another state's statute may have the same authority as a HCA under a M.G.L. c. 201D Health Care Proxy, depending on the applicable state statute. In this situation, a Prescribing Clinician must consult with the facility's or program's DMH legal office.

3. Emancipated Minors and Mature Minors

An Emancipated Minor or Mature Minor is entitled to consent to medical treatment to the same extent and in the same manner as an Adult.

4. Minors

Special procedures apply to children in the care and custody of the Department of Children and Families (DCF) or the custody of the Department of Youth Services (DYS). Informed Consent for treatment with Psychiatric Medications must be obtained in accordance with DCF and DYS regulations and policies and any agreements between those agencies and the Minor's LAR. Any questions concerning Informed Consent should be referred to the DMH legal office to consult with DCF or DYS counsel.

Children who are not in the care or custody of DCF or DYS and who receive services from DMH will rely on their LAR to provide Informed Consent on their behalf. Any questions concerning the LAR's authority to give Informed Consent should be referred to the DMH legal office.

5. Emergency Treatment

Any Adult or Emancipated Minor who is believed to lack the Capacity to provide Informed Consent to treatment with antipsychotic medication, but who is not the subject of a Substituted Judgment Order, has a right to refuse such treatment. This right may be overridden only in an emergency (see 104 CMR 27.10(1)(d)) to prevent the immediate, substantial, and irreversible deterioration of the individual's mental illness after consultation with the appropriate Facility Medical Director or Area Medical Director.

If the Prescribing Clinician determines that antipsychotic medications should be continued beyond the immediate, short-lasting emergency situation, the Prescribing Clinician must initiate the process to obtain a Substituted Judgment Treatment Order.

6. Routine and Preventative Care

Routine and preventative care provided in DMH facilities includes standard medical examinations, clinical tests, immunizations, and treatment for minor illnesses and injuries. A Competent Adult, LAR or Health Care Agent has the right to refuse routine and preventative treatment; however, this right may be overridden by the facility director when the treatment consists of a complete physical and lab tests required by law upon admission and annually thereafter, or immunizations required by law or necessary to prevent the spread of infection or disease.

VI. ADMINISTRATIVE RESPONSIBILITIES

- A.** Each facility or program covered under this policy shall ensure that Prescribing Clinicians have access to reliable written electronic medication information in common, everyday language about each prescribed Psychiatric Medication that is sensitive to the developmental needs of individuals of different ages and capacities.
- B.** Each facility or program covered under this policy shall ensure that Prescribing Clinicians, other staff involved in Psychiatric Medication administration, dispensing and education, and Human Rights Officers receive training regarding the requirements of this policy.
- C.** Each facility or program covered under this policy shall ensure, where applicable, that a current copy of each individual's Health Care Proxy, guardianship decree or Substituted Judgment Treatment Order is placed in the legal section of the individual's medical record.

VII. IMPLEMENTATION RESPONSIBILITY

The Deputy Commissioner for Clinical and Professional Services is responsible for ensuring that the person in charge of each facility or program implements this policy. This includes assuring that every Prescribing Clinician and Human Rights Officer understands their responsibilities with regard to helping individuals, and their LAR and/or HCA, as applicable, in the facility or program to understand their rights to provide Informed Consent for treatment with Psychiatric Medications.

VIII. REFERENCES

The following statutes, regulations and policies are applicable to this policy: M.G.L. c. 111, §70E (Public Health); MGL c. 112, §§12E and 12F (Minors Consent to Certain Treatments); M.G.L. c. 123, §8B (District Court Substituted Judgment Treatment Orders); M.G.L. c. 190B, §§ 5-209, 5-306A, 5-308, 5-309, 5-311 (Guardianships and Substituted Judgment Treatment Orders); M.G.L. c. 201D, §§2, and 5-7(Health Care Proxies); 104 CMR 25.04, 27.10 – 27.12, 28.02, 28.03, 28.06 and 28.10 (DMH); 110 CMR 11.00 (DCF), and 109 CMR 11.00 (DYS).

IX. REVIEW

This policy shall be reviewed six months after its effective date and at least every three years thereafter.

X. ATTACHMENTS

- A. Decision Charts Concerning Treatment Situations
- B. DMH Consent Form for Psychiatric Medications

**DECISION CHART CONCERNING PSYCHIATRIC MEDICATION TREATMENT
FOR ADULTS***

Patient's Legal Status	Accepts Treatment	Refuses Treatment	Emergency Treatment (Section V.G. 5)
Has Capacity	Treat	Do not treat	Do not treat if individual refuses treatment
Does not appear to have Capacity	Treat while pursuing a guardianship or Substituted Judgment Treatment Order	Do not treat Obtain a Substituted Judgment Treatment Order	Treat while pursuing a guardianship or Substituted Judgment Treatment Order
<u>Adjudicated Incapacitated</u> with <u>Substituted Judgment Order</u>	Follow Substituted Judgment Order	Follow Substituted Judgment Order	Treat on an interim basis while following procedures to modify Substituted Judgment Order
<u>Adjudicated Incapacitated</u> without <u>Substituted Judgment Order</u>	Treat with non-antipsychotics with guardians consent, and may treat with antipsychotic medication while pursuing a Substituted Judgment Order	Do not treat Follow procedures to obtain a Substituted Judgment Order	Treat on an interim basis while following procedures to obtain a Substituted Judgment Order

***Prescribing Clinicians are cautioned to review the analysis in the DMH Informed Consent Policy for Psychiatric Medications and/or consult with legal counsel rather than relying solely on this Decision Chart.**

**DECISION CHART CONCERNING PSYCHIATRIC MEDICATION TREATMENT
FOR MINORS***

Legal Status of Minor	Accepts Treatment	Refuses Treatment	Emergency Treatment with Antipsychotic Medication (Section V.G.5)
LAR is parent with legal custody	Treat with consent of parent	Treat with consent of parent	Treat with consent of parent
LAR is court-appointed guardian	Treat with non-antipsychotics with guardian's consent; treat with antipsychotics while pursuing Substituted Judgment Treatment Order	Treat with non-antipsychotics with guardian's consent; do not treat with antipsychotics without Substituted Judgment Treatment Order	Treat while pursuing Substituted Judgment Treatment Order
In custody of DCF, i.e. placed in custody of DCF pursuant to court order or through adoption surrender.	Defer to DCF re consent requirement for non-extraordinary treatment. Treatment with antipsychotics requires Substituted Judgment Treatment Order.	Defer to DCF re consent requirement for non-extraordinary treatment. Treatment with antipsychotics requires Substituted Judgment Treatment Order.	Treat while pursuing Substituted Judgment Treatment Order. Consult with DCF.
In care of DCF, i.e., receiving services from DCF pursuant to a Voluntary Placement Agreement	Defer to DCF re consent requirement for non-extraordinary treatment. Treatment with antipsychotics requires authorization by parent with legal custody or Substituted Judgment Treatment Order.	Defer to DCF re consent for routine treatment. Treatment with antipsychotics requires authorization by parent with legal custody or Substituted Judgment Treatment Order	Treat with consent of parent with legal custody or treat while pursuing Substituted Judgment Treatment Order. Consult with DCF.
In custody of DYS (and neither emancipated nor deemed a mature minor)	Consent/authorization must be obtained from parent/guardian (see above) or authorized by court., i.e., Substituted Judgment Treatment Order	Consent/authorization must be obtained from parent/guardian (see above) or authorized by court., i.e., Substituted Judgment Treatment Order	Treat with consent of parent with legal custody or treat while pursuing Substituted Judgment Treatment Order. Consult with DYS.
Emancipated Minor, with capacity to make treatment decisions.	Treat	Do not treat (assessment of capacity may be clinically indicated)	Do not treat if individual refuses treatment (assessment of capacity may be clinically indicated)

Legal Status of Minor	Accepts Treatment	Refuses Treatment	Emergency Treatment with Antipsychotic Medication (Section V.G.5)
Emancipated Minor, who lacks capacity to make treatment decisions and who has not been adjudicated to be incapacitated.	Treat, while pursuing guardianship (for non-extraordinary treatment) or Substituted Judgment Treatment Order.	Do not treat: need to obtain guardianship (for non-extraordinary treatment) or Substituted Judgment Treatment Order	Treat while pursuing Substituted Judgment Treatment Order
Emancipated Minor, adjudicated incapacitated without substituted judgment treatment order	Treat with non-antipsychotics with guardian's consent and may treat with antipsychotics while pursuing court authorization	Treat with non-antipsychotics with guardian's consent and may treat with antipsychotics while pursuing court authorization	Treat while pursuing court authorization
Emancipated Minor, adjudicated incapacitated with substituted judgment order	Treat in accordance with substituted judgment treatment order	Treat in accordance with substituted judgment treatment order	Treat in accordance with order; treat and follow procedures to amend/modify substituted judgment treatment order
Mature Minor (deemed to have capacity)	Treat	Do not treat (Reassessment of capacity and pursuit of substituted judgment order may be clinically indicated)	Do not treat if individual refuses treatment (unless reassessed as incapacitated and pursuing court authorization)
Minor with LAR whose capacity or decision-making authority is unclear.	Consult legal office	Consult legal office	Consult legal office

***This Decision Chart provides a summary of consent/authorization requirements for individuals who receive psychiatric medication treatment. Prescribing Clinicians are cautioned to review DMH Policy: Medication Education, Capacity Assessment, and Informed Consent for Psychiatric Medications and/or consult with legal counsel in individual cases.**