# **10-144 DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Chapter 52: REGULATIONS GOVERNING THE RESPONSIBILITIES OF HOSPITALS AND PHYSICIANS IN IMPLEMENTING AN ACT CONCERNING REQUIRED REQUEST FOR ORGAN DONATION**

**Summary**: These rules detail the responsibilities of hospitals and physicians In Implementing the legislation, "AN ACT Concerning Required Request for Organ Donation." They address the development of inter-hospital agreements, annual reporting requirements, and the training of persons who will perform the request for an anatomical gift. These rules also describe the monitoring mechanism that will be utilized by the Department of Health and Human Services (Department) to ensure that the Intent of the statute is met.

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**CHAPTER 1: DEFINITIONS**

 1. **Brain Death** - Brain death, as noted in 22 MRSA 52812, refers to the condition of an individual who has sustained irreversible cessation of all functions of the entire brain, including the brain stem. The determination of brain death shall be made In accordance with accepted medical standards.

 2. **Community Hospital** - For the purpose of these regulations, a community hospital Is a Maine general hospital whose role In Maine's organ procurement system Is to Identify patients who meet medical criteria to qualify as potential organ donors, request permission of appropriate Individuals (as defined In 22 MRSA §2902 (2)) for the donation of organs, and arrange for the transfer of these patients to regional hospitals where the organ procurement attempt will be made.

 3 **Community Hospital Agreement** - A community hospital agreement is a written document developed between community and regional hospitals and the Maine transplantation center. The purpose of the agreement Is to describe the roles and responsibilities of the community and regional hospitals and the Maine transplantation center in Maine's organ procurement system.

 4. **Donor Organ and Tissue** - A donor organ is a solid body part such as a heart, heart-lung, bone, kidney, liver or pancreas that can be surgically removed from a patient- donor and subsequently transplanted Into the body of a recipient. A donor tissue is another body part such as skin, eye/cornea, bone and blood that can also be removed from a patient donor and be donated to a patient who is a potential tissue recipient. It Is anticipated that requests for the gift of donor organ(s) from brain dead patients will also result In the procurement of donor tissues suitable for transplant.

 5. **General Hospital** - Is an acute health care facility with permanent Inpatient beds planned, organized, operated and maintained to offer, for a continuing period of time, facilities and services for the diagnosis of treatment, illness and deformity. Specifically excluded are state mental health institutes or non state mental health institutions as defined by 34-B MRSA §3801.

 6. **Inter-Hospital Agreement** - An Inter-hospital agreement Is a written document made by two or more Maine hospitals which establishes protocols for the retrieval and transportation of all or any part of a body found suitable for transplantation and for the costs associated with transplantation.

 7. **Maine Transplantation Center** - The Maine transplantation center Is a general hospital located In Maine that performs one or more of the following transplant procedures: kidney, heart, heart-lung, liver or pancreas. At this time, the Maine Medical Center is the Maine transplantation center. This facility will have several responsibilities n Maine's organ procurement system. It will have major responsibilities In assisting regional and community hospitals In the training of persons making the request for organ donation. This facility will also assist community hospitals In Identifying potential organ donors. It will serve as a facility where both organ procurement attempts are made and where organ transplantation procedures are performed. This hospital shall also have the responsibilities of Identifying patients in its own facility who meet medical criteria to qualify as potential organ donors and requesting permission of appropriate Individuals (as defined In 22 MRSA §2902 (2)) for the donation of organs of these patients so that organ procurement attempts can be made.

 8. **Potential Organ Donor** - A potential organ donor is a hospital patient, aged neonate - 60, who meets the medical criteria for brain death and does not have contraindications for organ donation.

 9. **Potential Organ or Tissue Donor** - A potential organ or tissue donor is a hospital patient, aged neonate -60, who meets the medical criteria for brain death and is a suitable candidate for organ or tissue donation based upon accepted medical standards. A patient who Is not a potential organ donor need not be considered a potential tissue donor. The need for an organ or tissue may be considered In determining whether a patient Is suitable as a potential organ or tissue donor.

 10. **Regional Hospitals** - For the purpose of these regulations, a regional hospital Is a Maine general hospital whose major role In Maine's organ procurement system is to serve as a facility where organ procurement attempts will be made. These hospitals shall also have the responsibilities of identifying those patients in their facility who meet medical criteria to qualify as potential organ donors and requesting permission of appropriate individuals (as defined in 22 MRSA §2902 (2)) for the donation of organs of these patients, so that organ procurement attempts can be made.

 11. **Regional Hospital Agreement** - A regional hospital agreement Is a written document developed by regional hospitals and transplantation centers. The purpose of the agreement shall be to describe the respective roles and responsibilities of the regional hospitals and transplantation centers In Maine's organ procurement system.

**CHAPTER 2: INTER-HOSPITAL AGREEMENTS**

 A. **Types of Inter-Hospital Agreements**: Two separate types of organ donation request inter-hospital agreements shall be developed by Maine's hospitals.

 1. **Community Hospital Agreement** - This agreement shall be developed between community and regional hospitals and the Maine transplantation center(s). The purpose of the agreement shall be to describe the respective roles and responsibilities of the community and regional hospitals and the Maine transplantation center(s) in Maine's organ procurement system.

 2. **Regional Hospital Agreement** - This agreement shall be developed between regional hospitals and the Maine transplantation center(s). The purpose of the agreement shall be to describe the respective roles and responsibilities of the regional hospitals and the Maine transplantation center(s) In Maine's organ procurement system.

 B. **Community Hospital Agreements**: - The Community hospital agreement shall include, but not be limited to the following Items:

 1. Statement of purpose;

 2. Description of the types of patients covered by the agreement:

 a. Individuals who are under treatment at the community hospital and who subsequently are found to meet medical criteria for brain death and to be potential organ donors; and

 b. Patients who are received at community hospitals and In the judgment of the attending physician are brain dead, but remain potentially viable organ donors. These patients shall be stabilized for transfer to an appropriate hospital for the organ donations to be performed.

 3. Detailing the types of personnel having responsibilities In Implementing -the procedural aspects of the agreement.

 4. Description of procedural steps entailed In Implementing the agreement:

 a. Identification of potential donor;

 b. request permission of donation of organ(s);

 c. documentation of request for consent for the gift of the donor organs;

 d. notification of regional center of Impending potential donor transfer by community hospital representatives;

 e. community hospital transfer arrangements made;

 f. patient transfer;

 g. responsibilities of regional hospitals after transfer of patient; and

 h. responsibilities of regional hospitals regarding medical examiner cases.

 5. Protocol for reimbursement of organ procurement costs

 C. **Regional Hospital Agreement**

 The regional hospital agreement shall Include, but not be limited to, the following Items:

 1. Statement of purpose;

 2. Description of the types of patients covered by the agreement:

 a. Individuals who are under treatment at the regional hospital and who subsequently are found to meet medical criteria for brain death and to be potential organ donors;

 b. Patients who are received at the regional hospital and In the Judgment of the attending physician are brain dead, but remain potentially viable organ donors; and

 c. Patients who are transferred from community hospitals for the purpose of organ donation.

 3. Detailing of the types of personnel having responsibilities In Implementing the procedural aspects of the agreement.

 4. Description of the procedural steps entailed In Implementing the agreement:

 a. Identification of potential donor Including determination of brain death;

 b. request permission for donation of organs;

 c. documentation of request for consent for the gift of donor organ(s);

 d. continuing care protocols of the patient-donor In preparation of procurement attempt;

 e. detailing of hospital's responsibilities regarding medical examiner cases;

 f. medical protocols relating to procurement of organs; and

 g. notification of appropriate Individuals after completion.

 5. Protocol for reimbursement of organ procurement costs

**CHAPTER 3: TRAINING OF PERSONS WHO WILL PERFORM THE REQUEST FOR AN ANATOMICAL GIFT**

 A. all persons making requests for donations shall have received training in accordance with this rule.

 B. The attending physician, who may be accompanied by another hospital representative trained and designated to assist In making the request, shall notify the appropriate person or persons, as defined In 22 MRSA 52902 (2), of the death and request consent to an organ donation. If the attending physician Is the only physician available to make the determination of death or Is otherwise unavailable, then the hospital administrator or his designated representatives shall make the request for organ donation.

 C. Training for persons requesting organ donations shall Include but not be limited to:

 1. The legal requirements of the Chapter 710, the Uniform Anatomical Gift Act (22 MRSA §2901-2910) and the necessity for completion of the medical record regarding organ donation requests;

 2. Specifics of organ donation, Including: Identification of potential donors, medical uses of donated organs, general medical concepts Involved In organ transplantation, procedures for declaring brain death, the history and success of transplant programs, reimbursement mechanisms for expenses relating to organ retrieval and the existing network for the procurement of organs and the systems for allocating donated organs;

 3. A review of the psychological, social, ethical and religious factors affecting willingness to donate organs and resistance to organ donation, and a review of materials developed to train Individuals to request organ donation In an appropriate manner;

 4. The family's right to refuse and the need to respect this right; and

 5. Circumstances which result In the unsuitability of anatomical gifts.

 D. The Maine transplantation center shall have primary responsibility for coordinating the training of persons making the request for organ donation. Regional and community hospitals shall work cooperatively with the Maine transplantation center to ensure that appropriate community and regional hospital personnel are trained.

**CHAPTER 4: MONITORING MECHANISMS**

 This chapter outlines the monitoring mechanisms that will be utilized by the Department to ensure that the Intent of the statute is met.

 A. **Reporting Requirements of Hospitals**

 1. Effective January 1, 1987, when a request for an anatomical gift is made by hospital personnel, the request and its disposition shall be noted in the decedents medical record. The form that shall be utilized to report this request is attached as Appendix A of these rules.

 2. Hospitals shall report annually to the Department the number of requests for anatomical gifts made and the number of organs retrieved on the Department's supplement to the American Hospital Association's (AHA) Annual Survey of Hospitals. Effective January 1, 1987, hospitals will begin accumulating the Information necessary to develop this annual report. The Internal reporting form for hospitals and the AHA survey supplemental format that shall be used to provide the Department with this information are attached as Appendixes B and C respectively.

 3. Hospitals shall demonstrate compliance by maintaining a file, available for the Department's Division of Licensing and Certification review by March 1, 1987, Including the following:

 a. Inter-hospital agreements as specified by 22 MRSA §2910 Sub-§3; and

 b. a training curriculum for training of organ procurement requests.

 B. **Description of Department's Monitoring Mechanism**

 I. Each year the Department's Office of Data, Research, and Vital Statistics staff will compile death certificate information on primary cause of death data (Data Source: International Classification of Diseases, Ninth Revision, or subsequent updates) to identify decedents aged 1 through 55 that would be potential suitable donor candidates. The specific diagnostic classification categories and corresponding International Classification of Diseases numerical code groupings that will be utilized by Department staff for monitoring purposes are listed in Appendix D.

 2. Department Division of Licensing and Certification staff will conduct a limited record review in conjunction with the regular periodic licensure-related inspections of the hospital. This review will be limited to a review of the medical records of the decedents that have been Identified as potentially suitable donor candidates. Dependent on the number of records applicable to the facility, either a representative sample or all of the relevant records will be reviewed. This review will be designed to find out whether a request for organ donation in appropriate situations had been made. If applicable, Department staff will consult with hospital staff to examine why donation requests were not made.

 3. If Department staff discovered that hospital medical staff were not making organ donation requests In appropriate situations, the hospital's medical director/chief of staff and administrator will be notified in writing about the problem. Department staff recommendations on how to remedy the problem will also be made through this correspondence.

 4. Department staff will periodically analyze the annual reporting requirement data information obtained on the hospital licensure inspections, the Inter-hospital agreements and other relevant information. If, based on an analysis of this information, the Department determines that a major compliance problem exists, then this will be reported to the Human Resources Committee of the Maine Legislature. Any report submitted to the legislature will also include recommendations on how to rowdy these compliance problem(s).

 C. Effective Date of Regulations. The effective date of these regulations shall be January 1, 1987.

EFFECTIVE DATE (ELECTRONIC CONVERSION):

 May 5, 1996

APPENDIX A

PERMISSION FOR ORGAN DONATION BY NEXT OF KIN\*

Hospital Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I /we\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ of\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_(\_\_\_\_\_\_\_)\_

 next of kin/guardian street address town and state relationship to patient

hereby give my/our permission to\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and the medical staff thereof, to

 hospital name

authorize the removal and subsequent donation of the following organ (s ) or tissue(s)

 \_\_ any appropriate organ

\_\_kidney \_\_eye/cornea \_\_heart \_\_heart/lung \_\_liver \_\_pancreas \_\_bone

of\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_to be used for such purposes, Including organ transplant,

 name of patient/deceased

as\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_may deem best, including transfer of such organs to

 regional hospital name

medical Institutions located outside the State of Maine.

 Permission is further granted for the -transfer of the patient to the hospital where the removal of the above mentioned organ(s) will occur and for the performance of any procedures -the are determined necessary in association with the removal of these organs.

 It Is understood that if permission is given prior to the actual death of\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,

 patient name

It will become effective only upon such death; and such permission may be relied upon by the \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, members of its medical staff and any medical

 regional hospital name

institutions which may ultimately receive the organs unless said permission is revoked in writing prior to pronouncement of death and removal of the donated organs.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

signature of next of kin/guardian witness

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 street witness

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Witnessed to obtaining signature

 city state ZIP this\_\_\_\_\_\_ day of\_\_\_\_\_\_\_, 19

Permission obtained by

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Name title

\*The following is a list, in order of priority, of persons so authorized: patient's spouse, patient's adult son or daughter, patient's mother or father, patient's adult sister or brother, patient's guardian at the time of death, other person authorized to dispose of patient's body. (See 22 MRSA §2902 (21).)

APPENDIX B

 Record of Request for an anatomical gift

 Internal Reporting Mechanism for hospitals

 \*\*\*\*Contact Agency for copy of this form\*\*\*\*

APPENDIX C

MAINE DEPARTMENT OF HEALTH AND HUMAN SERVICES

REQUESTS FOR ANATOMICAL GIFTS - ANNUAL REPORT\*

 Completion of the following questions fulfills your facilities requirement to report data on the number of requests for organ donations made by your facility annually under Public Law, Chapter 574.

 1. Please report the number of requests and the number of consents obtained by your facility for anatomical donations during your reporting period pursuant to Public Law, Chapter 574.

 a. \_\_\_\_\_\_\_\_ # of requests.

 b. \_\_\_\_\_\_\_\_ # of patients for whom consent was granted.

 IF YOUR FACILITY DID NOT PROCURE ORGANS DURING THE PAST YEAR, YOU HAVE COMPLETED THE REPORTING REQUIREMENTS UNDER PUBLIC LAW, CHAPTER 574. IF YOUR FACILITY PROCURED ORGANS DURING THE PAST YEAR, PLEASE CONTINUE.

 2. As a result of the requests made for anatomical gifts:

 a. how many donors provided an anatomical gift?\_\_\_\_\_\_\_\_\_\_\_

 b. how many organs and what type of organs were procured?

 Type of Number of Type of Number of Type of Number of

 Organ Organs Organ Organs Organs Organs

 \_ kidney \_\_\_\_\_\_ \_ heart \_\_\_\_\_ \_ heart/lung \_\_\_\_\_

 \_ liver \_\_\_\_\_\_ \_ cornea \_\_\_\_\_ \_ pancreas \_\_\_\_\_

 \_ bone marrow\_\_\_\_\_ \_ skin \_\_\_\_\_ \_ blood \_\_\_\_\_

 \_ bone \_\_\_\_\_ \_ other (specify)\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_

THANK YOU FOR YOUR COOPERATION

If you have any questions concerning this survey, please contact: Deborah Smiley at 287-3001

\*These questions will be added to the Department's annual American Hospital Association Survey Supplement.

APPENDIX D

LIST OF INTERNATIONAL CLASSIFICATION OF DISEASE (ICD) DIAGNOSTIC CLASSIFICATION CATEGORIES AND NUMERICAL CODE GROUPINGS UTILIZED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES FOR MONITORING PURPOSES

The following is a list of ICD diagnostic classification categories and corresponding numerical code groupings that will be utilized for monitoring purposes. This represents an Illustrative list of diagnostic categories that the Department, based on the recommendations of the Organ Transplants Required Request Advisory Committee, believes organ donation requests should be made (when a brain dead individual is a patient at a Maine hospital).

Current Diagnostic Classification Cateqory\* Current ICD Numerical Code Grouping\*\*

Fracture of skull 800 - 04

Fracture of rock trunk 805 - 09

Fracture of upper limbs 810 - 19

Fracture of lower limbs 820 - 29

Dislocation 830 - 39

Sprains and strains of shoulder and upper arm 840 - 48

Intercranial Injury, excluding those with skull fracture 850 - 54

Internal injury of chest, abdomen and pelvis 850 - 69

Open wound of head, neck and trunk 870 - 79

Open wound of upper limb 880 - 87

Open wound of lower limb 890 - 97

Injury to blood vessels 900 - 04

Late effects of Injuries, poisonings, poisonings, toxic

 effects and other external causes 905 - 09

Contusion of scalp, and neck, except eye(s) 905 - 24

Crushing injury 925 - 29

Effects of foreign body orifice 930 - 39

Burns 940 - 49

Injury to nerves and spinal cord 950 - 57

Certain traumatic complications and unspecified Injuries 958 - 59

Poisoning by Drugs Medicaments, and

 Biological substances 960 - 79

Toxic effects of substances chiefly non-medicinal

 as to source 980 - 89

Other and unspecified effects of external causes 990 - 95

Complications of surgical and medical care

 not elsewhere classified 996 - 99

Subarachnoid hemorrhage 430

Intracerebral hemorrhage 431

Other and unspecified intracranial hemorrhage 432

Notes for Coders

 \*These are the ICD-9 diagnostic classification categories. When these classifications are updated (ICD-1O is scheduled to be published in 1993), Department staff will update these diagnostic classification and numerical codes.

 \*\*For ICD-9 numerical codes, # 800- 999, nature of injury codes (and not external cause codes) are to be utilized. For ICD-9 codes #430- 32, "underlying" codes are to be utilized.

Statutory Authority: Public Law, Chapter 574 as passed by the second .session of the 112th Legislature provides the statutory authority for these rules (22 MRSA §2904 Sub-§5, 2907 Sub-§4, and §2910). Additionally, 22 MRSA §42 authorizes the Department to promulgate rules and regulations for the successful operation of the health laws.

APAO WORD VERSION CONVERSION (IF NEEDED) AND ACCESSIBILITY CHECK: July 16, 2025