ANATOMICAL GIFTS REPORT TO THE LEGISLATURE

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JANUARY 4, 2006

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January 4, 2006

Senator Arthur F. Mayo III, Co-Chair
Representative Hannah Pingree, Co-Chair
Committee on Health and Human Services
State House
Augusta, ME 04333

Re: Report on Anatomical Gifts

Dear Senator Mayo, Representative Pingree, and Members of the Committee:

With this letter I am transmitting to you a Legislative Report on Anatomical Gifts that was prepared by a team of professionals within the Maine Center for Disease Control and Prevention (formerly the Maine Bureau of Health) in response to legislation sponsored by Representative Barstow (Legislative Document 55) and endorsed by your committee in the last legislative session. That legislation required the Department of Health and Human Services (DHHS) to review current departmental rules relevant to anatomical gifts, as well as to explore the issues and concerns associated with anatomical gifts, and to produce a report for the Legislature by January 2006.

The impetus for this effort came from events dating back several years when the Chief Medical Examiner's Office (MEO) was involved in the obtaining of brains of deceased persons for the purpose of research by a private research institution. Subsequently there were criticisms of the way informed consent was obtained for the transfer of the brains from the MEO to the research institution. Some of the families of the deceased whose brains were used for research have sought redress through legal action.

In December 2004 the Attorney General's Office (the Administrative home of the MEO) developed a policy protocol that standardized the methods of obtaining consent for the MEO and those seeking organs or tissues for research or transplant purposes to follow. At that time, at the request of the Attorney General (AG) the DHHS-Bureau of Health (BOH) became involved in reviewing that protocol. The request was made because the AG was aware that DHHS already had promulgated rules on the same subject in 1987 through the then Office of Research, Data and Vital Statistics (ORDVS) in the then BOH. These Rules were known to be outdated due to changes in methods of organ procurement for transplant that had occurred at

the federal level following the original promulgation. As I was on medical leave in December 2004, Dr. Lani Graham, the Acting Director for the BOH, assumed leadership for this issue, which she retained throughout the effort at my request.

Recognizing the need to update the Rules, and in response to the Legislature, an Anatomical Gifts team was formed within DHHS, made up of four members of DHHS (Lani Graham, Elana Jellison, Don Lemieux, and Lorraine Wilson), and a representative of the AG's office, Paul Gauvreau. The team has met numerous times. In addition, a stakeholder group of advisors has met with the AGT as required by the legislation and considerable information has been received from groups outside of state government. As a result the AGT has developed recommendations for this committee, which reflect the input of stakeholders and the various challenges that were identified. This area has been revealed to be a very complex arena with multiple stakeholders and multiple concerns. The most significant issues that have been identified are laid out as clearly as possible in the Issues and Recommendations contained in this report.

Representative Barstow, the original sponsor of the enabling legislation, received a briefing on this report on December 22nd, 2005, from Dr. Lani Graham. Although he did not have time to review the report in its entirety, he indicated he was generally satisfied with the recommendations.

Please let me know if you have any questions or concerns about this report or if the committee would like a more formal presentation of the findings presented here.

Thank you for your interest and attention.

Sincerely,

Dora Anne Mills

Dora Anne Mills, MD, MPH
Director
Maine Center for Disease Control and Prevention

cc: Lucky Hollander, Legislative Liaison

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Anatomical Gifts: Executive Summary

As a result of legislation that was passed during the last Legislative session, the Department of Health and Human Services (DHHS), Maine Center for Disease Control and Prevention (formerly known as the Bureau of Health), was given the task of reviewing current Departmental Rules relevant to anatomical gifts and to produce a report for the Legislature regarding issues of concern related to anatomical gifts. An Anatomical Gifts Team (AGT) was assembled and met over a six-month period to develop the report. Stakeholders, as had been identified in the Legislation, were consulted and many complex problems were identified.

In brief the AGT is recommending that the current Department of Health and Human Services (DHHS) Rules be repealed as obsolete. In view of the fact that current statutory provisions are also obsolete or incomplete and require revision, the AGT is not able to recommend that DHHS go forward with comprehensive new Rules related to anatomical gifts at this time. However, in recognition of the fact that Maine people have expressed particular concern about the issue of informed consent, and that this issue continues to be largely unaddressed in the area of research, the AGT is recommending limited rulemaking directed specifically at the issue of informed consent. This would be a temporary solution in the absence of adequate statutory support and without a method of assuring compliance. Going forward with comprehensive statutory changes at this time is precluded both by the nature of this legislative session (emergency only) and by the fact that the federal government is expected to release a new Model Uniform Gifts Act within the next year that would be very useful for the Legislature to contemplate before major revisions are undertaken. Comprehensive rulemaking would be recommended to follow the statutory revisions. And in fact it is contemplated that several sets of comprehensive Rules would likely follow the statutory revisions. This rulemaking might or might not properly belong to the purview of the Maine Centers for Disease Control and Prevention (MCDC).

This area has been revealed to be a very complex arena with multiple stakeholders and multiple concerns. The most significant issues that have been identified are laid out as clearly as possible in the Issues and Recommendations that follow.

Issues for Legislative Consideration and Resolution

Issue: Should the current DHHS Rules be repealed?
Pros:

- DHHS did rulemaking in 1987 and these Rules are not compatible with current practice and are at odds with federal regulations.
- The presence of "Rules" suggests that DHHS is indeed monitoring the process of anatomical gifts, though in reality it is not.
- Despite the absence of effective State regulation, the whole Transplant process is working well in Maine as regulated by the federal government.
- Anatomical gifts for transplant currently represent the bulk of anatomical gifts in the state.
- There is no enforcement or monitoring of the current Rules

Cons:

- The presence of DHHS Rules provides some evidence of state concern about the process of informed consent

Recommendation: At a minimum, current DHHS Rules should be repealed, as they serve no effective purpose, send a message that something is being done when it isn't and are potentially confusing.

Issue: Should DHHS do rulemaking to strengthen procedures with respect to anatomical gifts from deceased persons for research and educational purposes?
Pros:

- There are multiple issues in this arena that need to be resolved with clarity and consistency.
- At present, outside of the policy protocol establishing procedures for the procurement of anatomical gifts through the Medical Examiner's Office set up by the Attorney General (AG), there is virtually no state regulation of the process of obtaining anatomical gifts for research or education.
- There is limited federal regulation of anatomical gifts for research and education.
- There is the possibility that even after death some organs and tissues could also be used for commercial purposes.

Cons:

- There is a small risk that DHHS rulemaking could inadvertently adversely affect the obtaining of gifts for transplant.
- This will require the setting up of a new state system including a process of registration, methods of assuring that those who are registered are following procedures, and methods of handling complaints from citizens and agencies alike.
- It will be necessary to obtain funding to support this process, as it cannot be done within existing resources.
- Due to the need for financial support and an adequate statutory base, this rulemaking should not proceed at this time.

Recommendation: DHHS should proceed with rulemaking for anatomical gifts from deceased persons for transplant, research, and educational purposes following necessary statutory assessment and revisions. The Legislature should either allocate new funding for the registration/enforcement process or enable the establishment of a fee system from Registrants to support the process.

Issue: Should any DHHS rulemaking for Anatomical Gifts exclude gifts that are destined for Transplant and apply only to gifts for research or education?
Pros:

- The current process for obtaining anatomical gifts for transplant is heavily regulated at the federal level and is currently working well in Maine.
- Lives depend very immediately on the current well-understood process for obtaining organs and tissues for transplant. There is a small risk that new rulemaking applied to the transplant process could adversely affect this important medical effort.

Cons:

- It will be confusing in itself to have two different processes/procedures, one of which is state regulated and the other regulated only from the federal level.
- It is not uncommon for anatomical gifts for research or education and those for transplant to come from the same donor. Two different procedures would be cumbersome.

Recommendation: If DHHS proceeds with any rulemaking at all, it should proceed with rulemaking that covers anatomical gifts from deceased persons for both research/education and transplant purposes.

Issue: Are other changes to the current Maine Uniform Anatomical Gifts Act (MUAGA) needed?
Pros:

- It would be less confusing if there were consistency in Maine statute regarding what entities, individuals, and purposes are covered under MUAGA.
- At present there are at least three different methods and requirements associated with procurement of anatomical gift depending on whether the gift is to be used for transplant, research or education. The first is heavily regulated, the latter two have very little regulation associated with procurement.
- The requirement for witness to signature for informed consent differs from two to one to none.
- MUAGA is not consistent with some other aspects of Maine law in that registered domestic partners do not have the authority to make decisions for their partners regarding anatomical gifts.
- MUAGA (passed in 1969) could be brought completely in line with the federal Organ Transplant Act (passed in 1984) regulating transplants.

Cons:

- It might be preferable to await the assessment with regard to anatomical gifts from living donors for research and educational purposes before making major statutory changes. That way all changes could be made at the same time.
- The current situation is working well for organ procurement for transplant.
- The current Maine statute has been updated several times such that its most antiquated aspects have been brought into line with federal government recommendations.
- It is expected that the Federal Government will publish a new Uniform Anatomical Gifts Act in 2006 with the expectation that states will begin adoption in 2007. This will cover informed consent for anatomical gifts for both research and transplant.

Recommendation: The Maine Legislature should not attempt to revise MUAGA until the new federal model act is available (expected sometime in 2006).

Issue: Should DHHS proceed with limited rulemaking in the absence of an appropriate statutory base and without financial support to assure available personnel to monitor compliance?

Pros:

- At this time there are no state Rules or procedures to guide Agencies or Organizations regarding the obtaining of informed consent from donors of anatomical gifts.
- Recently there was a great deal of concern expressed by Maine people regarding the way in which informed consent for an anatomical gift for research purposes was obtained through the Medical Examiner's office.
- Even limited Rules can provide some guidance to research institutions on the subject of obtaining informed consent for anatomical gifts.
- The bulk of anatomical gifts are not obtained through the Medical Examiner's office.
- It is unlikely that comprehensive rulemaking can be accomplished until after the next Legislative session, meaning that the new Rules would not go into effect until late 2007, assuming new legislation passed in the 2007 session.

Cons

- Without proper statutory authority Agencies or Organizations may ignore the Rules or argue that they are improper.
- Without registration and financially supported staff, there will be no assurance of compliance with these Rules.
- The time and effort it takes to go through a rulemaking process is considerable, it might make better sense to do the effort only once.
- Limited Rules as contemplated would probably only be in place for about 18 months.

Recommendation: DHHS should proceed with limited rulemaking in the spring of 2006, using the existing statutes, to provide specific guidance to Agencies and Organizations in the arena of Informed Consent.

Issue: Should DHHS rulemaking apply to both living and deceased donors of anatomical gifts for research/education and transplant?

Pros:

- There are few current state regulations that apply to the use of organs or tissues harvested from living donors in the course of medical treatment—for example a diseased gallbladder removed or a tumor. One of the exceptions to that are regulations around the use of fetal tissue harvested in the course of a miscarriage.
- Anecdotal evidence suggests that there are tissues and organs being harvested from living donors and used for research or education without the knowledge of the donor.
- Although there is clear federal regulation around the use of organs or tissues from living donors for research, there is no follow-up of that at the state level. There is also no federal legislation that relates to education (display of tumors etc.)
- Medical research is becoming more prevalent and this area is likely to grow quickly.
- In view of recent medical advances, there are now many uses of human tissue, including treatment as well as research, education and transplant. The value is increasing rapidly and there is limited understanding of the process of informed consent across these areas.

Cons:

- Once again the process for obtaining an anatomical gift for transplant from a living donor is already a highly regulated process.
- Recent changes in law to facilitate bequeaths from living donors for transplant purposes after death (the motor vehicle license registration process) could be put at risk.
- This is a very complex issue that, as yet, is not completely understood.
- In the research/education/treatment arena of living donation there are multiple stakeholders (individual physicians, the general public and others) who have not yet had a chance to consider this issue and would also be quite difficult to regulate.
- There are current federal regulations that require the establishment of an Internal Review Board to assess all research involving human subjects. This provides some protections in this arena.

Recommendation: DHHS should not attempt to do rulemaking on anatomical gifts from living donors at this time. The Legislature may wish to consider establishing a panel to assess the current status of this problem and make further recommendations.

Issue: Should penalties be available to sanction individuals or entities that violate Maine Law/Rule with respect to anatomical gifts?

Pros:

- Although the situation is expected to be rare, we have seen evidence that serious mistakes can be made with respect to anatomical gifts.
- As with enforcement, the very existence of penalties reminds individuals and entities that it is important to stay within the standards set by Maine people.
- If some form of redress is not available, those who believe they have been damaged will seek relief in the courts on their own.

- By default the current law in Maine could result in criminal penalties being applied to Institutions seeking anatomical gifts.

Cons:

- Very important work may be jeopardized by inappropriate application of penalties.

Recommendation: Penalties should be available to sanction individuals or entities that violate Maine Law/Rule with respect to anatomical gifts. At a minimum the Legislature should authorize the Attorney General to initiate requests for injunctive relief to address significant violations of the Maine organ/tissue procurement process.

Issue: Should DHHS revise its Rules on the disposition of human remains?

Pros:

- The current Rules do not cover the contracting out of disposal of Bio Hazardous material that has occurred in recent times, therefore the transportation of human remains in that context is not regulated.
- If new comprehensive Rules for anatomical gifts were promulgated, concerns would likely arise around the final disposition and transportation of gifts for research and education.
- There is evidence that the current Rules regarding disposition of human remains are not always well understood or accepted by the Agencies to which they apply.
- Current Rules do not take into account the transporting of a body for a private autopsy.

Cons:

- This would require considerable staff time and effort that might be better spent in other ways.
- It would be better to revise these Rules in tandem with any new Rules that might be drafted for anatomical gifts after statutory revisions.

Recommendation: DHHS should revise its Rules on the disposition of human remains, but this should be done in tandem with any comprehensive new Rules regarding anatomical gifts and following any revisions to the MUAGA statute and other related statutes.

Anatomical Gifts: Legislative Report

Introduction

In the 2005 Legislative session Legislative Document (LD 55) required the Department of Health and Human Services (DHHS), Bureau of Health (BOH), now The Maine Center for Disease Control and Prevention (MCDC) to review current Departmental Rules relevant to Anatomical Gifts, as well as explore the issues and concerns associated with Anatomical gifts, and to produce a report for the Legislature by January 2006.

The impetus for this effort came from events dating back several years when the Chief Medical Examiner's Office (MEO) was involved in the obtaining of brains of deceased persons for the purpose of research by a private research institution. Subsequently there were criticisms of the way informed consent was obtained for the transfer of the brains from the MEO to the research institution. Some of the families of the deceased whose brains were used for research have sought redress through legal action.

In December 2004 the Attorney General's Office (the Administrative home of the MEO) developed a policy protocol that standardized the methods of obtaining consent for the MEO and those seeking organs or tissues for research or transplant purposes to follow. At that time, at the request of the Attorney General (AG) the DHHS-public health became involved in reviewing that protocol. The request was made because the AG was aware that DHHS already had promulgated Rules on the same subject in 1987 through the then Office of Research, Data and Vital Statistics (ORDVS) in the then BOH. These Rules were known to be outdated due to changes in methods of organ procurement for transplant that had occurred at the federal level following the original promulgation

Recognizing the need to update the Rules, and in response to the Legislature, an Anatomical Gifts team was formed within DHHS, made up of four members of DHHS (Lani Graham, Elana Jellison, Don Lemieux, and Lorraine Wilson), and a representative of the AG's office, Paul Gauvreau. The team has met numerous times. Initially it was thought that the best approach would be to simply revise the BOH Rules by combining remnants of them with the AG's policy protocol. New Rules were in fact drafted and sent out to a list of stakeholders that had been generated. A stakeholder meeting was held in Augusta on 8/4/05 from 1-4PM and the preliminary draft was discussed at length along with legislative issues that had been identified. All the significant issues were summarized and sent out to the stakeholders along with a letter indicating that the DHHS team was considering not going forward with Rulemaking until further direction was obtained from the Legislature. A month for further input from stakeholders was allocated. Additional comments were received, but there were no comments adverse to the idea of delaying comprehensive Rulemaking. The DHHS team met again on four more occasions to develop recommendations for the Legislature that reflected the input of stakeholders and the various challenges that were identified.

Legal and Legislative Issues Pertaining To Draft Rules Relating to Maine Uniform Anatomical Gift Act

The Department of Health and Human Services is in the process of revising its existing rules governing organ and tissue donation in the State of Maine. The 122nd Maine Legislature enacted a resolve[1] which required the Department to review its rules regarding the responsibilities of hospitals and physicians in implementing the Maine Uniform Anatomical Gift Act, including the congruity of the rules to present practice regarding organ and tissue procurement, informed consent, conflict of interest and potential extension of the rules to research facilities not presently subject to Departmental regulation. The Department's rules are considered routine, technical rules under the Maine Administrative Procedures Act. In accordance with its legislative charge, the Department has prepared a preliminary draft revision of its existing rules and is planning to meet with stakeholders on August 4, 2005 to gather discussion and comment regarding the proposed rule revisions. The Department is required to report its recommendations to the Joint Standing Committee on Health and Human Services no later than January 31, 2006.

In the course of its rule review, the Department has identified legal and legislative issues which may be referred to the Legislature in the Department's report next January. The issues are as follows:

1. Certification

The draft rules propose that all Recovery Agencies which engage in organ or tissue procurement in the State of Maine properly register with the Department. In order to secure registration, a Recovery Agency must demonstrate it is in good professional standing, knowledgeable and capable of implementing the Department's Organ and Tissue Donation rules, has undertaken appropriate staff trainings and, in the case of federally designated Recovery Agencies, is in good standing with the relevant regulatory agency, either CMS or the U.S. Food and Drug Administration.

The Maine Uniform Anatomical Gift Act ("hereinafter "Uniform Act"), 22 M.R.S.A. Ch. 710, §§ 2901-2911, does not explicitly confer authority upon the Department to require registration of Recovery Agencies. However, 22 M.R.S.A. §2910(5) authorizes the Department to adopt any rules necessary to conduct training of persons who perform anatomical gift requests related to hospital-based deaths. 22 M.R.S.A. §2902(5) governing the manner of executing anatomical gifts, applies to all anatomical gifts, including gifts executed outside hospital settings.

The Department has determined that a registration program is necessary to assure all entities which engage in organ and tissue procurement in the State of Maine are properly trained and capable of complying with the Uniform Act. It appears the Department, pursuant to its general rulemaking authority established by 22 M.R.S.A. §42(1)[2], has statutory authority to impose a registration requirement upon recovery agencies which practice in the State of Maine.

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[1] 2005 Resolves, ch. 27

[2] 22 M.R.S.A.A. §42(1) (2004) provides in pertinent part:

2. Registration fees

A related issue is whether the Department has statutory authority to impose registration fees upon Recovery Agencies which propose to engage in organ and tissue procurement in Maine. As a practical matter, the Department will require the imposition of registration fees upon Recovery Agencies to properly administer and monitor compliance with provisions of the Uniform Act, and it's implementing rules, since the Department lacks sufficient discretionary revenue to sustain a position to implement the Act. It would appear the Department has the required rulemaking authority to include a registration fee schedule in its proposed rules, but it may be appropriate to refer this matter to the Legislature for further direction and guidance.

3. Enforcement and Sanctions

Civil Violations

The Maine Uniform Anatomical Gift Act does not provide for specific penalties for violation of the Act's provisions. As a result, the general penalty provisions established pursuant to Title 22 are applicable to the proposed rules. 22 M.R.S.A. §47 (2004) establishes Class E misdemeanor criminal offenses[3] for the following acts:

1) A person who hinders, obstructs or interferes with a departmental agent in the performance of his or her duties commits a Class E crime;

2) A person who violates a Departmental order, rule or violation made for the Protection of life or health commits a Class E crime;

3) A person who intentionally or knowingly fails, neglects, or refuses to perform any duty imposed upon him or her by Title 22 commits a Class E offense.

Except for the specific intent offense of failing to abide by a statutory duty established under Title 22, all other statutory or rule violations are defined as strict liability crimes under the Maine Criminal Code.[4]

Given the range of conduct subject to the proposed rules, it is recommended the Legislature consider authorizing the Department to impose civil penalties for rule violations. At the present time, the Department has no means of penalizing violations of its Organ and Tissue Donation rules, other than to refer violations to the Attorney General for potential criminal prosecution. Although certain violations of the Department's rules may warrant potential

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The department shall issue rules and regulations considered necessary and proper for the protection of life, health and welfare, and the successful operation of the health and welfare laws.

[3] A Class E criminal offense is punishable by imprisonment for a period not to exceed six months, a fine to exceed $1,000, or both.

[4] *See* 17-A §34(4-A) & 22 M.R.S.A. §47(4) (2004).

criminal prosecution, it seems apparent that technical or minor violations would warrant less severe enforcement action.

However, the Legislature should also review whether to authorize more severe criminal sanctions for egregious violations of the Department's rules. For example, a pattern of utter disregard for informed consent, the deliberate failure to register with the Department prior to seeking anatomical gifts, or the provision of compensation in exchange for securing anatomical gifts may warrant criminal prosecution greater than a Class E misdemeanor.

Accordingly it is recommended that the Department, when reporting back to the Legislature regarding its rulemaking progress, request the Legislature to review whether to grant the Department authority to pursue civil violations or more significant criminal offenses arising from the violation of the Department's rules.

Injunctive relief

In order to facilitate expeditious enforcement of the Department's Organ and Tissue Donation rules, the draft rules authorize the Department to refer to the Office of Attorney General rule violations for injunctive relief. Although the Department has existing statutory authority to refer rule violations to the Attorney General, it is proposed the Legislature specifically grant the Attorney General the authority to pursue injunctive relief in the event of rule violations. Generally, an applicant for injunctive relief must demonstrate to the motion court the following elements:

a) The petitioning party will experience irreparable harm if injunctive relief is not granted;

b) the petitioner's injuries, in the event injunctive relief were not granted, outweigh the harm to respondent in the event relief is granted;

c) the petitioner has demonstrated a likelihood it will prevail on the merits of its claim; and

d) the public interest will not be adversely affected by the award of injunctive relief.

Ingraham v. University of Maine at Orono, 44a A.2d 691, 693 (Me. 1982).

However, in the event the Legislature specifically authorizes the Attorney General to seek injunctive relief in the event of a statutory or rule violation, the State is not required to demonstrate irreparable injury or prevail on the competing harms issue because the Legislature has already determined that injunctive relief is an appropriate intervention. *U.V. Industries Inc. v. Posner,* 466 F. Supp. 1251, 1255 (D.C. Me. 1979). Accordingly, a statutory provision which allows the Department to refer a violation of its implementing regulations to the Attorney General for injunctive relief would facilitate the expeditious issuance of court injunctions in appropriate cases.

4. Statutory Consistency Relating to the Witnessing of Anatomical Gifts

During the past legislative session, the Legislature amended the Uniform Act to eliminate the requirement that anatomical gifts executed by means of a donor card be witnessed by two individuals.[5] Under present Maine law, an individual may execute an anatomical gift by means of a will, to become effective upon death. [6] Any testamentary anatomical gift would need to be duly witnessed. [7] However, a person may also make an anatomical gift by other means. 22 M.R.S.A. §2904(2)(2004) provides that, in addition to making an anatomical gift pursuant to Section 2902 of the Uniform Act, a person may make an anatomical gift by document other than a will. The gift becomes effective upon the death of the donor and acceptance by the donee. The statute also allows a donor to execute an anatomical gift by the following means:

(1) to execute a donor card signed by the donor;

(2) to participate in an electronic registry in which the donor is included; or

(3) to include on the donor's driver's license an organ donor decal, code or notation in accordance with 29-A M.R.S.A. § 1402-A.

It is likely that the Uniform Act does not establish the exhaustive means by which an anatomical gift may be accomplished. Section 2904(2) of the Act provides "a gift of any part of the body *under Section 2902, subsection 1*, may be made by document other than will" and granted post mortem effect. However, this language does not foreclose the possibility that Maine law authorizes the execution of anatomical gifts by other means.

At the outset, the Uniform Act does not define the term "anatomical gift". Although it is clear the Uniform Act only authorizes anatomical gifts which are effective upon the donor's death, it appears anatomical gifts outside the Uniform Act are permitted. Indeed 22 M.R.S.A. §2881 (2004) provides as follows:

> If any resident of the State requests or consents that after his death his body may be delivered to a regular physician or surgeon for the advancement of anatomical science, it may be used for that purpose, unless some kindred or family connection makes objection.

Section 2881 was enacted well before Maine adopted the Uniform Act.[8] Unlike the Uniform Act, which requires a written instrument to effectuate an anatomical gift, Section 2881 authorizes a person to consent to or request the use of his or her body for the advancement of anatomical science after the person's death , provided the person was a resident of the State at the time of the request. The statute does not impose a witness attestation requirement.

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[5] *See* P.L. 2005, c. 208, §1.
[6] *See* 22 M.R.S.A. §2904 (1) (2004).
[7] *See* 18-A M.R.S.A. §2-502.
[8] The statute was included in the 1954 codification of the Maine Revised Statutes. *See* R.S. 1954, c.66, §10.

The Uniform Act appears inconsistent with significant portions of Section 2881. Although both the Uniform Act, which authorizes anatomical gifts by means of a will, donor card, or other documents, and Section 2881, which authorizes a resident to request or consent to the use of his or her body for purposes of anatomical science, defer the effective date of the gift until after death, Section 2881 does not require a written instrument for the gift to be effective. Moreover, Section 2881 allows the donor's intent to be overridden upon objection from "some kindred or family connection", in contrast to the revised Uniform Act, which prohibits next of kin from overriding donor intent. It is not precisely clear what is meant by the term "kindred or family connection". Indeed, the cohort of individuals subject to this description is likely broader than the classes of individuals established by the Uniform Act authorized to approve an anatomical gift of the decedent's organs or tissue. [9]

Although anatomical gifts executed in accordance with the Uniform Act may only be effective at death, it appears a donor may also be able to execute an *inter vivos* anatomical gift by means of an advance directive or durable power of attorney. An attorney-in-fact granted a durable power of attorney over another appears able to execute an anatomical gift on behalf of the principal, depending upon the wording of the power of attorney. Furthermore, it appears an agent authorized to make health care decisions pursuant to an advance directive may be authorized to execute anatomical gifts on behalf of the principal, depending upon the wording of the advance directive. 18-A M.R.S.A. §5-802(b) provides:

> An adult or emancipated minor with capacity may execute a power of attorney for health care, which may authorize the agent to make any health-care decision the principal could have made while having capacity.

A health care directive must be duly signed by both the principal and two witnesses.[10] Similarly, a durable power of attorney must be witnessed by two disinterested individuals.[11] A will must also be witnessed by two disinterested individuals at the time of its execution.[12]

It appears the Legislature eliminated the witness requirement for the execution of anatomical gifts by such "other documents" as donor cards, drivers' licenses and electronic donor registries in order to facilitate the execution of anatomical gifts. Nevertheless, it now appears an individual may execute an anatomical gift by means of alternative documents, some of which require witness attestation (wills, durable power of attorney, advance directive), some of which do not (donor cards, driver's licenses, electronic donor registry), and may also request or consent to the use of his or her body for anatomical science without any instrument at all (Section 2881). This discrepancy in the manner in which anatomical gifts may be executed may be an appropriate subject for legislative review.

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[9] *See* 22 M.R.S.A. §2902(2).
[10] 18-A M.R.S.A. § 5-802(b)
[11] 18-A M.R.S.A. €5-506(b).
[12] 18-A M.R.S.A. §2-502.

5. Revisions in federal Organ Procurement Protocol

At the time Maine adopted the Uniform Anatomical Gift Act in 1969[13] hospitals were at the epicenter of organ procurement. Accordingly, the Maine Act required, for all hospital deaths, a specific protocol governing approaching next of kin in the event the decedent had not executed an *inter vivos* anatomical gift. [14] Hospitals were required to execute inter-hospital agreements to establish protocols for retrieval and transportation of body parts determined suitable for transplantation. Hospitals were required to report annually to the Department regarding the number of anatomical gifts made and organs retrieved for transplantation.

However, the 1984 Organ Transplant Act[15] completely restructured the process for organ procurement and transplantation in the United States, and required hospitals which participate in the federal Medicaid and Medicare programs to join organ procurement organization networks. Under the new OPO process, hospitals are required to enter into regional organ procurement organizations which establish the medical criteria for organ transplantation. The OTPN regulations establish criteria for identification of potential organ donors and recipients, the organ procurement process, the training of individuals engaged in organ procurement, the transportation of body parts for transplantation, the allocation of organs for transplantation, and the evaluation of organ transplantation policies. Maine hospitals participate in the regional organ transplantation network organized by the New England Organ Bank.

In light of the profound changes in organ procurement and transplantation policy in the U.S., the question arises as to whether the Legislature should revise the Anatomical Gift Act to conform statutory responsibilities to present practice.

6. Donation of Organs and Tissue for Medical Science and Education

The primary emphasis of the regional organ procurement organizations is to foster organ transplantation. There has evolved a comprehensive array of regulations governing organ transplantation to assure rigorous adherence to best medical practices and promote an equitable allocation of scare resources. In enacting the Maine Uniform Anatomical Gift Act, it appears the Legislature was focused upon establishing regulatory criteria governing anatomical gifts which were to become effective upon the death of the donor. Indeed, prior to the initial promulgation of the Uniform Anatomical Gift Act in 1968, the law was unsettled regarding legal rights to the decedents' body. The Uniform Act clarified this fundamental issue by determining that any adult person has the power to donate his or her own body upon death to a medical facility or to a physician for use for medical purposes, including research and organ transplantation. The Uniform Act also established a mechanism for legal surrogates to exercise anatomical gifts upon the death of the putative donor.

It appears the thrust of the Department's existing regulations apply to anatomical gifts for the purpose of organ transplantation. The DHHS Working Group tasked with developing revised

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[13] *See* P.L. 1969, c. 193
[14] *See* 22 M.R.S.A. §2910(1).
[15] See 42 U.S.C. Ch. 6A, Subchapter II.

rules has raised the issue of the efficacy of the regulatory environment pertaining to anatomical gifts for research purposes.

The U.S. Dept. of Heath and Human Services, Office of Inspector General, conducted a review of informed consent in tissue donation practices in January, 2001. The Inspector General voiced concerns about the commercialization of tissue banking and the methods used by recovery agencies in approaching next of kin for potential tissue donations. The Inspector General concluded federal laws and regulations do not address the manner in which tissue banks obtain consent, and the States' Uniform Anatomical Gift Acts do not address the nature of information which tissue banks should provide in soliciting consent. The Inspector General noted:

> Tissue banking and processing practices have gradually diverged from Donor families' expectations in recent years. The tissue banking industry has expanded and become more complex and costly. New ways of using tissue for medical treatment have been developed. ..[D]espite these changes, the industry's foundation remains that of human tissue altruistically donated by individuals and their families at an extraordinarily sensitive time. The special nature of this product, and the circumstances under which it is made available, call for steps to be taken above and beyond those that would apply to most other business or philanthropic enterprises.

This is not to suggest the field of organ/tissue for medical science is bereft of federal regulation. Two principal sources of federal regulation are (1) the U.S. Dept. of Health and Human Services Office of Human Research Protections ("OHRP" and (2) the U.S. Food and Drug Administration ("FDA". The OHRP administers federal regulations which govern federally funded or supported research on human subjects. [16] The OHRP regulations adopt the "Common Rule", and are applicable to all research involving human subjects conducted, supported, or otherwise subject to federal regulations. All federally supported medical research must provide assurances that the applicable research institution abides by relevant federal regulations and ethical principles in the conduct of medical research on human subjects. A main function of the Common Rule is to afford a mechanism under which research on human subjects is to be reviewed, approved and monitored by an Institutional Review Board ("IRB"), an independent ethical body to be established pursuant to federal regulations.[17] Among the criteria which an IRB must consider in deciding whether to approve a research project are (1) the nature of risks to the human subject; (2) equitable selection of research subjects; (3) informed consent to be sought from prospective subject or his/her legal representative; (4) documentation of informed consent; (5) monitoring of appropriate data to ensure the safety of the subject and (6) where appropriate, development of adequate provisions to protect the privacy of subjects and maintain confidentiality of individually identifiable research data.

The U.S. Food and Drug Administration has adopted regulations which are substantially similar to the Common Rule.[18] The FDA has jurisdiction to regulate research based upon its

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[16] *See* 45 C.F.R. Part 46.
[17] 45 C.F.R. §46.107.
[18] *See* 21 C.F.R Parts 50, 54, 56, 312 and 812.

responsibility to monitor the interstate shipment of investigational drugs and devices. The primary goal of the FDA regulatory regime is to assure the integrity of data collected during the investigatory phase of development of an FDA regulated product. It is important to note that the FDA regulations apply to medical research regardless of federal funding, assuming the research relates to products subject to FDA regulation.

Furthermore the National Institutes of Health ("NIH"), a principal funding source for medical research, have established criteria and guidances governing research practices. For example, the NIH Revitalization Act of 1993 [19] establishes regulations governing NIH funded research projects which parallel other federal standards governing tissue research on dead fetuses. The NIH Guidelines for Research Using Plenipotent Stem Cells required informed consent and prohibit financial incentives.

In addition to federal regulations, common law in this country also governs informed consent with respect to anatomical gifts. The lead case in this country is *Moore v. Regents of the University of California,* 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rapt. 146, 1990 Cal. LEXIS 2858 (1990), which, while affirming the right of a competent adult to submit to lawful medical treatment, establishes that, in order for a person's consent to be effective, it must be properly informed, and that, in soliciting a patient's consent to treatment, a physician has a fiduciary duty to disclose all information pertinent to the patient's decision, including any personal interests the physician may have in the proposed treatment or research. In *Moore* a patient who underwent a splenectomy was not informed of his physician's plans to use his discarded spleen for medical research purposes. The patient returned to the hospital on multiple occasions under the impression his hospital visits were related to his medical treatment when, in fact, his treating physicians surreptitiously used the visits to gather the subject's cells for purposes of undisclosed medical research. The defendant physicians and health care institutions in *Moore* were liable in tort for their wrongful actions in failing to disclose their personal interests in the medical procedures, or their underlying plans to use the patient's body organ for purposes of medical research.

Against this backdrop of federal regulation governing human subject research, and evolving informed consent case law, the issue is raised as to whether Maine should independently establish proper assurances that subjects whose donated organs or tissue will be used for purposes of medical science will be properly informed of their rights in the donation process, and that such donations will be free from compensation or other factors which may vitiate the subject's capacity for informed consent. The Legislature may wish to consider either revisions to the Uniform Anatomical Gift Act, or separate legislation, to assure that organ and tissue donations intended to advance medical science by conducted in a manner consonant with legislatively established values and principles.

[19] P.L. 103-43

Anatomical Gifts: Collateral Issues Regarding Transportation/Disposition of Human Remains

The Office of Vital Records has concerns regarding collateral issues from the Maine Uniform Anatomical Gift Act (MUAGA), specifically regarding disposition of human remains. The Department of Health and Human Services rules regarding disposition of human remains have not kept up with current practices regarding human remains transportation or disposition with the creation of MUAGA. As specified in the (DHHS) Rules, 10-146 CMR 1, Chapter 1. Transportation, Storage and Final Disposition of Dead Bodies, the definition of a "Dead Body" means a human body or parts of a human body, other than a fetus, from the condition of which it reasonably can be concluded that death occurred. The definition of a "Fetus" means a product of conception dead prior to the complete expulsion or extraction from its mother; the fetus shows no signs of life such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles.

In the past, hospitals disposed of human organs, tissue, and fetuses if requested by the individual or next of kin. The hospital typically did on-site disposition in the incinerator located at the facility. However, with implementation of Universal Precautions for Blood Bourne Pathogens, and regulations for handling Bio-Hazardous material, many hospitals have contracted out the disposal of their Bio-Hazardous material. This presents a dilemma in that the hospital has authority to dispose of the human organs, tissue or fetuses at their own facility, however, there is currently no regulations (from the perspective of disposition of human remains) regarding an independent agency picking up this Bio-Hazardous material, transporting to the private companies location of disposal, and disposing of the Bio-Hazardous material.

The Maine Uniform Anatomical Gift Act, which was primarily implemented for transplant of organs, has been adopted to cover research as well. If the DHHS 10-146 Rules, Chapter 1 were to be updated to include regulating transporting human organs, tissues and fetal remains for research and/or disposition by private contracting agencies, revenues could be generated from either issuance of a Disposition Permit (or Transportation Permit) from the private research or private Biohazard disposal agencies. This could conceivably be an annual fee/license that would allow for the transportation or disposition of the Bio-Hazardous material.

The DHHS Rules currently in place regarding disposal of a dead body or fetus are as follows:

2. Burial-Transit Permit (Disposition of Human Remains Permit)

A. Issue

1. Permit Required

a. A burial-transit permit (disposition permit) is required for any transport of a dead body, except transport by a funeral director having custody of the dead body from the site where death occurred (or where the funeral director received custody) to an establishment of a funeral director.

b. A burial-transit permit (disposition permit) is required for any transport of a dead body by an authorized person.

c. A burial-transit permit (disposition permit) is required for any transport of a dead body from the establishment(s) of the funeral director to another location.

d. A burial-transit permit (disposition permit) issued by the municipal clerk or subregistrar, or by the appropriate authority in another state or foreign country, shall authorize final disposition of the dead body by burial or entombment without further permit, and after presentation of a completed death certificate and a medical examiner's release, shall authorize cremation, burial at sea, use by medical science, or removal from the State.

e. Cremated remains of a dead body may be transported, buried, or otherwise disposed of without a burial-transit permit.

f. Parts of a living human being such as an amputated arm or leg may be buried or cremated without a permit.

g. A burial-transit permit (disposition permit) is required for temporary storage of a dead body for more than 14 days and up to eight months. Storage for more than eight months shall be treated as final disposition for the purposes of this rule.

h. A burial-transit permit (disposition permit) is required for disinterment of a dead body, as specified in section 5.

i. The circumstances under which a burial-transit permit (disposition permit) is required for transport or final disposition of a dead fetus are specified in section 7.

7. Disposition of Fetuses

Transportation and final disposition of fetal remains, regardless of the length of gestation, are subject to the same regulations as dead bodies except as specified in this section.

A. A facility may dispose of fetal remains directly without obtaining a burial-transit permit (disposition permit).

B. A burial-transit permit (disposition permit) is required if the fetal remains are to be buried in a cemetery, disposed of in a crematorium, buried at sea, used by medical science, or removed from the state.

C. Notwithstanding section 2(S)(3)(h) of this chapter, a burial-transit permit (disposition permit) for disposition of the remains of a fetus of less than 20 weeks gestation, or the product of an induced abortion of any gestation, shall be issued upon presentation of a statement from the facility that the parents have chosen to dispose of the remains outside the facility and that the required miscarriage or induced abortion report has been filed. The letter shall name the person who will be responsible for the disposition and shall contain that person's signature.

Although the DHHS Rules do cover the topic of transportation of dead bodies, it specifically references that the regulations for removal from temporary storage shall be applied.

D. Transportation

Regulations regarding the transportation of dead bodies shall apply to bodies removed from temporary storage.

6. Temporary Storage of Dead Bodies

A. Storage

Storage of dead bodies for eight months or less in vaults or other structures constructed for this purpose is not regarded as final disposition and removal of such bodies is not disinterment. If a body has been stored for more than eight months, a permit for disinterment must be obtained prior to removal from the vault.

B. Death certificate

When a dead body is to be stored more than 14 days, the death certificate shall show the disposition of the body as "entombment". The date of entombment shall be entered as the date of disposition. The place and location of entombment shall be entered as the name and location of "cemetery or crematory".

C. Permit

1. A burial-transit permit (disposition permit) is required when a dead body is to be stored more than 14 days. The municipal clerk or subregistrar shall issue a burial-transit permit (disposition permit) for temporary storage at the request of the funeral director or authorized person.

2. The funeral director or authorized person shall present the burial-transit permit (disposition permit) to the person in charge of the vault when the body is placed in the vault.

3. The person in charge of the vault shall endorse the burial-transit permit (disposition permit) and return it to the funeral director or authorized

person to retain for use when the dead body is removed for final disposition as specified in § 2 and sub-§ B.

The current DHHS Rules do not cover the "contracting out" that has occurred since the inception of disposal of Bio Hazardous material. Therefore, the regulations regarding transportation of human remains are lacking.

Given the existing DHHS Rules for Transportation, Storage and Final Disposition of Dead Bodies are not up to date with current practices, it is recommended that the DHHS Rules be updated to include a required Disposition Permit be issued for autopsy transports; and that Bio Hazardous Waste Companies and Private Research be required to register annually with a licensure fee for transporting human remains.

PROPOSED PRELIMINARY DRAFT CHAPTER 52 LIMITED

11/18/2005

10-144 DEPARTMENT OF HEALTH AND HUMAN SERVICES

CHAPTER 52 RULES RELATING TO IMPLEMENTATION OF THE MAINE UNIFORM ANATOMICAL GIFT ACT, THE EXECUTION OF ORGAN AND TISSUE DONATIONS, AND THE PROCEDURE FOR ORGAN AND TISSUE PROCUREMENT AND RECOVERY

Summary: These rules establish the responsibilities of hospitals, physicians, and organ and tissue recovery and procurement agencies participating in Organ or Tissue Procurement, and implement the Maine "Uniform Anatomical Gift Act, Title 22 M.R.S.A., Chapter 710, §2901 – 2911". The rules establish criteria to assure that organ and tissue donations by individuals or their next of kin are executed pursuant to informed consent. The rules require the development of inter-hospital agreements, and the procedures to be used to document compliance in training of persons who will perform the request for an anatomical gift.

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CHAPTER 1: DEFINITIONS

1. Community Hospital - For the purpose of these regulations, a community hospital is a duly licensed Maine general hospital required under applicable law to report all deaths to the federally-designated organ procurement organization, to identify patients who meet applicable criteria to qualify as potential organ donors, and to arrange for the transfer of such patients to regional hospitals where the organ procurement will be executed.

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

3. Decedent – Decedent means a deceased individual and includes a stillborn infant or fetus.

4. Department – Department shall mean the Maine Department of Health and Human Services.

5. Determination of Death – Determination of death, as described in Maine Statute, refers to an individual who has sustained either 1) irreversible cessation of circulatory and respiratory functions, or 2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards.

6. Donor – Donor means an individual, or their designated representative duly authorized by Maine law who makes a gift of all or part of his body, and includes a stillborn, infant or fetus that is to take effect at determination of death.

7. Donor Organ - A donor organ is a solid body part such as a heart, lung, kidney, liver, pancreas, intestine or small bowel that can be surgically removed from a donor for use in transplantation or for use in medical science.

8. Donor Tissue – Donor tissue is a body part such as skin, eye cornea, veins, heart valves, intestine, bone, brain and blood that can be removed from a donor, for use in transplantation or for use in medical science.

9. General Hospital - Is an acute health care facility, rehabilitation facility, or chronic disease 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 and/or treatment of, illness and deformity. Specifically excluded are state mental health institutes or non-state mental health institutions as defined by Maine Statute.

10. 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, or use in medical science, and for the costs associated with transplantation.

11. Maine Transplantation Center(s) - A Maine transplantation center is a licensed general hospital located in Maine, duly authorized to perform transplant procedures including, but not limited to, one or more of the following transplant procedures: kidney, heart, lung, liver, intestine, small bowel or pancreas. Any Maine Transplantation Center will have several responsibilities in Maine's organ procurement system. The facility(ies) will assist community hospitals in identifying potential organ donors. It will serve as a facility where both organ procurement attempts can be made and where organ transplantation procedures can be performed. This hospital shall also have the responsibilities of reporting all deaths in its own facility to the federally designated organ procurement organization, requesting permission of appropriate individuals as defined in Maine Statute for the donation of tissue of these patients so that tissue procurement attempts can be made.

12. Medical Science – Medical Science includes, but not by way of limitation, health related non-clinical research and scientific application of medical or health principals for the purpose of understanding medicine and medical treatment, the human body, or treatment of human diseases, but does not include any transplantation of organs, tissues, or cells intended for human therapy, even in the event the intended therapy is considered experimental in accordance with institutional protocol or generally accepted principles of medicine or medical research.

13. Nursing Facility – Nursing Facility means a facility licensed to provide Nursing services in the State of Maine.

14. Office of Chief Medical Examiner- The Office of Chief Medical Examiner established within the Office of Attorney General pursuant to 22 M.R.S.A. Section 3122.

15. Organ Procurement Organization – Organ procurement organization refers to the federally-designated organ/tissue procurement organization or representative(s) responsible for the State of Maine, which is responsible for determining whether an individual is a suitable candidate for organ or tissue donation, and for obtaining or verifying informed consent for organs or tissues to be used for transplant.

16. Recovery Agency- Recovery Agency means an organ procurement organization, tissue bank or any other entity subject to the Maine Uniform Anatomical Gift Act, 22 M.R.S.A., Chapter 710, Sections 2901-2911 which seeks authorization to receive organ or tissue donations in the State of Maine.

17. Regional Hospitals - For the purpose of these regulations, a regional hospital is a licensed Maine general hospital whose role in Maine's organ procurement system is to serve as a facility where organ procurement attempts will be made.

18. 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.

19. The Maine Uniform Anatomical Gift Act or the Uniform Anatomical Gift Act means the Maine Uniform Anatomical Gift Act, Title 22 M.R.S.A.Chapter 710 §§ 2901 – 2911.

CHAPTER 2: PROCEDURES TO BE FOLLOWED TO PERFORM A REQUEST FOR AN ANATOMICAL GIFT

A. This chapter establishes the minimum standards for full informed consent that must be met by any Recovery Agency, which requests an organ or tissue donation of any person in the State of Maine when securing informed consent before donated tissue or organs from any General Hospital or the Office of the Chief Medical Examiner will be released.

1. The Maine Department of Health and Human Services ("Department") may register individual Recovery Agencies that have in place appropriate policies, practices and procedures for obtaining necessary consent for organ and tissue donation in accordance with these rules. No Recovery Agency may engage in organ or tissue donation or procurement in the State of Maine unless duly registered by the Department in accordance with these rules.

2. In the absence of revocation or amendment of the donor's intent to execute an anatomical gift pursuant to the Maine Uniform Anatomical Gift Act, Title 22 M.R.S.A. Chapter 710, health care providers licensed in Maine and federally designated Organ Procurement Organizations and Recovery Agencies shall act in accordance with the donor's intention.

3. Specific Requirement for all Recovery Agencies. All Recovery Agencies must demonstrate strict adherence with the following requirements regarding requests for donations in the absence of donor intent as described in section

a. Individuals requesting consent for organ/tissue donation from the donor or the next-of-kin as defined in Maine Statute must receive initial and continuing training to the satisfaction of the Department.

b. Disclosure, in terms a layperson can understand, must be made to the next-of-kin regarding the specific tissue or organ that is being requested for recovery. For example, if an entire organ is to be recovered, this must be specifically disclosed. It is not sufficient to simply disclose that "tissue" will be recovered. Likewise, if it is necessary to recover an entire organ (e.g., the heart) to harvest specific parts of the organ (e.g., heart valves), this must be disclosed to the next-of-kin.

c. Next-of-kin must be informed whether the tissue and/or organ is intended to be used or modified for transplantation in a life-saving capacity, for transplantation in a life-enhancing capacity, and/or for medical research or education.

d. Next-of-kin must be informed that his/her consent is necessary for tissue or organ recovery and he/she may refuse or restrict such recovery, unless the donor has expressed the wish to donate prior to death.

e. The consent form must meet all requirements of applicable law, particularly Maine's Uniform Anatomical Gift act, as well as the requirements set forth in the Department rules.

f. A party requesting organ or tissue donation must review each element of the consent form with the next of kin prior to obtaining consent. If consent is to be obtained from the next-of-kin by means of telephonic communication, or by any other means of electronic communication, the requester must either read or display the entire consent form to the next-of-kin and complete the consent form in strict compliance with the instructions of the donor or next-of-kin. Witnesses to the organ or tissue request must listen or observe the entire consent communication; the requester, or a person acting upon the requester's behalf must electronically record the entire consent communication. In the event the request is conducted by means of electronic communication, the entire consent communication shall be preserved electronically.

g. A copy of the fully executed consent form must be provided to the next-of-kin within five (5) business days after execution. Additional written material explaining organ or tissue donation must be offered to the donor or next-of-kin.

h. A requesting party shall maintain suitable documentation of all consent forms, including all electronic media used in obtaining consent in accordance with applicable state and federal law, rules and regulations. The requesting party shall make available to the Department access to such documentation at all reasonable times and places.

i. No Recovery Agency or any other party requesting an anatomical gift may offer, promise, provide, or otherwise make available compensation for any person for the purpose of obtaining consent, including, but not by way of limitation, on the basis of any "finder's fee", or compensation on a per consent basis.

EFFECTIVE DATE OF REGULATIONS

EFFECTIVE DATE (ELECTRONIC CONVERSION):

PROPOSED COMPREHENSIVE PRELIMINARY DRAFT CHAPTER 52

11/18/2005

CHAPTER 52 RULES RELATING TO IMPLEMENTATION OF THE MAINE UNIFORM ANATOMICAL GIFT ACT, THE EXECUTION OF ORGAN AND TISSUE DONATIONS, AND THE PROCEDURE FOR ORGAN AND TISSUE PROCUREMENT AND RECOVERY

Summary: These rules establish the responsibilities of hospitals, *physicians*, and organ and tissue recovery and procurement agencies participating in Organ or Tissue Procurement, and implement the Maine "Uniform Anatomical Gift Act, Title 22 M.R.S.A., Chapter 710, §2901 – 2911". The rules establish criteria to assure that organ and tissue donations by individuals or their next of kin are executed pursuant to informed consent. The rules require the development of inter-hospital agreements, and the procedures to be used to document compliance in training of persons who will perform the request for an anatomical gift. The rules establish a mechanism for the Department of Health and Human Services (the Department) to monitor compliance with the Uniform Anatomical Gifts Act, and establish a procedure by which the Department shall authorize entities to participate in the procurement of body organs and tissue for purposes of transplantation and in medical science. The rules establish sanctions for non-compliance of the Maine Uniform Anatomical Gift and the Department rules.

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4. Department – Department shall mean the Maine Department of Health and Human Services.

5. Determination of Death – Determination of death, as described in Maine Statute, refers to an individual who has sustained either 1) irreversible cessation of circulatory and respiratory functions, or 2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards.

6. Donor – Donor means a individual, or their designated representative duly authorized by Maine law who makes a gift of all or part of his body, and includes a stillborn, infant or fetus that is to take effect at determination of death.

7. Donor Organ - A donor organ is a solid body part such as a heart, lung, kidney, liver, pancreas, intestine or small bowel that can be surgically removed from a donor for use in transplantation or for use in medical science.

8. Donor Tissue – Donor tissue is a body part such as skin, eye cornea, veins, heart valves, intestine, bone, brain and blood that can be removed from a donor, for use in transplantation or for use in medical science.

9. General Hospital - Is an acute health care facility, rehabilitation facility, or chronic disease 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 and/or treatment of, illness and deformity. Specifically excluded are state mental health institutes or non state mental health institutions as defined by Maine Statute.

10. 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, or use in medical science, and for the costs associated with transplantation.

11. Maine Transplantation Center(s) - A Maine transplantation center is a licensed general hospital located in Maine, duly authorized to perform transplant procedures including, but not limited to, one or more of the following transplant procedures: kidney, heart, lung, liver, intestine, small bowel or pancreas. Any Maine Transplantation Center will have several responsibilities in Maine's organ procurement system. The facility(ies) will assist community hospitals in identifying potential organ donors. It will serve as a facility where both organ procurement attempts can be made and where organ transplantation procedures can be performed. This hospital shall also have the responsibilities of reporting all deaths in its own facility to the federally-designated organ procurement organization, requesting permission of appropriate individuals as defined in Maine Statute for the donation of tissue of these patients so that tissue procurement attempts can be made.

12. Medical Science – Medical Science includes, but not by way of limitation, health related non-clinical research and scientific application of medical or health principals for the purpose of understanding medicine and medical treatment, the human body, or treatment of human diseases, but does not include any transplantation of organs, tissues, or cells intended for human therapy, even in the event the intended therapy is considered experimental in accordance with institutional protocol or generally accepted principles of medicine or medical research.

13. Nursing Facility – Nursing Facility means a facility licensed to provide Nursing services in the State of Maine.

14. Office of Chief Medical Examiner- The Office of Chief Medical Examiner established within the Office of Attorney General pursuant to 22 M.R.S.A. Section 3122.

15. Organ Procurement Organization – Organ procurement organization refers to the federally-designated organ/tissue procurement organization or representative(s) responsible for the State of Maine, which is responsible for determining whether an individual is a suitable candidate for organ or tissue donation, and for obtaining or verifying informed consent for organs or tissues to be used for transplant.

16. Recovery Agency- Recovery Agency means an organ procurement organization, tissue bank or any other entity subject to the Maine Uniform Anatomical Gift Act, 22 M.R.S.A., Chapter 710, Sections 2901-2911 which seeks authorization to receive organ or tissue donations in the State of Maine.

17. Regional Hospitals - For the purpose of these regulations, a regional hospital is a licensed Maine general hospital whose role in Maine's organ procurement system is to serve as a facility where organ procurement attempts will be made.

18. 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.

19. The Maine Uniform Anatomical Gift Act or the Uniform Anatomical Gift Act means the Maine Uniform Anatomical Gift Act, Title 22 M.R.S.A.Chapter 710 §§ 2901 – 2911.

CHAPTER 2: PROCEDURES TO BE FOLLOWED TO PERFORM A REQUEST FOR AN ANATOMICAL GIFT

A. This chapter establishes the minimum standards for full informed consent that must be met by any Recovery Agency, which requests an organ or tissue donation of any person in the State of Maine when securing informed consent before donated tissue or organs from any General Hospital or the Office of the Chief Medical Examiner will be released.

1. The Maine Department of Health and Human Services ("Department") may register individual Recovery Agencies that have in place appropriate policies, practices and procedures for obtaining necessary consent for organ and tissue donation in accordance with these rules. No Recovery Agency may engage in organ or tissue donation or procurement in the State of Maine unless duly registered by the Department in accordance with these rules.

2. In the absence of revocation or amendment of the donor's intent to execute an anatomical gift pursuant to the Maine Uniform Anatomical Gift Act, Title 22 M.R.S.A. Chapter 710, health care providers licensed in Maine and federally designated Organ Procurement Organizations and Recovery Agencies shall act in accordance with the donor's intention.

3. Specific Requirement for all Recovery Agencies. All Recovery Agencies must demonstrate strict adherence with the following requirements regarding requests for donations in the absence of donor intent as described in section 2.

i. Individuals requesting consent for organ/tissue donation from the donor or the next-of-kin as defined in Maine Statute must receive initial and continuing training to the satisfaction of the Department.

ii. Disclosure, in terms a layperson can understand, must be made to the next-of-kin regarding the specific tissue or organ requested to be recovered. For example, if an entire organ is to be recovered, this must be specifically disclosed. It is not sufficient to simply disclose that "tissue" will be recovered. Likewise, if it is necessary to recover an entire organ (e.g., the heart) to harvest specific parts of the organ (e.g., heart valves), this must be disclosed to the next-of-kin.

iii. Next-of-kin must be informed whether the tissue and/or organ is intended to be used or modified for transplantation in a life-saving capacity, for transplantation in a life-enhancing capacity, and/or for medical research or education.

iv. Next-of-kin must be informed that his/her consent is necessary for tissue or organ recovery and he/she may refuse or restrict such recovery, unless the donor has expressed the wish to donate prior to death.

v. The consent form must meet all requirements of applicable law, particularly Maine's Uniform Anatomical Gift act, as well as the requirements set forth in the Department rules.

vi. A party requesting organ or tissue donation must review each element of the consent form with the next of kin prior to obtaining consent. If consent is to be obtained from the next-of-kin by means of telephonic communication, or by any other means of electronic communication, the requester must either read or display the entire consent form to the next-of-kin and complete the consent form in strict compliance with the instructions of the donor or next-of-kin. Witnesses to the organ or tissue request must listen or observe the entire consent communication, the entire consent communication must be electronically recorded by the requester, or a person acting upon the requester's behalf. In the event the request is conducted by means of electronic communication, the entire consent communication shall be preserved electronically.

vii. A copy of the fully executed consent form must be provided to the next-of-kin within five (5) business days after execution. Additional written material explaining organ or tissue donation must be offered to the donor or next-of-kin.

viii. A requesting party shall maintain suitable documentation of all consent forms, including all electronic media used in obtaining consent in accordance with applicable state and federal law, rules and regulations.

The requesting party shall make available to the Department access to such documentation at all reasonable times and places.

ix. No Recovery Agency or any other party requesting an anatomical gift may offer, promise, provide, or otherwise make available compensation for any person for the purpose of obtaining consent, including, but not by way of limitation, on the basis of any "finder's fee", or compensation on a per consent basis.

3. Demonstration of Compliance by a Federally Designated Recovery Agency. In order to demonstrate compliance with this policy a Recovery Agency that operates under federal regulation must attest or affirm that:

a. It has reviewed the specific requirements for Recovery Agencies set forth in Section A.2 and will fully comply therewith;

b. It is in good standing as one or both of the following:

(i.) An Organ Procurement Organization as designated by the U. S. Department of Health and Human Services Centers for Medicare and Medicaid Services ("CMS") [see 42 Code of Federal Regulations ("CFR") §486.306].

(ii.) A Tissue Bank registrant with the U. S. Department of Health and Human Services Food and Drug Administration ("FDA") [see e.g., the new Good Tissue Practices regulations at 21 CFR Part 16].

c. It is an accredited member in good standing with one or both of the following organizations, and is in full compliance with their standards for securing informed consent:

1. The Association of Organ Procurement Organizations ("AOPO").

2. The American Association of Tissue Banks ("AATB").

d. It will notify the Department immediately of any significant change in certification, registration or accreditation status or the agency's policies, practices or procedures that materially impacts the ability of the agency to meet the requirements of this Rule regarding securing full informed consent from the next-of-kin, as defined in Maine Statute; and

e. It maintains internal policies or procedures that demonstrate compliance with Maine's Uniform Anatomical Gift Act; Department regulations; and, where applicable, federal law found

at 42 USC §273 and 1320b-8 with accompanying regulations found at 42 CFR §121.1 and 486.301 *et seq.*

4. A Recovery Agency that attests or affirms that it meets and will comply with the above described requirements must so attest or affirm in writing signed by the Chief Executive Officer or other official of the Recovery Agency with authority to do so, on behalf of the Recovery Agency. The writing must indicate that the official has read the requirements and attests or affirms that the Recovery Agency meets and will comply with the requirements. The Recovery Agency must provide the Department with copies of documents evidencing compliance with paragraph 3(b) and 3(c) above. The Recovery Agency must also provide the Department with copies of the consent forms that will be used by the Recovery Agency authorizing donation of any organ(s) or tissue(s) by the donor's next-of-kin; and any disclosure form used by the Recovery Agency in connection with a donation made by a document of gift as defined in Maine Statute or pursuant to the Maine Organ Donor Registry as described in Maine Statute.

5. Demonstration of Compliance by Other Recovery Agencies. A Recovery Agency that does not operate under federal regulation as set forth in the previous subsection and that requests that donated tissue or organs be released from the Office of the Chief Medical Examiner ("OCME"), a hospital, a funeral home, or other facility must provide the Department with the following:

   a. Copies of internal policies or procedures that demonstrate compliance with Maine's Uniform Anatomical Gift Act, as described in Maine Statute; the Department rules, and where applicable, federal law found at 42 USC §273 and 1320b-8 with accompanying regulations found at 42 CFR §121.1 and 486.301 *et seq.*;

   b. A full description of the uses for which the donated tissue/organs are being requested;

   c. Description of procedure for obtaining consent for donation of tissue/organs from a donor or next-of-kin;

   d. Copies of the consent forms that will be used by the Recovery Agency authorizing donation of any organ or tissue by the donor or donor's next of kin; and any disclosure form used by the Recovery Agency in connection with a donation made by a document of gift as defined by Maine Statute or pursuant to the Maine Organ Donor Registry as described by Maine Statute;

e. Description of quality control procedures to ensure that consent was informed;

f. Copies of any educational or follow-up materials provided to a donor or next-of-kin; and

g. Training requirements for employees and agents involved in obtaining consent for donation.

h. Additionally, the Recovery Agency must attest or affirm that:

(i) It has reviewed the specific requirements for Recovery Agencies set forth in Section A(2) above and will comply therewith.

(ii) It agrees to maintain internal policies or procedures that demonstrate compliance with Maine's Uniform Anatomical Gift Act; Department regulations; and, where applicable, federal law found at 42 USC §273 and 1320b-8 with accompanying regulations found at 42 CFR §121.1 and 486.301 *et seq.*

(iii) It will notify the Department immediately of any significant change in the agency's status or in the agency's policies, practices or procedures that materially impact the ability of the agency to meet the requirements of this policy regarding securing full informed consent from a donor or next-of-kin;

i. The Recovery Agency must supply the OCME, hospital or funeral home with a copy of the approved certification from the Department prior to the release of donated tissue or organ(s).

j. A Recovery Agency that attests or affirms that it meets and will comply with the above-described requirements must so attest or affirm in writing signed by the Chief Executive Officer or other official of the Recovery Agency with authority to do so, on behalf of the Recovery Agency. The writing must indicate that the official has read the requirements and attests or affirms that the Recovery Agency meets and will comply with requirements; Appendix C.

k. A Recovery Agency submits the fee for certification from the Department.

6. Approval of Recovery Agencies for Tissue/Organ Donations. The Department will review all information submitted by a Recovery Agency under section 5 above to determine whether the agency meets the

requirements of this policy and has in place sufficient policies, practices and procedures to meet the standards set forth in this policy for obtaining informed consent for organ and tissue donation. Once the Department has determined that the Recovery Agency meets these requirements, and has in place sufficient policies, practices and procedures, the Department will so notify the Recovery Agency.

In order to maintain ongoing approval by the Department, all Recovery Agencies approved under section 6 above must attest or affirm compliance with the requirements of this Rule on an annual basis or per research project.

CHAPTER 3: 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 determination of death.

b. Patients who are received at community hospitals and in the judgment of the attending physician are determined to be 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. Notify federally designated Organ Procurement Organization of the determination of death or imminent death,

   c. Documentation of request for consent for the gift of the donor organ(s) in the absence of donor's designation;

   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 or are expected to meet medical criteria for determination of 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 determined to be dead, but remain potentially viable organ or tissue 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 death;

b. Notify federally designated Organ Procurement Organization of the determination of death;

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.

CHAPTER 4: MONITORING AND ENFORCEMENT 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. When a report is made to the federally designated organ procurement organization, the report shall be noted in the decedent's or donor's medical record. A copy of the informed consent or document of gift and disclosure form should be retained in the patient's medical file.

2. Hospitals shall demonstrate compliance by maintaining a file, available for the Department's Division of Licensing and Certification review including the following:

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

b. Any training curriculum for training of organ/tissue procurement requests.

B. Description of Department's Monitoring Mechanism

1. 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 were identified as potentially suitable organ or tissue donor candidates. Dependent on the number of records applicable to the facility, either a representative sample or all of the relevant records may be reviewed.

2. If Department staff determine that hospital personnel which participate in organ or tissue donation requests are in violation of these rules, the hospital's medical director/chief of staff and administrator will be notified in writing by the Department. The Department may include Departmental staff recommendations on how to remedy the problem by such correspondence.

3. 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; 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 remedy these compliance problem(s).

CHAPTER 5: SANCTIONS

Enforcement action. The Department is authorized to impose one or more of the following sanctions in the event of a violation of Maine Statute, or the rules adopted by the Department to implement the provisions of such chapter and the Department determines that a sanction is necessary and appropriate to assure compliance with the Maine Uniform Anatomical Gift Act and these rules.

A. The Department may refer the matter to the Department or Board that issued a license to the party in violation for such action as the Department or Board considers appropriate.

B. The Department may refer the matter to the Attorney General and request the filing of a complaint with the Superior Court in the county in which the person resides or the entity is located or in Kennebec County seeking injunctive relief

and an order to require that person or entity to comply with the requirements of the Maine Uniform Anatomical Gifts Act, or these rules.

C. The Department may decline to certify any person or entity as suitable to participate in organ or tissue recovery in the State of Maine.

D. The Department may require the person or entity to demonstrate additional training to the Department's satisfaction to assume that the person or entity is qualified to perform requests for anatomical gifts in the State of Maine.

E. Pursuant to 22 M.R.S.A. §47 (2004), a person or entity which (1) violates any provision of the Maine Uniform Anatomical Gift Act, (2) violates any provisions of these rules, (3) hinders, obstructs, or interferes with any Departmental employee or agent in the performance of the Department's duties and responsibilities pursuant to the Maine Uniform Anatomical Gift Act, or these rules, or (4) intentionally or knowingly fails, neglects or refuses to perform any duties imposed upon him or her by the Maine Uniform Anatomical Gift Act, or these rules, commits a Class E criminal offense. The Department may refer any such violation to the Attorney General for appropriate criminal prosecution.

F. Good faith exception. Pursuant to 22 M.R.S.A. §2901(3)(2004), a person who acts in good faith and in accordance with the terms of the Maine Uniform Anatomical Gift Act, or these rules, or pursuant to the anatomical gift laws of another state or foreign country shall not be liable for damages in any civil action or subject to prosecution in any criminal proceeding for such actions.

G. Administrative review. Any party aggrieved by a Departmental action taken pursuant to subsections A, C, or D of this section may request administrative review by filing a request with the Department for a fair hearing in accordance with the provisions of the Maine Administrative Procedures Act, Title 5, M.R.S.A., Chapter 375, Subchapter IV.

EFFECTIVE DATE OF REGULATIONS

EFFECTIVE DATE (ELECTRONIC CONVERSION):

APPENDIX A

Permission for Organ Donation by Next-of-Kin*
Record of Request for an anatomical gift

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

APPENDIX B

Record of Request for an anatomical gift
Internal Reporting Mechanism for hospitals

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

APPENDIX C

Materials Transfer Agreement for an anatomical gift for research purposes.

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

Anatomical Gift Stakeholders Meeting
August 4, 2005

The following are bullets from the discussion from the Anatomical Gift Stakeholders meeting:

Chapter 1

Definitions:

- The definition of donor – concern regarding the fact that donor has traditionally been defined as a deceased individual – not a living individual. Suggestion to add to the definition after the word fetus, *to take effect at the time of death.*

- The definition of Donor Organ – concern over the term medical science – suggestion to change to *research or education.*

- The definition of Donor Tissue – the last portion of the sentence beginning with and be donated – suggestion to change to *for use in transplantation or for use in research or education.*

- The definition of General Hospital – federal definitions and regulations has changed that now include rehab hospitals and chronic disease hospitals. Maine does not have any chronic disease hospitals, however, we do have acute rehab hospital(s). Suggestion to include these types of hospitals in the definition.

- The Organ Procurement Organization – suggestion to add in the next to the last line where it states and for obtaining *or verifying* consent. Suggested to delete the word informed before consent.

- Question/concern over the definition of next-of-kin, which is defined in statute, but is not defined in the rules. This definition differs from the definition of next-of-kin in Title 22 §2843-A Custody of remains of deceased persons. This definition covers an estranged couple as well as the domestic partnership (effective 7/30/2004).

- The definition of Recovery Agency – concern that not all entities would be covered under this definition e.g. pathology, private research, University of New England. Suggestion to ensure the definition encompasses these entities.

Comment: Education, research, transplant – is too much trying to be covered in context – too many areas that are not specific enough in the overview?

Chapter 2

Procedures to be followed to perform a request for an anatomical gift.

- A. Suggestion to delete full informed from the first line. Second/third line to delete tissue bank, organ procurement organization or research organization or any other entity. To replace with *Recovery Agency.* The next to the last line (same paragraph) to delete hospital and to change to *General Hospital.*

- 1. Suggestion on second line to capitalize the *R* in recovery.

- Need to clarify why donor or next-of-kin is in place instead of simply next-of-kin as donations are after death, and the majority of organs harvested are for transplant not research; suggestion to delete donor and leave next of kin throughout chapter 2. If referring to a living donor spell it out and be specific.

- Page 7, 2. 4th & 5th lines suggestion to delete organ procurement organizations and recovery agencies, replace with *Organ Procurement Organizations and Recovery Agencies.*

- Page 7 3. Suggestion to capitalize *Recovery Agencies.* 2nd line to add the word *All* at the beginning of the sentence, capitalize *Recovery Agencies*; delete the word strict. Last line, add *in the absence of donor intent as described in section 2.*

- Page 7 a. question, how will the Department determine "satisfactory training"?

- Page 7, b. Comment; This requirement only makes sense after death because prior to death it will not be known which organs and or tissues may be suitable. Therefore, it applies only to next-of-kin.

- Page 7 letter f. the 8th line down, to delete strict before the word compliance. The 10th, 11th & 14th lines to add *consent* after the word entire and before communication. The reason for only recording the consent portion of the communication is that a detailed and very personal medical/social history of the donor is discussed with next-of-kin.

- Page 8, letter I, first line, capitalized *Recovery Agency.* 4th line to add after any person *for the purpose of obtaining consent* and delete *or agency engaged in any anatomical gift request.* 6th line, to add after "finders fee" *or;* delete case add *consent* before the word basis. Delete the remainder of the sentence or otherwise for either soliciting or obtaining consent for an anatomical gift.

Comment: The staff at NEOB is compensated for their work in organ procurement as well as their agents for obtaining consent. Compensation provisions need to regulate only improper procurement.

- Page 8, 3. Capitalize Agency 92nd line).
- Page 8, a. capitalize Recovery Agencies, delete Section A.2, replace with *Chapter 2A.*
- Page 8 c. Delete full before compliance; delete informed before consent.
- Page 8 d. 5th line delete policy replace with *Rule*; delete full informed before consent
- Page 10 h (i) capitalize *Recovery Agency.*
- Page 11, j, Appendix C – what will Appendix C contain? Currently it references a materials transfer agreement.
- Page 11, 6. Line 3, add after Recovery Agency *under section 5 above.*
- Page 11, 6. Second paragraph add after Recovery Agencies *approved under section 6 above.* 3rd line delete policy add *Rule.*

Comment: Does this apply to Federally Designated Organ Procurement Organizations and Recovery Agencies – they are accredited every 3 years, therefore, should not their accredit ion period coincide with State requirements? Discussion raised concerns over annual or per research project certification process. Hospitals are also accredited every few years.

Chapter 3

Inter-Hospital Agreements

Inter Hospital Agreements – this section needs updating due to changes in federal requirements. Comments on this section will be e-mailed to Dr. Graham for incorporation.

- Page 12, 4. b., add *or imminent death* at the end of the sentence.
- Page 12, 4. c, add *in the absence of donor's designation;* to end of sentence.
- Page 13, 2, a. add after found to meet in 2nd line, *or are expected to meet*;
- Page 13, 2, b. add after viable organ *or tissue.*
- Page 13, 4, b. add at the end of sentence *or imminent death.*
- Page 13, 4, c. add at the end of sentence *in the absence of donor designation.*

Chapter 4

Monitoring and Enforcement Mechanisms

- Page 14, A, 1, 3rd line delete informed, before consent; add after consent *or document of gift and disclosure form.*

- May have to separate transplant vs. Recovery Agency for research.

Comments: Concern that the rules are not specific enough to cover all entities that may be performing research vs. transplant e.g. path labs (private path can be living or deceased donations), private research, UNE. Concern over consent generalities vs. specificity in the rules.

Does Chapter 4 cover private research if request is not made through a hospital? References hospitals only.

Chapter 5

Sanctions

It was clarified that the reference in the Rules to possible criminal proceedings is not new, that this language is the current language in Maine Statute under Title 22 §47.

Discussion ensued regarding the Good Faith clause vs. the statute reference for criminal proceedings. Want to ensure that the fear of possible criminal action does not deter from organ transplant or medical research. Need to clean up Statute in order to ensure the Uniform Anatomical Gift Act Good Faith clause does not become lost in the legal process. Suggestion to include language regarding intentional negligence, pattern of behavior etc.

Closing: Concerns as to what the Department is looking for from Stakeholders.

- Written comment? Yes
- Will there be another round of drafting for Rules? Yes, but not until written comment received – allow a month to receive written comments.
- Will the Department be going to formal Rule making or will the Department hold off? The Department has to report to the Legislature by January 31, 2006, and due to the number of areas in which it appears Maine Statute needs addressing due to the passing of LD 107, it appears the Department would hold off on formal rule making, prepare a report to the legislature on findings from reviewing and creating a preliminary draft for Rule changes.

Section VI. Tissue And Organ Donation

Realizing the quality of life and the life saving possibilities presented through expedient procurement of organs and tissues, every request received by the Office of the Chief Medical Examiner ("OCME") to allow tissue or organ donation from a decedent that is under the jurisdiction of the Medical Examiner will be received with the greatest consideration and sensitivity. First and foremost, the staff of the OCME must ensure that laws of the state will be met and that the determination of cause and/or manner of death and criminal prosecution will not be compromised by removal of organs or tissue. The OCME and the Office of the Attorney General also recognize and acknowledge the importance of full informed consent for the decedent's next-of-kin as a crucial element of the organ and/or tissue donations process. This policy is written and will be enforced as a cooperative effort of both offices to allow organ and tissue donation to proceed expediently while protecting the interests of families in a time of emotional turmoil and grief.

This policy is divided into the following areas:

A. Full Informed Consent Requirements for all Recovery Agencies requesting authorization from the OCME. This part includes the procedures by which both federally recognized and other Recovery Agencies may be approved by the OAG and the OCME preceding any tissue and/or organ recovery in the State of Maine.

B. After full informed consent is provided, this part establishes the protocol that must be followed when requesting authorization from the OCME on individual medical examiner cases including the procedure to be followed when requesting use of the OCME facilities for recovery.

C. Defines circumstances under which tissue or organ recovery can take place at the OCME facility.

D & E. These final two parts define conflict of interest and prohibit compensation of OCME employees and those contracting with the office with respect to organ and tissue recovery agencies.

A. Informed Consent for Recovery of Tissue and Organs

This policy establishes the minimum standards for full informed consent that must be met by any tissue bank, organ procurement organization or research organization (a "Recovery Agency") when securing informed consent before the OCME will release donated tissue or organs from any medical examiner case.

1. Recognition of Recovery Agencies

The requirements set forth below provide a process by which the OCME and the Office of the Attorney General may recognize individual Recovery Agencies as having in place appropriate policies, practices and procedures for obtaining necessary consent for organ and

tissue donation. The OCME reserves the right to revoke its recognition if it receives credible information regarding practices that fall short of the standards set forth herein.

2. Specific Requirements for All Recovery Agencies

All Recovery Agencies must demonstrate strict adherence with the following requirements regarding requests for donations.

(a) Individuals requesting consent for organ/tissue donation from next-of-kin must receive initial and continuing training that meets the requirements of DHHS Regulation, Code of Maine Regulation ("CMR") 10-144, Chapter 52.

(b) Disclosure, in terms a layperson can understand, must be made to the next-of-kin regarding the specific tissue or organ requested to be recovered from the decedent. For example, if an entire organ is to be recovered, this must be specifically disclosed. It is not sufficient to simply disclose that "tissue" will be recovered. Likewise, if it is necessary to recover an entire organ (e.g., the heart) to harvest specific parts of the organ (e.g., heart valves), this must be disclosed to the next-of-kin.

(c) Next-of-kin must be informed whether the tissue and organ is intended to be used or modified for transplantation in a life-saving capacity, for transplantation in a life-enhancing capacity, and/or for medical research or education. If it is known that the recovered tissue or organ is to be used solely for medical research or education, this must be disclosed to the next-of-kin.

(d) Next-of-kin must be informed that his/her consent is necessary for tissue or organ recovery and he/she may refuse or restrict such recovery.

(e) The consent form must meet all requirements of applicable law, particularly Maine's Uniform Anatomical Gift Act, as well as the requirements set forth in this policy.

(f) The consent form must be reviewed with the next-of-kin before final consent is given. If next-of-kin consent is to be obtained telephonically, the requester shall read the entire consent form to the next-of-kin and complete the form in strict accordance with the next-of-kin's instructions. Another person serving as a witness must listen to the entire conversation between the requestor and next-of-kin, must acknowledge this to the next-of-kin and must so indicate on the consent form with signature. The conversation between the requestor, the next-of-kin and the witness must be audio-recorded.

(g) A copy of the fully executed consent form must be provided to the next-of-kin within five business days after execution. Additional written material explaining organ or tissue donation must be offered to the next-of-kin.

(h) Records of all consent forms (including audio recordings of consent obtained telephonically) must be maintained by the Recovery Agency in accordance with applicable laws and must be available for inspection by the OCME at any time.

(i) Compensation must not be paid to any individual employed by or working for the Recovery Agency based on a "finder's fee" or per case basis for soliciting and obtaining consent for an organ or tissue donation.

3. Demonstration of Compliance by a Federally Recognized Recovery Agency

In order to demonstrate compliance with this policy a Recovery Agency that operates under federal regulation must attest or affirm that:

(a) It has reviewed the specific requirements for recovery agencies set forth in Section A.2 and will fully comply therewith;

(b) It is in good standing as one or both of the following:

(i) An Organ Procurement Organization as designated by the U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services ("CMS")[20].

(ii) A Tissue Bank registrant with the U.S. Department of Health and Human Services Food and Drug Administration ("FDA")[21].

(c) It is an accredited member in good standing with one or both of the following organizations and is in full compliance with their standards for securing informed consent:

(i) The Association of Organ Procurement Organizations ("AOPO").

(ii) The American Association of Tissue Banks ("AATB").

(d) It will notify the OCME immediately of any significant change in certification, registration or accreditation status or the agency's policies, practices or procedures that materially impacts the ability of the agency to meet the requirements of this policy regarding securing full informed consent from next-of-kin; and

(e) It maintains internal policies or procedures that demonstrate compliance with Maine's Uniform Anatomical Gift Act, 22 MRSA §§2901 – 2911; Maine Department of Health and Human Services ("DHHS") regulations found at Code of Maine Regulations ("CMR") 10-144, Chapter 52; and, where applicable, federal law found at 42 USC §§273 and 1320b-8 with accompanying regulations found at 42 CFR §§121.1 and 486.301 *et seq.*

[20] *See* 42 Code of Federal Regulations ("CFR") §486.306

[21] *See e.g.*, the new Good Tissue Practices regulations at 21 CFR Part 16

A Recovery Agency that attests or affirms that it meets and will comply with the above-described requirements must so attest or affirm in writing signed by the Chief Executive Officer or other official of the Recovery Agency with authority to do so, on behalf of the Recovery Agency. The writing must indicate that the official has read the requirements and attests or affirms that the Recovery Agency meets and will comply with the requirements. The Recovery Agency must provide the OCME with copies of documents evidencing compliance with paragraphs 3(b) and 3(c) above. The Recovery Agency must also provide the OCME with copies of the consent forms that will be used by the Recovery Agency authorizing donation of any organ(s) or tissue(s) by the donor's next-of-kin; and any disclosure form used by the Recovery Agency in connection with a donation made by a document of gift[22] or pursuant to the Maine Organ Donor Registry pursuant to Title 29-A Section 1402-A.

4. Demonstration of Compliance by Other Recovery Agencies.

A Recovery Agency that does not operate under federal regulation as set forth in the previous subsection and that requests that donated tissue or organs be released from the OCME must provide the OCME with the following:

(a) Copies of internal policies or procedures that demonstrate compliance with Maine's Uniform Anatomical Gift Act, 22 MRSA §§2901 – 2911; Maine Department of Health and Human Services ("DHHS") regulations found at Code of Maine Regulations ("CMR") 10-144, Chapter 52; and, where applicable, federal law found at 42 USC §§273 and 1320b-8 with accompanying regulations found at 42 CFR §§121.1 and 486.301 *et seq.*;

(b) A full description of the uses for which the donated tissue/organs are being requested;

(c) Description of procedure for obtaining consent for donation of tissue/organs from next-of-kin;

(d) Copies of the consent forms that will be used by the Recovery Agency authorizing donation of any organ or tissue by the donor's next-of-kin; and any disclosure form used by the Recovery Agency in connection with a donation made by a document of gift[23] or pursuant to the Maine Organ Donor Registry at Title 29-A Section 1402-A;

(e) Description of quality control procedures to ensure that consent was informed;

(f) Copies of any educational or follow-up materials provided to next-of-kin; and

(g) Training requirements for employees and agents involved in obtaining consent for donation.

[22] As defined by the Maine Anatomical Gift Act at Title 22 Sections 2904 and 2911.
[23] As defined by the Maine Anatomical Gift Act at Title 22 Sections 2904 and 2911.

Additionally, the Recovery Agency must attest or affirm that:

- It has reviewed the specific requirements for recovery agencies set forth in Section A(2) above and will comply therewith.

- It agrees to maintain internal policies or procedures that demonstrate compliance with Maine's Uniform Anatomical Gift Act, 22 MRSA §§2901 – 2911; Maine Department of Health and Human Services ("DHHS") regulations found at Code of Maine Regulations ("CMR") 10-144, Chapter 52; and, where applicable, federal law found at 42 USC §§273 and 1320b-8 with accompanying regulations found at 42 CFR §§121.1 and 486.301 *et seq.*

- It will notify the OCME immediately of any significant change in the agency's status or in the agency's policies, practices or procedures that materially impact the ability of the agency to meet the requirements of this policy regarding securing full informed consent from next-of-kin;

A Recovery Agency that attests or affirms that it meets and will comply with the above-described requirements must so attest or affirm in writing signed by the Chief Executive Officer or other official of the Recovery Agency with authority to do so, on behalf of the Recovery Agency. The writing must indicate that the official has read the requirements and attests or affirms that the Recovery Agency meets and will comply with the requirements.

5. Approval of Recovery Agencies for Tissue/Organ Donations

The Office of the Attorney General, with assistance from the OCME, will review all information submitted by a Recovery Agency to determine whether the agency meets the requirements of this policy and has in place sufficient policies, practices and procedures to meet the standards set forth in this policy for obtaining informed consent for organ and tissue donation. Once the Office of the Attorney General, with assistance from the OCME, has determined that the Recovery Agency meets these requirements and has in place sufficient policies, practices and procedures, the OCME will so notify the Recovery Agency.

In order to maintain ongoing approval by the OCME, all Recovery Agencies must attest or affirm compliance with the requirements of this policy on an annual basis.

6. OCME Staff Training

All OCME employees, or individuals under written contract with the OCME, shall be provided a copy of this policy within one month of its implementation. All new staff, and any contractors with the OCME who may be in any way involved with the organ or tissue procurement process, shall also receive a copy of this policy upon hire. All employees must sign a form indicating they have received a copy of this policy; have read the

policy; have discussed it with their supervisor; and understand their responsibilities under this policy. This form must also include an attestation that they are aware of and will comply with sub-sections D and E of this policy regarding compensation and conflict of interest.

B. OCME Protocol for Individual Tissue or Organ Recovery

The following section of the protocol defines the steps that shall be followed by the OCME in response to a specific request to allow organ and/or tissue recovery in a medical examiner case.

1. Any request for organs and/or tissue received from a Recovery Agency must be immediately communicated to the on call Chief Medical Examiner (CME) or on call Deputy Medical Examiner (DCME) at the OCME for authorization. In certain circumstances, additional investigation or information may be required from a hospital, law enforcement agency or physician before the OCME can make a decision regarding donation.

2. Once a decision is made by the on-call CME or DCME the OCME will immediately communicate that decision to the requesting Recovery Agency.

3. If the OCME has determined that organ and/or tissue recovery is allowable, the Recovery Agency must request full informed consent from the next-of-kin.

4. The request for informed consent must fully comply with the procedures set forth in this policy. A consent form, executed in accordance with this policy must be provided (in original, faxed copy, or scanned/pdf format) to the OCME. That consent form shall be maintained in individual case files at the OCME.

5. Upon request by the next-of-kin (or other person with legal authority to request such information), the OCME shall assist the next-of-kin with obtaining an additional copy of the executed consent form, as well as a copy of the audio recording (in cases of telephonic consent).

6. No informed consent form may be acted upon by the OCME unless the Recovery Agency has been approved under this policy and the consent form evidences compliance with this policy. Any questions or doubts as to the completeness or authenticity of the informed consent form must be resolved before any recovery action is taken.

7. In any reported death, where the deceased has not been transported to a hospital, the OCME shall telephonically notify the New England Organ Bank (as the federally designated regional Recovery Agency) with the following exceptions:

(a) Ages less than 36 weeks gestation or greater than 80 years.

(b) Intravenous drug overdose or any evidence of intravenous drug use.

(c) Known HIV, Hepatitis B or Hepatitis C infection.

(d) Time of death greater than 12 hours prior to time refrigerated (to the best of the known information).

(e) Known history of leukemia, lymphoma, ALS.

(f) Meningitis or Sepsis as possible cause of death.

(g) Any known active infectious process at time of death.

(h) Degenerative neurologic disorders of unknown etiology.

(i) Inmate in correctional facility.

C. Use of OCME Facilities

If, in the opinion of the Chief Medical Examiner or on-call Deputy Chief Medical Examiner, it would be in the State's interest and would facilitate efficient operation of the OCME for the Recovery Agency to procure organ(s) and/or tissue(s) at the OCME facility, the OCME may authorize the procurement to take place in the facility.

1. Prior to authorizing procurement at the OCME facility, the Chief Medical Examiner or on-call Deputy Chief Medical Examiner must find the following:

(a) That an informed consent authorization for procurement as specified in this policy manual has been received and approved.

(b) That an autopsy has been or will be performed on the donor's body at the OCME facility.

(c) That procurement will not interfere with the performance of the autopsy, with other autopsies, or with any other required tasks of the OCME.

2. The following procedures must be followed by the Recovery Agency after receiving OCME approval for using the OCME facility for procurement:

(a) Procurement procedures must occur during the normal operating hours of the OCME.

(b) No Recovery Agency staff or other outside personnel shall be in the autopsy room without adequate supervision.

(c) All equipment needed for the procurement procedures, including personal protective equipment, must be supplied by the Recovery Agency performing the procedure.

(d) The disposal of any waste generated during the procedure is the responsibility of the Recovery Agency.

(e) Recovery Agency personnel must sign a form acknowledging that the State of Maine assumes no liability for injuries or exposures that occur during the procurement procedures.

D. Prohibition on Compensation for OCME Employees

No OCME employee or individual under written contract with the OCME may receive payment from a Recovery Agency or any other organization or individual for any services provided in connection with tissue and/or organ procurement.

E. Conflicts of Interest

No OCME employee or individual under written contract with the OCME may be involved in any way, either directly or indirectly, with securing informed consent for donations from next-of-kin for any Recovery Agency except as otherwise required by law.

F. Effective Date and Transition

This policy is effective January 31, 2005. However, the New England Organ Bank (the "NEOB"), as the federally recognized Recovery Agency for the region, shall be deemed to be approved as a Recovery Agency under Section A(5) of this policy for 90 days or until the NEOB completes the demonstration of compliance with this policy pursuant to Section A(3), if sooner than 90 days.