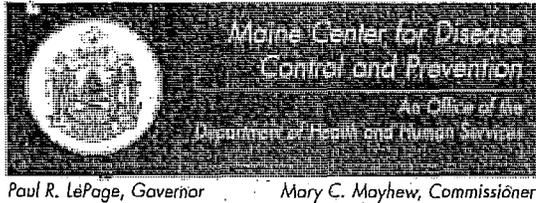


MAINE STATE LEGISLATURE

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From: Shelia Pinette, Director, Maine Center for Disease Control and Prevention
To: Joint Standing Committee on Health and Human Services
Date: March 4, 2014
Re: Report on Resolve Chapter 58

Issue: The Department of Health and Human Services, Maine Center for Disease Control and Prevention (Maine CDC), Data, Research, and Vital Statistics (DRVS) office has been directed to clarify the processes regarding the registration of recovery agencies for tissue and organ donation for Resolve of LD 123 passed in the 126th session of the Maine State Legislature in 2013. A report must be prepared and presented to the Maine Legislative Joint Standing Committee of Health and Human Services.

Background: The Resolve for LD 123 requires DRVS to examine the current processes for registration of recovery agencies for tissue organ donation to determine if the current policies of the Office of the Maine Chief Medical Examiner and the Department meet the statutory requirements under the Revised Uniform Anatomical Gift Act. The resolve also directs DRVS to consult with the Maine Office of the Chief Medical Examiner, the Maine Bureau of Motor Vehicles (BMV), the Organ Donation Advisory Council, the New England Organ Bank (NEOB), and other interested parties including those in the funeral profession to report the findings, recommendations and suggested legislation to the Joint Standing Committee on Health and Human Services no later than January 1, 2014.

Highlights: The current process for registration of recovery agencies involved in tissue and organ donation in Maine was introduced by a policy implemented in 2005 by the Maine Office of Chief Medical Examiner and the Maine Office of Attorney General (AG). The policy requires any tissue bank, organ procurement organization, or research organization (a "recovery agency") to provide documentation to the Maine Attorney General's office and the Maine Office of Chief Medical Examiner before they are allowed to recover any tissue or organs. Although the policy meets the statutory requirements under the Revised Uniform Anatomical Gift Act, the policy specifically does not cover all the deaths in the State of Maine, only those whose deaths fall under the jurisdiction of the Maine Office of Chief Medical Examiner. In past discussions with Margaret Greenwald, Maine's Chief Medical Examiner, the few independent researchers who have contacted the Maine Office of Chief Medical Examiner have either declined to proceed or have pursued a partnership with the New England Organ Bank (NEOB). The England Organ Bank is currently the only organization that has met the criteria established by the Attorney General's office and actively provides ongoing documentation each year to maintain eligibility status in Maine.

DRVS has had limited success in obtaining information on the processes regarding the registration of recovery agencies for tissue and organ donation. When researching and consulting with other states in the United States, the National Association for Public Health Statistics and Information Systems (NAPHSIS), and the National Center for Health Statistics (NCHS), it has been learned that most jurisdictions throughout the country are in

similar situations trying to establish processes and rules for the registration of recovery agencies. Please see the attached chart that DRVS has prepared containing the research results amongst other states.

Over the past seven months, DRVS has consulted with Alexandria Glazier, Vice President of the New England Organ Bank (NEOB); Sean Fitzpatrick, Director of Public Affairs, New England Organ Bank; Dr. Margaret Greenwald, Maine Chief Medical Examiner; William Stokes, Deputy Attorney General, Maine Office of Attorney General; Jonathan Hull, Attorney designated on behalf of Funeral Consumers Alliance of Maine; Sally Belanger, Executive Director, Maine Funeral Directors Association; and Rick Desjardins, Director of Public Services, Maine Bureau of Motor Vehicles and Members of the Organ Donation Advisory Council; per the consultation discussed current policies and processes currently being enforced for the registration of recovery agencies for tissue and organ donation.

Documentation sent to the Maine CDC, Data, Research and Vital Statistics as part of the consultations we have conducted includes:

- The organ donation policy implemented in 2005 by the Maine Office of Chief Medical Examiner and the Maine Office of Attorney General
- A copy of the confirmation letter provided from the Maine Attorney General's office to an approved recovery agency verifying internal process for the review of consent forms used for recovery of tissue and organs
- Copies of authorization and disclosure forms in which a recovery agency provides to the Maine Office of Attorney General
- Documentation indicating proof of designation of an organ procurement organization with the United States Department of Health and Human Services Centers for Medicare and Medicaid Services
- Documentation indicating proof of registration of a tissue bank registrant with the United States Department of Health and Human Services Food and Drug Administration
- Documentation indicating proof of being an accredited member with the Association of Organ Procurement Organizations ("AOPO") or the American Association of Tissue Banks ("AATB")

Based on review of the documentation received from the parties mentioned above and the research material gathered from other states; draft rules have been developed by DRVS and reviewed by the Maine Office of the Chief Medical Examiner, the Maine Bureau of Motor Vehicles, the Organ Donation Advisory Council, New England Organ Bank, and the Maine Funeral Directors Association to fulfill the requirements for the promulgation of rules.

The drafted rule was sent to all parties mentioned in the resolve of LD 123 for their review. Several comments and suggestions were recorded and incorporated into the second revision of the proposed rules. A meeting to follow up with stakeholders was convened in November 2013 to discuss the proposed rules. Minutes were taken during the meeting and recorded. Once again, parties provided DRVS with several comments and suggestions which were incorporated into the third revision of drafted rules. This version, as well as the meeting minutes were sent to all aforementioned parties on November 25, 2013. DRVS provided all parties a two week timeframe to submit questions, comments and suggestions on the third version prior to the initiation of any formal rule-making. The deadline provided to parties during this informal process was December 20, 2013.

The drafted rule establishing registration requirements for recovery agencies with the Maine Center for Disease Control and Prevention prior to requesting, recovering, or otherwise facilitating in an anatomical gift has been

drafted as specified in Title 22 §2962. The rule provides for the collection of reasonable registration fees, provides exemptions for recovery agencies that are in good standing with their federal oversight agencies. The rule also ensures compliance with the policy on consent for organ and tissue donation implemented by the Maine Office of the Chief Medical Examiner and the Maine Office of the Attorney General which became effective on January 31, 2005.

No legislation will be suggested for consideration and is not necessary for the finalization of this rule.

For Further Information, please contact:

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SUMMARY: These rules establish registration requirements for recovery agencies with the Maine Center for Disease Control and Prevention prior to requesting, ~~receiving~~ recovering, or otherwise participating-facilitating in an anatomical gift. The rules set reasonable registration fees, provide exemptions for recovery agencies that are in good standing with their federal oversight agencies, and ensures compliance with the policy on consent for organ and tissue donation effective January 31, 2005 implemented by the Office of the Chief Medical Examiner and the Office of the Attorney General in Maine. Pursuant to 22 M.R.S.A. §2962(2), these rules are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

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PURPOSE: The purpose of these rules is to establish a process governing the registration of recovery agencies, provide exemptions for organ procurement organizations designated by the United States Department of Health and Human Services and tissue banks registered with the United States Department of Health and Human Services, Food and Drug Administration that are in good standing with their respective federal oversight agencies, and may provide for exemptions for other recovery agencies if such agencies operate in full compliance with this chapter.

1. Definitions

- A. "Department" means the Department of Health and Human Services.
- BA. "Recovery Agency" means an eye bank, organ procurement organization, tissue bank, educational or medical institution, or research organization that participates in or facilitates the execution of an anatomical gift.
- C. "State Registrar" means the State Registrar, Deputy State Registrar or other designated employee from the Data, Research, and Vital Statistics office.
- D. "To Present" means to deliver the documents in person, by mail, electronically, secured fax, or other methods approved by the State Registrar.
- E. "Vital Statistics" means the Maine Center for Disease Control and Prevention, Data, Research, and Vital Statistics office.

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2. Registration

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A. Registration Requirements

- 1. A Recovery Agency must apply to be registered by the Department prior to requesting, recovering, or otherwise facilitating in an anatomical gift and must meet all the requirements in this chapter.

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2. Approved registrations are valid for a period of three years from the date of filing unless the Recovery Agency is considered exempt as specified in section 2 subsection B of this chapter or upon expiration of the confirmation letter certified from the Maine Office of the Attorney General as specified in section 2 subsection C(2).
3. Recovery Agencies must meet all responsibilities specified in section 2 subsection C of this chapter for registration to occur.
4. Recovery Agencies considered to be exempt as specified in section 2(B) below and have been operating in Maine prior to enactment of this rule are considered to be exempt from registration requirements specified in this section.

B. Exemptions

1. Organ procurement organizations designated by the United States Department of Health and Human Services are exempt from any registration fees and need apply only one time to be registered with the Department. The federally designated organ procurement organization must notify the State Registrar immediately if their federal designation is ever revoked.
2. Tissue Banks registered with the United States Department of Health and Human Services, Food and Drug Administration are exempt from any registration fees and need apply only one time to be registered with the Department. The federally registered tissue bank must notify the State Registrar immediately if their federal designation is ever revoked.
3. Other recovery agencies if such agencies operate in full compliance with the Revised Uniform Anatomical Gift Act as specified in Title 22, Chapter 710-B are exempt from any registration fees and need apply only one time to be registered with the Department upon approval of the State Registrar.

CA. Responsibility of Recovery Agency

1. The Recovery Agency must complete and present the registration form provided by the State Registrar to Data, Research, and Vital Statistics (DRVS). The registration form ~~is~~ completed by entering all of the required information:
 - a. name and mailing address of Recovery Agency
 - b. name and contact information of Chief Executive Officer or other official of the Recovery Agency with authority to do so, on behalf of the Recovery Agency
 - c. date of submission
 - d. indication of ~~good standing designation~~ of an organ procurement organization as ~~designated by~~ with the United States Department of Health and Human Services Centers for Medicare and Medicaid Services

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- e. ~~indication of good standing registration of~~ a tissue bank registrant with the United States Department of Health and Human Services Food and Drug Administration
- f. ~~indication of accredited member in good standing with the~~ Association of Organ Procurement Organizations ("AOPO") or the American Association of Tissue Banks ("AAATB")
- g. acknowledgement to maintain internal policies and procedures that demonstrate compliance with Maine's Revised Uniform Anatomical Gift Act, ~~and where applicable, M.R.S.A. 22 §§2941 - 2965;~~ Maine Department of Health and Human Services (DHHS) regulations found at Code of Maine Regulation (CMR) 10-144, Chapter 52; ~~and, where applicable, federal and federal law found at 42 USC §§273 and 1320b-8 with~~ accompanying regulations found at CFR 42 §§121.1 and 486.301.

22. In addition to the registration form, ~~a the~~ Recovery Agency must ~~provide present~~ the ~~approval confirmation letter from certified from~~ the Maine Office of the Attorney General stating the Recovery Agency ~~is in~~ is in full compliance with the policy of the Maine Office of the Chief Medical Examiner effective January 31, 2005 regarding tissue and organ donation.

33. ~~The fee for registration of a Recovery Agency shall must be paid at the time pay~~ the registration form, confirmation letter, and other supporting documents, ~~when applicable, are presented registration fee of \$ — to Data, Research, and Vital Statistics unless the Recovery Agency is considered exempt as specified in section 2 subsection B of this chapter.~~

~~The Recovery Agency must submit the registration form to the state registrar, together with such supporting information as required. The state registrar will approve, modify, or disapprove the registration form within 10 to 14 business days of receiving the Recovery Agency's submission.~~

4. ~~Exempt recovery agencies specified in subsection 2 (B) must register as an exempt recovery agency pursuant to 22 MRSA §2962 subsection 2.~~

5. ~~Federal designated organ procurement organizations must register one time with the state registrar and are exempt from any registration fees. The organ procurement organization must notify the state registrar immediately if their federal designation is ever revoked by the United States Department of Health and Human Services.~~

4. Records of all consent forms, approved registration form, confirmation letter from the Maine Office of the Attorney General, or other documents presented to the State Registrar for registration must be retained by the Recovery Agency in accordance with applicable laws and must be available for inspection upon request.

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B. Exemptions for Registration Requirements

- 1. Organ procurement organizations designated by the United States Department of Health and Human Services.
- 2. Tissue banks registered with the United States Department of Health and Human Services, Food and Drug Administration.
- 3. Other recovery agencies if such agencies operate in full compliance with the Revised Uniform Anatomical Gift Act as specified in Title 22, Chapter 710-B.

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DC. Responsibility of State Registrar

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1. The State Registrar shall ~~must~~ evaluate all registration forms and evidence ~~documents submitted presented~~ in support of a Recovery Agency and shall ~~must~~ approve the registration when supported by ~~the appropriate evidence documents~~.

2. The State Registrar must approve, modify or reject the Recovery Agency's registration form within 10 to 14 business days. If additional time is needed to review the Recovery Agency's registration form, the State Registrar will notify the Recovery Agency in writing within the 10 to 14 day time frame and must take no more than 10 to 14 additional days to approve, modify or reject the registration.

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32. When a Recovery Agency does not present the minimum documentation required in the regulations for registration of a Recovery Agency to occur or when the State Registrar has reasonable cause to question the validity or adequacy of the documents presented by the Recovery Agency's documentary evidence, the State Registrar shall ~~must reject not allow the registration of the~~ Recovery Agency and shall advise the Recovery Agency of the reason for this action and shall further advise the Recovery Agency of the right to appeal to a court of competent jurisdiction.

43. When satisfied that all of the requirements of law and rule in this chapter have been met, the State Registrar shall ~~must~~ accept the registration form for filing, sign the registration and enter the date on which it has been registered or filed.

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5. The State Registrar will present the registered Recovery Agency with a certificate of registration.

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D. Retention of Registration Form and Documentary Evidence

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61. A copy of the registration form presented by the Recovery Agency shall ~~must~~ be retained by the State Registrar ~~up to for a period up to three years or upon~~ renewal of registration.

once every three years.

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72. A copy of the approval ~~confirmation~~ letter from the Maine Office of the Attorney General shall ~~must~~ be retained by the State Registrar ~~for a period up to three years up to~~ upon renewal of registration, ~~once every three years~~.

- ~~83.~~ A copy of other documents ~~any evidence presented shall must~~ be retained by the State Registrar for a period up to three years or upon up to renewal of registration, ~~once every three years.~~
- ~~4.~~ Records of all ~~consent forms, registration form, approval letter from the Maine Office of the Attorney General, or other documentary evidence presented to the state registrar~~ must be retained by the Recovery Agency in accordance with applicable laws and must be available for inspection by the state registrar at any time.

STATUTORY AUTHORITY: 22 MRSA §§2941 - 2965

EFFECTIVE DATE:

EFFECTIVE DATE (ELECTRONIC CONVERSION):



Maine Center for Disease
Control and Prevention
An Office of the
Department of Health and Human Services

Maine Center for Disease Control and Prevention (Maine CDC)
244 Water Street
11 State House Station
Augusta, Maine 04333-0011
(207) 287-3771
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Recovery Agency Registration Form

1. Name of Recovery Agency	
2. Mailing Address of Recovery Agency (Street and number, city or town, county, state, and zip code)	
This Registration Form ensures the minimum standards for full informed (1) consent, (2) protocol, (3) circumstances and (4) conflicts of interest for organ and tissue donation have been met and recognized by the Office of Chief Medical Examiner and the Office of the Attorney General before any registration of a Recovery Agency occurs in the State of Maine, Data, Research, and Vital Statistics (DRVS)	
Informed Consent for Recovery of Tissue and Organs (Check all that apply)	
Required <input type="checkbox"/>	Recovery Agency requesting registration has been recognized by the Office of Chief Medical Examiner (OCME) for having the appropriate policies, practices and procedures necessary for obtaining consent for organ and tissue donation.
Required <input type="checkbox"/>	Recovery Agency requesting registration has met the full informed consent requirements specified in the Policy for Tissue and Organ Donation set forth by the OCME and the Office of the Attorney General (AG) and has been notified of approval. (Approval letter must accompany this registration form.)
<input type="checkbox"/>	Recovery Agency requesting registration is designated by the United States Department of Health and Human Services Centers for Medicare & Medicaid Services ("CMS"), or registered with the United States Department of Health and Human Services Food and Drug Administration ("FDA").
<input type="checkbox"/>	Recovery Agency requesting registration is in good standing with their respective federal oversight agencies, the Association of Organ Procurement Organizations ("AOPO") or the American Association of Tissue Banks ("AATB").
Required <input type="checkbox"/>	Recovery Agency requesting registration acknowledges to maintain internal policies and procedures that demonstrate compliance with Maine's Revised Uniform Anatomical Gift Act, where applicable, 22MRSA §§2941 – 2965; Maine Department of Health and Human Services (DHHS) regulations found at Code of Maine Regulation (CMR) 10-144, Chapter 52; an federal law found at 42 USC §§273 and 1320b-8 with accompanying regulations found at 42 CFR §§121.1 and 486.301.
Signature of Chief Executive Office or Authorized Official of Recovery Agency	
Date of Submission	
Email Address	
Phone Number	
DRVS ONLY	
Signature of State Registrar	
Date Filed	
Payment <input type="checkbox"/> Cash <input type="checkbox"/> Check # _____ <input type="checkbox"/> Credit Card <input type="checkbox"/> Other	

Comparision of State's Establishment of Registries for Anatomical Recovery Organizations

Specifics of State's Registries												
State	Responsible Agency/ Department	Number of Staff	Expertise or Special Skills	Estimated Cost	Application Process	Registration Fee/Amount and Frequency	Number of Registered Organizations	Access to Donor Registry	Records are Audited and Inspected	Enforcement, Fines or Revocation	Medical Examiner or Hospital Cooperation	Hospital Required to Enter into Agreement
California	Donate Life Calif. Organ and Tissue Donor Reg.							Yes, reasonable	Yes	\$50,000 or imprisonment up to 5 yrs.	Yes	Yes, reasonable
Missouri	Dept. of Health and Senior Services	2 to 4	Yes, due to web-based system w/ multiple portals	grant received	online registration		5	Yes, combined access			Yes	
New Jersey	Dept. of Health and Senior Services					Yes, yearly renewal		Yes, limited access	Yes	\$1,000 up to \$5,000. May revoke reg.	Yes	
Ohio	Secretary of State Designee	3	database (IT)	Second Chance trust fund 2108.34	forms	Yes Yes, yearly renewal		Yes	Yes		Coroner	Yes
Oregon	State Mortuary and Cemetery Board								Yes	\$1000 or may revoke reg. \$50,000 or imprisonment up to 5 yrs.	Yes	
Rhode Island	Dept. of Health and Human Services							Yes	Yes		Yes	
South Carolina	Secretary of State Designee				Internet	Yes, yearly renewal	6	Yes	Yes	\$50,000 fine or 5 yr imprisonment	Coroner, ME, Hospital	Yes

Virginia	Dept. of Health and Human Services				database		4	Yes, reasonable		Class 4 felony	Yes	
Washington	Dept. of Licensing		Electronic Transfer					Yes, combined	Yes	Class C felony	Yes Coroner, ME, Hospital	Yes
West Virginia	Health and Family Services		Yes, web-based system, multiple users	grant received minimal cost (see written response)	internet portal uploads new registrations		5	Yes, combined access				
Wisconsin	Dept. of Health Services, Division of Public Health	1	certain IT applications maintained by State	WAMS (grant)	completes form and submits, background checks	No charge	3 organizations, over 100 staff members have access	Yes, reasonable	Yes		Yes	

Notes: These data compiled by Maine Center for Disease Control and Prevention, Data, Research, and Vital Statistics:

States were contacted in an attempt to complete the missing data items or for further clarification. Only one, Wisconsin, responded and provided the legislation.

Source: web searches originating from <http://www.organdonor.gov/index.html>. This website is U.S. Department of Health and Human Services

Government Information on Organ and Tissue Donation and Transplantation. Other sites included each individual state's websites and HRSA's <http://optn.transplant.hrsa.gov/members/search.asp>