

RULES AND REGULATIONS PERTAINING TO PROCUREMENT OF ANATOMICAL GIFTS FROM PERSONS WITH UNKNOWN INTENT



STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH

December 1990

AS AMENDED:

January 2002 (re-filing in
accordance with the provisions
of section 42-35-4.1 of the
Rhode Island General Laws, as
amended)

January 2007 (re-filing in
accordance with the provisions
of section 42-35-4.1 of the
Rhode Island General Laws, as
amended)

December 2007 (Repeal)

COMPILER'S NOTES:

This regulation has been repealed in its entirety due to repeal of its enabling statute [RIGL 23-18.6] on 6 July 2007, pursuant to PL 2007-476.

INTRODUCTION

~~The Rules and Regulations Pertaining to Anatomical Gifts (R23-18.6-ANGFT) are promulgated pursuant to the authority conferred under 23-18.6-5b of the General Laws of Rhode Island, as amended, and are established for the purpose of providing uniform protocols for procuring anatomical gifts at the time of death, from persons with unknown intent.~~

~~Pursuant to the provisions of Section 42-35-3(e) of the General Laws of Rhode Island, 1956, as amended, the following were given consideration: 1) Alternative approaches to the regulations; 2) duplication or overlap with other state regulations; and 3) significant economic impact placed on small business as defined in Chapter 42-35 of the General Laws through these regulations. No alternative approach, overlap or duplication or economic impact was identified.~~

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PART I — *Definitions*

SECTION 1.0 — *Definitions*

Whenever used in these rules and regulations, the following terms shall be construed to mean:

- 1.1 — ~~"Anatomical Gift"~~ means a donation of all or part of a human body to take effect upon or after death.
- 1.2 — ~~"Death"~~ means irreversible cessation of all functions of the entire brain, including the brain stem.
- 1.3 — ~~"Consent"~~ means informed decision to grant permission for organ donation.
- 1.4 — ~~"Death or time of death"~~ means determination of a point in time at which death occurred as certified by a physician who attends the donor, or if none, legal certification of death by a physician in keeping with currently acceptable medical criteria.
- 1.5 — ~~"Decedent"~~ means a deceased individual and includes a stillborn infant or fetus.
- 1.6 — ~~"Document of Gift"~~ means a card, a statement attached to or imprinted on a motor vehicle operator's or chauffeur's license, a will, or other writing used to make an anatomical gift.
- 1.7 — ~~"Donor"~~ means an individual who makes an anatomical gift of all or part of the individual's body.
- 1.8 — ~~"Hospital"~~ means a facility licensed, accredited, or approved as a hospital under the law of any state or a facility operated as a hospital by the United States government, a state, or a subdivision of a state.
- 1.9 — ~~"Part"~~ means an organ, tissue, eye, bone, artery, blood, fluid, or other portion of a human body.
- 1.10 — ~~"Person"~~ means an individual, corporation, business trust, estate, trust partnership, joint venture, association, government, governmental subdivision or agency, or any other legal or commercial entity.
- 1.11 — ~~"Physician" or "Surgeon"~~ means an individual licensed or otherwise authorized to practice medicine and surgery or osteopathy and surgery under the law of any state.
- 1.12 — ~~"Procurement organization"~~ means federally designated procurement organization accredited, and/or approved under the laws of any state for procurement, distribution, or storage of human bodies or parts. (For Rhode Island, this is the New England Organ Bank)
- 1.13 — ~~"State"~~ means a state, territory, or possession of the United States, the District of Columbia, or the commonwealth of Puerto Rico.

PART II — *General Requirements*

SECTION 2.0 — **General Requirements**

2.0 — ~~The Director of the Department of Health, in conjunction with the Federally designated organ/tissue procurement organization, herein adopts regulations relating to making an anatomical gift, or gifts, in instances where the intent of the decedent is unknown.~~

PART III — ~~*The Gift: Process, And Purpose*~~

SECTION 3.0 — ~~*Protocol For Procurement:*~~

~~3.1 — It shall be the responsibility of each hospital to develop procedures for addressing the issues of organ and tissue donation, when death occurs in a hospital and in situations when the intention of the deceased is unknown.~~

~~3.1.1 Said procedures shall encourage reasonable discretion and sensitivity to the family circumstances in all discussion regarding donations of tissue or organs and should take into account the deceased individual's religious beliefs or obvious nonsuitability for organ and tissue donation in determining whether or not to make the request.~~

~~3.1.2 The protocol shall require documentation of the request in the decedent's medical record. If no request has been made, the reason should be documented.~~

~~3.1.3 Whether or not consent is granted, the statement shall indicate the name of the person granting or refusing the consent, and his/her relationship to the decedent.~~

~~3.1.4 Each hospital shall submit a copy of the protocol to the Department of Health.~~

~~3.2 — The Inquiry Process:~~

~~3.2.1 The hospital shall actively support the education of all appropriate hospital personnel concerning organ and tissue donation on a regular basis.~~

~~3.2.2 When, in the opinion of the attending physician or other competent medical personnel, a death is imminent, or has occurred, a representative designated by the hospital administration shall notify the federally designated organ/tissue procurement organization of pending death.~~

~~A discussion of possible donation of organs/tissues shall take place according to medical criteria established by the federally designated organ/tissue procurement organization, and will be documented in the medical record.~~

~~3.2.3 If at or near the time of death, there is no record of the patient making or refusing to make an anatomical gift, the hospital administrator or a designee shall discuss the option with persons authorized as individuals in Section 4.1 to make or refuse to make an anatomical gift. This must be done with reasonable discretion and consideration to the following:~~

- ~~a) sensitivity to the circumstances of the family;~~
- ~~b) the religious beliefs of the patient;~~
- ~~c) obvious medical non-suitability for organ or tissue donation.~~

~~The above shall be documented in the patient record, including the outcome of the decision.~~

~~3.2.4 If, according to medical standards established by the Federally designated organ/tissue procurement organization, or one of the other exceptions delineated in section 3.2.3 applies, a gift is not suitable, an entry must be made in the medical record of the patient, stating the name and affiliation of the individual and the reason for not asking the next of kin or designee.~~

~~3.3 — Lack of Medical Record and/or Unknown Intent:~~

~~3.3.1 A reasonable search for document of gift or other information identifying the bearer as a donor, or as an individual who has refused to make an anatomical gift may be made by:~~

- ~~(1) a law enforcement officer, fire fighter, paramedic or other emergency rescuer finding an individual whom the searcher believes is dead or near death; and~~
- ~~(2) a hospital upon the admission of an individual at or near the time of death, if no other source of that information is available;~~

~~3.3.2 If a document of gift or evidence of refusal to make an anatomical gift is located by the search, and the individual or body to whom it relates is taken to a hospital, the hospital must be notified of the contents and the documents must be sent to the hospital; and~~

~~3.3.3 A hospital shall cooperate in the implementation of an anatomical gift or release and removal of a body part in all cases when a donor has been identified.~~

~~3.3.4 A representative designated by the Hospital Administrator shall notify the procurement organization, if appropriate.~~

~~3.3.5 If, according to medical standards established by the Federally designated organ/tissue procurement agency, a gift is not suitable, an entry must be made in the medical record of the patient, stating the name and affiliation of the individual, and the reason for not asking the next of kin or designee.~~

~~SECTION 4.0 — *Persons Authorized To Make An Anatomical Gift*~~

~~4.1 — Any member of the following classes of persons, in order of priority listed, may make an anatomical gift of all or a part of the decedent's body for an authorized purpose, unless the decedent, at the time of death, has made an unrevoked refusal to make that anatomical gift:~~

- ~~(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 grandparent of the decedent and~~
- ~~(6) a guardian of the person of the decedent at the time of death.~~

~~4.1.2 An anatomical gift may not be made by a person listed in subsection 4.1 if:~~

- ~~(1) A person in a prior class is available at the time of death to make the gift;~~
- ~~(2) the person proposing to make an anatomical gift knows of a refusal or contrary indication by the decedent or; and~~
- ~~(3) the person proposing to make an anatomical gift knows of an objection to making an anatomical gift by a member of the person's same class or a prior class.~~

~~4.1.3 An anatomical gift by a person authorized under subsection 4.0 must be made by:~~

- ~~(1) a document of gift signed by the person OR;~~

- ~~(2) the person's telegraphic, recorded telephonic (or other recorded message); OR~~
~~(3) other form of communication from the person that is immediately reduced to writing and signed by the recipient.~~

SECTION 5.0 — *Purposes For Which Anatomical Gifts May Be Made*

~~5.1 — The following persons may become donors of anatomical gifts for the purposes stated:~~

- ~~1) A hospital, physician, surgeon, or federally designated organ/tissue procurement organization for transplantation, therapy, medical or dental education, research or advancement of medical or dental science;~~
- ~~2) an accredited medical or dental school, college or university for education, research, advancement of medical or dental science;~~
- ~~3) a designated individual for transplantation or therapy needed by that individual; or~~
- ~~4) A designated donee in the case of a living related donor/donee or donation of entire body to a medical school for research prior to and well in advance of death. If the donee is unavailable, the anatomical gift may be accepted by any hospital.~~

~~5.1.1 The donee may NOT accept an anatomical gift:~~

~~If the donee is aware of the decedent's refusal or contrary indications to make an anatomical gift, OR~~

~~If the gift is opposed by a class of person (as indicated in Section 4.0) having priority to act, OR~~

~~If the gift is opposed by another person in the priority class.~~

PART IV — *Severability*

Section 6.0 — *Severability*

6.1 — ~~If any provision of these rules and regulations or the application thereof to any individual, facility or circumstance shall be held invalid, such invalidity shall not affect the provisions or application of the rules and regulations which can be given effect, and to this end the provisions of the regulations are declared to be severable.~~