

CIRCULAR LETTER: DHCQ 04-6-442

TO: Chief Executive Officers
Acute Care Hospitals

FROM: Paul I. Dreyer, Ph.D.
Associate Commissioner

DATE: June 7, 2004

RE: New Consent Requirements for Autopsy

The Department of Public Health recently promulgated amendments to 105 CMR 130.000 (the hospital licensure regulation) regarding procedures required for consent to autopsy, including consent to disposition of organs following an autopsy (see Attachment A). The amendments, which will become effective on June 18, 2004, will require hospitals to do the following:

- Obtain consent in order to conduct an autopsy;
- Use a consent form that meets the minimum requirements set forth in the regulation;
- Return any organs removed during the autopsy (except for those organs for which prolonged fixation or detailed examination is required to complete the autopsy) with the body unless the person authorizing the autopsy directs otherwise. This will also apply to an autopsy performed at a hospital on behalf of the Medical Examiner's office, once the Medical Examiner's office has released the body and organs.
- Provide a copy of the consent form to the person who authorized the autopsy; and
- Establish written policies and procedures for obtaining and documenting consent to autopsy and disposition of organs.

The amendments also establish the same order of priority for persons authorized to give consent as is specified in 105 CMR 800.030 (the regulation governing organ donation). If you have any questions about the new regulations, please call Carol Balulescu, Deputy General Counsel, at 617-624-5220.

Attachment A

130.381: Definitions

The following definitions apply in 105 CMR 130.382 through 130.387.

Autopsy means a post mortem examination performed by a physician, including the removal and examination of organs, to determine a medical disease, medical condition, or the cause and manner of death, or for other diagnostic, education, quality improvement, or research purposes.

Decedent means a deceased individual or fetus, including a stillborn infant.

Organ means organs, tissues, and other parts of a human body, including but not limited to eyes, skin, bones, and arteries. “Organ” shall not mean tissue samples or fluids that are retained to determine the cause and manner of death.

Order of priority means the ranking of an individual who is qualified to provide consent to an autopsy.

130.382: Autopsy Consent Procedures

(A) No hospital shall permit the autopsy of a decedent without the consent of the authorized person named in 105 CMR 130.386. Any such consent shall meet the requirements set forth in 105 CMR 130.384.

(B) No hospital that performs an autopsy shall use organs removed from the body for any purpose other than to determine a medical disease or condition, or the cause or manner of death unless the person authorizing the autopsy consents to such other use, or unless otherwise required by law. Any such consent shall meet the requirements set forth in 105 CMR 130.384(A)(6).

130.383: Autopsies Performed Pursuant to M.G.L. c. 38, § 4

The requirements of 105 CMR 130.382 through 130.387 shall not apply to autopsies performed at a hospital pursuant to M.G.L. c. 38, § 4; provided, however, that when the chief medical examiner or his designee releases the body of a decedent, the hospital shall not retain or otherwise dispose of any organs released with the body without consent that meets the requirements of 105 CMR 130.384(A)(6).

130.384: Autopsy Consent Requirements

(A) The hospital shall use a standardized written autopsy consent form that includes at a minimum:

- (1) the name of the decedent and date and time of death;
- (2) the name of the hospital where the autopsy is to be conducted;
- (3) the general purpose for which the autopsy is to be conducted;
- (4) opportunity for the person authorizing the autopsy to state any specific requests or concerns regarding the autopsy. If the hospital is unable to comply with any such request or address any such concern, the hospital shall not perform an autopsy on the decedent.
- (5) opportunity for the person authorizing the autopsy to specify any limitations on the autopsy;
- (6) a separate section regarding disposition of the organs following the autopsy, including the following:
 - (a) notification that the person authorizing the autopsy has the right to control the final disposition of the organs;
 - (b) a statement that the hospital will return all organs with the body of the decedent at the time the body is released, except for those organs for which prolonged fixation or complete detailed examination is required to complete the autopsy, unless the person authorizing the autopsy affirmatively designates an alternate disposition. The hospital shall specify those particular organ(s) for which prolonged fixation or detailed examination is required to complete the autopsy and inform the person authorizing the autopsy that he or she has the right to control the final disposition of the organ(s) being retained. If at the time consent is requested the hospital cannot specify with certainty the organs for which prolonged fixation or detailed examination is required, it shall so state and shall specify the time and manner in which it will provide the information about such organs to the person authorizing consent.
 - (c) opportunity to designate the disposition of the organs, including but not limited to for research purposes. The hospital may limit such disposition to those methods that conform to all applicable requirements for safe handling and disposal of organs.
- (7) the signature and printed name of the person who obtained the consent, including his or her title and relationship to the hospital;

- (8) the signature and printed name of a witness to the consent;
- (9) the date and time of the signing of the consent form;
- (10) the printed name of the person who is authorized to consent to the autopsy pursuant to 105 CMR 130.386, including his or her relationship to the decedent; and
- (11) the signature of the person authorizing the autopsy.

(B) The hospital shall provide a copy of the signed consent form to the person authorizing the autopsy.

130.385: Telephonic Consent

A hospital may obtain consent to autopsy by telephone. Such consent shall be valid without the signature of the person authorizing consent if it meets all of the following requirements:

(A) The consent shall follow a conversation that meets the following requirements:

- (1) The person requesting the consent shall read in its entirety the consent form specified in 105 CMR 130.384 to the person authorizing consent and shall mark answers to all items in the presence of the witness;
- (2) The person authorizing consent shall have the opportunity to ask questions regarding the scope and purpose of the autopsy; and
- (3) The witness shall listen to the conversation in its entirety, with the permission of all parties to the conversation.

(B) The hospital shall provide a copy of the consent form to the person authorizing the autopsy.

(C) The consent form shall state that the authorization was received by telephone.

130.386: Classes of Persons Authorized to Consent

(A) The following order of priority is set forth for persons authorized to give consent for an autopsy:

- (1) the spouse of the decedent;
- (2) an adult son or daughter of the decedent;
- (3) either parent of the decedent;
- (4) an adult brother or sister of the decedent;

(5) a guardian of the decedent at the time of death; or

(6) any person authorized or under obligation to dispose of a body.

(B) If a member of the highest priority class available to give consent opposes the autopsy and makes such opposition known to the hospital prior to the autopsy, the hospital shall not perform an autopsy on the decedent.

(C) If the class that is authorized to give consent to an autopsy contains more than one member, the hospital is required to obtain consent from only one member of that class. If a member of the same class as the person who is authorized to give consent to an autopsy opposes the autopsy and makes such opposition known to the hospital prior to the autopsy, the hospital shall not perform an autopsy on the decedent.

(D) A separated spouse, if available after diligent search, shall explicitly waive consent in writing or by a witnessed telephonic communication before a member of a lower priority class is authorized to give consent.

(E) A person of the highest priority class available to give consent who has not yet attained the age of 18, is not emancipated, or has been adjudicated mentally incompetent may not be the consenting party of record.

(F) A woman who is under the age of 18 years old may consent to the autopsy of her deceased child or fetus.

130.387: Responsibilities of Hospital

The hospital shall establish written policies and procedures consistent with 105 CMR 130.382 through 130.387, including procedures for obtaining and documenting consent that meets the requirements in 105 CMR 130.384 and 130.385.