

HB

214

FISCAL NOTE

STATE OF ALASKA
2005 LEGISLATIVE SESSION

Fiscal Note Number: _____
 Bill Version: HB214CS(HES)-DHSS-DPH-04-06-05
 () Publish Date: _____
 Dept. Affected: Health & Social Services
 RDU: Public Health
 Component: Community Health/EMS Services

Revision Date/Time (Note if correction): _____
 Title: ANATOMICAL GIFTS

Sponsor: MCGUIRE
 Requester: HOUSE (HES)

Component No. 2078

Expenditures/Revenues (Thousands of Dollars)

Note: Amounts do not include inflation unless otherwise noted below.

OPERATING EXPENDITURES	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011
Personal Services						
Travel						
Contractual						
Supplies						
Equipment						
Land & Structures						
Grants & Claims						
Miscellaneous						
TOTAL OPERATING	0.0	0.0	0.0	0.0	0.0	0.0

CAPITAL EXPENDITURES						
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CHANGE IN REVENUES (0)						
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FUND SOURCE (Thousands of Dollars)

1002 Federal Receipts						
1003 GF Match						
1004 GF						
1037 GF/Mental Health						
Other(Specify Type-do not abbreviate)						
Other(Specify Type-do not abbreviate)						
TOTAL	0.0	0.0	0.0	0.0	0.0	0.0

Estimate of any current year (FY2005) cost: _____
 Mark this box (X) if funding for this bill is included in the Governor's FY 2006 budget proposal:

POSITIONS

Full-time						
Part-time						
Temporary						

ANALYSIS: (Attach a separate page if necessary)

This bill would add a requirement for EMS responders to notify an organ procurement agency for deaths which occur outside of a hospital, and of the victim's intent to donate - or not donate - organs.

The state will notify EMS providers, instructors, first responders, and ground and air medical services of the new reporting requirement. The cost of preparing and mailing these notifications was initially identified as \$6.5, but it has been determined these costs can be avoided by coordinating notification of this new requirement with other EMS provider communication efforts.

Thus, the fiscal impact is zero.

Prepared by: Richard Mandsager, M.D.
 Division: Public Health
 Approved by: Joel S. Gilbertson, Commissioner
 Agency: Department of Health and Social Services

Phone 465-3090
 Date/Time 04/05/2005
 Date 04/06/2005

ALASKA STATE LEGISLATURE

Session
State Capitol Building, Room 118
Juneau, Alaska 99801-1182
Phone (907) 465-2995
Fax (907) 465-6592

Interim
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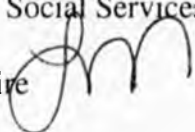
REPRESENTATIVE LESIL MCGUIRE
HOUSE DISTRICT 28

Chair
Judiciary Committee

Member
House Leadership
Rules Committee
Health, Education
& Social Services
Committee
Oil & Gas Committee
Military & Veterans'
Affairs Committee

MEMORANDUM

To: Representative Peggy Wilson, Chair
House Health, Education & Social Services Committee

From: Representative Lesil McGuire 

Date: March 30, 2005

Re: Request for Hearing, HB 214: Anatomical Gifts

I respectfully request that HB 214: Anatomical Gifts, be scheduled for a hearing at your earliest convenience. I have attached the following for your information:

1. Sponsor Statement
2. Sectional Analysis
3. HB 214
4. Fiscal Notes
5. Applicable Statutes and Federal Regulations
6. Relevant Articles

If you have any questions please feel free to contact me personally, or my staff, Vanessa Tondini, at 4990. Thank you very much.

ALASKA STATE LEGISLATURE

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HOUSE DISTRICT 28

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Health, Education
& Social Services
Committee
Oil & Gas Committee
Military & Veterans'
Affairs Committee

Sponsor Statement **HB 214**

"An Act relating to anatomical gifts and the anatomical gift donor registry program."

Last year the Alaska Legislature passed the Anatomical Gifts Registry Bill, which created an official organ donor registry program at the Department of Motor Vehicles. Through this program an organ donor's wishes are kept on record in a central database and are transferred to Life Alaska Donor Services, the state's organ & tissue donor program. This information allows Life Alaska to quickly match the donor's gift to a potential recipient, saving time and lives.

HB 214 makes several simple but important changes to existing law to further the intent of the original enabling legislation and to continue to move the donor registry forward in the State of Alaska. This bill works to make the Alaska Donor Registry program inclusive rather than exclusive, offers expanded definitions that act to clarify the agencies that are responsible for donation within the state as well as for the people who are trained to do the actual recovery procedures, allows increased notification for greater donation potential, and clears up inconsistencies between federal rulings and state laws.

When the Anatomical Gifts Registry Bill was submitted for consideration and subsequently passed into law in the 2004 legislative session, it was done so with the clear intent that the donor registry be operated from within the State of Alaska and not controlled by an out-of-state agency. However, as the law now reads, an out-of-state organ procurement organization has sole control of the registry, excluding the in-state procurement organization. HB 214 would change AS 13.50 to be inclusive rather than exclusive allowing access to both in-state and out-of-state procurement organizations. The current definition of "procurement organization" within AS 13.50.190 and the definition of "organ procurement organization" within AS 13.52.390 are defined as the "organization designated by the United States Department of Health and Human Services..." This definition is restricted to the regional organ procurement organization only. While it is important to have the regional organ procurement organization represented in the state, it is equally important that the in-state procurement organization not be excluded from donation and donation decisions that benefit all Alaskans. HB 214 will change the definitions within both sections to be more inclusive of all procurement organizations and allow them to function equally for the good of donation throughout Alaska.

Also, the current definition of "technician" within AS 13.52.390 is too restrictive and not in line with the laws of any other state. Recognized technicians throughout the state who recover tissues have never been licensed or certified by the State Medical Board. In fact, the State Medical Board does not have a process to license or certify technicians to procure tissues. The FDA, which regulates the tissue procurement agencies, defines a technician under 21 CFR 1271.170 for recovery personnel only by "requir[ing] establishments to employ sufficient personnel with the necessary education, experience, and training to ensure competent performance of their assigned functions." HB 214 will change the definition of technician to more closely reflect the good tissue practices set out by the federal government.

In addition, AS 13.52.200(e) currently only addresses notification to the hospital. HB 214 would expand notification by allowing for law enforcement officers, fire fighters, paramedics, or other emergency rescuer personnel to contact a procurement organization directly. This would allow timely notification on non-hospital deaths to increase the potential of donation within the state.

Finally, there are two paragraphs within AS 13.52 that will be repealed in HB 214; the first being AS 13.52.200(b). This is in direct contradiction to 42 CFR 482.45, which requires the hospital to notify a procurement organization that will determine suitability of donation on *all* deaths or *imminent* deaths. The second is AS 13.52.200(c). This is burdensome to the hospital and is duplicating efforts that are already being done.

LEGAL SERVICES

DIVISION OF LEGAL AND RESEARCH SERVICES
LEGISLATIVE AFFAIRS AGENCY
STATE OF ALASKA

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FAX (907) 465-2029
Mail Stop 3101


State Capitol
Juneau, Alaska 99801-1182
Deliveries to: 129 6th St., Rm. 329

MEMORANDUM

March 24, 2005

SUBJECT: Sectional Summary of HB 214 relating to anatomical gifts and the anatomical gift donor registry program
(Work Order No. 24-LS0410\F)

TO: Representative Lesil McGuire
Attn: Vanessa

FROM:  Theresa Bannister
Legislative Counsel

You have requested a sectional summary of the above-described bill. As a preliminary matter, note that a sectional summary of a bill should not be considered an authoritative interpretation of the bill and the bill itself is the best statement of its contents.

Section 1. Defines "procurement organization" for the donor registry program.

Section 2. Adds definitions of "donor," "gift," and "part" for the donor registry program.

Section 3. Deletes a reference to AS 13.52.200 to reflect the repeal of AS 13.52.200(c) by sec. 11 of the bill.

Section 4. Makes conforming amendments to reflect the change in terminology to "procurement organization."

Section 5. Makes conforming amendments to reflect the change in terminology to "procurement organization."

Section 6. If an individual or body is taken to a hospital, and if a document of gift or evidence of refusal to make a gift is located under AS 13.52.200(d)(1), this subsection requires the hospital and a procurement organization to be notified of the contents of the document of gift or the evidence of refusal. If the individual or body is not taken to a hospital, requires certain persons (those identified in AS 13.52.200(d)(1)) to notify a procurement organization and send the document or evidence to the procurement organization.

Section 7. Makes a conforming amendment to reflect the change in terminology to "procurement organization."

Representative Lesil McGuire
March 24, 2005
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Section 8. Makes a conforming change to reflect the repeal of AS 13.52.200(b) and (c) by sec. 11 of the bill.

Section 9. Defines "procurement organization" for AS 13.52.200.

Section 10. Amends the definition of "technician" for AS 13.52 to mean an individual who has the education, training, and experience necessary to competently remove or process a part.

Section 11. Repeals a provision stating that a hospital administrator (or a designee) is not required to contact an organ procurement organization if an anatomical gift is not suitable for donation. Repeals a provision requiring that an entry be made in a patient's record relating to the discussion by a representative of an organ procurement organization with the family, agent, or surrogate of the patient. Repeals the definition of "organ procurement organization."

If I may be of further assistance, please advise.

TLB:med
05-211.mcd

FISCAL NOTE

STATE OF ALASKA
2005 LEGISLATIVE SESSION

Fiscal Note Number: _____
 Bill Version: HB214 DHSS-DPH-03-30-05
 () Publish Date: _____
 Dept. Affected: Health & Social Services
 RDU Public Health
 Component Community Health/EMS Services

Revision Date/Time (Note if correction): _____
 Title ANATOMICAL GIFTS

Sponsor MCGUIRE

Requester _____

Component No. 2078

Expenditures/Revenues (Thousands of Dollars)

Note: Amounts do not include inflation unless otherwise noted below.

OPERATING EXPENDITURES	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011
Personal Services	2.7					
Travel						
Contractual						
Supplies	3.8					
Equipment						
Land & Structures						
Grants & Claims						
Miscellaneous						
TOTAL OPERATING	6.5	0.0	0.0	0.0	0.0	0.0

CAPITAL EXPENDITURES						
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CHANGE IN REVENUES (0)						
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FUND SOURCE (Thousands of Dollars)

1002 Federal Receipts						
1003 GF Match						
1004 GF	6.5					
1037 GF/Mental Health						
Other(Specify Type-do not abbreviate)						
Other(Specify Type-do not abbreviate)						
TOTAL	6.5	0.0	0.0	0.0	0.0	0.0

Estimate of any current year (FY2005) cost: _____

Mark this box (X) if funding for this bill is included in the Governor's FY 2006 budget proposal:

POSITIONS

Full-time						
Part-time						
Temporary						

ANALYSIS: (Attach a separate page if necessary)

This bill would add a requirement for EMS responders to notify an organ procurement agency and transmit organ donation documentation for deaths which occur outside of a hospital. The fiscal note addresses the cost to the state of mailing out notice of the reporting requirement to EMS providers, instructors, First Responder services, and Ground and Air Medical Services, but does not reflect the cost to the services, many of whom are operating under severe fiscal constraints, including rural EMS services.

Staff time: Preparation of training materials & 3 mailings to EMS providers, instructors & services: \$2.7.

Supplies: Supplies & postage for 3 mailings: \$3.8.

Prepared by: Richard Mandsager, MD
 Division: Public Health
 Approved by: Joel S. Gilbertson, Commissioner
 Agency: Department of Health and Social Services

Phone 465-3090
 Date/Time 03/30/2005
 Date 03/30/2005

FISCAL NOTE

STATE OF ALASKA
2005 LEGISLATIVE SESSION

Fiscal Note Number: _____
 Bill Version: HB 214
 () Publish Date: _____

Revision Date/Time (Note if correction):
 Title Anatomical Gifts

Dept. Affected: Commerce
 RDU Occupational Licensing (117)
 Component Occupational Licensing

Sponsor McGuire, Kerttula, Gruenberg
 Requester State Affairs

Component No. 2360

Expenditures/Revenues (Thousands of Dollars)

Note: Amounts do not include inflation unless otherwise noted below.

OPERATING EXPENDITURES	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011
Personal Services						
Travel						
Contractual						
Supplies						
Equipment						
Land & Structures						
Grants & Claims						
Miscellaneous						
TOTAL OPERATING	0.0	0.0	0.0	0.0	0.0	0.0

CAPITAL EXPENDITURES						
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CHANGE IN REVENUES ()						
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FUND SOURCE (Thousands of Dollars)

1002 Federal Receipts						
1003 GF Match						
1004 GF						
1005 GF/Program Receipts						
1037 GF/Mental Health						
Other 1156 - Receipt Supported Services						
TOTAL	0.0	0.0	0.0	0.0	0.0	0.0

Estimate of any current year (FY2005) cost: 00
 Mark this box (X) if funding for this bill is included in the Governor's FY 2006 budget proposal:

POSITIONS

Full-time						
Part-time						
Temporary						

ANALYSIS: (Attach a separate page if necessary)

HB 214 amends AS 13.50 relating to anatomical gifts and the gift donor registry program. New funds are not required to implement the provisions of this bill.

Prepared by: Jennifer Strickler, Administrative Manager Phone (907) 465-2144
 Division: Occupational Licensing Date/Time 3/29/05 6:31 PM
 Approved by: Edgar Blatchford, Commissioner Date 3/29/2005
 Agency: Commerce, Community, and Economic Development

FISCAL NOTE

STATE OF ALASKA
2005 LEGISLATIVE SESSION

Fiscal Note Number: _____
 Bill Version: HB214-DPS-ASTD-3-30-05
 () Publish Date: _____

Revision Date/Time (Note if correction): _____ Dept. Affected: Public Safety
 Title "An Act relating to anatomical gifts and the anatomical RDU Alaska State Troopers
gift donor registry program." Component AST Detachments
 Sponsor Representative McGuire
 Requester House State Affairs Component No. 2325

Expenditures/Revenues (Thousands of Dollars)

Note: Amounts do not include inflation unless otherwise noted below.

OPERATING EXPENDITURES	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011
Personal Services						
Travel						
Contractual						
Supplies						
Equipment						
Land & Structures						
Grants & Claims						
Miscellaneous						
TOTAL OPERATING	0.0	0.0	0.0	0.0	0.0	0.0

CAPITAL EXPENDITURES						
-----------------------------	--	--	--	--	--	--

CHANGE IN REVENUES ()						
-------------------------------	--	--	--	--	--	--

FUND SOURCE (Thousands of Dollars)

1002 Federal Receipts						
1003 GF Match						
1004 GF						
1005 GF/Program Receipts						
1037 GF/Mental Health						
Other (Specify Type--Do not abbreviate)						
TOTAL	0.0	0.0	0.0	0.0	0.0	0.0

Estimate of any current year (FY2005) cost: 0.0

Mark this box (X) if funding for this bill is included in the Governor's FY 2006 budget proposal:

POSITIONS

Full-time						
Part-time						
Temporary						

ANALYSIS: (Attach a separate page if necessary)

This bill impacts the Department of Public Safety by amending AS 13.52.200. The amendment requires law enforcement officers dealing with a body or individual from a death or impending death that is taken to a hospital, to additionally notify a procurement organization with documentation of an anatomical gift (organ donation) or evidence of refusal to make a gift. Also, if the individual or body is not taken to a hospital, law enforcement officers shall now notify a procurement organization and send the document or other evidence to the procurement organization.

Passage of this bill will have no fiscal impact on the Department of Public Safety.

Prepared by: Lieutenant Todd Sharp Phone 907-465-3223
 Division Alaska State Troopers Date/Time 3/30/05 4:35 PM
 Approved by: Commissioner William Tandeske Date 3/30/2005
 Agency Department of Public Safety

Sec. 13.50.190. Definitions.

In AS 13.50.100 - 13.50.190,

(1) "department" means the Department of Administration;

(2) "donation" means a monetary donation made under AS 13.50.150;

(3) "fund" means the anatomical gift awareness fund established under AS 13.50.160;

(4) "motor vehicle or identification document" means

(A) a motor vehicle registration, a driver's license, or an instruction permit, or a renewal of the registration, license, or permit; or

(B) an identification card issued under AS 18.65.310;

(5) "procurement organization" means an organization that has been designated by the United States Department of Health and Human Services to coordinate activities for the procurement of body parts for any portion of this state;

(6) "reasonable costs" includes the cost of

(A) computer programming and installing software and software upgrades;

(B) employee training that is specific to a registry or the donation program established under AS 13.50.150;

(C) producing literature that is specific to a registry or the donation program established under AS 13.50.150; and

(D) making hardware upgrades or handling other issues for a registry or the donation program established under AS 13.50.150;

(7) "registry" means a donor registry established under AS 13.50.110;

(8) "registry information" means information obtained under AS 13.50.100;

(9) "state" means a state, territory, or possession of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

Sec. 13.52.200. Routine inquiry and required request; search and notification.

(a) If, at or near the time of death of a patient, there is no medical record that the patient has made or refused to make an anatomical gift, the hospital administrator or a designee of the hospital shall contact an organ procurement organization so that the organ procurement organization may discuss the potential to make a gift with the family, agent, or surrogate of the patient. The organ procurement organization shall discuss the potential gift with reasonable discretion and sensitivity to the circumstances of the family.

(b) Notwithstanding (a) of this section, a hospital administrator or other designee of the hospital is not required to contact an organ procurement organization if the gift is not suitable, based on accepted medical standards, for a purpose specified in AS 13.52.210.

(c) An entry shall be made in the medical record of the patient, stating the name and affiliation of the individual from the organ procurement organization who discusses the potential gift with the family, agent, or surrogate under (a) of this section, and the relationship to the patient of the family member, agent, or surrogate with whom the potential gift was discussed.

(d) The following persons shall make a reasonable search for a document of gift or other information identifying the bearer as a donor or as an individual who has refused to make an anatomical gift:

(1) a law enforcement officer, fire fighter, paramedic, or other emergency rescuer finding an individual who the searcher believes is dead or near death; and

(2) a hospital or an organ procurement organization, upon the admission of an individual at or near the time of death, if there is not immediately available any other source of that information.

(e) If a document of gift or evidence of refusal to make an anatomical gift is located by the search required by (d)(1) of this section, and the individual or body to whom it relates is taken to a hospital, the hospital must be notified of the contents, and the document or other evidence must be sent to the hospital.

(f) If, at or near the time of death of a patient, a hospital knows that an anatomical gift has been made under AS 13.52.170 or 13.52.180(a), or that a patient or an individual identified as in transit to the hospital is a donor, the hospital shall notify an organ procurement organization. The hospital shall cooperate in the implementation of the anatomical gift or release and removal of a part.

(g) Notwithstanding AS 13.52.090, a person who fails to discharge the duties imposed by this section is not subject to criminal or civil liability but is subject to appropriate administrative sanctions.

(h) The commissioner of health and social services shall adopt regulations to implement (a) - (c) of this section.

Sec. 13.52.390. Definitions.

In this chapter, unless the context otherwise requires,

- (1) "advance health care directive" means an individual instruction or a durable power of attorney for health care;
- (2) "agent" means an individual designated in a durable power of attorney for health care to make a health care decision for the individual granting the power;
- (3) "anatomical gift" means an individual instruction that makes a donation of all or a part of an individual's body to take effect upon or after death;
- (4) "artificial nutrition and hydration" means medically appropriate nutrition and hydration delivered
 - (A) through an intravenous needle placed directly in a vein; or
 - (B) by a tube that is inserted into a functioning gastrointestinal tract;
- (5) "available" means, when referring to a person, that the
 - (A) person's existence is known;
 - (B) person can be contacted;
 - (C) person does not lack capacity;
 - (D) person does not refuse to accept the position; and
 - (E) person is willing to make a health care decision;
- (6) "best interest" means that the benefits to the individual resulting from a treatment outweigh the burdens to the individual resulting from that treatment after assessing
 - (A) the effect of the treatment on the physical, emotional, and cognitive functions of the patient;
 - (B) the degree of physical pain or discomfort caused to the individual by the treatment or the withholding or withdrawal of the treatment;
 - (C) the degree to which the individual's medical condition, the treatment, or the withholding or withdrawal of treatment results in a severe and continuing impairment;
 - (D) the effect of the treatment on the life expectancy of the patient;
 - (E) the prognosis of the patient for recovery, with and without the treatment;
 - (F) the risks, side effects, and benefits of the treatment or the withholding of treatment; and

(G) the religious beliefs and basic values of the individual receiving treatment, to the extent that these may assist the decision-maker to determine benefits and burdens;

(7) "capacity," except in (9) of this section, means an individual's ability to receive and evaluate information effectively or communicate decisions to the extent necessary to make mental health treatment decisions;

(8) "cardiopulmonary resuscitation" means an attempt to restore spontaneous circulation;

(9) "competent" means that an individual has the capacity

(A) to assimilate relevant facts and to appreciate and understand the individual's situation with regard to those facts; and

(B) to participate in treatment decisions by means of a rational thought process;

(10) "decedent" means a deceased individual or infant, but does not include a dead or stillborn fetus;

(11) "department" means the Department of Health and Social Services;

(12) "document of gift" means a card, a statement attached to or imprinted on a driver's license, a will, an advance health care directive under AS 13.52.300, or another writing used to make an anatomical gift;

(13) "donor" means an individual who makes an anatomical gift;

(14) "do not resuscitate identification" means an identification card, form, necklace, or bracelet that carries the standardized design or symbol developed by the department under AS 13.52.065 to signify, when carried or worn, that the carrier or wearer is an individual for whom a physician has issued a do not resuscitate order;

(15) "do not resuscitate order" means a directive from a licensed physician that emergency cardiopulmonary resuscitation should not be administered to a qualified patient;

(16) "durable power of attorney for health care" means a power of attorney that remains in effect when the principal lacks capacity; in this paragraph, "power of attorney" means the designation of an agent to make health care decisions for the individual granting the power;

(17) "generally accepted health care standards" includes the protocol for do not resuscitate orders that is adopted under AS 13.52.065 ;

(18) "guardian" means a judicially appointed person having authority to make a health care decision for an individual;

(19) "health care" means any care, treatment, service, or procedure to maintain, diagnose, or otherwise affect an individual's physical or mental condition;

(20) "health care decision" means a decision made by an individual or the individual's agent, guardian, or surrogate regarding the individual's health care, including

(A) selection and discharge of health care providers and institutions;

(B) approval or disapproval of proposed diagnostic tests, surgical procedures, and programs of medication;

(C) direction to provide, withhold, or withdraw artificial nutrition and hydration if providing, withholding, or withdrawing artificial nutrition, artificial hydration, or artificial nutrition and hydration is in accord with generally accepted health care standards applicable to health care providers or institutions;

(D) the administration or withdrawal of psychotropic medications, the use of electroconvulsive treatment, and the admission to a mental health facility; and

(E) making an anatomical gift at death;

(21) "health care facility" means a nursing home, a rehabilitation center, a long-term care facility, and any other health care institution that administers health care and that provides overnight stays in the ordinary course of the facility's business;

(22) "health care institution" means an institution, facility, or agency licensed, certified, or otherwise authorized or permitted by law to provide health care in the ordinary course of business;

(23) "health care provider" means an individual licensed, certified, or otherwise authorized or permitted by law to provide health care in the ordinary course of business or practice of a profession;

(24) "hospital" means a facility

(A) licensed, accredited, or approved as a hospital under the laws of this state; or

(B) operated as a hospital by the United States government, this state, or a subdivision of this state;

(25) "individual instruction" means an individual's direction concerning a health care decision for the individual;

(26) "life-sustaining procedures" means any medical treatment, procedure, or intervention that, in the judgment of the primary physician, when applied to a patient with a qualifying condition, would not be effective to remove the qualifying condition, would serve only to prolong the dying process, or, when administered to a patient with a condition of permanent unconsciousness, may keep the patient alive but is not expected to restore consciousness; in this paragraph, "medical treatment, procedure, or intervention" includes assisted ventilation, renal dialysis, surgical procedures, blood transfusions, and the administration of drugs, including antibiotics, or artificial nutrition and hydration;

(27) "mental health facility" has the meaning given to "designated treatment facility" in AS 47.30.915 ;

(28) "mental health treatment" means electroconvulsive treatment, treatment with psychotropic medication, or admission to and retention in a health care institution for mental health treatment;

(29) "organ procurement organization" means an organization that has been designated by the United States Department of Health and Human Services to coordinate activities for the procurement of

body parts for any portion of this state;

(30) "part" means an organ, tissue, an eye, a bone, an artery, blood, fluid, or another portion of a human body, except fetal tissue;

(31) "permanent unconsciousness" means a condition

(A) that, to a high degree of medical certainty, will last permanently without improvement;

(B) in which, to a high degree of medical certainty, thought, sensation, purposeful action, social interaction, and awareness of self and the environment are absent; and

(C) for which, to a high degree of medical certainty, initiating or continuing life-sustaining procedures, in light of the patient's medical outcome, provides only minimal medical benefit;

(32) "person" means an individual, corporation, business trust, estate, trust, partnership, joint venture, association, government, governmental subdivision, governmental agency, or another legal or commercial entity;

(33) "physician" or "surgeon" means an individual licensed or otherwise authorized to practice medicine and surgery or osteopathy and surgery under the laws of any state;

(34) "primary physician" means a physician designated by an individual, or by the individual's agent, guardian, or surrogate, to have primary responsibility for the individual's health care or, in the absence of a designation or if the designated physician is not reasonably available, a physician who undertakes the responsibility;

(35) "qualified patient" means a patient with a qualifying condition who is eligible for do not resuscitate identification;

(36) "qualifying condition" means a terminal condition or permanent unconsciousness in a patient;

(37) "reasonably available" means available using a level of diligence appropriate to the seriousness and urgency of an individual's health care needs;

(38) "state" means a state, territory, or possession of the United States, the District of Columbia, or the Commonwealth of Puerto Rico;

(39) "supervising health care provider" means the primary physician or the physician's designee, or the health care provider or the provider's designee who has undertaken primary responsibility for an individual's health care;

(40) "surrogate" means an individual, other than a patient's agent or guardian, authorized under this chapter to make a health care decision for the patient;

(41) "technician" means an individual who is licensed or certified by the State Medical Board to remove or process a part;

(42) "terminal condition" means an incurable or irreversible illness or injury

- (A) that without administration of life-sustaining procedures will result in death in a short period of time;
- (B) for which there is no reasonable prospect of cure or recovery;
- (C) that imposes severe pain or otherwise imposes an inhumane burden on the patient; and
- (D) for which, in light of the patient's medical condition, initiating or continuing life-sustaining procedures will provide only minimal medical benefit.

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*** THIS SECTION IS CURRENT THROUGH THE MARCH 17, 2005 ISSUE OF ***
*** THE FEDERAL REGISTER ***

TITLE 21 -- FOOD AND DRUGS
CHAPTER I -- FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER L -- REGULATIONS UNDER CERTAIN OTHER ACTS ADMINISTERED BY THE FOOD AND DRUG ADMINISTRATION
PART 1271 -- HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS
SUBPART D -- CURRENT GOOD TISSUE PRACTICE [EFFECTIVE MAY 25, 2005.]

21 CFR 1271.170

§ 1271.170 Personnel. [Effective May 25, 2005.]

[PUBLISHER'S NOTE: This section was added at 69 FR 68612, 68683, Nov. 24, 2004, effective May 25, 2005.]

(a) General. You must have personnel sufficient to ensure compliance with the requirements of this part.

(b) Competent performance of functions. You must have personnel with the necessary education, experience, and training to ensure competent performance of their assigned functions. Personnel must perform only those activities for which they are qualified and authorized.

(c) Training. You must train all personnel, and retrain as necessary, to perform their assigned responsibilities adequately.

HISTORY: [69 FR 68612, 68683, Nov. 24, 2004]

AUTHORITY: AUTHORITY NOTE APPLICABLE TO ENTIRE PART :
42 U.S.C. 216, 243, 264, 271.

NOTES: [EFFECTIVE DATE NOTE: 69 FR 68612, 68683, Nov. 24, 2004, added Subpart D, effective May 25, 2005.]

NOTES APPLICABLE TO ENTIRE TITLE:

Cross References: Food Safety and Inspection Services, Department of Agriculture: See Meat and Poultry Inspection, 9 CFR CHAPTER III.

Federal Trade Commission: See Commercial Practices, 16 CFR chapter I.

U.S. Customs Service, Department of the Treasury: See Customs Duties, 19 CFR chapter I.

Internal Revenue Service, Department of the Treasury: See Internal Revenue, 26 CFR chapter I.

Bureau of Alcohol, Tobacco, and Firearms, Department of the Treasury: See Alcohol, Tobacco Production and Firearms, 27 CFR chapter I.

NOTES APPLICABLE TO ENTIRE CHAPTER:

[EDITORIAL NOTE: For nomenclature changes to chapter I see 59 FR 14366, Mar. 28, 1994.]

[PUBLISHER'S NOTE: For the uniform compliance date for food labeling regulations under Chapter I, see 61 FR 67710, Dec. 24, 1996; 61 FR 68145, Dec. 27, 1996; 62 FR 49881, Sept. 23, 1997.]

NOTES APPLICABLE TO ENTIRE PART:

[PUBLISHER'S NOTE: The authority citation for Part 1271 was revised at 69 *FR* 29786, 29829, May 25, 2004, effective May 25, 2005. For the convenience of the user, the authority citation effective May 25, 2005, has been set out below:

42 *U.S.C.* 216, 243, 263a, 264, 271.]

111 words

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*** THIS SECTION IS CURRENT THROUGH THE MARCH 17, 2005 ISSUE OF ***
*** THE FEDERAL REGISTER ***

TITLE 42 -- PUBLIC HEALTH
CHAPTER IV -- CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND
HUMAN SERVICES
SUBCHAPTER G -- STANDARDS AND CERTIFICATION
PART 482 -- CONDITIONS OF PARTICIPATION FOR HOSPITALS
SUBPART C -- BASIC HOSPITAL FUNCTIONS

42 CFR 482.45

§ 482.45 Condition of participation: Organ, tissue, and eye procurement

(a) Standard: Organ procurement responsibilities. The hospital must have and implement written protocols that:

(1) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the hospital. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose;

(2) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

(3) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its options to donate organs, tissues, or eyes or to decline to donate. The individual designated by the hospital to initiate the request to the family must be an organ procurement representative or a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;

(4) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;

(5) Ensure that the hospital works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.

(b) Standard: Organ transplantation responsibilities. (1) A hospital in which organ transplants are performed must be a member of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274) and abide by its rules. The term "rules of the OPTN" means those rules provided for in regulations issued by the Secretary in accordance with section 372 of the PHS Act which are enforceable under 42 CFR 121.10. No hospital is considered to be out of compliance with section 1138(a)(1)(B) of the Act, or with the requirements of this paragraph, unless the Secretary has given the OPTN formal

notice that he or she approves the decision to exclude the hospital from the OPTN and has notified the hospital in writing.

(2) For purposes of these standards, the term "organ" means a human kidney, liver, heart, lung, or pancreas.

(3) If a hospital performs any type of transplants, it must provide organ-transplant-related data, as requested by the OPTN, the Scientific Registry, and the OPOs. The hospital must also provide such data directly to the Department when requested by the Secretary.

HISTORY: [63 FR 33856, 33874, June 22, 1998]

AUTHORITY: AUTHORITY NOTE APPLICABLE TO ENTIRE PART:
Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

NOTES: [EFFECTIVE DATE NOTE: 63 FR 33856, 33874, June 22, 1998, added this section, effective Aug. 21, 1998.]

NOTES APPLICABLE TO ENTIRE CHAPTER:

[PUBLISHER'S NOTE: Nomenclature changes affecting Chapter IV appear at 45 FR 53806, Aug. 13, 1980; 50 FR 12741, Mar. 29, 1985; 50 FR 33034, Aug. 16, 1985; 51 FR 41338, Nov. 14, 1986; 53 FR 6634, Mar. 2, 1988; 53 FR 47201, Nov. 22, 1988; 56 FR 8852, Mar. 1, 1991; 66 FR 39450, 39452, July 31, 2001; 67 FR 36539, 36540, May 24, 2002.]

NOTES APPLICABLE TO ENTIRE PART:

[PUBLISHER'S NOTE: For Federal Register citations concerning Part 482 clarifications, see: 67 FR 61805, Oct. 2, 2002.]

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Life Alaska moves donor registry forward

Sunday, March 13, 2005 - by Joy Mapaye

Anchorage, Alaska - Last year, Life Alaska made a plea to state lawmakers to create a computerized central registry for organ donors.

In June 2004, the registry became a reality with the signing of House Bill 337. The registry would include a new computerized driver's license which allows the Department of Motor Vehicles to enter a donor's information into a central computer system.

By June 2004, roughly 60,000 donors were in the Life Alaska registry. When the first DMV numbers were uploaded this number jumped to 80,000.



Shawn Wilson/KTUU-TV



Shawn Wilson/KTUU-TV

Today, there are about 170,000 donors listed according to the DMV. The registry grows by 200 to 300 names every day.

Life Alaska says it remembers all those who have helped others in a celebration service held each year. Denise Och is one of those at the event. Och lost her son, Nathanael, in an accident about two years ago. The family made the decision to donate his organs and tissues.

"We knew his character. We knew the kind of person that he was, and so the decision that we made as a family was based on what we thought he would want and we've never regretted it," said Och (right).



Shawn Wilson/KTUU-TV

"For years we've had donor cards and other means but the electronic registry allows one by the Internet to check a name instantly. Is this person on the registry? And so we're able to in every case know in Alaska if a person is on the registry," said Bruce Zalneraitis of Life Alaska donor services.



Life Alaska says the direct impact here is the cut down in waiting time, which can mean the difference between life and death. Prior to the change, about 10 to 15 names of people who passed away would appear in the registry every year. Now, five to 10 names appear each week.

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Life Alaska says about 25 other states have some form of electronic registry but the group says this number is changing as new laws go into effect.

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- **State bill tries to record organ donors (March 14, 2004)**
Representatives of Alaska's Organ Procurement Program thanked 100 donor families who gathered together Sunday. With the help of the families, the lives of the 80 Alaskans who were at the meeting have been saved.
- **New bill could save thousands of Alaskan lives (June 15, 2004)**
Gov. Frank Murkowski is scheduled to sign House Bill 337 into law Wednesday. The bill would create an official organ donor registry at the Department of Motor Vehicles, and it is just one way organ donation in Alaska is getting easier.

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New bill could save thousands of Alaskan lives

June 15, 2004 - by Joy Mapaye

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Anchorage, Alaska - Gov. Frank Murkowski is scheduled to sign House Bill 337 into law Wednesday. The bill would create an official organ donor registry at the Department of Motor Vehicles, and it is just one way organ donation in Alaska is getting easier.

At Alaska's Department of Motor Vehicles, an organ donor's wish will now be on record. Currently the department doesn't keep records of those who sign up to become organ and tissue donors, but House Bill 337 will change that, allowing the DMV to transfer an organ donor's wishes to Life Alaska.

"We're very excited that Governor Murkowski is due to sign that into legislation," said Brenda Stewart of Life Alaska donor services.

Stewart says the new registry would allow Life Alaska to quickly match the donor's gift to a potential recipient, saving time and lives.

According to the Joint Commission on Accreditation of Healthcare Organizations, more than 85,000 Americans are on the waiting list for life-saving transplants, and more than 6,000 people who are awaiting a transplant die each year.

The group says it has now begun a major initiative to break down barriers that limit donations, including cultural ones. At Life Alaska, however, that process is well underway with a special partnership at the Alaska Native Medical Center.

"The relationship with Life Alaska has been one that has developed or evolved over years," said Phyllis Goodwin, the director of critical care services at the Alaska Native Medical Center.

Goodwin said that in 1991, when she first arrived at the Alaska Native Medical Center, they didn't do organ donations. But over the years it began working on education campaigns with Life Alaska to help the community and help boost Alaska Native donors.

"We've seen our donation numbers increase over time," Goodwin said.

Goodwin says educational campaigns as well as a growing public awareness on organ and tissue donation are helping. Life Alaska agrees and says one person can make a big difference.

Life Alaska says aside from its educational outreach, it works to help families through the grieving process, and during this time the focus is on those who need help.

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"It's less about a background or a culture of a person and more about reaching out to people in need," Stewart said. "And if that's done in a caring and sensitive way, then it empowers people to make that decision that's right for them."

It's a decision Life Alaska says education, awareness and the new registry at the DMV are all helping people make.

Becoming part of the registry is optional. The new law will go into effect 90 days after the governor signs the bill.

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AMENDMENT #1 - PASSED

OFFERED IN THE HOUSE

BY REPRESENTATIVE MCGUIRE

TO: HB 214

- 1 Page 2, lines 29 - 30:
- 2 Delete "and send the document or other evidence to the procurement
- 3 organization"

pg 2 ln 25

The bill would impose a requirement on law enforcement and first responders to notify an organ procurement organization when patients die outside of a hospital and to send documentation or evidence to the organization which demonstrates the patient's intent to make or refuse to make an anatomical gift.

The bill is problematic for the following reasons: (1) it imposes an obligation on EMS responders to search for and remove the drivers' license or organ donation card of a dying person, which could be offensive to family members and expose the responders to accusations of theft, including identity theft. The obligation to transmit the documentation to a procurement organization is unreasonably burdensome and could increase potential liability for removal or loss of the documentation. (2) It would create an unfunded financial burden on small volunteer services to train their providers and circulate materials with the telephone number and address for the procurement organization. Assuming the bill language "send" allows faxed transmission of the documentation, it would require services to purchase and maintain equipment for the purpose of capturing an image of organ donor documentation and transmitting it to the procurement agency by scanner, digital camera and/or fax machine. (3) It would impose a fiscal burden for training on EMS Regions who have operated for the last 14 years under straight line, or flat funding, despite increases in all cost categories. (4) Concerns exist about who is responsible and at what cost, to maintain the body until arrangements for removal and transport can be made. (5) An unexpected or unattended death is potentially a crime scene until law enforcement has determined otherwise. Prior to that time, EMS responders risk damaging evidence if they search for identification or organ donor documentation, thereby disturbing the scene.

Possible Amendments:

A#2
PASSED
Section AS 13.52.200(e)(1): delete "...and a procurement organization...". The hospital already has an obligation to notify the organization under AS 13.52.200(a) and (f). The burden to notify should not be imposed additionally on the first responder.

Section AS 13.52.200(e)(2): delete "...shall notify a procurement organization and send the document or other evidence to the procurement organization" and replace it with "shall notify the public safety answering point, as defined in AS 29.35.137(8) if one serves the community. The public safety answering point shall notify the procurement organization." This would remove the burden from individual responders and small communities with volunteer radio dispatch systems.

In both sections, delete the requirement to send the document or other evidence to the procurement organization. Life Alaska has indicated that the dispatcher can transmit the name and identifying information of the patient or decedent to enable them to check the donor registry database. This would make sending the documentation unnecessary. Alternatively, the obligation for sending organ donation documentation should be limited to law enforcement personnel who will be present at most of these situations, except for expected home deaths and in rural areas that have no village public safety officer.

Kathy Hope Erickson

From: Vanessa Tondini
Sent: Tuesday, April 05, 2005 1:08 PM
To: Kathy Hope Erickson
Cc: Vanessa Tondini
Subject: HB 214

Hi Kathy,

Bruce Scandling, HESS, is preparing an updated zero FN for HB 214, in response to the amendment we plan to offer today in HESS cmte. When you get the CS back from Leg. Legal, could you please fax it to him at 586-1877 and then he will get you the updated FN ASAP. Please list it as a new FN (the motion can be made in cmte. "with attached zero fn's, including any forthcoming fiscal note from HESS) and wait to get it before you hand the bill into the clerk to be read across. If you have any questions, call me at 4990 or Bruce at x3486.

Thank you so much!
Vanessa

4/5/2005