

H B

306

HOUSE COMMITTEE REPORT

1/27

(7)

Date referred: 5/7/87

FURTHER REFERRALS:

Judiciary

DATE: 1-27-88

The Health, Education and Social Services Committee has considered

HB 306

"An Act relating to anatomical gifts."

RECOMMENDS:

- replace with CS HB 306 (HESS) the same title
- attached amendment(s) a new title
- do pass
- do not pass
- no recommendation
- individual recommendations
- additional referral to the _____ Committee

ADOPTS: _____ letter of intent

ATTACHES NEW FISCAL NOTE(S):

- fiscal impact same as previous fiscal note published _____
- zero fiscal note same as previous zero fiscal note published _____
- zero with analysis

SIGNING DO PASS:

Ellis

Walter Stanley

Russell E. Bell

Willa F. Koppen

Bill Hunt

Alexander Greenberg

Donald Douley

SIGNING OTHER RECOMMENDATIONS:

Willa F. Koppen

 CO-Chairman's signature
Ellis

FISCAL NOTE

REQUEST:

Revision Date: _____
Title: An Act relating to anatomical gifts.
Sponsor: Gruenberg
Requestor: Senate HESS

Agency Affected: Public Safety
BRU: Motor Vehicles
Components: Field Services

EXPENDITURES/REVENUES: (Thousands of Dollars)

OPERATING	FY 88	FY 89	FY 90	FY 91	FY 92	FY 93
PERSONAL SERVICES						
TRAVEL						
CONTRACTUAL						
SUPPLIES						
EQUIPMENT						
LAND & STRUCTURES						
GRANTS, CLAIMS						
MISCELLANEOUS						
TOTAL OPERATING	-0-	-0-	-0-	-0-	-0-	-0-

CAPITAL						
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REVENUE						
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FUNDING: (Thousands of Dollars)

GENERAL FUND						
FEDERAL FUNDS						
OTHER						
TOTAL	-0-	-0-	-0-	-0-	-0-	-0-

POSITIONS:

FULL-TIME						
PART-TIME						
TEMPORARY						

ANALYSIS : (Attach a separate page if necessary)

No fiscal impact on this department.

Prepared by: Jay N. Dulany *JND 1/29/88* Phone: 269-5551
Division: Motor Vehicles Date: 1-29-88

Approved by Commissioner: David Holtz *Dep. Comm.* Date: 2-3-88
Agency: Public Safety

Distribution (by preparer):
Legislative Finance
Legislative Sponsor
Requestor
Office of Management and Budget
Impacted Agency(ies)

MEMORANDUM

TO: House HESS Committee Members

FROM: House HESS Committee Staff

RE: Proposed HESS CS's for HB 306 - Anatomical Gifts

DATE: January 22, 1988

.....

"L" Draft:

Adds to 11/9/87 draft that a person registering a vehicle shall be given written information regarding anatomical gifts and that if others request written information they will get it. As per Rep. Hudson.

"B" Draft:

In addition to amendment added in "L" draft, provides that applicant registering vehicle in person shall also be asked orally if they wish to be an organ donor.

LM/dm

*MS working draft
Hudson #1*

5-1006L
Hein
1/22/88

Original sponsors: Gruenberg, Grussendorf,
Koponen, et al.

1 IN THE HOUSE

BY THE HEALTH, EDUCATION AND
SOCIAL SERVICES COMMITTEE

2 CS FOR HOUSE BILL NO. 306 (HESS)

3 IN THE LEGISLATURE OF THE STATE OF ALASKA

4 FIFTEENTH LEGISLATURE - SECOND SESSION

5 A BILL

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8 * Section 1. AS 13.50.010(a) is amended to read:

9 (a) A person of sound mind who is 18 [19] or more years of age
10 may make a gift to take effect upon death, of all or a part of the
11 person's body for a purpose specified in AS 13.50.020.

12 * Sec. 2. AS 13.50 is amended by adding new sections to read:

13 Sec. 13.50.014. REQUESTS BY HOSPITALS FOR ANATOMICAL GIFTS. (a)
14 When a person dies in a hospital or is pronounced dead after arriving
15 at a hospital, the administrator or a designated employee shall re-
16 quest a gift under AS 13.50.010(b), unless the administrator or em-
17 ployee knows that the person has executed a gift.

18 (b) Each hospital in the state shall develop procedures for
19 identifying potential donors of gifts, requesting gifts, notifying and
20 coordinating with eye banks, tissue banks, and organ procurement
21 agencies, and assisting in the procurement, removal, storage, and
22 transportation of gifts. The procedures must specify the circum-
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24 the gift is unsuitable, if the request is likely to offend the donor's
25 religious beliefs, or if making the request is likely to cause undue
26 emotional distress to the person who would be asked to make the gift.
27 The procedures must encourage reasonable discretion and sensitivity.

28 (c) The commissioner of health and social services may exempt
29 from the requirements of this section a hospital that lacks the means

1 to properly remove, store, or transport gifts.

2 Sec. 13.50.016. INVESTIGATIONS BY LAW ENFORCEMENT AND MEDICAL
3 PERSONNEL. Law enforcement or medical personnel who respond to the
4 scene of an accident or emergency involving the death of a person and
5 who know that the person executed a gift shall inform appropriate
6 hospital personnel of the gift.

7 * Sec. 3. AS 13.50.060(a) is amended to read:

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9 accepts a gift of the entire body, the donee may, subject to the terms
10 of the gift, authorize embalming and the use of the body in funeral
11 services. If the gift is of a part of the body, the donee, upon the
12 death of the donor and before embalming shall have the part removed
13 without unnecessary mutilation. After removal of the part of the
14 body, custody of the remainder of the body vests in the surviving
15 spouse, next of kin, or a person other than the spouse or next of kin
16 who is authorized to dispose of the body. A person described in
17 AS 13.50.010(b) and the estate of the donor may not be held liable for
18 the cost of an examination under AS 13.50.010(e) or any costs related
19 to the removal, storage, or transportation of a gift.

20 * Sec. 4. AS 13.50.060(c) is amended to read:

21 (c) A person who acts in good faith in accordance with the terms
22 of this chapter or the anatomical gift laws of another state or coun-
23 try is not liable for damages for the act in a [ANY] civil action or
24 subject to prosecution in a [ANY] criminal proceeding for the act.

25 * Sec. 5. AS 13.50 is amended by adding a new section to read:

26 Sec. 13.50.065. REGULATIONS. The commissioner of health and
27 social services shall adopt regulations for the appropriate training
28 of hospital employees who are designated under AS 13.50.014 to request
29 gifts and for the implementation of this chapter.

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2 (8) "gift" means an anatomical gift of all or part of a
3 person's body.

4 * Sec. 7. AS 18.65 is amended by adding a new section to read:

5 Sec. 18.65.311. ANATOMICAL GIFT DOCUMENT. (a) The department
6 shall provide, at the time that an identification card is issued, a
7 form for a document by which the card holder may make an anatomical
8 gift under AS 13.50 (Uniform Anatomical Gifts Act). The document (1)
9 may not be larger than an identification card, (2) must contain suffi-
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11 execution of the document, and (3) must provide a means by which the
12 donor may cancel the gift. If the document making an anatomical gift
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14 attached to the identification card. A symbol indicating the exis-
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16 right-hand corner on the face of the identification card.

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20 an anatomical gift. The department shall, by placement of posters and
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22 advice, if requested, make known to the applicant the procedure neces-
23 sary to execute a gift under AS 13.50.

24 * Sec. 8. AS 28.10.021 is amended by adding a new subsection to read:

25 (c) The department shall make known to all applicants the
26 procedure for executing a gift under AS 13.50 (Uniform Anatomical
27 Gifts Act) by displaying posters in the offices in which applications
28 are taken, by providing a brochure or other written information to
29 each person who applies in person or by mail, and, if requested, by

*include
written
info
Hudson*

1 providing oral advice.

2 * Sec. 9. AS 28.15.061(d) is repealed and reenacted to read:

3 (d) An employee of the department who processes a driver's
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 11 providing oral advice.

same
rewritten
with
anatomically
Harrison

*§ 9 changes Section 8 of
 previous version to
 rewrite § AS 28.15.061(d)*

*MS work draft
Hudson #142*

5-10J6B
Hein
1/22/88

Original sponsors: Gruenberg, Grussendorf,
Koponen, et al.

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5-1006B
Hein
11/9/87

Original sponsors: Gruenberg, Grussendorf,
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Ellis

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1 advice, if requested, make known to the applicant the procedure neces-
2 sary to execute [COMPLETE] a [DOCUMENT OF] gift under AS 13.50 [THE]
3 (Uniform Anatomical Gifts Act) [(AS 13.50)].
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STATE OF ALASKA
THE LEGISLATURE

POUCH Y - STATE CAPITOL
JUNEAU, ALASKA 99811
907-465-3800

LEGISLATIVE AFFAIRS AGENCY
LEGISLATIVE REFERENCE LIBRARY

May, 1988

Copies of minutes listed below were originally included in this file. The minutes are available on the STAIRS database CMPR. In order to save space copies of minutes have not been left in the files.

Mary Van Nimwegen

H HESS

10-23-87

H HESS

1-21-88

8:30 a.m.

POSITION PAPER

HOUSE BILL 306

"An Act relating to anatomical gifts."

Advances in medical knowledge and technology have greatly increased the feasibility of and demand for transplantation of human tissues and organs. For a number of reasons, demand exceeds supply. HB 306 attempts to facilitate organ and tissue donation by: (1) lowering from 19 years to 18 years the age of persons who may execute gifts of tissues or organs; (2) requiring hospitals to establish procedures for requesting donations from survivors; (3) requiring responders at the scene of an accident to inform the hospital receiving the body of a person killed in the accident if it is known to the responders that the person has executed a donation; (4) clarifying that survivors cannot be held liable for costs associated with an anatomical gift; and (5) requiring employees of the Division of Motor Vehicles to inquire when processing an application for a driver's license whether the applicant wishes to execute an anatomical gift.

It is the department's understanding that legislation similar to HB 306 has been enacted or is under consideration in about half the states. The department also understands that there is similar federal legislation requiring hospital participation in the seeking of organ donations as a condition of participation in the federal Medicare program.

There are strict requirements for assuring the viability of certain types of organs. Therefore, because of distance and lack of fully equipped facilities in certain areas of the state, Alaska may not be able to participate as fully in organ donation as might be hoped. Nevertheless, a more systematic approach to securing organ donation is worthwhile. The success of the effort could probably be enhanced if there were an expanded effort by private or state agencies to educate the public about tissue and organ donation.

Position

The Department of Health and Social Services supports this legislation.

Recommended by: Elizabeth Ward
Elizabeth Ward, M.N.
Director
Division of Public Health

Date: 10/20/87

Approved by: Myra M. Munson
Myra M. Munson, Commissioner
Department of Health and Social
Services

Date: 10/20/87

9
on the issue of one Germany. When West German President Richard von Weizacker's said that, "The Germans in the two German states belong to the same nation," the East German leader replied, "It is dangerous and senseless to mourn the German Reich that perished so shamefully."

X from

Organ Transplants — Proper Priority

Though you'd be interested to see this noted an Editorial

AS MEDICAL TECHNIQUES necessary for successful transplantation of human organs improve, particularly in the field of suppressing the immune system's normal (but potentially-fatal) rejection reaction, the need for healthy, available body parts increases. The list of potential recipients grows.

Fairness dictates there should be some orderly method of making such life-giving donations available on a reasonable and balanced basis.

It is the nature of the world we live in that the poignant case attracting national sympathy becomes the one most likely to receive succor. The public will be pulling for the patient it can identify with. That builds pressure to help. But such factors should not dominate what is essentially a straightforward, scientific action.

SO IT IS ENCOURAGING to learn that a little-noticed, new federal law will require hospitals to start identifying patients who could donate their kidneys, livers, hearts or lungs to people in need of them. Many hospitals that do not ask for organ donations will now have to do so.

The new requirements grow out of legislation sponsored by Senator Albert Gore Jr., D-Tenn., and carry out recommendations of a federal advisory group that favored "a single national system for organ sharing" with uniform policies and standards to assure "equitable access to organ transplantation."

Members of that panel had quite properly emphasized that organs should be distributed according to objective criteria, rather than on the basis of who could generate the most publicity or high-level political interest in a particular case.

A FEW NUMBERS can serve to give weight to the need for such a law. A total of 8,960 kidney transplants were performed last year, compared to 5,358 in 1982.

Yet there are nearly 10,000 people waiting for new kidneys. Some 450 people are waiting for hearts; 300 for livers, and 91 people need heart-lung transplants.

This is a situation that needs to be handled with sensitivity and discretion. But the law represents a humanitarian response to a growing need. And should be recognized as such.

Public Law 98-507
98th Congress

An Act

To provide for the establishment of the Task Force on Organ Transplantation and the Organ Procurement and Transplantation Network, to authorize financial assistance for organ procurement organizations, and for other purposes.

Oct. 19, 1984
[S. 2048]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "National Organ Transplant Act".

National Organ
Transplant Act.
42 USC 201 note.
Health.

TITLE I—TASK FORCE ON ORGAN PROCUREMENT AND
TRANSPLANTATION

ESTABLISHMENT AND DUTIES OF TASK FORCE

SEC. 101. (a) Not later than ninety days after the date of the enactment of this Act, the Secretary of Health and Human Services (hereinafter in this title referred to as the "Secretary") shall establish a Task Force on Organ Transplantation (hereinafter in this title referred to as the "Task Force").

42 USC 273 note.

(b)(1) The Task Force shall—

(A) conduct comprehensive examinations of the medical, legal, ethical, economic, and social issues presented by human organ procurement and transplantation,

(B) prepare the assessment described in paragraph (2) and the report described in paragraph (3), and

(C) advise the Secretary with respect to the development of regulations for grants under section 371 of the Public Health Service Act.

Post, p. 2342.

(2) The Task Force shall make an assessment of immunosuppressive medications used to prevent organ rejection in transplant patients, including—

(A) an analysis of the safety, effectiveness, and costs (including cost-savings from improved success rates of transplantation) of different modalities of treatment;

(B) an analysis of the extent of insurance reimbursement for long-term immunosuppressive drug therapy for organ transplant patients by private insurers and the public sector;

(C) an identification of problems that patients encounter in obtaining immunosuppressive medications; and

(D) an analysis of the comparative advantages of grants, coverage under existing Federal programs, or other means to assure that individuals who need such medications can obtain them.

(3) The Task Force shall prepare a report which shall include—

Report.

(A) an assessment of public and private efforts to procure human organs for transplantation and an identification of factors that diminish the number of organs available for transplantation;

(B) an assessment of problems in coordinating the procurement of viable human organs including skin and bone;

(C) recommendations for the education and training of health professionals, including physicians, nurses, and hospital and emergency care personnel, with respect to organ procurement;

(D) recommendations for the education of the general public, the clergy, law enforcement officers, members of local fire departments, and other agencies and individuals that may be instrumental in effecting organ procurement;

(E) recommendations for assuring equitable access by patients to organ transplantation and for assuring the equitable allocation of donated organs among transplant centers and among patients medically qualified for an organ transplant;

(F) an identification of barriers to the donation of organs to patients (with special emphasis upon pediatric patients), including an assessment of—

(i) barriers to the improved identification of organ donors and their families and organ recipients;

(ii) the number of potential organ donors and their geographical distribution;

(iii) current health care services provided for patients who need organ transplantation and organ procurement procedures, systems, and programs which affect such patients;

(iv) cultural factors affecting the family with respect to the donation of the organs; and

(v) ethical and economic issues relating to organ transplantation needed by chronically ill patients;

(G) recommendations for the conduct and coordination of continuing research concerning all aspects of the transplantation of organs;

(H) an analysis of the factors involved in insurance reimbursement for transplant procedures by private insurers and the public sector;

(I) an analysis of the manner in which organ transplantation technology is diffused among and adopted by qualified medical centers, including a specification of the number and geographical distribution of qualified medical centers using such technology and an assessment of whether the number of centers using such technology is sufficient or excessive and of whether the public has sufficient access to medical procedures using such technology; and

(J) an assessment of the feasibility of establishing, and of the likely effectiveness of, a national registry of human organ donors.

MEMBERSHIP

42 USC 273 note.

Sec. 102. (a) The Task Force shall be composed of twenty-five members as follows:

(1) Twenty-one members shall be appointed by the Secretary of which:

(A) nine members shall be physicians or scientists who are eminent in the various medical and scientific specialties related to human organ transplantation;

(B) three members shall be individuals who are not physicians and who represent the field of human organ procurement;

(C) four members shall be individuals who are not physicians and who as a group have expertise in the fields of law,

theology, ethics, health care financing, and the social and behavioral sciences;

(D) three members shall be individuals who are not physicians or scientists and who are members of the general public; and

(E) two members shall be individuals who represent private health insurers or self-insurers.

(2) The Surgeon General of the United States, the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Administrator of the Health Care Financing Administration shall be ex officio members.

(b) No individual who is a full-time officer or employee of the United States may be appointed under subsection (a)(1) to the Task Force. A vacancy in the Task Force shall be filled in the manner in which the original appointment was made. A vacancy in the Task Force shall not affect its powers.

(c) Members shall be appointed for the life of the Task Force.

(d) The Task Force shall select a Chairman from among its members who are appointed under subsection (a)(1).

(e) Thirteen members of the Task Force shall constitute a quorum, but a lesser number may hold hearings.

(f) The Task Force shall hold its first meeting on a date specified by the Secretary which is not later than thirty days after the date on which the Secretary establishes the Task Force under section 101. Thereafter, the Task Force shall meet at the call of the Chairman or a majority of its members, but shall meet at least three times during the life of the Task Force.

(g)(1) Each member of the Task Force who is not an officer or employee of the United States shall be compensated at a rate equal to the daily equivalent of the annual rate of basic pay in effect for grade GS-18 of the General Schedule under section 5332 of title 5, United States Code, for each day (including traveltime) during which such member is engaged in the actual performance of duties as a member of the Task Force. Each member of the Task Force who is an officer or employee of the United States shall receive no additional compensation.

(2) While away from their homes or regular places of business in the performance of duties for the Task Force, all members of the Task Force shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under sections 5702 and 5703 of title 5, United States Code.

SUPPORT FOR THE TASK FORCE

SEC. 103. (a) Upon request of the Task Force, the head of any Federal agency is authorized to detail, on a reimbursable basis, any of the personnel of such agency to the Task Force to assist the Task Force in carrying out its duties under this Act. 42 USC 273 note.

(b) The Secretary shall provide the Task Force with such administrative and support services as the Task Force may require to carry out its duties.

REPORT

SEC. 104. (a) The Task Force may transmit to the Secretary, the Committee on Labor and Human Resources of the Senate, and the 42 USC 273 note.

- Committee on Energy and Commerce of the House of Representatives such interim reports as the Task Force considers appropriate
- Report. (b) Not later than 7 months after the date on which the Task Force is established by the Secretary under section 101, the Task Force shall transmit a report to the Secretary, the Committee on Labor and Human Resources of the Senate, and the Committee on Energy and Commerce of the House of Representatives on its assessment under section 101(b)(2) of immunosuppressive medications used to prevent organ rejection.
- Report. (c) Not later than twelve months after the date on which the Task Force is established by the Secretary under section 101, the Task Force shall transmit a final report to the Secretary, the Committee on Labor and Human Resources of the Senate, and the Committee on Energy and Commerce of the House of Representatives. The final report of the Task Force shall include—
- (1) a description of any findings and conclusions of the Task Force made pursuant to any examination conducted under section 101(b)(1)(A),
 - (2) the matters specified in section 101(b)(3), and
 - (3) such recommendations as the Task Force considers appropriate.

TERMINATION

- 42 USC 273 note. SEC. 105. The Task Force shall terminate three months after the date on which the Task Force transmits the report required by section 104(c).

TITLE II—ORGAN PROCUREMENT ACTIVITIES

- SEC. 201. Part H of title III of the Public Health Service Act is amended to read as follows:

"PART H—ORGAN TRANSPLANTS

"ASSISTANCE FOR ORGAN PROCUREMENT ORGANIZATIONS

- Grants.
42 USC 273. "SEC. 371. (a)(1) The Secretary may make grants for the planning of qualified organ procurement organizations described in subsection (b).
- "(2) The Secretary may make grants for the establishment, initial operation, and expansion of qualified organ procurement organizations described in subsection (b).
- "(3) In making grants under paragraphs (1) and (2), the Secretary shall—
- "(A) take into consideration any recommendations made by the Task Force on Organ Transplantation established under section 101 of the National Organ Transplant Act, and
- "(B) give special consideration to applications which cover geographical areas which are not adequately served by organ procurement organizations.
- "(b)(1) A qualified organ procurement organization for which grants may be made under subsection (a) is an organization which, as determined by the Secretary, will carry out the functions described in paragraph (2) and—
- "(A) is a nonprofit entity,
- Ante. p. 2339.

"(B) has accounting and other fiscal procedures (as specified by the Secretary) necessary to assure the fiscal stability of the organization,

"(C) has an agreement with the Secretary to be reimbursed under title XVIII of the Social Security Act for the procurement of kidneys, 42 USC 1395.

"(D) has procedures to obtain payment for non-renal organs provided to transplant centers,

"(E) has a defined service area which is a geographical area of sufficient size which (unless the service area comprises an entire State) will include at least fifty potential organ donors each year and which either includes an entire standard metropolitan statistical area (as specified by the Office of Management and Budget) or does not include any part of such an area,

"(F) has a director and such other staff, including the organ donation coordinators and organ procurement specialists necessary to effectively obtain organs from donors in its service area, and

"(G) has a board of directors or an advisory board which—

"(i) is composed of—

"(I) members who represent hospital administrators, intensive care or emergency room personnel, tissue banks, and voluntary health associations in its service area,

"(II) members who represent the public residing in such area,

"(III) a physician with knowledge, experience, or skill in the field of histocompatibility,

"(IV) a physician with knowledge or skill in the field of neurology, and

"(V) from each transplant center in its service area which has arrangements described in paragraph (2)(G) with the organization, a member who is a surgeon who has practicing privileges in such center and who performs organ transplant surgery,

"(ii) has the authority to recommend policies for the procurement of organs and the other functions described in paragraph (2), and

"(iii) has no authority over any other activity of the organization.

"(2) An organ procurement organization shall—

"(A) have effective agreements, to identify potential organ donors, with a substantial majority of the hospitals and other health care entities in its service area which have facilities for organ donations,

"(B) conduct and participate in systematic efforts, including professional education, to acquire all useable organs from potential donors,

"(C) arrange for the acquisition and preservation of donated organs and provide quality standards for the acquisition of organs which are consistent with the standards adopted by the Organ Procurement and Transplantation Network under section 372(b)(2)(D),

"(D) arrange for the appropriate tissue typing of donated organs,

"(E) have a system to allocate donated organs among transplant centers and patients according to established medical criteria,

"(F) provide or arrange for the transportation of donated organs to transplant centers,

"(G) have arrangements to coordinate its activities with transplant centers in its service area,

"(H) participate in the Organ Procurement Transplantation Network established under section 372,

"(I) have arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage, and distribution of tissues as may be appropriate to assure that all useable tissues are obtained from potential donors, and

"(J) evaluate annually the effectiveness of the organization in acquiring potentially available organs.

Appropriation
authorization.

"(c) For grants under subsection (a) there are authorized to be appropriated \$5,000,000 for fiscal year 1985, \$8,000,000 for fiscal year 1986, and \$12,000,000 for fiscal year 1987.

"ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

42 USC 274.

"SEC. 372. (a) The Secretary shall by contract provide for the establishment and operation of an Organ Procurement and Transplantation Network which meets the requirements of subsection (b). The amount provided under such contract in any fiscal year may not exceed \$2,000,000. Funds for such contracts shall be made available from funds available to the Public Health Service from appropriations for fiscal years beginning after fiscal year 1984.

"(b)(1) The Organ Procurement and Transplantation Network shall carry out the functions described in paragraph (2) and shall—

"(A) be a private nonprofit entity which is not engaged in any activity unrelated to organ procurement, and

"(B) have a board of directors which includes representatives of organ procurement organizations (including organizations which have received grants under section 371), transplant centers, voluntary health associations, and the general public.

"(2) The Organ Procurement and Transplantation Network shall—

"(A) establish in one location or through regional centers—

"(i) a national list of individuals who need organs, and

"(ii) a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list, especially individuals whose immune system makes it difficult for them to receive organs,

"(B) maintain a twenty-four-hour telephone service to facilitate matching organs with individuals included in the list,

"(C) assist organ procurement organizations in the distribution of organs which cannot be placed within the service areas of the organizations,

"(D) adopt and use standards of quality for the acquisition and transportation of donated organs,

"(E) prepare and distribute, on a regionalized basis, samples of blood sera from individuals who are included on the list and whose immune system makes it difficult for them to receive organs, in order to facilitate matching the compatibility of such individuals with organ donors,

"(F) coordinate, as appropriate, the transportation of organs from organ procurement organizations to transplant centers,

"(G) provide information to physicians and other health professionals regarding organ donation, and

"(H) collect, analyze, and publish data concerning organ donation and transplants.

"SCIENTIFIC REGISTRY

"Sec. 373. The Secretary shall, by grant or contract, develop and maintain a scientific registry of the recipients of organ transplants. The registry shall include such information respecting patients and transplant procedures as the Secretary deems necessary to an ongoing evaluation of the scientific and clinical status of organ transplantation. The Secretary shall prepare for inclusion in the report under section 376 an analysis of information derived from the registry.

42 USC 274a.

"GENERAL PROVISIONS RESPECTING GRANTS AND CONTRACTS

"Sec. 374. (a) No grant may be made under section 371 or 373 or contract entered into under section 372 or 373 unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be in such form and shall be submitted in such manner as the Secretary shall by regulation prescribe.

Grants.
42 USC 274b.

"(b)(1) In considering applications for grants under section 371—

"(A) the Secretary shall give priority to any applicant which has a formal agreement of cooperation with all transplant centers in its proposed service area,

"(B) the Secretary shall give special consideration to organizations which met the requirements of section 371(b) before the date of the enactment of this section, and

"(C) the Secretary shall not discriminate against an applicant solely because it provides health care services other than those related to organ procurement.

The Secretary may not make a grant for more than one organ procurement organization which serve the same service area.

Prohibition.

"(2) A grant for planning under section 371 may be made for one year with respect to any organ procurement organization and may not exceed \$100,000.

"(3) Grants under section 371 for the establishment, initial operation, or expansion of organ procurement organizations may be made for two years. No such grant may exceed \$500,000 for any year and no organ procurement organization may receive more than \$800,000 for initial operation or expansion.

"(c)(1) The Secretary shall determine the amount of a grant made under section 371 or 373. Payments under such grants may be made in advance on the basis of estimates or by the way of reimbursement, with necessary adjustments on account of underpayments or overpayments, and in such installments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of such grants.

"(2)(A) Each recipient of a grant under section 371 or 373 shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the undertaking in connection with which such grant was made, and the amount of that

Records.

- portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.
- Audit. “(B) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipient of a grant under section 371 or 373 that are pertinent to such grant.
- “(d) For purposes of this part:
- “(1) The term ‘transplant center’ means a health care facility in which transplants of organs are performed.
- “(2) The term ‘organ’ means the human kidney, liver, heart, lung, pancreas, and any other human organ (other than corneas and eyes) specified by the Secretary by regulation and for purposes of section 373, such term includes bone marrow.

“ADMINISTRATION

- 42 USC 274c. “SEC. 375. The Secretary shall, during fiscal years 1985, 1986, 1987, and 1988, designate and maintain an identifiable administrative unit in the Public Health Service to—
- 42 USC 1395. Public information. “(1) administer this part and coordinate with the organ procurement activities under title XVIII of the Social Security Act, “(2) conduct a program of public information to inform the public of the need for organ donations, “(3) provide technical assistance to organ procurement organizations receiving funds under section 371, the Organ Procurement and Transplantation Network established under section 372, and other entities in the health care system involved in organ donations, procurement, and transplants, and
- Report. “(4) one year after the date on which the Task Force on Organ Transplantation transmits its final report under section 104(c) of the National Organ Transplant Act, and annually thereafter through fiscal year 1988, submit to Congress an annual report on the status of organ donation and coordination services and include in the report an analysis of the efficiency and effectiveness of the procurement and allocation of organs and a description of problems encountered in the procurement and allocation of organs.

“REPORT

- 42 USC 274d. “SEC. 376. The Secretary shall annually publish a report on the scientific and clinical status of organ transplantation. The Secretary shall consult with the Director of the National Institutes of Health and the Commissioner of the Food and Drug Administration in the preparation of the report.”

TITLE III—PROHIBITION OF ORGAN PURCHASES

- Penalties. 42 USC 274e. SEC. 301. (a) It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.
- (b) Any person who violates subsection (a) shall be fined not more than \$50,000 or imprisoned not more than five years, or both.
- (c) For purposes of subsection (a):
- (1) The term “human organ” means the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin,

and any other human organ specified by the Secretary of Health and Human Services by regulation.

(2) The term "valuable consideration" does not include the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ.

(3) The term "interstate commerce" has the meaning prescribed for it by section 201(b) of the Federal Food, Drug and Cosmetic Act.

21 USC 321.

TITLE IV—MISCELLANEOUS

BONE MARROW REGISTRY DEMONSTRATION AND STUDY

SEC. 401. (a) Not later than nine months after the date of enactment of this Act, the Secretary of Health and Human Services shall hold a conference on the feasibility of establishing and the effectiveness of a national registry of voluntary bone marrow donors.

42 USC 273 note.

(b) If the conference held under subsection (a) finds that it is feasible to establish a national registry of voluntary donors of bone marrow and that such a registry is likely to be effective in matching donors with recipients, the Secretary of Health and Human Services, acting through the Assistant Secretary for Health, shall, for purposes of the study under subsection (c), establish a registry of voluntary donors of bone marrow. The Secretary shall assure that—

(1) donors of bone marrow listed in the registry have given an informed consent to the donation of the bone marrow; and

(2) the names of the donors in the registry are kept confidential and access to the names and any other information in the registry is restricted to personnel who need the information to maintain and implement the registry, except that access to such other information shall be provided for purposes of the study under subsection (c).

If the conference held under subsection (a) makes the finding described in this subsection, the Secretary shall establish the registry not later than six months after the completion of the conference.

(c) The Secretary of Health and Human Services, acting through the Assistant Secretary for Health, shall study the establishment and implementation of the registry under subsection (b) to identify the issues presented by the establishment of such a registry, to evaluate participation of bone marrow donors, to assess the imple-

Report.

mentation of the informed consent and confidentiality requirements, and to determine if the establishment of a permanent bone marrow registry is needed and appropriate. The Secretary shall report the results of the study to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate not later than two years after the date the registry is established under subsection (b).

Approved October 19, 1984.

LEGISLATIVE HISTORY—S. 2048 (H.R. 5580) (H.R. 4080):

HOUSE REPORTS: No. 98-575, Pt. 1, accompanying H.R. 4080 (Comm. on Energy and Commerce), No. 98-769 accompanying H.R. 5580 (Comm. on Energy and Commerce), and No. 98-1127 (Comm. of Conference).

SENATE REPORT No. 98-382 (Comm. on Labor and Human Resources).

CONGRESSIONAL RECORD, Vol. 130 (1984):

Apr. 11, considered and passed Senate.

June 20, 21, H.R. 5580 considered and passed House; S. 2048, amended, passed in lieu.

Oct. 3, House agreed to conference report.

Oct. 4, Senate agreed to conference report.

WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS, Vol. 20, No. 42 (1984):

Oct. 19, Presidential statement.

○

B. Organ Procurement

When renal transplantation became an effective form of therapy in the 1980s, it was necessary to develop systems for procuring kidneys from cadaveric donors. Early programs were established to provide centralized services that might include provision for surgical retrieval, tissue typing, maintaining lists and tissue characteristics of potential recipients, and organ distribution (transportation) to cooperating transplant centers.

The United States now operates the largest organ procurement effort in the world. Nationwide there are currently approximately 120 Medicare approved OPAs. Approximately 7,000 cadaveric kidneys were obtained in the United States in 1986. This effort has come about largely through the OPAs funded by the Medicare ESRD program. The number of patients on waiting lists for a kidney transplant totaled 10,000 in 1986.

Each OPA routinely transports organs; for example, more than 40 percent of all transplanted kidneys are obtained in a locale different from the site in which transplantation occurs.

OPAs also procure organs other than kidneys used in transplantation. In 1986, 1368 heart, 924 liver, 45 heart-lung, and 140 pancreas or islet cell transplants were performed in the United States.

Virtually all of these organs came from donors identified by the organ procurement system, nearly all of whom also donated kidneys. Waiting lists are much smaller for organs other than kidneys. Approximately 300 people were waiting for donor hearts and 400 waiting for donor livers in 1986. Pediatric patients make up about one-third of the waiting list for liver transplants, but organs are most scarce for this group.

Although OPAs play a central role in locating and placing transplantable human organs, OPAs vary in size, strategies, personnel, and organization.

OPAs currently approved for supplying kidneys for Medicare patients can be divided into two organizationally distinct groups. Nearly half of the OPAs are independently incorporated non-profit entities whose sole function is the procurement of human organs. These independent organ procurement agencies (IOPAs) are approved by HCFA if they comply with our definition of an OPA (42 CFR 405.2102). We prescribe four services that an OPA must perform or coordinate the performance of in order to be approved: Recovery of kidneys, preservation of kidneys, transportation of donated kidneys, and the maintenance of a system to locate prospective recipients for the recovered kidneys. Our

instructions to approved IOPAs require them to develop a standard kidney acquisition charge, which is billed to the transplant center at the time an organ is furnished. The transplant center pays the IOPA and bills Medicare for that cost. We have established cost reporting requirements in our regulations and instructions at 42 CFR 413.178 to make adjustments at the end of the cost reporting year.

The remaining OPAs are hospital-based organ procurement agencies (HOPAs). These HOPAs are located within the administrative structure of a hospital approved to perform kidney transplants, usually within the department of surgery or the division of transplantation, or both. The costs of organ procurement activities of HOPAs are recorded in a kidney acquisition cost center and billed by the hospital separately from the actual transplantation procedure costs that are billed when transplantation occurs (42 CFR 412.90(e)). Medicare cost adjustments, if needed, are made for the HOPA when the hospital's cost report is settled. HOPAs are generally directly responsible to a transplant surgeon and work, for the most part, primarily for that transplant center.

II. Legislation

The National Organ Transplant Act of 1984 (Pub. L. 98-507), created a Task Force on Organ Transplantation, which conducted a comprehensive examination of all aspects of organ procurement and transplantation. In addition to many other findings and specific recommendations, the Task Force concluded that an overriding problem, common to all organ transplant procedures, is the serious gap between the need for organs and the supply of organs available for transplantation. The Task Force found that many opportunities for obtaining organs were lost because of oversights or shortcomings in the present procurement process. One recommendation adopted by the Task Force was that OPAs be strengthened by establishing criteria that they must meet in order to be certified, and that all hospitals, as a condition of participation in Medicare, be required to adopt policies and procedures for routinely identifying potential organ and tissue donors and providing next-of-kin with appropriate opportunities for donation. The Task Force also recommended periodic recertification of the OPAs, requiring the OPAs to meet performance standards and that there be only one agency per service area. (See Organ Transplantation, Report of the Task

Force on *Organ Transplantation*, April 1988, pp. 5, 31-34, 59-61, 117-122.)

Congress adopted these recommendations when enacting section 9318 of the Omnibus Budget

Reconciliation Act of 1988 (OBRA 88),

Pub. L. 99-509, which added a new section 1138 to the Act. Section 1138(a)

of the Act allows a hospital that otherwise meets the conditions of participation for the Medicare or Medicaid programs to participate in either program only if:

(1) The hospital establishes written protocols to identify potential organ or tissue donors that:

(a) Assure that families of potential donors are made aware that they have an option to donate organs or tissue and an option to decline to donate;

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

(c) Require that an organ procurement agency designated by the Secretary of HHS under 1138(b)(1)(F) be notified of potential donors; and

(2) In the case of a hospital in which organ transplants are performed, the hospital is a member of, and abides by the rules of, the Organ Procurement and Transplantation Network (the Network) established in accordance with section 372 of the Public Health Service Act.

This section applies to hospitals participating in the Medicare or Medicaid program as of October 1, 1967.

Section 1138(b) of the Act requires that, on or after October 1, 1987, Medicare and Medicaid pay for organ procurement costs attributable to payments made to an OPA only if the OPA satisfies the conditions below. The OPA:

(a)(i) Is a qualified organ procurement organization (as described in section 371(u) of the Public Health Service Act) that is operating under a grant made under section 371(a) of that Act, or

(ii) Has been certified or recertified by the Secretary within the previous two years as meeting the standards to be a qualified organ procurement organization;

(b) Meets the applicable Medicare or Medicaid requirements for organ procurement agencies;

(c) Meets performance-related standards prescribed by the Secretary;

(d) Is a member of, and abides by the rules and requirements of, the Organ Procurement and Transportation Network established under section 372 of the Public Health Service Act;

(e) Allocates organs, within its service area and nationally, in accordance with

100TH CONGRESS
1ST SESSION

7/11/87
S. 1633

II

To amend the Public Health Service Act to revise and extend the program of assistance to organ procurement organizations, and for other purposes.

IN THE SENATE OF THE UNITED STATES

AUGUST 7 (legislative day, AUGUST 5), 1987

Mr. BYRD (for Mr. GORE) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

A BILL

To amend the Public Health Service Act to revise and extend the program of assistance to organ procurement organizations, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "Organ Transplant
5 Amendments Act of 1987".

6 **SEC. 2. ASSISTANCE FOR ORGAN PROCUREMENT ORGANIZA-**
7 **TIONS.**

8 (a) **ADDITIONAL GRANT AUTHORITY.**—Section 371(a)
9 of the Public Health Service Act (42 U.S.C. 273(a)) is
10 amended—

1 (1) in paragraph (2), by inserting "consolidation,"
2 after "operation,";

3 (2) by redesignating paragraph (3) as paragraph
4 (4) and inserting after paragraph (2) the following new
5 paragraph:

6 "(3) The Secretary may make grants for special
7 projects designated to increase the number of organ
8 donors.;" and

9 (3) in paragraph (4) (as redesignated in paragraph
10 (2) of this subsection)—

11 (A) by striking "(1) and (2)," and inserting
12 "(1), (2), and (3),"; and

13 (B)(i) by striking "and" at the end of sub-
14 paragraph (A);

15 (ii) by striking the period and inserting "
16 and"; and

17 (iii) by adding at the end the following new
18 subparagraph:

19 "(C) with respect to carrying out paragraph
20 (3), give special consideration to proposals from
21 existing such organizations."

22 (b) LIMITATIONS ON ADDITIONAL GRANT AUTHOR-
23 ITY.—Section 374(b)(3) of the Public Health Service Act (42
24 U.S.C. 274(b)(3)) is amended in the first sentence by striking

1 “section 371” and all that follows through “organizations”
2 and inserting “paragraphs (2) and (3) of section 371(a)”.

3 (c) DESCRIPTION OF ORGAN PROCUREMENT ORGANI-
4 ZATION.—Section 371(b) of the Public Health Service Act
5 (42 U.S.C. 273(b)) is amended—

6 (1) in paragraph (1)(E)—

7 (A) by striking “size which” and inserting
8 “size such that”; and

9 (B) by striking “will include” and all that
10 follows through “year” and inserting the follow-
11 ing: “the organization can reasonably expect to
12 procure organs from not less than fifty donors
13 each year”;

14 (2) in paragraph (2)(E)—

15 (A) by inserting “equitably” after “organs”;
16 and

17 (B) by striking “centers and”; and

18 (3) in paragraph (2)—

19 (A) by striking “and” at the end of subpara-
20 graph (I);

21 (B) by striking the period and inserting “,
22 and”; and

23 (C) by adding at the end the following new
24 subparagraph:

1 (3) in subparagraph (F) (as redesignated in para-
2 graph (1)(A) of this section), by striking "basis," and
3 inserting the following: "basis (and, to the extent prac-
4 ticable, among regions or on a national basis),".

5 (4)(A) by striking "and" at the end of subpara-
6 graph (H) (as redesignated in paragraph (1)(A) of this
7 section);

8 (B) by striking the period and inserting ", and";
9 and

10 (C) by adding at the end the following new sub-
11 paragraph:

12 "(J) carry out studies and demonstrations projects
13 for the purpose of improving procedures for organ pro-
14 curement and allocation."

15 (b) CONSIDERATION OF CRITICAL COMMENTS.—Sec-
16 tion 372 of the Public Health Service Act (42 U.S.C. 274) is
17 amended by adding at the end the following new subsection:

18 "(c) The Secretary shall establish procedures for—

19 (1) receiving from interested persons critical
20 comments relating to the manner in which the Organ
21 Procurement and Transplantation Network is carrying
22 out the duties of the Network under subsection (b); and

23 (2) the consideration by the Secretary of such
24 critical comments."

1 SEC. 4. ADMINISTRATION.

2 Section 375 of the Public Health Service Act (42
3 U.S.C. 274c) is amended—

4 (1) in the matter preceding paragraph (1), by
5 striking “1985, 1986, 1987, and 1988,” and inserting
6 “1985 through 1990,”; and

7 (2) in paragraph (4), by striking “one year” and
8 all that follows through “annual report” and inserting
9 the following: “not later than April 1 of each of the
10 years 1988 and 1990, submit to the Congress a
11 report”.

12 SEC. 5. REPORT.

13 Section 376 of the Public Health Service Act (42
14 U.S.C. 274d) is amended by striking “shall annually” and
15 inserting the following: “shall, not later than October 1 of
16 each year,”.

○



ALASKA HOUSE OF REPRESENTATIVES
RESEARCH AGENCY

TO: Heather Arnett DATE: 10/21/87

FROM: Karla Hart

Here are the organ transplant bills you requested. If we can provide any further assistance, please call.

Karla

P.S. As I mentioned on 10/16, HB1633 is in the committee on Labor and Resources since Aug. 7 and there has been no action on it.

Pouch Y, State Capitol
Juneau, Alaska 99811
(907) 461-3991

§ 271. Penalties for violation of quarantine laws

Code of Federal Regulations Interstate commerce sanitation, see 21 CFR
Communicable disease control procedures, 21 1250.1
CFR 1240.3

PART H—ORGAN TRANSPLANTS

§ 272. Assistance for organ procurement organizations

(a) Grant authority of Secretary

(1) The Secretary may make grants for the planning of qualified organ procurement organizations described in subsection (b) of this section.

(2) The Secretary may make grants for the establishment, initial operation, and expansion of qualified organ procurement organizations described in subsection (b) of this section.

(3) In making grants under paragraphs (1) and (2), the Secretary shall—

(A) take into consideration any recommendations made by the Task Force on Organ Transplantation established under section 101 of the National Organ Transplant Act, and

(B) give special consideration to applications which cover geographical areas which are not adequately served by organ procurement org_____

(b) Qualified organizations

(1) A qualified organ procurement organization for which grants may be made under subsection (a) of this section is an organization which, as determined by the Secretary, will carry out the functions described in paragraph (2) and—

(A) is a nonprofit entity,

(B) has accounting and other fiscal procedures (as specified by the Secretary) necessary to assure the fiscal stability of the organization,

(C) has an agreement with the Secretary to be reimbursed under title XVIII of the Social Security Act [42 U.S.C.A. § 1395 et seq.] for the procurement of kidneys,

(D) has procedures to obtain payment for non-rural organs provided to transplant centers,

(E) has a defined service area which is a geographical area of sufficient size which (unless the service area comprises an entire State) will include at least fifty potential organ donors each year and which either includes an entire standard metropolitan statistical area (as specified by the Office of Management and Budget) or does not include any part of such an area,

(F) has a director and such other staff, including the organ donation coordinators and organ procurement specialists necessary to effectively obtain organs from donors in its service area, and

(G) has a board of directors or an advisory board which—

(i) is composed of—

(I) members who represent hospital administrators, intensive care or emergency room personnel, tissue banks, and voluntary health associations in its service area.

(II) members who represent the public residing in such area,

(III) a physician with knowledge, experience, or skill in the field of histocompatibility,

(IV) a physician with knowledge or skill in the field of neurology, and

(V) from each transplant center in its service area which has arrangements described in paragraph (2)(G) with the organization, a member who is a surgeon who has practicing privileges in such center and who performs organ transplant surgery,

(ii) has the authority to recommend policies for the procurement of organs and the other functions described in paragraph (2), and

(iii) has no authority over any other activity of the organization.

- (2) An organ procurement organization shall—
 - (A) have effective agreements, to identify potential organ donors, with a substantial majority of the hospitals and other health care entities in its service area which have facilities for organ donations,
 - (B) conduct and participate in systematic efforts, including professional education, to acquire all useable organs from potential donors,
 - (C) arrange for the acquisition and preservation of donated organs and provide quality standards for the acquisition of organs which are consistent with the standards adopted by the Organ Procurement and Transplantation Network under section 274(b)(2)(D) of this title,
 - (D) arrange for the appropriate tissue typing of donated organs,
 - (E) have a system to allocate donated organs among transplant centers and patients according to established medical criteria,
 - (F) provide or arrange for the transportation of donated organs to transplant centers,
 - (G) have arrangements to coordinate its activities with transplant centers in its service area,
 - (H) participate in the Organ Procurement Transplantation Network established under section 274 of this title,
 - (I) have arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage, and distribution of tissues as may be appropriate to assure that all useable tissues are obtained from potential donors, and
 - (J) evaluate annually the effectiveness of the organization in acquiring potentially available organs.

(c) Authorization of appropriations

For grants under subsection (a) of this section there are authorized to be appropriated \$5,000,000 for fiscal year 1985, \$8,000,000 for fiscal year 1986, and \$12,000,000 for fiscal year 1987.

(July 1, 1944, c. 373, Title III, § 371, as added Oct. 19, 1984, Pub.L. 98-507, Title II, § 201, 98 Stat. 2342.)

References in Text. Section 101 of the National Organ Transplant Act, referred to in subsec. (a)(7), is set out as a note under this section.

Title XVIII of the Social Security Act, referred to in subsec. (b)(1)(C), is classified generally to subchapter XVIII (§ 1395 et seq.) of chapter 7 of this title.

Prior Provisions. Section, Act July 1, 1944, c. 373, Title III, § 371, as added July 28, 1956, c. 772, Title II, § 201, 70 Stat. 709, authorizing grants to the Territory of Alaska for an integrated mental health program was repealed by Pub.L. 86-70, § 31(b)(1), June 25, 1959, 73 Stat. 148. Another section 371 of Act July 1, 1944, added by Act Aug. 3, 1956, c. 907, § 1, 70 Stat. 960, is set out as section 275 of this title.

Short Title. Short Title of National Organ Transplant Act, see section 1 of Pub.L. 98-507 set out as a Short Title note under section 201 of this title.

Task Force on Organ Procurement and Transplantation. Title I of Pub.L. 98-507 provided that:

"ESTABLISHMENT AND DUTIES OF TASK FORCE

"Sec. 101(a) Not later than ninety days after the date of the enactment of this Act [Oct. 19, 1984], the Secretary of Health and Human Services (hereinafter in this title [this note] referred to as the 'Secretary') shall establish a Task Force on Organ Transplantation (hereinafter in this title [this note] referred to as the 'Task Force').

(b)(1) The Task Force shall—

- (A) conduct comprehensive examinations of the medical, legal, ethical, economic, and social issues presented by human organ procurement and transplantation,
 - (B) prepare the statement described in paragraph (2) and the report described in paragraph (3), and
 - (C) advise the Secretary with respect to the development of regulations for grants under section 371 of the Public Health Service Act [this section].
- (2) The Task Force shall make an assessment of immunosuppressive medications used to prevent organ rejection in transplant patients, including—
- (A) an analysis of the safety, effectiveness, and costs (including cost-savings from improved success rates of transplantation) of different modalities of treatment;
 - (B) an analysis of the extent of insurance reimbursement for long-term immunosuppressive drug therapy for organ transplant patients by private insurers and the public sector;
 - (C) an identification of institutions that patients encounter in obtaining immunosuppressive medications; and
 - (D) an analysis of the comparative advantages of grants, coverage under existing Federal programs, or other means to assure that individuals who need such medications can obtain them.
- (3) The Task Force shall prepare a report which shall include—
- (A) an assessment of public and private efforts to procure human organs for transplants-

tion and an identification of factors that diminish the number of organs available for transplantation;

(B) an assessment of problems in coordinating the procurement of viable human organs including alive and deceased;

(C) recommendations for the education and training of health professionals, including physicians, nurses, and hospital and emergency care personnel, with respect to organ procurement;

(D) recommendations for the education of the general public, the clergy, law enforcement officers, members of local fire departments, and other agencies and individuals that may be instrumental in effecting organ procurement;

(E) recommendations for assuring equitable access by patients to organ transplantation and for assuring the equitable allocation of donated organs among transplant centers and among patients medically qualified for an organ transplant;

(F) an identification of barriers to the donation of organs to patients (with special emphasis upon pediatric patients), including an assessment of—

(i) barriers to the improved identification of organ donors and their families and organ recipients;

(ii) the number of potential organ donors and their geographical distribution;

(iii) current health care services provided for patients who need organ transplantation and organ procurement procedures, systems, and programs which affect such patients;

(iv) cultural factors affecting the family with respect to the donation of the organs; and

(v) ethical and economic issues relating to organ transplantation needed by chronically ill patients;

(G) recommendations for the conduct and coordination of continuing research concerning all aspects of the transplantation of organs;

(H) an analysis of the factors involved in insurance reimbursement for transplant procedures by private insurers and the public sector;

(I) an analysis of the manner in which organ transplantation technology is diffused among and adopted by qualified medical centers, including a specification of the number and geographical distribution of qualified medical centers using such technology and an assessment of whether the number of centers using such technology is sufficient or excessive and of whether the public has sufficient access to medical procedures using such technology; and

(J) an assessment of the feasibility of establishing, and of the likely effectiveness of, a national registry of human organ donors.

"MEMBERSHIP

"Sec. 102(a) The Task Force shall be composed of twenty-five members as follows:

(1) Twenty-one members shall be appointed by the Secretary of which:

- (A) nine members shall be physicians or scientists who are eminent in the various medical and scientific specialties related to human organ transplantation;

(B) three members shall be individuals who are not physicians and who represent the field of human organ procurement;

(C) four members shall be individuals who are not physicians and who as a group have expertise in the fields of law, theology, ethics, health care financing, and the social and behavioral sciences;

(D) three members shall be individuals who are not physicians or scientists and who are not members of the general public; and

(E) two members shall be individuals who represent private health insurance or self-insurers.

(2) The Surgeon General of the United States, the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Administrator of the Health Care Financing Administration shall be ex officio members.

(3) No individual who is a full-time officer or employee of the United States may be appointed under subsection (a)(1) to the Task Force. A vacancy in the Task Force shall be filled in the manner in which the original appointment was made. A vacancy in the Task Force shall not affect its powers.

(4) Members shall be appointed for the life of the Task Force.

(5) The Task Force shall select a Chairman from among its members who are appointed under subsection (a)(1).

(6) Thirteen members of the Task Force shall constitute a quorum, but a lesser number may hold hearings.

(7) The Task Force shall hold its first meeting on a date specified by the Secretary which is not later than thirty days after the date on which the Secretary establishes the Task Force under section 101. Thereafter, the Task Force shall meet at the call of the Chairman or a majority of its members, but shall meet at least three times during the life of the Task Force.

(8)(A) Each member of the Task Force who is not an officer or employee of the United States shall be compensated at a rate equal to the daily equivalent of the annual rate of basic pay in effect for grade GS-18 of the General Schedule under section 5332 of title 5, United States Code [section 5332 of Title 5, Government Organization and Employees] for each day (including travel time) during which such member is engaged in the actual performance of duties as a member of the Task Force. Each member of the Task Force who is an officer or employee of the United States shall receive no additional compensation.

(B) While away from their homes or regular places of business in the performance of duties for the Task Force, all members of the Task Force shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under sections 5702 and 5703 of title 5, United States Code [sections 5702 and 5703 of Title 5, Government Organization and Employees].

"SUPPORT FOR THE TASK FORCE

"Sec. 103(a) Upon request of the Task Force, the head of any Federal agency is authorized to detail, on a reimbursable basis, any of the person-

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net of such agency to the Task Force to assist the Task Force in carrying out its duties under this Act (Pub.L. 98-507. See Short Title note under section 201 of this title).

"(b) The Secretary shall provide the Task Force with such administrative and support services as the Task Force may require to carry out its duties.

"REPORT

"Sec. 104(a) The Task Force may transmit to the Secretary, the Committee on Labor and Human Resources of the Senate, and the Committee on Energy and Commerce of the House of Representatives such interim reports as the Task Force considers appropriate.

"(b) Not later than 7 months after the date on which the Task Force is established by the Secretary under section 101, the Task Force shall transmit a report to the Secretary, the Committee on Labor and Human Resources of the Senate, and the Committee on Energy and Commerce of the House of Representatives on its assessment under section 101(b)(2) of immunosuppressive medications used to prevent organ rejection.

"(c) Not later than twelve months after the date on which the Task Force is established by the Secretary under section 101, the Task Force shall transmit a final report to the Secretary, the Committee on Labor and Human Resources of the Senate, and the Committee on Energy and Commerce of the House of Representatives. The final report of the Task Force shall include—

"(1) a description of any findings and conclusions of the Task Force made pursuant to any examination conducted under section 101(b)(1)(A),

"(2) the matters specified in section 101(b)(3), and

"(3) such recommendations as the Task Force considers appropriate.

"TERMINATION

"Sec. 105 The Task Force shall terminate three months after the date on which the Task Force transmits the report required by section 104(c)."

Bone Marrow Registry, Demonstration and Study. Section 401 of Pub.L. 98-507 provided that:

"(a) Not later than six months after the date of enactment of this Act [Oct. 19, 1984], the Secretary of Health and Human Services shall hold a conference on the feasibility of establishing and the effectiveness of a national registry of voluntary bone marrow donors.

"(b) If the conference held under subsection (a) finds that it is feasible to establish a national registry of voluntary donors of bone marrow and that such a registry is likely to be effective in matching donors with recipients, the Secretary of Health and Human Services, acting through the Assistant Secretary for Health, shall, for purposes of the study under subsection (c), establish a registry of voluntary donors of bone marrow. The Secretary shall assure that—

"(1) donors of bone marrow listed in the registry have given an informed consent to the donation of the bone marrow; and

"(2) The names of the donors in the registry are kept confidential and occur in the names and any other information in the registry is restricted to personnel who need the information to maintain and implement the registry, except that access to such other information shall be provided for purposes of the study under subsection (c).

"If the conference held under subsection (a) makes the finding described in this subsection, the Secretary shall establish the registry not later than six months after the completion of the conference.

"(c) The Secretary of Health and Human Services, acting through the Assistant Secretary for Health, shall study the establishment and implementation of the registry under subsection (b) to identify the issues presented by the establishment of such a registry, to evaluate participation of bone marrow donors, to assess the implementation of the informed consent and confidentiality requirements, and to determine if the establishment of a permanent bone marrow registry is needed and appropriate. The Secretary shall report the results of the study to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate not later than two years after the date the registry is established under subsection (b)."

Legislative History. For legislative history and purpose of Pub.L. 98-507, see 1984 U.S. Code Cong. and Adm. News, p. 3973.

under section 273 of this title), transplant centers, voluntary health associations, and the general public.

(2) The Organ Procurement and Transplantation Network shall—

(A) establish in one location or through regional centers—

(i) a national list of individuals who need organs, and

(ii) a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list, especially individuals whose immune system makes it difficult for them to receive organs,

(B) maintain a twenty-four-hour telephone service to facilitate matching organs with individuals included in the list,

(C) assist organ procurement organizations in the distribution of organs which cannot be placed within the service areas of the organizations,

(D) adopt and use standards of quality for the acquisition and transportation of donated organs,

(E) prepare and distribute, on a regionalized basis, samples of blood sera from individuals who are included on the list and whose immune system makes it difficult for them to receive organs, in order to facilitate matching the compatibility of such individuals with organ donors,

(F) coordinate, as appropriate, the transportation of organs from organ procurement organizations to transplant centers,

(G) provide information to physicians and other health professionals regarding organ donation, and

(H) collect, analyze, and publish data concerning organ donation and transplants.

(July 1, 1984, c. 371, Title III, § 372, as added Oct. 19, 1984, Pub.L. 98-507, Title II, § 701, 98 Stat. 2344.)

¹ So in original. Probably should be "compatibility".

Prior Provisions. Section, Act July 1, 1964, c. 373, Title III, § 372, as added July 28, 1956, c. 771, Title II, § 201, 70 Stat. 710, and amended June 25, 1959, Pub.L. 86-70, § 31(b)(2)-(4), 73 Stat. 143, which related to grants to Alaska for school health programs and payment for con-

struction of hospital facilities was omitted in the general revision of this part by Pub.L. 98-507, Title II, § 201, Oct. 19, 1984, 98 Stat. 2345. Legislative History. For legislative history and purpose of Pub.L. 98-507, see 1984 U.S. Code Cong. and Adm. News, p. 3973.

§ 274a. Scientific registry

The Secretary shall, by grant or contract, develop and maintain a scientific registry of the recipients of organ transplants. The registry shall include such information respecting patients and transplant procedures as the Secretary deems necessary to an ongoing evaluation of the scientific or clinical status of organ transplantation. The Secretary shall prepare for inclusion in the report under section 274d of this title an analysis of information derived from the registry.

(July 1, 1984, c. 373, Title III, § 373, as added Oct. 19, 1984, Pub.L. 98-507, Title II, § 201, 98 Stat. 2345.)

Legislative History. For legislative history and purpose of Pub.L. 98-507, see 1984 U.S. Code Cong. and Adm. News, p. 3973.

§ 274b. General provisions respecting grants and contracts

(a) Application requirements

No grant may be made under section 273 or 274a of this title or contract entered into under section 274 or 274a of this title unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be in such form and shall be submitted in such manner as the Secretary shall by regulation prescribe.

(b) Special considerations and priority; planning and establishment grants

(1) In considering applications for grants under section 273 of this title—

(A) the Secretary shall give priority to any applicant which has a formal agreement of cooperation with all transplant centers in its proposed service area,

(B) the Secretary shall give special consideration to organizations which meet the requirements of section 273(b) of this title before October 19, 1984, and

(C) the Secretary shall not discriminate against an applicant solely because it provides health care services other than those related to organ procurement.

The Secretary may not make a grant for more than one organ procurement organization which serve the same service area.

(2) A grant for planning under section 273 of this title may be made for one year with respect to any organ procurement organization and may not exceed \$160,000.

(3) Grants under section 273 of this title for the establishment, initial operation, or expansion of organ procurement organizations may be made for two years. No such grant may exceed \$100,000 for any year and no organ procurement organization may receive more than \$800,000 for initial operation or expansion.

(c) Determination of grant amount; advance payments; recordkeeping; access for purposes of audits and examinations

(1) The Secretary shall determine the amount of a grant made under section 273 or 274a of this title. Payments under such grants may be made in advance on the basis of estimates or by the way of reimbursement, with necessary adjustments on account of underpayments or overpayments, and in such installments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of such grants.

(2)(A) Each recipient of a grant under section 273 or 274a of this title shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the undertaking in connection with which such grant was made, and the amount of that portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(B) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipient of a grant under section 273 or 274a of this title that are pertinent to such grant.

(d) Definitions

For purposes of this part:

(1) The term "transplant center" means a health care facility in which transplants of organs are performed.

(2) The term "organ" means the human kidney, liver, heart, lung, pancreas, and any other human organ (other than corneas and eyes) specified by the Secretary by regulation and for purposes of section 274a of this title, such term includes bone marrow.

(July 1, 1944, c. 373, Title III, § 374, as added Oct. 19, 1984, Pub.L. 98-507, Title II, § 201, 98 Stat. 2345.)

Legislative History. For legislative history and purpose of Pub.L. 98-507, see 1984 U.S. Code Cong. and Adm. News, p. 3973.

§ 274c. Administration

The Secretary shall, during fiscal years 1985, 1986, 1987, and 1988, designate and maintain an identifiable administrative unit in the Public Health Service to—

(1) administer this part and coordinate with the organ procurement activities under title XVIII of the Social Security Act [42 U.S.C.A. § 1395 et seq.],

(2) conduct a program of public information to inform the public of the need for organ donations,

(3) provide technical assistance to organ procurement organizations receiving funds under section 273 of this title, the Organ Procurement and Transplantation Network established under section 274 of this title, and other entities in the

health care system involved in organ donations, procurement, and transplants, and

(4) one year after the date on which the Task Force on Organ Transplantation transmits its final report under section 104(c) of the National Organ Transplant Act, and annually thereafter through fiscal year 1988, submit to Congress an annual report on the status of organ donation and coordination services and include in the report an analysis of the efficiency and effectiveness of the procurement and allocation of organs and a description of problems encountered in the procurement and allocation of organs.

(July 1, 1944, c. 373, Title III, § 375, as added Oct. 19, 1984, Pub.L. 98-507, Title II, § 201, 98 Stat. 2346.)

References in Text. Title XVIII of the Social Security Act, referred to in par. (7), is classified generally to subchapter XVIII (§ 1395 et seq.) of chapter 7 of this title.

Section 104(c) of the National Organ Transplant Act, referred to in par. (4), is set out as a note under section 273 of this title.

Legislative History. For legislative history and purpose of Pub.L. 98-507, see 1984 U.S. Code Cong. and Adm. News, p. 3973.

§ 274d. Report

The Secretary shall annually publish a report on the scientific and clinical status of organ transplantation. The Secretary shall consult with the Director of the National Institutes of Health and the Commissioner of the Food and Drug Administration in the preparation of the report.

(July 1, 1944, c. 373, Title III, § 376, as added Oct. 19, 1984, Pub.L. 98-507, Title II, § 201, 98 Stat. 2346.)

Legislative History. For legislative history and purpose of Pub.L. 98-507, see 1984 U.S. Code Cong. and Adm. News, p. 3975.

§ 274e. Prohibition of organ purchases

(a) Prohibition

It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.

(b) Penalties

Any person who violates subsection (a) of this section shall be fined not more than \$50,000 or imprisoned not more than five years, or both.

(c) Definitions

For purposes of subsection (i) of this section:

(1) The term "human organ" means the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin, and any other human organ specified by the Secretary of Health and Human Services by regulation.

(2) The term "valuable consideration" does not include the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ.

(3) The term "interstate commerce" has the meaning prescribed for it by section 321(b) of Title 21.

(Pub.L. 98-507, Title III, § 301, Oct. 19, 1984, 98 Stat. 2346.)

Cross-References. Section enacted as part of the National Organ Transplant Act and not as part of the Public Health Service Act.

Legislative History. For legislative history and purpose of Pub.L. 98-507, see 1984 U.S. Code Cong. and Adm. News, p. 3975.

(D) Except as otherwise specifically provided, the amendments made by subsections (a) through (j) [inserting this section, amending sections 302, 303, 402, 1302, 1303, and 1394a of this title, and section 2000 of Title 7, Agriculture, repealing section 411 of this title, and amending provisions set out as a note under section 1302 of this title] shall become effective on April 1, 1963. In the case of any State which submits a plan describing a good faith effort by such State to come into compliance with the requirements of such subsections, the Secretary of Health and Human Services (or, in the case of the State unemployment compensation program, the Secretary of Labor, or, in the case of the food stamp program, the Secretary of Agriculture) may by waiver grant a delay in the effective date of such subsections, except that no such waiver may delay the effective date of section 1177(c) of the Social Security Act (subsec. (c) of this section) (as added by subsection (a) of this section), or delay the effective date of any other provision of or added by this section beyond September 30, 1964."

Immigration and Naturalization Service to Establish Verification System by Oct. 1, 1967. Section 121(c)(1) of Pub.L. 90-603 provided that: "The Commissioner of Immigration and Naturalization shall implement a system for the verification of immigration status under paragraphs (3) and (4)(3)(D) of section 1177(d) of the Social Security Act (subsec. (d) of this section) (as amended by this section) so that the system is available to all the States by not later than October 1, 1967. Such system shall not be used by the Immigration and Naturalization Service for administrative (non-criminal) immigration enforcement purposes and shall be implemented in a manner that provides for verification of immigration status without regard to the sex, color, race, religion, or nationality of the individual involved."

Studies and Reports by Comptroller General to Congress and Executive Agencies and Depart-

ments. Section 121(d) of Pub.L. 90-603 provided that:

"GAO Reports.—

"(D) Report on current pilot project.—The Comptroller General shall—

"(A) examine current pilot projects relating to the System for Alien Verification of Eligibility (SAVE) operated by, or through cooperative agreements with, the Immigration and Naturalization Service, and

"(B) report, not later than October 1, 1967, to Congress and to the Commissioner of the Immigration and Naturalization Service concerning the effectiveness of such projects and any problems with the implementation of such projects, particularly so they may apply to implementation of the system referred to in subsection (c)(1) (set out as a note above).

"(D) Report on implementation of verification system.—The Comptroller General shall—

"(A) monitor and analyze the implementation of such system,

"(B) report to Congress and to the appropriate Secretaries described in subsection (c)(4)(D)(ii) (set out as a note above) by not later than April 1, 1969, on such implementation, and

"(C) include in such report such recommendations for changes in the system as may be appropriate."

Legislative History. For legislative history and purpose of Pub.L. 90-369, see 1964 U.S. Code Cong. and Adm. News, p. 697. See, also, Pub.L. 79-509, 1946 U.S. Code Cong. and Adm. News, p. 3607.

Literary References

Agriculture § 2.6(T).

Social Security and Public Welfare § 194.2, 194.7, 241.30, 341.

C.J.S. Agriculture §§ 77, 28.

C.J.S. Social Security and Public Welfare §§ 116, 118, 133, 211 to 213.

(2) For purposes of this subsection, the term "organ" means a human kidney, liver, heart, lung, pancreas, and any other human organ or tissue specified by the Secretary for purposes of this subsection.

(b) Organ procurement agency standards

(1) The Secretary shall provide that payment may be made under subchapter XVIII or XIX of this chapter with respect to organ procurement costs attributable to payments made to an organ procurement agency only if the agency—

(A) is a qualified organ procurement organization (as described in section 273(b) of this title) that is operating under a grant made under section 273(a) of this title, or (B) has been certified or recertified by the Secretary within the previous two years as meeting the standards to be a qualified organ procurement organization (as so described);

(B) meets the requirements that are applicable under such title for organ procurement agencies;

(C) meets performance-related standards prescribed by the Secretary;

(D) is a member of, and abides by the rules and requirements of, the Network;

(E) allocates organs, within its service area and nationally, in accordance with medical criteria and the policies of the Network; and

(F) is designated by the Secretary as an organ procurement organization payments to which may be treated as organ procurement costs for purposes of reimbursement under such subchapter.

(2) The Secretary may not designate more than one organ procurement organization for each service area (described in section 278(b)(1)(E) of this title) under paragraph (1)(F).

(Aug. 14, 1935, c. 531, Title XI, § 1133, as added Oct. 21, 1936, Pub.L. 74-608, Title IX, § 9318a, 180 Stat. 2069.)

¹ So in original. Probably should be "in".

Effective Date. Section 9318(b) of Pub.L. 79-509 provided that subsec. (a) of this section shall apply to hospitals participating in the programs under subchapters XVIII and XIX of this chapter as of Oct. 1, 1967, and that subsec. (b) of

this section shall apply to costs of organs procured on or after Oct. 1, 1967.

Legislative History. For legislative history and purpose of Pub.L. 79-509, see 1966 U.S. Code Cong. and Adm. News, p. 1607.

PART B—PEER REVIEW OF UTILIZATION AND QUALITY OF HEALTH CARE SERVICES

§ 1320c. Purpose

Effective Date. Section 149 of Pub.L. 97-348, as amended Pub.L. 98-369, Title 10, § 2154(c)(3)(C), July 18, 1984, 98 Stat. 1102, provided that: "The amendments made by this subtitle [subtitle C of Pub.L. 97-248, comprising sections 141 to 150 of such Public Law which enacted this part, amended sections 1393b-1, 1393g, 1393k, 1393l, 1393s, 1393y, 1395oc, 1395pp, 1395a and 1396b of this title, omitted

sections 1320c-14 to 1320c-19, 1320c-21, and 1320c-22 of this title, and enacted provisions set out as notes under this section and section 1305 of this title] shall, subject to section 150 [section 150 of Pub.L. 97-248, set out as a note below], be effective with respect to contracts entered into or renewed on or after the date of the enactment of this Act [Sept. 3, 1982]"

§ 1320c-1. Definition of utilization and quality control peer review organization

The term "utilization and quality control peer review organization" means an entity which—

(1)(A) is composed of a substantial number of the licensed doctors of medicine and osteopathy engaged in the practice of medicine or surgery in the area and who are representative of the practicing physicians in the area, designated by the Secretary under section 1320c-2 of this title, with respect to which the entity shall perform services under this part, or (B) has available to it, by arrangement or otherwise, the services of a sufficient number of licensed doctors of medicine or osteopathy engaged in the practice of medicine or surgery in such area to assure that adequate peer review of the services provided by the various medical specialties and subspecialties can be assured;

§ 1320b-5. Hospital protocols for organ procurement and standards for organ procurement agencies

(a) Establishment of protocols; membership in Organ Procurement and Transplantation Network

(1) The Secretary shall provide that a hospital meeting the requirements of subchapter XVIII or XIX of this chapter may participate in the program established under such subchapter only if—

(A) the hospital establishes written protocols for the identification of potential organ donors that—

(i) assure that families of potential organ donors are made aware of the option of organ or tissue donation and their option to decline,

(ii) encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of such families, and

(iii) require that an organ procurement agency designated by the Secretary pursuant to subsection (b)(1)(F) of this section be notified of potential organ donors; and

(B) in the case of a hospital in which organ transplants are performed, the hospital is a member of, and abides by the rules and requirements of, the Organ Procurement and Transplantation Network established pursuant to section 274 of this title (in this section referred to as the "Network").

PROCLAMATIONS

No. 5643

Proclamation 5643 of April 29, 1987

National Organ and Tissue Donor Awareness Week, 1987

52 F.R. 15935

By the President of the United States of America

A Proclamation

Spring is a season of promise and renewal, and nothing could be more fitting during this time than to reflect on God's abundant miracles of life and growth.

Organ and tissue donorship presents an opportunity to share in these miracles. Medical technology has made it possible for thousands of Americans to benefit from organ and tissue transplantation. Sometimes this means restored vision or help for severe burns; sometimes, a heart, liver, or bone marrow transplant. But whatever the case, organ and tissue donorship shows the magnificent generosity of the American people.

More and more Americans are aware of organ and tissue donorship, thanks to much education about this worthy cause. The American Council on Transplantation has promoted organ and tissue donorship diligently for the last 4 years. Others, such as the National Kidney Foundation, the Lions Club, the Children's Transplant Association, and the Boy Scouts of America, have joined in the effort.

The results are most encouraging. Millions of Americans now carry organ and tissue donor cards. Many States give people the opportunity to sign donor cards when they complete their driver's license forms. Our schools and our media have also become involved in this cause.

But it is each American family and each citizen who makes organ and tissue donorship work. The generosity of organ and tissue donation is a very private matter between individuals and God, the giver of life. So, as all of us rejoice this springtime on the hope and promise of life, let us also think about signing organ and tissue donor cards. We keep that promise alive by helping others in need.

The Congress, by Senate Joint Resolution 89, has authorized and requested the President to issue a proclamation observing the week of April 26 through May 2, 1987, as "National Organ and Tissue Donor Awareness Week".

NOW, THEREFORE, I, RONALD REAGAN, President of the United States of America, do hereby proclaim the week of April 26 through May 2, 1987, as National Organ and Tissue Donor Awareness Week. I ask health care professionals, educators, the media, public and private service organizations, and all Americans to join in supporting this humanitarian cause.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-ninth day of April, in the year of our Lord nineteen hundred and eighty-seven, and of the Independence of the United States of America the two hundred and eleventh.

Reagan

Ronald Reagan

THOMAS C. WOOD, M.D., F.A.C.P.

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STATEMENT IN TESTIMONY

DATE: October 21, 1987.
TO: Legislative Hearing.
RE: House Bill #306 (Sponsors Gruenberg, Grussendorf, Koponen, et al).
FROM: Thomas C. Wood, M.D., F.A.C.P.

I appreciate the opportunity to present testimony at this legislative hearing. Because of late notification, I was unable to come to this hearing and greatly appreciate the willingness of Kathy Purinton, R.N., to read this statement.

An earlier draft of the bill was submitted to me, and I replied in writing on April 8, 1987. A copy of this letter to Representative Gruenberg and Senator Fischer will be appended to my comments today.

My greatest concern with the bill as submitted is the application of the law to all hospitals within the state except those exempted by the Commissioner of Health & Social Services. At present, only hospitals in major cities are able to remove tissues for organ transplantation, and it seems most appropriate to me to direct the law and subsequent regulations to those specific hospitals in Fairbanks, Anchorage, Juneau, and Ketchikan, where there is the medical expertise for the removal of appropriate organs and tissue and for their transfer to a transplant center.

The identification and support of potential donors is as much a requirement for successful organ donation as is the legal identification of such donors either by the individual himself or his next of kin. Ideally, after brain death has been declared, the heart-beating cadaver is maintained until suitable transfer to the operating room on a respirator, at which time the organs are removed and sent to appropriate receiving institutions for actual use in transplantation. Alternatively, in an unusual circumstance, the entire cadaver can be transported via air ambulance to a major transplant center where multiple organs can be removed and utilized. This situation obviously exists in only the major population and transportation centers of the state.

There are strict medical criteria which are used before accepting a donation. These will include the knowledge of the donor's past medical history, the absence of any infectious disease, willingness of the next of kin to either honor the donor's request for organ donation or provide that consent themselves, and finally the necessary medical support services to insure that appropriate organs can be removed and transported in a viable condition. Even under the very best of circumstances, this requires involvement of many members of the organ transplant team, the coroner, and appropriate hospital personnel.

CONTINUED ON PAGE TWO...

Statement in Testimony

Re: House Bill #306.

PAGE TWO.

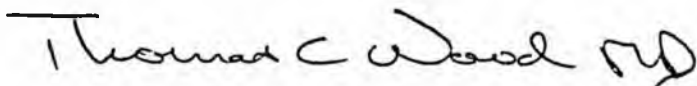
October 21, 1987.

Within Anchorage, only approximately one out of every ten or fifteen identified potential donors is ever utilized for organ donation because of the above conditions. To require personnel in smaller hospitals unfamiliar with the medical and transportation requirements for organ donation is likely to increase emotional distress among the survivors as well as overload the currently available personnel familiar with the transplantation program.

Two final comments include the absolute necessity for insuring that the hospital and appropriate medical personnel do not accrue any liability for either asking permission for organ donation from an inappropriate potential donor or from the failure to identify an appropriate donor. The bill must also be in compliance with the new federal law regarding request for organ donation.

Thank you again for allowing me to present testimony at this legislative hearing.

Respectfully,

A handwritten signature in cursive script that reads "Thomas C. Wood" followed by a stylized monogram or initials.

THOMAS C. WOOD, M.D., F.A.C.P.
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TCW/ft

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James B. Watson III, M.D.

INFECTIOUS DISEASES:

Paul L. Steer, M.D., FACP

NEPHROLOGY:

Steven B. Tucker, M.D.

HEMATOLOGY/ONCOLOGY:

James M. Sprott, M.D.
Mary L. Stewart, M.D.

October 21, 1987

TO WHOM IT MAY CONCERN:

Re: Impending Legislation Regarding Organ Donation

At the present time there are currently more recipients awaiting heart, liver and kidney transplants than there are organs available to satisfy that need.

It is my feeling, therefore, that efforts to increase the availability of organs for appropriate use need be increased.

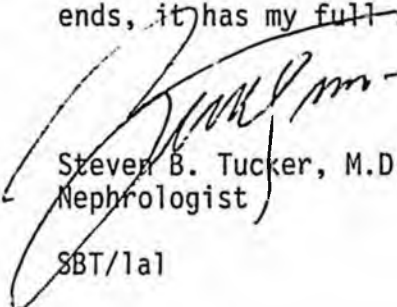
It is for this reason, therefore, that I support legislation predominantly directed at increasing public awareness of the organ shortage, as well as increasing specific family counselling in appropriate instances.

Alaska has always participated in an organ donation program, predominantly with the University of Washington in Seattle. We are now part of the Northwest Organ Procurement Agency and have been active in this regard.

As outlined, therefore, I am in agreement with the general spirit of the legislation, particularly as it addresses increased involvement at the Division of Motor Vehicles so that new drivers are specifically counselled as to organ donation and would also increase the involvement of the hospital staff to approach patients and their families in circumstances where organ donation may well be appropriate.

I also believe it is vitally important that in a remote area such as Alaska that small rural hospitals where the facilities for appropriate organ donation are not available not be held accountable to this legislation. I likewise think it is imperative that any bill include specific legal language that prevents lawsuits arising from either families who were upset that they were approached and also specifically prevents families from lawsuits where for one reason or another they were, in fact, not approached regarding this subject.

The purpose of this legislation in my opinion is not to open potential legal avenues for suit, but to increase the availability for organs in a situation where there is national shortage. If this legislation will accomplish those ends, it has my full support.


Steven B. Tucker, M.D.
Nephrologist

SBT/1a1

NORTHWEST ORGAN PROCUREMENT AGENCY



- 2) request permission of the coroner for recovery of donated organs
- 3) present the option to donate to the family when it is appropriate
- 4) encourages discretion and sensitivity in dealing with families - training of the personnel who will be requesting the gifts. It is important to ask, but it is just as important to answer all questions and support their decision. Needs to be done without infringing on people's deeply held values and rights.
- 5) In Alaska, logistics and medical facilities in rural communities may exempt hospitals from meeting the requirement set forth in this legislation. 6) No cost to the family
- 7) Law and medical emergency personnel to check for donor cards at the scene of the accident and inform the hospital staff of such
- 8) Encouraging the MVD to ask all persons orally if they wish to be an organ donor when applying for their identification card. (70-80% public favor organ donation, yet statistics show 19% have signified it on their drivers license or ID card) Education of MVD employees concerning organ donation is essential so they can handle the questions.
- 9) When acting in good faith, the person acting in accordance with the law will not be liable for damages or subject to prosecution.

There is, however, that the legislation does not cover:

- 1) Page 1, Sec 2 (b) The national law identifies two additional situations when it is inappropriate to request a gift - religious beliefs and actual notice of contrary indications by the deceased or family members.
- 2) Bottom of page 2 and top of page 3, Sec 4 (a) It is misleading to assume in Alaska for total body donation for the purposes of medical education or research that there would not be a cost to the family/estate for the transportation of the gift. U. of W. (our closest medical school) provides free transportation for only a 75 mile radius. Therefore, for Alaskans wishing to donate a gift of the entire body, the transportation cost would be their responsibility.

One final point, I would like to make, is that JCAH (Joint Commission Accreditation of Hospitals) has included organ donation policies as a standard for accreditation after January 1988.

I strongly support this legislation because the "gift of life" depends on the recognition of potential organ donors; on the recognition depends on an awareness of the need for organs and a knowledge of the procedure for donation and transplantation. It provides that human connection of encouraging personal decisions about organ donation and following through a process when it is appropriate.

I commend Max Grunberg, Grussendorf, Kopenon for the creative approach of restructuring the Alaska's Uniform Anatomical Gift Act with this "required request" legislation. Most states have drafted a separate bill, but I feel Alaska approach is also very appropriate. Thank you.