

Disclaimer: The information contained in this chapter is not intended to be used as legal advice. Please refer to the most current specific state statutes and your own legal counsel when warranted. Some statutes may be referred to throughout this chapter.

General Consent for Treatment¹

Consent is the voluntary agreement by a person in the possession and exercise of sufficient mentality to make an intelligent choice to allow for medical services or treatment.

Express Consent: A written general consent is considered to be a legally advisable and wise risk management practice. Such a consent should be obtained from a patient, or from a person authorized* to consent on a patient's behalf, before any medical treatment is to be performed.

Implied consent: In certain emergent situations, consent can be implied by the nature of the patient's condition. Each facility should have a policy and procedure regarding documentation for when and how implied consent should be obtained.

References:

- 24 M.R.S.A. §2905
- 17-A M.R.S.A. §109(2)(C)
- 17-A M.R.S.A. §106(7)(A)
- 42 C.F.R. §482.13 (Condition of Participation; patient's right to make informed decisions)
- Joint Commission Standards of Accreditation RI.2.40, Elements of Performance for RI.2.40
- 10-144 C.M.R. Chapter 112, §XII.E.2 (Maine hospital licensing rules; medical record must contain, when appropriate, consents); §XII.E.4 (Maine hospital licensing rules; informed consent must be obtained from patient or authorized representative prior to initiation of treatment, except when consent is presumed in an emergency).

***Authorized persons: patient, legal guardian, durable medical power of attorney**

Consent for Surgical Procedures, Other Procedures, or Treatments (Informed Consent):

Informed consent requires that a patient have a full understanding about which he or she is consenting. It is the responsibility of the physician or other licensed independent practitioner (LIP) to disclose to the patient the information necessary in order to make an informed decision regarding a proposed medical or surgical procedure.

An informed consent discussion and form should include the following elements;

- the nature of the patient's injury or illness
- the procedure or treatment consented to

- the nature and purpose of the proposed treatment
- the risks and probable consequences of the proposed treatment
- the probability that the proposed treatment will be successful
- any alternative methods of treatment and their associated risks and benefits
- the risks and prognosis if no treatment is rendered
- an indication that the patient understands the nature of any proposed treatment, the alternatives, the risks involved, and the probable consequences of the proposed treatment
- as appropriate, the name of a surgical assistant and their role in the procedure
- the signatures of the patient, physician and qualified witness(es)
- the date the consent is signed

References:

- 42 C.F.R. §482.51(b)(2) (Condition of Participation for surgical services; a properly executed informed consent form for each operation must be in the patient's chart before surgery, except in emergencies)
- 42 C.F.R. §482.24(c)(2)(v) (Condition of Participation for medical records services; all patient records must document properly executed consent forms for procedures and treatments specified by the medical staff, or when written patient consent is required by Federal or State law)
- Medicare State Operations Manual, Appendix A, Interpretive Guidelines to 42 C.F.R. §482.24(c)(2)(v) and 42 C.F.R. §482.51(b)(2)
- 10-144 C.M.R. Chapter 112, §XVII(A)(1)(h) (hospital licensing rules; hospital must document evidence in record that patient received adequate information regarding risks, benefits and possible surgical alternatives to make an informed decision regarding proposed surgery)
- Joint Commission Standards of Accreditation RI.2.40, Elements of Performance for RI.2.40

Consent for Anesthesia Services (Informed Consent): see definition above

References:

- 42 C.F.R. §482.52(b)(1) (Condition of Participation for anesthesia services)
- Medicare State Operations Manual, Appendix A, Interpretive Guidelines to 42 C.F.R. §482.52(b) and §482.52(b)(1) (hospital's anesthesia policies and procedures must address patient consent)
- 10-144 C.M.R. Chapter 112, §XVII.B (hospital licensing rules regarding consent for anesthesia)

Consent to Organ and Tissue Donation:

Maine hospitals are mandated to report all deaths to the New England Organ Bank (NEOB). NEOB staff are responsible for contacting the decedent's family and screening for a potential donation. NEOB is also responsible for obtaining consent and having copies sent to the facility for inclusion in the patient's medical record.

References:

- 22 M.R.S.A. §2910

- 22 M.R.S.A. §2911(2) (written override of donor’s intent by next of kin)
- 10-144 C.M.R. Chapter 52 and Appendix A (required request; permission for organ donation by next of kin)
- 42 C.F.R. §482.45(a)(3) (required request Condition of Participation)
- Joint Commission Standards of Accreditation RI.2.80, Elements of Performance for RI.2.80(9)

Consent for Treatment for Breast Cancer:

In 1989, the Health Security Act was amended to require that specific information about treatment alternatives be given to patients diagnosed with breast cancer, in order to enable them to make informed treatment decisions.

The statute cited below describes the means by which a physician can meet its provisions. A form signed by the patient indicating that he/she has received the oral and written information is to be included in the medical record.

- 24 M.R.S.A. §2905-A

Consent for Sterilization (MaineCare):

In order for health care facilities to receive payment from MaineCare for sterilization procedures and hysterectomies, the patient must give voluntary informed consent. The consent forms must be of the design furnished by the federal government or an exact copy and must be completed within the timeframes outlined in the statute.

Upon completion, one copy of the signed consent is given to the patient, one copy is retained in the patient medical record and one copy is forwarded to MaineCare with the usual billing invoice.

- 34-B M.R.S.A. §7004(1); 34-B M.R.S.A. §7003(4)
- 42 C.F.R. §441.257; 42 C.F.R. §441.258; Appendix to 42 C.F.R. Part 441, Subpart F (required consent form for sterilizations and hysterectomies reimbursed by Medicaid)

Consent for Abortion (Adults):

A physician may not perform an abortion unless, prior to the performance, the attending physician certifies in writing that the woman has given her informed, written consent freely and without coercion. The statute cited below outlines the minimum requirements for a valid informed consent.

Reference:

- 22 M.R.S.A. §1599-A

Consent to Photograph Patient or Videotape Procedure:

Photographs and video images may be obtained to document care, to document abuse and neglect, and for medical education, teaching or publicity. Consent should be obtained from the

patient or legally authorized representative anytime a photograph or video image of a patient is taken. A valid authorization should be obtained from the patient or legally authorized representative when a copy of a photograph or video is to be released to outside requestors.

Reference:

- MeHIMA Legal Guide-refer to Photographs, Videotapes, and Other Images

Consent to Participate in Research:

Investigators are required to obtain an informed consent of the subject or the subject's legally authorized representative. The consent should discuss the purpose of the research, procedures to be followed and identification of those procedures which are experimental. Additionally, there should be a discussion of risks and benefits, alternative procedures or courses of treatment, the maintenance of confidential records and the subject's rights as related to the research project. The advice of legal counsel is recommended prior to initiating research consents as each project may include significant differences in the scope of the research.

Reference:

- 14-193 C.M.R. Chapter 1, §XI(D)(2) and §XI(G)(4)
- 45 C.F.R. §46.116; 45 C.F.R. §46.117
- Joint Commission Standards of Accreditation RI.2.180, Elements of Performance for RI.2.180

Consent/Refusal of EMTALA Transfer:

The Emergency Medical Treatment and Active Labor Act (EMTALA) is the Federal statute that requires hospitals with emergency departments to comply with specific medical screening, stabilizing treatment and appropriate transfer without consideration for ability to pay.

EMTALA consent/refusal forms should be carefully designed to capture all the requirements described in the sections cited below. EMTALA forms become part of the legal medical record; only copies should be sent with the patients to the receiving facility.

References:

- 42 C.F.R. 489.24(c)(2) (documentation of written informed refusal of emergency medical treatment)
- 42 C.F.R. 489.24(c)(4) (documentation of written informed refusal of EMTALA transfer)
- 42 C.F.R. 489.24(d)(1)(ii)(A) (documentation of written informed request for EMTALA transfer)
- 42 C.F.R. 489.24(d)(1)(ii)(B)-(C) (written medical certification of appropriateness of EMTALA transfer)

MINORS

In the case of a minor patient (under age 18), health information is generally released only upon the written authorization of the patient’s parent, legal guardian or legally authorized representative.

Maine law does recognize however, certain circumstances in which a minor may consent to medical treatment and therefore would also be the individual authorized to release information regarding that treatment. These circumstances are:

1. Minors who have been living separately from parents or legal guardians for at least 60 days and are independent of parental support.
2. Minors who are now or who have been legally married.
3. Minors who are or have been members of the Armed Forces of the United States.
4. Minors who have been emancipated by a court order.

Medical Conditions for Which a Minor May Give Consent

1. Minors receiving treatment for sexually transmitted disease, substance abuse, mental health issues, and sexual assault forensic examination to collect evidence after an alleged sexual assault.
2. Minors receiving family planning services who are a parent or are married or “who may suffer in the professional judgment of a physician probable health hazards if such services are not provided.”
3. Minors between the ages of 14 to 18 must consent to the administration of psychotropic drugs prior to the use of the medication.

References:

- 22 M.R.S.A. §1503: General Consent for Treatment for Emancipated, Married, and Certain Other Special Classes
- 22 M.R.S.A. § 1908
- MeHIMA legal guide—General Rules chapter

For specific circumstances regarding a minor’s ability to consent to treatments or procedures, please refer to the following Maine statutes:

- 22 M.R.S.A. §1507: Consent to Sexual Assault Forensic Examination
- 22 M.R.S.A. §1502: Consent by Minors for Treatment of Alcohol or Substance Abuse, Venereal Disease Emotional or Psychological Problems, or Sexual Assault
- 22 M.R.S.A. §1823: Consent for Hospitalization of Minor Longer than 16 Hours.
- 22 M.R.S.A § 1597-A: Consent for Abortion

Consent for HIV Testing:

No person may perform an HIV test without first obtaining the written informed consent of the person being tested. Informed consent is not required for repeated HIV testing by health care providers to monitor the course of an established infection.

Individuals who are the subject of HIV tests must be offered pretest and post-test counseling. The counseling must include the nature and reliability and significance of the HIV test, the confidential nature of the test, and information on good preventative practices and HIV risk reduction plans. Persons offered counseling under this section may decline the offer by signing a waiver stating that counseling was offered and was declined.

- 5 M.R.S.A. § 19203-A; 5 M.R.S.A § 19204-A
- 5 M.R.S.A § 19201 (5-A)
- MeHIMA legal guide—refer to HIV Chapter

Consent for Treatment for Mental Health Services:

Voluntary Admission: A client may be admitted for extended treatment and care in a mental health facility by informed consent if the chief administrative officer of the facility or his designee has determined that the client has been informed of and understands the nature, purpose and proposed duration of the admission and voluntarily consents to the proposed admission.

Reference:

- 34-B M.R.S.A § 5473

Involuntary Admission: Any health officer, law enforcement officer or other person may make a written application to admit a person to a mental hospital stating the belief that the person is mentally ill and, because of the illness, poses a likelihood of serious harm and the ground for this belief. The application must be accompanied by a dated certificate by a qualified licensed health care professional which states that the person has been examined and found to be mentally ill and poses a likelihood of harm. The application and accompanying certificate must be reviewed by a Justice of the Superior Court, Judge of the District Court, Judge of Probate or a justice of the peace. Upon review, the judge or justice shall endorse the forms and arrange for them to be forwarded to the admitting mental hospital.

Reference:

- 34-B M.R.S.A § 6863
- MeHIMA legal guide—refer to Mental Health Records Chapter.

Uniform Health-Care Decisions Act: Decisions by a Surrogate

A surrogate is authorized to make health care decisions for a patient who is an adult or emancipated minor if the patient has been determined by the primary physician to lack capacity and no agent or guardian has been appointed. Exception: a surrogate may not deny surgery, procedures or other interventions that are lifesaving and medically necessary.

Any member of the following classes of the patient's family who is reasonably available, in descending order of priority, may act as a surrogate:

- a. The spouse, unless legally separated;
- b. An adult who shares an emotional, physical and financial relationship with the patient similar to that of a spouse;
- c. An adult child;
- d. A parent;
- e. An adult brother or sister;
- f. An adult grandchild;
- g. An adult niece or nephew, related by blood or adoption;
- h. An adult aunt or uncle, related by blood or adoption;
- i. Another adult relative of the patient related by blood or adoption, who is familiar with the patient's personal values and is reasonably available for consultation.

Reference:

- 18-A M.R.S.A. § 5-805

¹Excerpted from *Legal Aspects of Health Care Administration, 6 Edition, George D. Pozgar and Nina Santucci Pozgar, Aspen Publishers, Inc. 1996.*

Rev 5/07