26:6-68

LEGISLATIVE HISTORY CHECKLIST

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LAWS OF:	2008	CHAP	TER:	49		
NJSA:	26:6-68	(Requires anatomical research recovery organizations to register with DHSS)				
BILL NO:	S753	(Substituted for	A1935)			
SPONSOR(S): Codey and others						
DATE INTRODUCED: January 8, 2008						
COMMITTEE: ASSEMBLY:						
		SENATE:	Health	, Human Services and Senior Citizens		
AMENDED DURING PASSAGE: Ye			Yes			
DATE OF PAS	SAGE:	ASSE	MBLY:	June 16, 2008		
		SENA	TE:	March 17, 2008		
DATE OF APP	ROVAL	July 22	2, 2008			
FOLLOWING ARE ATTACHED IF AVAILABLE:						
FINAL TEXT OF BILL (First reprint enacted)						
S753	SPON	SOR'S STATEM	ENT:	(Begins on page 5 of original bill)	Yes	
	COMM	IITTEE STATEM	ENT:	ASSEMBLY:	No	
				SENATE:	Yes	
(Audio archived	l recordir	ngs of the commi	ttee mee	tings, corresponding to the date of the co	mmittee statement, may	

(Audio archived recordings of the committee meetings, corresponding to the date of the committee statement, *may possibly* be found at www.njleg.state.nj.us)

	FLOOR AMENDMENT STATEMENT:			
	LEGISLATIVE FISCAL ESTIMATE:			
A1935	SPONSOR'S STATEMENT:	(Begins on page	e 5 of original bill)	Yes
	COMMITTEE STATEMENT:		ASSEMBLY:	Yes
			SENATE:	No
	FLOOR AMENDMENT STATEMENT:			No
	LEGISLATIVE FISCAL ESTIMA	ATE:		No

(continued)

FOLLOWING WERE PRINTED:

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REPORTS:	No
HEARINGS:	No
NEWSPAPER ARTICLES:	No

LAW

§§1-9 -C.26:6-68 to 26:6-76 §10 - Note to §§1-9

P.L. 2008, CHAPTER 49, approved July 22, 2008 Senate, No. 753 (First Reprint)

AN ACT concerning anatomical gifts for educational and research 1 2 use and supplementing Title 26 of the Revised Statutes. 3 4 **BE IT ENACTED** by the Senate and General Assembly of the State 5 of New Jersey: 6 7 1. This act shall be known and may be cited as the "Anatomical 8 Research Recovery Organization Act." 9 10 2. It is the public policy of this State to safeguard the health and 11 well-being of its citizens, and to ensure the respectful and 12 consensual disposition and use of human bodies and parts donated for education, research, and the advancement of medical, dental, or 13 mortuary science. The need for and use of such anatomical gifts for 14 15 education, research, and the advancement of medical, dental, or mortuary science is of sufficient frequency so as to require that 16 17 minimum standards for anatomical research recovery organizations 18 be established. 19 20 3. As used in this act: 21 "Anatomical research recovery organization" means a nonprofit corporation engaged in the recovery of a human body or part 22 donated for education, research, or the advancement of medical, 23 24 dental, or mortuary science pursuant to P.L.1969, c.161 (C.26:6-57 25 et seq.) ¹or any subsequent statute adopted pursuant thereto¹, where 26 part or all of the recovery takes place in this State. Anatomical 27 research recovery organization shall not include an accredited 28 institution of higher education in this State that uses an anatomical 29 gift for its own educational or research purposes and is not engaged 30 in the distribution of a human body or part to another person or 31 entity. 32 "Commissioner" means the Commissioner of Health and Senior 33 Services. 34 "Department" means the Department of Health and Senior 35 Services. 36 "Distribution" means the removal of a human body or part from 37 a storage location to any other location for educational or research use, or the advancement of medical, dental, or mortuary science. 38 EXPLANATION - Matter enclosed in bold-faced brackets thus in the above bill is

Matter underlined <u>thus</u> is new matter. Matter enclosed in superscript numerals has been adopted as follows:

not enacted and is intended to be omitted in the law.

¹Senate SHH committee amendments adopted February 14, 2008.

1 "Education" means the use of the whole body or parts for 2 purposes of teaching or training individuals, including medical or 3 dental professionals and students, with regard to the anatomy and 4 characteristics of the human body.

5 "Human body part" or "part" means organs, tissues, eyes, bones,
6 blood vessels, and any other portions of a deceased human body
7 which are subject to an anatomical gift pursuant to P.L.1969, c.161
8 (C.26:6-57 et seq.) ¹or any subsequent statute adopted pursuant
9 <u>thereto</u>¹, but does not include blood collected pursuant to P.L.1945,
10 c.301 (C.26:2A-1 et seq.).

11 "Recovery" means the obtaining of a human body or part, 12 including, but not limited to, determining or obtaining consent or 13 authorization for donation of the human body or part, performing 14 surgical or other technical procedures for recovering the body or 15 part, and processing the body or part. Recovery does not include 16 actions taken by a medical examiner or coroner as part of his 17 professional duties.

18 "Research" means the conduct of scientific testing and 19 observation designed to result in the acquisition of generalizable 20 knowledge. Research does not include an autopsy or other 21 investigation conducted for the purpose of obtaining information 22 related to the decedent.

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4. a. No person shall engage in the recovery of a human body or part donated in this State for education, research, or the advancement of medical, dental, or mortuary science pursuant to P.L.1969, c.161 (C.26:6-57 et seq.) ¹or any subsequent statute adopted pursuant thereto¹, unless the person is registered as an anatomical research recovery organization with the Department of Health and Senior Services pursuant to this act.

The registration required pursuant to this act shall be in addition to any license or permit required by a local board of health, other local health agency, or any State or federal agency.

b. The registration shall be valid for a one-year period and may
be renewed subject to compliance with the requirements of this act.
The commissioner shall establish such registration and renewal fees
as may be reasonable and necessary to carry out the purposes of this
act.

c. The commissioner may enter and inspect the premises of any
anatomical research recovery organization and the books and
records as is reasonably necessary to carry out the provisions of this
act.

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44 5. An anatomical research recovery organization operating in
45 this State shall demonstrate compliance with the following
46 requirements:

S753 [1R]

1 a. A physician licensed in this State or the state in which the 2 organization is incorporated shall serve as medical director, and 3 shall be responsible for ensuring compliance with the provisions of 4 this act, the hiring of qualified personnel, and the maintenance of 5 records required under this act.

b. The organization shall be a federally tax-exempt nonprofit7 corporation.

c. The organization shall create, compile, or maintain a complete
record on each donor from which it recovers a human body or part
for educational or research purposes or the advancement of medical,
dental or mortuary science, which shall include, at a minimum:

(1) documentation that the donor has designated the anatomical
gift for educational or research purposes or for the advancement of
medical, dental, or mortuary science, as specified in section 3 of
P.L.1969, c.161 (C.26:6-59) ¹or any subsequent statute adopted
pursuant thereto¹. The documentation may be in the form of a
signed document of gift, or verifiable documentation that taped
telephonic consent has been obtained;

(2) documentation of the identity and address of each entity
which has been in possession of the human body or part prior to the
organization, such as a funeral home, coroner, hospital, organ
procurement organization, or tissue bank; and

(3) documentation of the use and disposition of each human
body or part, including the name and address of each person who
receives a human body or part directly from the organization.

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6. It shall be a violation of this act for any person to obstruct,
hinder, delay or interfere, by force or otherwise, with the
performance by the commissioner of any duty under the provisions
of this act.

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32 7. If the commissioner has reason to believe that a condition exists or has occurred at an anatomical research recovery 33 34 organization in violation of the provisions of this act, which is 35 dangerous to the public health, he may order the organization to 36 correct the violation and may immediately suspend the registration of the organization until the correction is completed. If a registrant 37 38 denies that a violation exists or has occurred, the registrant shall 39 have the right to apply to the commissioner for a hearing. The 40 hearing shall be held and a decision rendered within 48 hours of the receipt of the request. If the commissioner rules against the 41 42 registrant, the registrant may apply to a court of competent 43 jurisdiction for injunctive relief against the commissioner's order.

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8. a. Any person who violates the provisions of this act or an
order of the commissioner shall be liable for the first offense to a
penalty of not more than \$1,000, and for the second and each

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1 succeeding offense for a penalty of not more than \$5,000. The

2 penalties shall be sued for and collected in a summary proceeding in

3 accordance with "Penalty Enforcement Law of 1999," P.L.1999,

4 c.274 (C.2A-58-10 et seq.).

b. In addition to any civil penalties provided under this section,
the commissioner may suspend or revoke a registration made
pursuant to this act for a violation of any provision of this act.

8 c. Except as provided in section 7 of this act, before denying to 9 grant or renew a registration, or suspending or revoking a 10 registration, pursuant to this act, the commissioner shall provide notice of the denial, revocation, or suspension, together with a 11 12 specification of charges to the applicant or registrant, personally or 13 by certified mail to the address of record, and the notice shall set 14 forth the particular reasons for the denial, suspension, or revocation. 15 The denial, suspension, or revocation shall become effective 30 16 days after mailing, unless the applicant or registrant, within the 30-17 day period, meets the requirements of the department or files with 18 the department a written answer to the charges and gives written 19 notice to the department of its desire for a hearing, in which case 20 the denial, suspension, or revocation may be held in abeyance until 21 the hearing has been concluded and a final decision rendered by the 22 commissioner.

23 The commissioner shall afford the applicant or registrant an 24 opportunity for a prompt hearing on the question of the granting, 25 suspension, or revocation of the registration. The procedure 26 governing the hearing shall be in accordance with the rules and 27 regulations of the department. Either party may be represented by 28 counsel of its own choosing, and has the right to subpoena 29 witnesses and to compel their attendance on forms furnished by the 30 department. The commissioner shall render a written decision 31 stating conclusions and reasons therefor.

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9. The commissioner shall adopt rules and regulations pursuant
to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B1 et seq.) to carry out the purposes of this act. The regulations may
specify qualifications for personnel, including the medical director,
employed at an anatomical research recovery organization and
standards related to recovery of human bodies or parts.

40 10. This act shall take effect on the 180th day following41 enactment.

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46 Requires anatomical research recovery organizations to register47 with DHSS.

SENATE, No. 753

STATE OF NEW JERSEY 213th LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2008 SESSION

Sponsored by: Senator RICHARD J. CODEY District 27 (Essex)

Co-Sponsored by: Senator Gordon

SYNOPSIS

Requires anatomical research recovery organizations to register with DHSS.

CURRENT VERSION OF TEXT

Introduced Pending Technical Review by Legislative Counsel



(Sponsorship Updated As Of: 2/15/2008)

S753 CODEY

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 AN ACT concerning anatomical gifts for educational and research use and supplementing Title 26 of the Revised Statutes.
 BE IT ENACTED by the Senate and General Assembly of the State of New Jersey:

5 6

7 1. This act shall be known and may be cited as the "Anatomical8 Research Recovery Organization Act."

9

10 2. It is the public policy of this State to safeguard the health and well-being of its citizens, and to ensure the respectful and 11 12 consensual disposition and use of human bodies and parts donated 13 for education, research, and the advancement of medical, dental, or 14 mortuary science. The need for and use of such anatomical gifts for 15 education, research, and the advancement of medical, dental, or 16 mortuary science is of sufficient frequency so as to require that 17 minimum standards for anatomical research recovery organizations 18 be established.

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20 3. As used in this act:

21 "Anatomical research recovery organization" means a nonprofit 22 corporation engaged in the recovery of a human body or part 23 donated for education, research, or the advancement of medical, 24 dental, or mortuary science pursuant to P.L.1969, c.161 (C.26:6-57 25 et seq.), where part or all of the recovery takes place in this State. 26 Anatomical research recovery organization shall not include an 27 accredited institution of higher education in this State that uses an 28 anatomical gift for its own educational or research purposes and is 29 not engaged in the distribution of a human body or part to another 30 person or entity.

31 "Commissioner" means the Commissioner of Health and Senior32 Services.

33 "Department" means the Department of Health and Senior34 Services.

35 "Distribution" means the removal of a human body or part from
36 a storage location to any other location for educational or research
37 use, or the advancement of medical, dental, or mortuary science.

38 "Education" means the use of the whole body or parts for 39 purposes of teaching or training individuals, including medical or 40 dental professionals and students, with regard to the anatomy and 41 characteristics of the human body.

"Human body part" or "part" means organs, tissues, eyes, bones,
blood vessels, and any other portions of a deceased human body
which are subject to an anatomical gift pursuant to P.L.1969, c.161
(C.26:6-57 et seq.), but does not include blood collected pursuant to
P.L.1945, c.301 (C.26:2A-1 et seq.).

1 "Recovery" means the obtaining of a human body or part, 2 including, but not limited to, determining or obtaining consent or 3 authorization for donation of the human body or part, performing 4 surgical or other technical procedures for recovering the body or 5 part, and processing the body or part. Recovery does not include 6 actions taken by a medical examiner or coroner as part of his 7 professional duties.

8 "Research" means the conduct of scientific testing and 9 observation designed to result in the acquisition of generalizable 10 knowledge. Research does not include an autopsy or other 11 investigation conducted for the purpose of obtaining information 12 related to the decedent.

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4. a. No person shall engage in the recovery of a human body or part donated in this State for education, research, or the advancement of medical, dental, or mortuary science pursuant to P.L.1969, c.161 (C.26:6-57 et seq.), unless the person is registered as an anatomical research recovery organization with the Department of Health and Senior Services pursuant to this act.

The registration required pursuant to this act shall be in addition
to any license or permit required by a local board of health, other
local health agency, or any State or federal agency.

b. The registration shall be valid for a one-year period and may
be renewed subject to compliance with the requirements of this act.
The commissioner shall establish such registration and renewal fees
as may be reasonable and necessary to carry out the purposes of this
act.

c. The commissioner may enter and inspect the premises of any
anatomical research recovery organization and the books and
records as is reasonably necessary to carry out the provisions of this
act.

32

5. An anatomical research recovery organization operating in
this State shall demonstrate compliance with the following
requirements:

a. A physician licensed in this State or the state in which the
organization is incorporated shall serve as medical director, and
shall be responsible for ensuring compliance with the provisions of
this act, the hiring of qualified personnel, and the maintenance of
records required under this act.

b. The organization shall be a federally tax-exempt nonprofitcorporation.

c. The organization shall create, compile, or maintain a complete
record on each donor from which it recovers a human body or part
for educational or research purposes or the advancement of medical,
dental or mortuary science, which shall include, at a minimum:

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(1) documentation that the donor has designated the anatomical 1 2 gift for educational or research purposes or for the advancement of 3 medical, dental, or mortuary science, as specified in section 3 of 4 P.L.1969, c.161 (C.26:6-59). The documentation may be in the 5 form of a signed document of gift, or verifiable documentation that taped telephonic consent has been obtained; 6 7 (2) documentation of the identity and address of each entity 8 which has been in possession of the human body or part prior to the 9 organization, such as a funeral home, coroner, hospital, organ 10 procurement organization, or tissue bank; and (3) documentation of the use and disposition of each human 11 12 body or part, including the name and address of each person who 13 receives a human body or part directly from the organization. 14 15 6. It shall be a violation of this act for any person to obstruct, 16 hinder, delay or interfere, by force or otherwise, with the 17 performance by the commissioner of any duty under the provisions 18 of this act. 19 20 7. If the commissioner has reason to believe that a condition 21 exists or has occurred at an anatomical research recovery 22 organization in violation of the provisions of this act, which is 23 dangerous to the public health, he may order the organization to 24 correct the violation and may immediately suspend the registration 25 of the organization until the correction is completed. If a registrant 26 denies that a violation exists or has occurred, the registrant shall 27 have the right to apply to the commissioner for a hearing. The 28 hearing shall be held and a decision rendered within 48 hours of the 29 receipt of the request. If the commissioner rules against the 30 registrant, the registrant may apply to a court of competent 31 jurisdiction for injunctive relief against the commissioner's order. 32 33 8. a. Any person who violates the provisions of this act or an 34 order of the commissioner shall be liable for the first offense to a 35 penalty of not more than \$1,000, and for the second and each 36 succeeding offense for a penalty of not more than \$5,000. The penalties shall be sued for and collected in a summary proceeding in 37 38 accordance with "Penalty Enforcement Law of 1999," P.L.1999, 39 c.274 (C.2A-58-10 et seq.). 40 b. In addition to any civil penalties provided under this section, 41 the commissioner may suspend or revoke a registration made 42 pursuant to this act for a violation of any provision of this act. 43 c. Except as provided in section 7 of this act, before denying to 44 grant or renew a registration, or suspending or revoking a 45 registration, pursuant to this act, the commissioner shall provide 46 notice of the denial, revocation, or suspension, together with a 47 specification of charges to the applicant or registrant, personally or

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by certified mail to the address of record, and the notice shall set 1 2 forth the particular reasons for the denial, suspension, or revocation. 3 The denial, suspension, or revocation shall become effective 30 4 days after mailing, unless the applicant or registrant, within the 30-5 day period, meets the requirements of the department or files with the department a written answer to the charges and gives written 6 7 notice to the department of its desire for a hearing, in which case 8 the denial, suspension, or revocation may be held in abeyance until 9 the hearing has been concluded and a final decision rendered by the 10 commissioner. 11 The commissioner shall afford the applicant or registrant an opportunity for a prompt hearing on the question of the granting, 12 13 suspension, or revocation of the registration. The procedure 14 governing the hearing shall be in accordance with the rules and 15 regulations of the department. Either party may be represented by 16 counsel of its own choosing, and has the right to subpoena 17 witnesses and to compel their attendance on forms furnished by the 18 department. The commissioner shall render a written decision 19 stating conclusions and reasons therefor. 20 21 9. The commissioner shall adopt rules and regulations pursuant 22 to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-23 1 et seq.) to carry out the purposes of this act. The regulations may 24 specify qualifications for personnel, including the medical director, 25 employed at an anatomical research recovery organization and 26 standards related to recovery of human bodies or parts. 27 28 This act shall take effect on the 180th day following 10. 29 enactment. 30 31 32 **STATEMENT** 33 34 This bill requires anatomical research recovery organizations to 35 register with the Department of Health and Senior Services (DHSS) 36 in order to safeguard the health and well-being of the citizens of the 37 State, and to ensure the respectful and consensual disposition and 38 use of human bodies and parts donated for education, research, and 39 the advancement of medical, dental, or mortuary science. 40 The need for and use of such anatomical gifts for education, 41 research, and the advancement of medical, dental, or mortuary 42 science is of sufficient frequency so as to require that minimum 43 standards for anatomical research recovery organizations be 44 established. Currently, there is no State regulation of entities that 45 engage in the recovery of human bodies and parts, in this State,

46 donated for education and research.

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An anatomical research recovery organization (ARRO) is 1 2 defined as a nonprofit corporation engaged in the recovery of a 3 human body or part donated for education, research, or the 4 advancement of medical, dental, or mortuary science pursuant to 5 P.L.1969, c.161 (C.26:6-57 et seq.), where part or all of the recovery takes place in this State. An ARRO does not include an 6 7 accredited institution of higher education in this State that uses an 8 anatomical gift for its own educational or research purposes and is 9 not engaged in the distribution of a human body or part to another 10 person or entity.

The bill provides that a person shall not engage in the recovery of a human body or part donated in this State for education, research, or the advancement of medical, dental, or mortuary science, unless the person is registered as an ARRO with the DHSS. The registration shall be valid for a one-year period and may be renewed subject to compliance with the requirements of the bill.

An ARRO operating in this State shall demonstrate compliancewith the following requirements:

-- A physician licensed in this State or the state in which the
organization is incorporated shall serve as medical director, and
shall be responsible for ensuring compliance with the provisions
of the bill, the hiring of qualified personnel, and the maintenance
of records required under the bill;

24 -- The organization shall be a federally tax-exempt nonprofit25 corporation;

-- The organization shall create, compile, or maintain a complete
 record on each donor from which it recovers a human body or
 part for educational or research purposes or the advancement of
 medical, dental or mortuary science, which shall include, at a
 minimum:

(1) documentation that the donor has designated the
anatomical gift for educational or research purposes or for the
advancement of medical, dental, or mortuary science. The
documentation may be in the form of a signed document of gift,
or verifiable documentation that taped telephonic consent has
been obtained;

37 (2) documentation of the identity and address of each entity
38 which has been in possession of the human body or part prior to
39 the ARRO, such as a funeral home, coroner, hospital, organ
40 procurement organization, or tissue bank; and

41 (3) documentation of the use and disposition of each human
42 body or part, including the name and address of each person who
43 receives a human body or part directly from the ARRO.

The bill provides that it is a violation of the bill for any person to obstruct, hinder, delay or interfere, by force or otherwise, with the performance by the Commissioner of Health and Senior Services of any duty under the bill. If the commissioner has reason to believe

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that a condition exists or has occurred at an ARRO which is 1 2 dangerous to the public health, he may order the ARRO to correct 3 the violation and may immediately suspend the registration of the 4 ARRO until the correction is completed. If a registrant denies that a 5 violation exists or has occurred, the registrant shall have the right to 6 apply to the commissioner for a hearing. The hearing shall be held 7 and a decision rendered within 48 hours of the receipt of the 8 request. If the commissioner rules against the registrant, the registrant may apply to a court of competent jurisdiction for 9 10 injunctive relief against the commissioner's order.

11 A person who violates the provisions of the bill or an order of 12 the commissioner shall be liable to a penalty of not more than 13 \$1,000 for the first offense, and not more than \$5,000 for the 14 second and each succeeding offense. In addition to any civil 15 penalties, the commissioner may suspend or revoke a registration 16 for a violation of any provisions of the bill.

17 The bill takes effect on the 180th day following enactment.

SENATE HEALTH, HUMAN SERVICES AND SENIOR CITIZENS COMMITTEE

STATEMENT TO

SENATE, No. 753

with committee amendments

STATE OF NEW JERSEY

DATED: FEBRUARY 14, 2008

The Senate Health, Human Services and Senior Citizens Committee reports favorably and with amendments Senate Bill No. 753.

As amended by committee, this bill, the "Anatomical Research Recovery Organization Act," requires anatomical research recovery organizations to register with the Department of Health and Senior Services (DHSS) in order to safeguard the health and well-being of the citizens of the State, and to ensure the respectful and consensual disposition and use of human bodies and parts donated for education, research, and the advancement of medical, dental, or mortuary science.

The need for and use of such anatomical gifts for education, research, and the advancement of medical, dental, or mortuary science is of sufficient frequency so as to require that minimum standards for anatomical research recovery organizations be established. Currently, there is no State regulation of entities that engage in the recovery of human bodies and parts, in this State, donated for education and research.

Specifically, the bill provides as follows:

- An anatomical research recovery organization (ARRO) is defined as a nonprofit corporation engaged in the recovery of a human body or part that has been donated for education, research, or the advancement of medical, dental, or mortuary science pursuant to the "Uniform Anatomical Gift Act," P.L.1969, c.161 (C.26:6-57 et seq.) or any subsequent statute adopted pursuant thereto, where part or all of the recovery takes place in this State. An ARRO does not include an accredited institution of higher education in this State that uses an anatomical gift for its own educational or research purposes and is not engaged in the distribution of a human body or part to another person or entity.
- A person shall not engage in the recovery of a human body or part donated in this State for education, research, or the advancement of medical, dental, or mortuary science, unless the person is registered with the DHSS as an ARRO. The registration shall be valid for a

one-year period and may be renewed subject to compliance with the requirements of the bill.

• An ARRO operating in this State shall demonstrate compliance with the following requirements:

-- A physician licensed in this State or the state in which the organization is incorporated shall serve as medical director, and shall be responsible for ensuring compliance with the provisions of the bill, the hiring of qualified personnel, and the maintenance of records required under the bill;

-- The organization shall be a federally tax-exempt nonprofit corporation;

-- The organization shall create, compile, or maintain a complete record on each donor from which it recovers a human body or part for educational or research purposes or the advancement of medical, dental or mortuary science, which shall include, at a minimum:

--(1) documentation that the donor has designated the anatomical gift for educational or research purposes or for the advancement of medical, dental, or mortuary science. The documentation may be in the form of a signed document of gift, or verifiable documentation that taped telephonic consent has been obtained;

--(2) documentation of the identity and address of each entity which has been in possession of the human body or part prior to the ARRO, such as a funeral home, coroner, hospital, organ procurement organization, or tissue bank; and

--(3) documentation of the use and disposition of each human body or part, including the name and address of each person who receives a human body or part directly from the ARRO.

- It is a violation of the bill for any person to obstruct, hinder, delay or interfere, by force or otherwise, with the performance by the Commissioner of Health and Senior Services of any duty under the bill. If the commissioner has reason to believe that a condition exists or has occurred at an ARRO which is dangerous to the public health, he may order the ARRO to correct the violation and may immediately suspend the registration of the ARRO until the correction is completed. If a registrant denies that a violation exists or has occurred, the registrant shall have the right to apply to the commissioner for a hearing. The hearing shall be held and a decision rendered within 48 hours of the registrant, the registrant may apply to a court of competent jurisdiction for injunctive relief against the commissioner's order.
- A person who violates the provisions of the bill or an order of the commissioner shall be liable to a penalty of not more than \$1,000 for the first offense, and not more than \$5,000 for the second and each succeeding offense. In addition to any civil penalties, the

commissioner may suspend or revoke a registration for a violation of any provisions of the bill.

• The bill takes effect on the 180th day following enactment.

The committee adopted a technical amendment to the bill concerning references to the "Uniform Anatomical Gift Act," to provide that in the event that act is repealed and replaced with a new uniform act (as is provided for in Senate Bill No. 754, which the committee also considered on this date) that the references would also apply to the new law.

This bill is similar to Assembly Bill No. 1935 (Conaway), which is pending before the Assembly Health and Senior Services Committee.

This bill was pre-filed for introduction in the 2008-2009 session pending technical review. As reported, the bill includes the changes required by technical review, which has been performed.

ASSEMBLY, No. 1935 STATE OF NEW JERSEY 213th LEGISLATURE

INTRODUCED JANUARY 28, 2008

Sponsored by: Assemblyman HERB CONAWAY, JR. District 7 (Burlington and Camden)

SYNOPSIS

Requires anatomical research recovery organizations to register with DHSS.

CURRENT VERSION OF TEXT

As introduced.



1 AN ACT concerning anatomical gifts for educational and research 2 use and supplementing Title 26 of the Revised Statutes. 3 4 **BE IT ENACTED** by the Senate and General Assembly of the State 5 of New Jersey: 6 7 1. This act shall be known and may be cited as the "Anatomical 8 Research Recovery Organization Act." 9 10 2. It is the public policy of this State to safeguard the health and 11 well-being of its citizens, and to ensure the respectful and consensual disposition and use of human bodies and parts donated 12 for education, research, and the advancement of medical, dental, or 13 mortuary science. The need for and use of such anatomical gifts for 14 15 education, research, and the advancement of medical, dental, or 16 mortuary science is of sufficient frequency so as to require that 17 minimum standards for anatomical research recovery organizations 18 be established. 19 20 3. As used in this act: 21 "Anatomical research recovery organization" means a nonprofit 22 corporation engaged in the recovery of a human body or part 23 donated for education, research, or the advancement of medical, 24 dental, or mortuary science pursuant to P.L.1969, c.161 (C.26:6-57 25 et seq.), where part or all of the recovery takes place in this State. 26 Anatomical research recovery organization shall not include an 27 accredited institution of higher education in this State that uses an 28 anatomical gift for its own educational or research purposes and is 29 not engaged in the distribution of a human body or part to another 30 person or entity. 31 "Commissioner" means the Commissioner of Health and Senior 32 Services. "Department" means the Department of Health and Senior 33 34 Services. 35 "Distribution" means the removal of a human body or part from 36 a storage location to any other location for educational or research 37 use, or the advancement of medical, dental, or mortuary science. 38 "Education" means the use of the whole body or parts for 39 purposes of teaching or training individuals, including medical or 40 dental professionals and students, with regard to the anatomy and 41 characteristics of the human body. 42 "Human body part" or "part" means organs, tissues, eyes, bones, 43 blood vessels, and any other portions of a deceased human body 44 which are subject to an anatomical gift pursuant to P.L.1969, c.161 (C.26:6-57 et seq.), but does not include blood collected pursuant to 45 46 P.L.1945, c.301 (C.26:2A-1 et seq.). 47 "Recovery" means the obtaining of a human body or part, including, but not limited to, determining or obtaining consent or 48

A1935 CONAWAY

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authorization for donation of the human body or part, performing
surgical or other technical procedures for recovering the body or
part, and processing the body or part. Recovery does not include
actions taken by a medical examiner or coroner as part of his
professional duties.

6 "Research" means the conduct of scientific testing and 7 observation designed to result in the acquisition of generalizable 8 knowledge. Research does not include an autopsy or other 9 investigation conducted for the purpose of obtaining information 10 related to the decedent.

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4. a. No person shall engage in the recovery of a human body or part donated in this State for education, research, or the advancement of medical, dental, or mortuary science pursuant to P.L.1969, c.161 (C.26:6-57 et seq.), unless the person is registered as an anatomical research recovery organization with the Department of Health and Senior Services pursuant to this act.

18 The registration required pursuant to this act shall be in addition19 to any license or permit required by a local board of health, other20 local health agency, or any State or federal agency.

b. The registration shall be valid for a one-year period and may
be renewed subject to compliance with the requirements of this act.
The commissioner shall establish such registration and renewal fees
as may be reasonable and necessary to carry out the purposes of this
act.

c. The commissioner may enter and inspect the premises of any
anatomical research recovery organization and the books and
records as is reasonably necessary to carry out the provisions of this
act.

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5. An anatomical research recovery organization operating in
this State shall demonstrate compliance with the following
requirements:

a. A physician licensed in this State or the state in which the
organization is incorporated shall serve as medical director, and
shall be responsible for ensuring compliance with the provisions of
this act, the hiring of qualified personnel, and the maintenance of
records required under this act.

b. The organization shall be a federally tax-exempt nonprofit40 corporation.

c. The organization shall create, compile, or maintain a complete
record on each donor from which it recovers a human body or part
for educational or research purposes or the advancement of medical,
dental or mortuary science, which shall include, at a minimum:

(1) documentation that the donor has designated the anatomical
gift for educational or research purposes or for the advancement of
medical, dental, or mortuary science, as specified in section 3 of
P.L.1969, c.161 (C.26:6-59). The documentation may be in the

form of a signed document of gift, or verifiable documentation that

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2 taped telephonic consent has been obtained; 3 (2) documentation of the identity and address of each entity 4 which has been in possession of the human body or part prior to the 5 organization, such as a funeral home, coroner, hospital, organ 6 procurement organization, or tissue bank; and 7 (3) documentation of the use and disposition of each human 8 body or part, including the name and address of each person who 9 receives a human body or part directly from the organization. 10 6. It shall be a violation of this act for any person to obstruct, 11 12 hinder, delay or interfere, by force or otherwise, with the 13 performance by the commissioner of any duty under the provisions 14 of this act. 15 16 7. If the commissioner has reason to believe that a condition 17 exists or has occurred at an anatomical research recovery organization in violation of the provisions of this act, which is 18 19 dangerous to the public health, he may order the organization to 20 correct the violation and may immediately suspend the registration 21 of the organization until the correction is completed. If a registrant 22 denies that a violation exists or has occurred, the registrant shall 23 have the right to apply to the commissioner for a hearing. The 24 hearing shall be held and a decision rendered within 48 hours of the 25 receipt of the request. If the commissioner rules against the 26 registrant, the registrant may apply to a court of competent 27 jurisdiction for injunctive relief against the commissioner's order. 28 29 8. a. Any person who violates the provisions of this act or an 30 order of the commissioner shall be liable for the first offense to a 31 penalty of not more than \$1,000, and for the second and each 32 succeeding offense for a penalty of not more than \$5,000. The 33 penalties shall be sued for and collected in a summary proceeding in 34 accordance with "Penalty Enforcement Law of 1999," P.L.1999, 35 c.274 (C.2A-58-10 et seq.). 36 b. In addition to any civil penalties provided under this section, 37 the commissioner may suspend or revoke a registration made pursuant to this act for a violation of any provision of this act. 38 39 c. Except as provided in section 7 of this act, before denying to 40 grant or renew a registration, or suspending or revoking a 41 registration, pursuant to this act, the commissioner shall provide 42 notice of the denial, revocation, or suspension, together with a 43 specification of charges to the applicant or registrant, personally or 44 by certified mail to the address of record, and the notice shall set 45 forth the particular reasons for the denial, suspension, or revocation. 46 The denial, suspension, or revocation shall become effective 30 47 days after mailing, unless the applicant or registrant, within the 30-48 day period, meets the requirements of the department or files with

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the department a written answer to the charges and gives written

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notice to the department of its desire for a hearing, in which case 3 the denial, suspension, or revocation may be held in abeyance until 4 the hearing has been concluded and a final decision rendered by the 5 commissioner. 6 The commissioner shall afford the applicant or registrant an 7 opportunity for a prompt hearing on the question of the granting, 8 suspension, or revocation of the registration. The procedure 9 governing the hearing shall be in accordance with the rules and 10 regulations of the department. Either party may be represented by 11 counsel of its own choosing, and has the right to subpoena witnesses and to compel their attendance on forms furnished by the 12 The commissioner shall render a written decision 13 department. 14 stating conclusions and reasons therefor. 15 16 9. The commissioner shall adopt rules and regulations pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-17 18 1 et seq.) to carry out the purposes of this act. The regulations may 19 specify qualifications for personnel, including the medical director, 20 employed at an anatomical research recovery organization and standards related to recovery of human bodies or parts. 21 22 23 This act shall take effect on the 180th day following 10. 24 enactment. 25 26 27 **STATEMENT** 28 29 This bill requires anatomical research recovery organizations to 30 register with the Department of Health and Senior Services (DHSS) 31 in order to safeguard the health and well-being of the citizens of the 32 State, and to ensure the respectful and consensual disposition and 33 use of human bodies and parts donated for education, research, and 34 the advancement of medical, dental, or mortuary science. 35 The need for and use of such anatomical gifts for education, research, and the advancement of medical, dental, or mortuary 36 37 science is of sufficient frequency so as to require that minimum 38 standards for anatomical research recovery organizations be 39 established. Currently, there is no State regulation of entities that 40 engage in the recovery of human bodies and parts, in this State, 41 donated for education and research. 42 An anatomical research recovery organization (ARRO) is 43 defined as a nonprofit corporation engaged in the recovery of a 44 human body or part donated for education, research, or the 45 advancement of medical, dental, or mortuary science pursuant to 46 P.L.1969, c.161 (C.26:6-57 et seq.), where part or all of the 47 recovery takes place in this State. An ARRO does not include an accredited institution of higher education in this State that uses an 48

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1 anatomical gift for its own educational or research purposes and is 2 not engaged in the distribution of a human body or part to another 3 person or entity. 4 The bill provides that a person shall not engage in the recovery 5 of a human body or part donated in this State for education, 6 research, or the advancement of medical, dental, or mortuary 7 science, unless the person is registered as an ARRO with the DHSS. 8 The registration shall be valid for a one-year period and may be 9 renewed subject to compliance with the requirements of the bill. 10 An ARRO operating in this State shall demonstrate compliance 11 with the following requirements: 12 -- A physician licensed in this State or the state in which the organization is incorporated shall serve as medical director, and 13 14 shall be responsible for ensuring compliance with the provisions 15 of the bill, the hiring of qualified personnel, and the maintenance 16 of records required under the bill; 17 -- The organization shall be a federally tax-exempt nonprofit 18 corporation; 19 -- The organization shall create, compile, or maintain a complete 20 record on each donor from which it recovers a human body or 21 part for educational or research purposes or the advancement of 22 medical, dental or mortuary science, which shall include, at a 23 minimum: 24 (1) documentation that the donor has designated the 25 anatomical gift for educational or research purposes or for the advancement of medical, dental, or mortuary science. 26 The 27 documentation may be in the form of a signed document of gift, or verifiable documentation that taped telephonic consent has 28 29 been obtained; 30 (2) documentation of the identity and address of each entity 31 which has been in possession of the human body or part prior to the ARRO, such as a funeral home, coroner, hospital, organ 32 33 procurement organization, or tissue bank; and 34 (3) documentation of the use and disposition of each human 35 body or part, including the name and address of each person who receives a human body or part directly from the ARRO. 36 37 The bill provides that it is a violation of the bill for any person to obstruct, hinder, delay or interfere, by force or otherwise, with the 38 39 performance by the Commissioner of Health and Senior Services of 40 any duty under the bill. If the commissioner has reason to believe that a condition exists or has occurred at an ARRO which is 41 42 dangerous to the public health, he may order the ARRO to correct 43 the violation and may immediately suspend the registration of the 44 ARRO until the correction is completed. If a registrant denies that a 45 violation exists or has occurred, the registrant shall have the right to 46 apply to the commissioner for a hearing. The hearing shall be held 47 and a decision rendered within 48 hours of the receipt of the 48 request. If the commissioner rules against the registrant, the

registrant may apply to a court of competent jurisdiction for
 injunctive relief against the commissioner's order.

3 A person who violates the provisions of the bill or an order of

4 the commissioner shall be liable to a penalty of not more than

5 \$1,000 for the first offense, and not more than \$5,000 for the

6 second and each succeeding offense. In addition to any civil

7 penalties, the commissioner may suspend or revoke a registration

8 for a violation of any provisions of the bill.

9 The bill takes effect on the 180th day following enactment.

STATEMENT TO

ASSEMBLY, No. 1935

with committee amendments

STATE OF NEW JERSEY

DATED: MARCH 3, 2008

The Assembly Health and Senior Services Committee reports favorably and with committee amendments Assembly Bill No. 1935.

As amended by the committee, this bill, which is designated the "Anatomical Research Recovery Organization Act," requires anatomical research recovery organizations to register with the Department of Health and Senior Services (DHSS) in order to safeguard the health and well-being of the citizens of the State, and to ensure the respectful and consensual disposition and use of human bodies and parts donated for education, research, and the advancement of medical, dental, or mortuary science. The need for and use of such anatomical gifts for education, research, and the advancement of medical, dental, or mortuary science is of sufficient frequency to require that minimum standards for anatomical research recovery organizations be established. Currently, there is no State regulation of entities that engage in the recovery of human bodies and parts, in this State, donated for education and research.

The bill provides specifically as follows:

- The bill defines an anatomical research recovery organization (ARRO) to mean a nonprofit corporation engaged in the recovery of a human body or part that has been donated for education, research, or the advancement of medical, dental, or mortuary science pursuant to the "Uniform Anatomical Gift Act," P.L.1969, c.161 (C.26:6-57 et seq.) or any subsequent statute adopted pursuant thereto, where part or all of the recovery takes place in this State. An ARRO does not include an accredited institution of higher education in this State that uses an anatomical gift for its own educational or research purposes and is not engaged in the distribution of a human body or part to another person or entity.
- A person is prohibited from engaging in the recovery of a human body or part donated in this State for education, research, or the advancement of medical, dental, or mortuary science, unless the person is registered with the DHSS as an ARRO. The registration is to be valid for a one-year period and may be renewed subject to compliance with the requirements of the bill.

• An ARRO operating in this State must demonstrate compliance with the following requirements:

-- A physician licensed in this State or the state in which the organization is incorporated is to serve as medical director, and to be responsible for ensuring compliance with the provisions of the bill, the hiring of qualified personnel, and the maintenance of records required under the bill;

-- The organization must be a federally tax-exempt nonprofit corporation;

-- The organization is to create, compile, or maintain a complete record on each donor from which it recovers a human body or part for educational or research purposes or the advancement of medical, dental or mortuary science, which includes, at a minimum:

(1) documentation that the donor has designated the anatomical gift for educational or research purposes or for the advancement of medical, dental, or mortuary science. The documentation may be in the form of a signed document of gift, or verifiable documentation that taped telephonic consent has been obtained;

(2) documentation of the identity and address of each entity which has been in possession of the human body or part prior to the ARRO, such as a funeral home, coroner, hospital, organ procurement organization, or tissue bank; and

(3) documentation of the use and disposition of each human body or part, including the name and address of each person who receives a human body or part directly from the ARRO.

- It is a violation of the bill for any person to obstruct, hinder, delay or interfere, by force or otherwise, with the performance by the Commissioner of Health and Senior Services of any duty under the bill. If the commissioner has reason to believe that a condition exists or has occurred at an ARRO which is dangerous to the public health, he may order the ARRO to correct the violation and may immediately suspend the registration of the ARRO until the correction is completed. If a registrant denies that a violation exists or has occurred, the registrant has the right to apply to the commissioner for a hearing; and the hearing is to be held and a decision rendered within 48 hours of the registrant, the registrant may apply to a court of competent jurisdiction for injunctive relief against the commissioner's order.
- A person who violates the provisions of the bill or an order of the commissioner is liable to a penalty of not more than \$1,000 for the first offense, and not more than \$5,000 for the second and each succeeding offense. In addition to any civil penalties, the commissioner may suspend or revoke a registration for a violation of any provisions of the bill.
- The bill takes effect on the 180th day following enactment.

As reported by the committee, this bill is identical to Senate Bill No. 753 (1R) (Codey/Buono), which is currently pending before the Senate.

COMMITTEE AMENDMENTS

The committee amendments to the bill incorporate references to the "Uniform Anatomical Gift Act," in order to provide that, if that law is repealed and replaced with a new statute (as provided for in Assembly Bill No. 2206, which the committee also reported on this date), the references would also apply to the new statute.

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For Kids e: July 22, 2008	For More Information: Sean Darcy Jim Gardner Phone: 609-777-2600
Acting Governor Codey Signs New Jersey Hero Act	
Establishes State as Pioneer in Organ Donation	
LIVINGSTON - Acting Governor Richard J. Codey today signed legislation that forges New Jersey's	s standing as a
pioneer in organ donation by requiring residents to make organ donation decisions before applying	for a driver's
license and requires mandatory organ donation education for high school students.	
"Our goal is to generate a collective awareness about the importance of organ donation so that the	se who want to
donate will. Ultimately, we want to move this important conversation out of the emergency room, v	where illness and
http://www.nj.gov/governor/news/news/2008/approved/20080722a.html (1 of 4) [10/28/2008 12:32:07 PM]	

injury already create a profound burden, and into the living room, where a thoughtful and deliberate decision can be reached without the pain of loss looming on the horizon. Hopefully, one day organ donation will no longer be an afterthought, but a forethought," said Acting Governor Codey.

The bill, S755/A2083 also known as the "New Jersey Hero Act," creates an interactive component to the already existing Donate Life Registry provided by the New Jersey Motor Vehicle Commission (MVC). Approximately 23.53 % of New Jersey drivers/ID holders currently have the donor designation.

With the legislation every resident 18 years of age or older applying for a driver's license or identification card is required to answer a few simple, yet potentially life-saving questions, regarding organ donation. If an individual is not ready to make that decision, they may designate a decision maker on their behalf. The designated decision maker component is not recorded in the MVC database, but will act much like a living will. If a person does not wish to become a donor or designate a decision maker on their behalf, they must check off a box acknowledging that they have reviewed the importance of making an organ donation decision. This process will be available in nine months but will not be mandatory for five years in order to allow for adequate public education.

Overall, the measure is a crucial component to increasing the number of organ donors in the Garden State because it alleviates certain fears that the donor decision will affect the quality of care received in an emergency room.

"The death of a loved one can be devastating to a family, but families of organ donors at least have a measure of solace in knowing their loved one's final act was to give the gift of life to someone else in need," said Senator Joseph F. Vitale (D-Middlesex), a sponsor of the Hero Act and Chair of the Senate Health Committee. "Through these new laws, we're raising the dialogue about organ donation, and ensuring that New Jerseyans talk to their loved ones about the possibility of becoming a donor. By increasing awareness of organ donation programs, we can maximize participation and save lives."

The bill also incorporates a comprehensive education component at the high school and collegiate levels. Under the NJ Hero Act, New Jersey is the first state to incorporate mandatory organ donation education into the high school core curriculum, beginning with the 2009-2010 school year. At the collegiate level, institutions of higher education will be required to provide information on New Jersey's organ donor policies through student health services.

organ and tissue donation," said Assemblyman McKeon (D-Essex). "Ensuring every resident knows the vital importance of organ donation will make it easier for many more people to take the simple but truly heroic step that can help save a life."

As of March 2008, 4,341 New Jersey residents were awaiting organ transplants. In 2007, 692 New Jersey residents received 696 lifesaving organ transplants; 195 New Jersey residents became organ donors that same year. More than 2,470 New Jersey residents have died on the organ donor waiting list over the last 10 years.

Assembly sponsors of the bill include Assemblymen John F. McKeon (D-Essex), Albert Coutinho (D-Essex/Union) and Patrick Diegnan, Jr. (D-Middlesex) and Assemblywoman Mila M. Jasey (D-Essex).

The second piece of legislation signed, S753/A1935, the "Anatomical Research Recovery Organization Act," provides substantial oversight of the disposition and use of human bodies and parts donated for education and research. Prior to the bill, very little regulation existed with regard to who may recover, or distribute these donations.

A body, part, or tissue, once gifted to an unlicensed, unregistered, unregulated entity may be virtually untraceable. With this legislation, anatomical research recovery organizations are now required to register with the New Jersey Department of Health and Senior Services (DHSS) and establish and follow certain standards for operation.

Codey and Senator Barbara Buono (D-Middlesex) are primary sponsors of S753/A1935. Assembly sponsors include Assemblyman Herb Conaway, Jr., (D-Burlington) and Assemblywoman Valerie Vainieri Huttle (D-Bergen).

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Senate President Richard J. Codey (D-Essex) is serving as Acting Governor while Governor Jon S. Corzine is in Israel.

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Photos from Governor Corzine's public events are available in the Governor's Newsroom section

on the State of New Jersey web page.

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