

481—51.8 (135B) Organ and tissue—requests and procurement.

51.8(1) Each hospital licensed in accordance with Iowa Code chapter 135B shall have in place written policies and protocols for organ and tissue donation. Hospital policies and protocols for organ and tissue donation shall require that the patient, or appropriate person able to consent on behalf of the patient, be made aware of the option to donate as well as the option to refuse donation and the ability, if any, to revoke consent once given.

a. Hospitals shall be familiar with the uniform anatomical gift law, Iowa Code chapter 142C, and shall develop policies and protocols for consent to organ and tissue donation by either the patient or an appropriate person to consent on the patient's behalf consistent with that law's provisions.

b. Hospital policies and protocols for organ and tissue donation shall set forth the responsibilities of the attending physician or physicians, nursing staff, and other appropriate hospital staff persons in the organ and tissue donation process. At a minimum, the policies shall set forth who in particular is authorized to make an organ or tissue donor request and that all such requests shall be made only in accordance with clearly delineated written protocol approved by the hospital's medical staff and governing board.

c. Hospital policies and protocols for organ and tissue donation shall provide that the attending physician inform appropriate family members or others of impending death or that death has occurred prior to an organ or tissue donor request.

d. Hospital policies and protocols for organ and tissue donation shall set forth those situations in which donation shall not be made including, but not necessarily limited to, the following:

(1) Where the patient is not medically suitable, as determined by the organ or tissue procurement organization;

(2) Where the hospital lacks the appropriate facilities or equipment for maintaining the patient or the organs for the time and in the manner necessary to facilitate appropriate procurement of the organ(s);

(3) Where the medical examiner has refused to release the body, except a donor request may be made where the medical examiner indicates that the body will be available at a time where the patient remains medically suitable for organ or tissue donation;

(4) Where the hospital has appropriate documentation that the patient or the appropriate person to consent on behalf of the patient does not want to consider the donation option;

(5) Rescinded IAB 8/6/03, effective 9/10/03.

e. Hospital policies and protocols for organ and tissue donation shall require documentation in the patient's medical record of the fact that a donor request was made and either accepted or refused, stating to whom the request was made and who accepted or refused; or that a donor request was not made, stating the reason why no request was made; or that a consent previously given was subsequently revoked.

f. Method and manner of consent, where consent to organ or tissue donation has been given, shall be noted in the patient's medical record. Where revocation of consent, if applicable, occurs, the manner and method of revocation shall also be noted in the patient's medical record.

g. Where the patient has validly executed a donation prior to death, attempt will be made to notify appropriate family members, if reasonably available, of the donation before the procurement process begins.

h. Hospital policies and protocols for organ and tissue donation shall provide for ongoing communication with the patient's family or other appropriate representatives regarding the donation process, the present status of that process and unexpected delays in the process, and family rights and responsibilities following organ or tissue donation.

51.8(2) Determination of death.

a. No organ or tissue shall be removed from a donor until death has been determined according to the requirements of Iowa law and generally acceptable standards of medical practice.

b. Death is defined by Iowa Code section 702.8 as a condition determined by the following standards:

A person will be considered dead if in the announced opinion of a physician licensed pursuant to Iowa Code chapter 148, 150, or 150A, a physician assistant licensed pursuant to Iowa Code chapter 148C, or a registered nurse or a licensed practical nurse licensed pursuant to Iowa Code chapter 152, based on ordinary standards of medical practice, that person has experienced an irreversible cessation of spontaneous respiratory and circulatory functions. In the event that artificial means of support preclude a determination that these functions have ceased, a person will be considered dead if in the announced opinion of two physicians, based on ordinary standards of medical practice, that person has experienced an irreversible cessation of spontaneous brain functions. Death will have occurred at the time when the relevant functions ceased.

c. The surgeon performing the organ removal shall not participate in the determination of brain death.

d. The patient's medical record shall include documentation of the date and time of death and identification of the practitioner or practitioners who determined death, as provided in 51.8(2) "b."

51.8(3) Determination of medical suitability.

a. At or near the time of the patient's death or when death has occurred, no organ and tissue donor request shall be made until the patient has been determined by the designated organ or tissue procurement organization to be medically suitable for organ or tissue donation.

b. Each hospital shall consult with a recognized organ and tissue procurement program or programs in establishing medical requirements for organ and tissue donation and in evaluating a particular patient's suitability for donation. Where required by federal law, hospitals shall work only with organ or tissue procurement organizations designated by the Department of Health and Human Services (DHHS). Organ and tissue procurement programs maintain guidelines for determining medical suitability and generally will provide a hospital with a copy of those guidelines which may be incorporated into the hospital's own policies and protocol for organ and tissue donation.

51.8(4) Organ and tissue procurement.

a. Hospital policies and protocol for organ and tissue donation shall set forth the process to be used for contacting an organ procurement organization (OPO).

b. Hospitals with an agreement with the designated OPO shall take into account the terms and conditions of the agreement in developing their policies and protocols. Hospitals shall contact only the OPO designated by the federal Department of Health and Human Services.

c. Generally an OPO will assume the costs of procuring medically suitable organs and tissues, including costs borne by the donating hospital in maintaining the patient until organ retrieval can occur as well as in the retrieval process itself. A hospital shall be familiar with its financial obligations, if any, in the procurement process and with cost accounting/reporting responsibilities it bears, if any, under Medicare and Medicaid. In situations, if any, where the patient or the patient's family may be liable for certain costs associated with organ donation or procurement, the patient or person able to consent for the patient shall be fully informed of the potential financial obligations at the time of request and before consent is either given or refused.

d. When an organ or tissue is retrieved for transplantation purposes, the hospital shall ensure that the medical records of the donor and, if applicable, the recipient fulfill the requirements for any surgical inpatient medical record. Medical record documentation shall include the method of maintenance of the patient while awaiting organ or tissue retrieval and operative report documentation (including an autopsy if an autopsy has been performed) regarding the removal of the organ or tissue.

e. The procurement process shall not occur until necessary consent by the patient or appropriate person to consent on behalf of the patient is received and documented. Also, in cases requiring the involvement of the medical examiner, release of the body must be authorized by the medical examiner and documented.

f. Where a donor specifies to whom the organ or tissue donation is to be made, the hospital shall first contact the named donee to determine whether the donee accepts the donation. Where the donee refuses the donation or is unable for other reasons to accept, then the hospital shall document in the medical record the fact that the donation was not accepted. The hospital shall then notify the appropriate

consenting party that the donation was not accepted and determine whether the consenting party desires to make further donation. A hospital shall make good faith effort to cooperate in the donation/procurement process where a specific donee has been named but shall not be required to participate in the donation process where procurement for a specific donee would result in undue burden or unreasonable cost to the hospital; in such situations, the hospital shall notify the appropriate consenting party and determine whether the consenting party desires to make further donation.

g. Where consent has been given for organ or tissue donation, revocation of prior consent, if applicable, shall not be effective once surgical procedures have begun on either the donor or the recipient.

51.8(5) Informed consent. Hospital policies and protocols for organ and tissue donation shall be consistent with informed consent provisions provided by the organ or tissue procurement organization.

51.8(6) Confidentiality. Hospital policies and protocols for organ and tissue donation shall provide that donor and recipient patient-identifying information shall be kept confidential except and only to the extent necessary to assist and complete the procurement and transplant process.

51.8(7) Training of hospital personnel. Hospital policies and protocols for organ and tissue donation shall include provisions for initial and ongoing training of hospital medical, nursing, and other appropriate staff persons regarding the various aspects of the organ and tissue donation and procurement process. The type and extent of training will vary from hospital to hospital, based on factors such as likelihood of medically suitable donors, capabilities for maintaining organ donors/patients, referral sources for potential organ and tissue donor candidates, and overall participation in organ and tissue procurement and transplants.

This rule is intended to implement Iowa Code section 135B.7.