Approved 2-24-87
Date

MINUTES OF THE SENATE COMMITTEE ON PUBLIC HEALTH AND WELFARE.

The meeting was called to order by SENATOR ROY M. EHRLICH at
Chairperson

10:00 a.m./pxm. on February 17, 1987 in room 526-S of the Capitol.

All members were present except:

Committee staff present:
Bill Wolff, Legislative Research
Norman Furse, Revisor of Statutes Office
Clarene Wilms, Committee Secretary

Conferees appearing before the committee:
Robert Mullen, Administrator of Hospital #1, Lyons, Kansas
Charles Shields, M.D. St. Francis Hospital, Wichita, Kansas
Senator Eugene Anderson
Jane Warmbrodt, Director, Professional Education, Midwest Organ Bank, Kansas City, Missouri
Roger Park, M.D., Wichita, Kansas
John A. Schneider, Commissioner for Income Maintenance and Medical Programs, Social Rehabilitation Services
Written testimony, Marilyn Belshe, Infirmary Administrator, State Penitentiary, Lansing, Kansas

Others attending: see attached list

SB-154 - An Act relating to hospital districts; concerning attachment of territory to district;

Robert Mullen testified and presented written testimony supporting SB-154. Mr. Mullen stated that the purpose of this bill was to clarify the statutes as to whether or not a new area being brought into an existing district had to be physically contiguous with the existing district. The wording, lines 0027-0033 of SB-154 would clarify the existing language in KSA-80-2522 and should remove any procedural doubts concerning future expansion of hospital districts. (attachment 1)

SB-144 - An Act concerning social welfare; including liver transplants as a covered procedure under the state medical care plan for needy persons.

Charles Shields, M.D. testified in support of SB-144. Dr. Shields stated that although the transplants were not performed in Kansas, minimal funds were needed to cover hospital costs. Funds are needed just to get an individual placed on the waiting list in a region that does transplants. It was further stated that while doctors and anesthesiologists will waive their fees, the hospitals need funds to provide care. Dr. Shields reminded the committee that even if a person does not get a transplant there is still hospital care for terminal cases. Dr. Shields also told the committee that SB-19 was needed in order to clear up difficulties experienced in the organ retrieval field.

Senator Anderson testified and presented written testimony in support of SB-144. Senator Anderson stated that at the present time regulations will pay for cancer treatment but will not pay for transplants. It was also stated that the expense is not too great to save lives. The Senator also reminded the committee that Medicaid did receive federal funds to help with these expenses. (attachment 2)

Jane Warmbrodt testified and presented written testimony in support of SB-144. Ms. Warmbrodt stated that the Federal Government has committed millions of dollars to kidney transplants and will soon begin paying for selected heart transplants. The success rate for these procedures is no higher than liver

transplants. It was also stated that many private insurers will cover liver transplants so that the entire financial burden would not be borne by state agencies but there are people, because of inability to pay, who are being denied a transplant. (attachment 3) Ms. Warmbrodt also spoke in support of SB-19. At times there are problems when organ retrieval teams are denied access by coroners, consequently, SB-19 would clarify this situation. (attachment 4)

Roger Park, M.D., testified and presented a fact sheet pertaining to liver transplantation. Dr. Park stated that he came to the committee as a physician who was endeavoring to help the children who had no way of funding needed transplants. (attachment 5)

John Schneider testified and presented written testimony stating concerns regarding SB-144. Mr. Schneider stated that because of the exceedingly high cost involved for liver transplants, the medical assistance program does not reimburse for liver transplantation. It was stated that the cost to the state would be approximately $96,320 in state funds. Also to be considered is the cost of the immunosuppressive drug costs of $51,000 annually. Mr. Schneider further stated that because of the exhorbitant cost of this procedure and because it is still fraught with problems and complications, the legislature was encouraged not to cover liver transplants at this time unless it is able to sufficiently fund other needed services of the medical assistance program for Kansas elderly, disabled and poor. (attachment 6)

The chairman requested the wishes of the committee regarding SB-154. Senator Morris moved to pass SB-154 out favorable. Senator Bond seconded the motion and the motion carried.

Written testimony was presented to the committee pertaining to SB-113 and Lansing State Penitentiary policies from Marilyn Belshe, Infirmary Administrator. Ms. Belshe stated that local optomitrists perform optical examinations and write prescriptions for glasses and also test for glaucoma. Any further care is referred to a doctor and special care is referred to Kansas University Medical Center. (attachment 7)

The committee will meet February 18, 1987, 10 a.m. room 526-S.

The meeting adjourned at 10:55 a.m.

SENATE
PUBLIC HEALTH AND WELFARE COMMITTEE
DATE February 17, 1987

(PLEASE PRINT) NAME AND ADDRESS	ORGANIZATION
Jane Warmbrodt	Midwest Organ Bank
Roger Park, M.D	Pediatrician - Pediatric Gastroenterologist
Mary Ellen Parker	St. Francis Hospital - Wichita
CHARLES SHIELD MD	St. Francis Hospital Wichita
M. Hoover	Topeka Cap-Journal
KEITH R. LANDIS	CHRISTIAN SCIENCE COMMITTEE ON PUBLICATION FOR KANSAS
EDNA FUNK, LLOYD FUNK	Church Coalition
Kathryn Klussen - Docking State Office Bldg	SRS
John Schneider " "	SRS
Ken Schatzmeyer	KS Pharmacists Assoc
Doris Brummett	Observer "Close-Up KS."
Harold W. Reed	Hosp. Dist #1 Rice Co. Ks.
Nancy Davis	Ks. State Nurses Assoc.
Terri Rosselot	Ks. State Nurses' Assoc.
Gary Robbins	KS Optometric Assn
Harold Riegel	Ks Assn Osteopathic Med.
Michael O'Keefe	University of Kansas medical Center

HOSPITAL DISTRICT NO. 1 OF
RICE COUNTY, KANSAS
Lyons, Kansas 67554
Phone 316-257-5173

TESTIMONY ON SENATE BILL # 154
before the
SENATE PUBLIC HEALTH AND WELFARE COMMITTEE
FEBRUARY 17, 1987

Ladies and gentlemen of the committee, I am Robert Mullen, Administrator of Hospital District # 1, Lyons, and I appreciate the opportunity to testify on Senate Bill # 154. I would especially like to thank Roy Ehrlich, my State Senator and Chairman of this committee, and Tom Bell of the Kansas Hospital Association, for their assistance in preparing this piece of legislation. I would also like to introduce Harold Reed, the Chairman of our hospital board.

I will keep my comments on the bill as short and to the point as possible. However, I believe that a brief explanation of the events which lead to the drafting of this bill would be proper for a better understanding of the issue.

Hospital District # 1 of Rice County includes the cities of Lyons and Chase, but not the city of Sterling. Sterling is nine miles south of Lyons, and five miles south of the southern boundary of the hospital district. Since 1974, when the Sterling hospital closed, there has been only one hospital in Rice County.

Two to three years ago, a number of Sterling citizens expressed an interest in joining our hospital district, mainly because our hospital is the primary provider of health care for that community. One of the four family practice physicians on the admitting staff of our hospital resides in Sterling and has an established practice in that community. There has not been a great deal of interest in joining the district expressed by those landowners living in the area between the city limits of Sterling and the boundary of the existing district.

When we began to explore the statutory basis for bringing a new area into the existing district (KSA 80-2522), the question arose as to whether or not a new area had to be physically contiguous with the

SPHW
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Attachment 1

existing district. It was the opinion of our hospital attorney that the statute was not clear on this issue, primarily because the definition of "attachment" is not clear.

In October of 1986, our county attorney was asked to write to the Kansas Attorney General for an opinion on this issue before proceeding any further. The Attorney General's opinion (#86-151) concluded:

> " . . . in that the statute contains no territorial limitations on a political subdivision which may wish to petition for attachment to an existing hospital district, a city may petition to be included in a hospital district when no part of the city is contiguous to or adjacent to any boundary of the hospital district."

Following receipt of this opinion, our hospital board and attorney thoroughly discussed the issue. Although the Attorney General had ruled that a new political subdivision does not have to be contiguous to an existing district, it was our conclusion that the statute needed to be clarified for future reference. Subsequently, the proposed additional wording which appears in lines 27 through 33 was drafted. Specifically, the question of whether or not a new area must be contiguous to the territory of an existing hospital district is answered. The wording also specifies that the new political subdivision must be located wholly within the county in which the hospital for the district is located, and does not include within its territory, in whole or in part, the taxing area of another hospital.

I feel that the proposed wording in this bill will serve to clarify the existing language found in KSA 80-2522, and should not create any new problems for other hospital districts throughout the state. The new wording is merely "housekeeping" in nature, and if adopted, should remove any procedural doubts concerning future expansion of hospital districts.

Once again, thank you for your time and consideration of this issue. I would be glad to try to answer any questions that you may have.

STATE OF KANSAS

EUGENE (GENE) ANDERSON
SENATOR, DISTRICT TWENTY-NINE
SEDGWICK COUNTY
P.O. BOX 4598
WICHITA, KANSAS 67204-0598

TOPEKA

SENATE CHAMBER

COMMITTEE ASSIGNMENTS
MEMBER CONFIRMATIONS
EDUCATION
FEDERAL AND STATE AFFAIRS
PUBLIC HEALTH AND WELFARE

MR. CHAIRMAN, MEMBERS OF THE COMMITTEE:

ARTICLE 7, CHAPTER 39 OF THE KANSAS STATUTES ANNOTATED DIRECTS THE SECRETARY OF SOCIAL AND REHABILITATION SERVICES TO DEVELOPE A MEDICAL CARE PLAN FOR PROVIDING MEDICAL CARE FOR NEEDY PERSONS, AND THE SPONSORS OF SENATE BILL 144 WOULD REQUIRE THE INCLUSION OF LIVER TRANSPLANTS IN THE SCOPE OF THAT PLAN BUT WITHIN THE LIMITATIONS OF APPROPRIATIONS.

DURING THE INTERIM, THE PUBLIC HEALTH AND WELFARE COMMITTEE STUDIED THE STATES POLICY FOR REIMBURSING FOR ORGAN TRANSPLANTS THROUGH THE MEDICAL ASSISTANCE PROGRAM, THAT COMMITTEE ALSO REVIEWED THE PROVISIONS OF THE NATIONAL ORGAN TRANSPLANT ACT OF 1984, PUBLIC LAW 98-507.

I HAVE ATTACHED A COPY, OF THE COMMITTEES REPORT ON PROPOSAL 26, ALONG WITH A COPY OF SENATE CONCURRENT RESOLUTION 1601, INTRODUCED BY THIS COMMITTEE. THIS RESOLUTION MAKES A REQUEST OF THE SECRETARY OF SOCIAL AND REHABILITATIVE SERVICES TO AMEND THREE REGULATIONS WHICH NOW PRECLUDE LIVER TRANSPLANTS AS COVERED SERVICES UNDER THE MEDICAID AND MEDIKAN PROGRAMS.

SENATE CONCURRENT RESOLUTION 1601, IF ADOPTED MIGHT RESOLVE THE EXISTING PROBLEM WHICH MAKES OUR STATE ONE OF ONLY SIXTEEN (16) THAT HAVE NO PROVISIONS FOR PROVIDING TRANSPLANT ASSISTANCE TO NEEDY FAMILIES OR INDIVIDUALS HOWEVER, THE SPONSORS OF SENATE BILL 144 BELIEVE THE PROBLEM IS SERIOUS ENOUGH THAT LEGISLATIVE ACTION IS NEEDED IN THE FORM OF THIS BILL TO ADDRESS THE PROBLEM.

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2-17-87
attachment 2

ACCORDING TO THE TASK FORCE ON ORGAN TRANSPLATION, THE COST OF A LIVER TRANSPLANT RANGES FROM $135,000 TO $250,000 DOLLARS AND FOR A HEART TRANSPLANT $60,000 TO $120,000 DOLLARS. MUCH OF THIS COST IS RELATED TO HOSPITALIZATION AND THE PROCEDURES THEMSELVES. ONE METHOD OF REDUCING THOSE DIRECT COST TO THE RECEPIENTS MIGHT BE HAVE SUCH PROCEDURES DONE AT THE UNIVERSITY OF KANSAS MEDICAL CENTER WHEN THE PATIENT QUALIFIES FOR ASSISTANCES UNDER THE SECRETARY'S MEDICAL HEALTH CARE PLAN FOR THE NEEDY.

THERE HAS BEEN MUCH PUBLICITY IN THE WICHITA COMMUNITY REGARDING TWO YOUNG ADULTS NEEDING SUCH ASSISTANCE NEITHER BEING ABLE TO AFFORD THE COST OR RECEIVE ASSISTANCE FROM THE STATE OR BENEFIT FROM PUBLIC LAW 98-507. SENATE BILL 144, AS WELL AS SENATE CONCURRENT RESOLUTION WOULD REMOVE THOSE RESTRICTIONS WHICH PROHIBITED THOSE TWO KANSANS FROM RECEIVING ANY STATE ASSISTANCE.

EUGENE ANDERSON, SENATOR
29TH DISTRICT

Session of 1987

Senate Concurrent Resolution No. 1601

By Special Committee on Public Health and Welfare

Re Proposal No. 26

12-15

A CONCURRENT RESOLUTION concerning the scope of hospital and physician services covered under the Kansas medicaid/medikan program; requesting the modification of K.A.R. 30-5-81, 30-5-88, 30-5-151 and 30-5-156.

Be it resolved by the Senate of the State of Kansas, the House of Representatives concurring therein: That the secretary of social and rehabilitation services is hereby requested to modify K.A.R. 30-5-81, 30-5-88, 30-5-151 and 30-5-156, as follows:

30-5-81. Scope of hospital services. (a) Each hospital shall be medicare certified.

(b) Outpatient services shall be covered with the following limitations:

(1) Services shall be ordered by an attending physician who is not serving as an emergency room physician, except for those services related to emergency situations. Orders shall be related specifically to the present diagnosis of the recipient.

(2) Prosthetic devices shall replace all or part of an internal body organ, including the replacement of these devices.

(3) Rehabilitative therapies shall be restorative in nature, shall be provided following physical debilitation due to acute physical trauma or physical illness and shall be prescribed by the attending physician.

(4) Services provided in the emergency department shall be emergency services.

(5) Elective surgery shall not be covered, except for sterilization operations or for participants in the EPSDT program.

(6) Ambulance services shall not be covered.

(c) Inpatient services shall be covered, subject to the follow-

ing limitations:

(1) Services shall be ordered by a physician and shall be related specifically to the present diagnosis of the recipient.

(2) Transplant surgery shall be limited to corneal, kidney, *liver* and bone marrow transplants and services related to such transplants.

(3) Procurement of the organ related to transplant surgery shall not be covered.

(4) A physician hospital admittance profile, taking into consideration physician specialty and application, shall be kept on all physicians. The agency shall require prior authorization for hospital admission by any physician who, in the judgment of medical consultants, continues to admit patients to the hospital unnecessarily.

(5) Inpatient services shall be limited to those provided on days of stay that are determined to be medically necessary.

(6) Reimbursement shall not be made for services provided on days of discharge.

(7) Long-term care services in swing beds shall be provided pursuant to 42 CFR 405 subpart K and 442 subpart F, revised October 1, 1984, which are adopted by reference.

(8) Therapeutic and diagnostic surgical services, and related services that can be performed on an outpatient basis, shall not be reimbursed on an inpatient basis unless medical necessity is documented.

(9) Inpatient services shall be subject to a utilization review to determine medical necessity at the time of admission and on a continued stay basis. Utilization review of all inpatient services shall be conducted by the hospital unless exempted by the division of medical programs. Utilization reviews conducted by a hospital or qualified contractor may be subject to further review by the division of medical programs.

(10) Certain non-Kansas hospitals may be required to submit documentation of medical necessity if the stay exceeds the 75th percentile of number of days of stay, as indicated in the 1981 edition of the "professional activity study hospitals" (PAS), north central region edition. The percentile of number of days of stay

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shall be based on the primary diagnosis and, as appropriate, on any secondary or multiple diagnosis.

(11) Psychiatric services in an acute general hospital shall be limited to a specific number of days per admission, as specified by the division of medical programs, unless an extended length of stay has been authorized by the division of medical programs prior to the last day of the specified limit, or has been certified through a utilization review process approved by the agency.

(12) Psychotherapy, directed by a psychiatrist or approved hospital staff under the direction of a psychiatrist, shall be provided to each psychiatric patient on a daily basis.

(13) Acute detoxification services shall not exceed eight days.

(14) Substance abuse treatment services shall not exceed 25 days, excepting EPSDT participants who are covered up to 45 days.

(15) Inpatient acute care related to substance abuse treatment services shall be limited to those patients who are in need of acute detoxification or a drug and alcohol treatment program approved by the division of medical programs.

(16) Elective surgery shall not be covered, except for sterilization operations or for participants in the EPSDT program.

(17) Therapeutic home visits shall not be covered unless the absence occurs during the last three days of the stay, and the absence extends overnight.

30-5-88. Scope of physician services. (a) Except as set forth in subsection (b), the program shall cover medically necessary services (recognized under Kansas law) provided to program recipients by physicians who are licensed to practice medicine and surgery in the jurisdiction in which the service is provided.

(b) The following services shall be excluded from coverage under the program, except as noted:

(1) Visits. The following types of visits shall be excluded:

(A) Office visits when the only service provided is an injection or some other service for which a charge is not usually made;

(B) nonpsychiatric office visits which exceed 12 per calendar year;

(C) psychiatric office visits which exceed an average of 24

2-5

hours of individual therapy or 24 hours of group therapy or any combination of these per calendar year, unless the recipient is a participant in the EPSDT program and:

(i) Psychiatric services do not exceed three hours per month; or

(ii) are being rendered pursuant to a plan approved by the agency. Prior authorization for the plan shall be required. The plan shall not exceed a two-year period and shall be subject to a reimbursement limit established by the secretary. Quarterly progress reports shall be submitted to the division of medical programs;

(D) inpatient hospital visits in excess of those allowable days for which the hospital is paid or would be paid if there were no spenddown requirements; and

(E) nursing home visits in excess of one per month unless medical necessity is documented.

(2) Consultations. Consultations shall be excluded as follows:

(A) Consultations which are absent a written report;

(B) inpatient hospital consultations in excess of one per condition per ~~10~~ *ten*-day period unless written documentation confirming medical necessity is attached to the claim; and

(C) other consultations in excess of one per condition per 60 day period unless written documentation confirming medical necessity is attached to the claim.

(3) Surgical procedures. Surgical procedures shall be excluded as follows:

(A) Procedures that are experimental, pioneering, cosmetic, or designated as noncovered, *except that liver transplants shall not be considered experimental for the purposes of this section*;

(B) transplants, other than corneal, kidney, *liver* and bone marrow transplants, and related services;

(C) procurement of an organ related to transplant surgery;

(D) services of a surgical assistant when surgery is determined not to require an assistant; and

(E) elective surgery, except for sterilization operations or for participants in the EPSDT program.

(4) Miscellaneous procedures. Miscellaneous procedures shall be excluded as follows:

(A) Diagnostic radiological and laboratory services unless the services are medically necessary to diagnose or treat injury, illness or disease;

(B) physical therapy unless:

(i) Performed by a physician or registered physical therapist under the direction of a physician; and

(ii) prescribed by the attending physician;

(C) medical services of medical technicians unless the technicians are under the direct supervision of a physician; and

(D) inpatient services which were provided on days of hospital stay which are determined to not be medically necessary.

(5) Family planning services and materials.

(A) Family planning services and materials shall be excluded unless:

(i) The services are provided by a physician, family planning clinic, or county health department;

(ii) written informed consent is obtained as necessary; and

(iii) the scope of services provided are in compliance with applicable federal and state statutes and regulations;

(B) reverse sterilizations shall be excluded.

(6) Concurrent care. Concurrent care shall be excluded unless the patient:

(A) Has two or more diagnoses involving two or more systems; and

(B) the special skills of two or more physicians are essential in rendering quality medical care. The occasional participation of two or more physicians in the performance of one procedure shall be recognized. Each physician involved shall submit that physician's usual charge only for that portion of the procedure for which the physician is actually responsible.

(7) Psychological services for an individual entitled to receive these services as a part of care or treatment from a facility already being reimbursed by the program or by a third party payor shall be excluded.

(8) Services provided by physician extenders shall be ex-

cluded, except as listed below:

(A) Adult care home visits;

(B) routine, annual medical history and physical;

(C) subsequent day hospital visits;

(D) routine, standard home visit; and

(E) standard office visit.

30-5-151. Scope of hospital services for adult medikan program recipients. (a) Outpatient coverage shall be limited to the following services:

(1) Emergency care;

(2) nonelective surgery, except for sterilization operations;

(3) laboratory and diagnostic radiology services;

(4) diagnostic computerized axial tomography scans and ultrasonic studies;

(5) chemo- and radiation therapy;

(6) renal dialysis for recipients who cannot utilize home dialysis; and

(7) prior authorized rehabilitative therapies if there are no home health agency services available.

(b) Inpatient coverage shall be limited to the following services:

(1) Nonelective surgery and sterilization operations that cannot be done on an outpatient basis;

(2) corneal, kidney, *liver* and bone marrow transplants, including related services. Services related to the procurement of the organ shall not be covered;

(3) acute medical care which cannot be provided on an outpatient basis;

(4) complicated deliveries and 48 hours for uncomplicated, normal delivery;

(5) eight days for acute detoxification;

(6) medically necessary substance abuse treatment services, as approved by the division of medical programs;

(7) psychiatric services in an acute general hospital shall be limited to acute psychiatric diagnoses as defined by the secretary and to a specific number of days per admission, as specified by the division of medical programs, unless an extended length of

stay has been authorized by the division of medical programs prior to the last day of the specified limit, or has been certified through utilization review process approved by the agency;

(8) rehabilitative therapies which are restorative in nature, provided following physical debilitation due to acute physical trauma or physical illness, and prescribed by the attending physician; and

(9) therapeutic home visits if the absence occurs during the last three days of the stay, and the absence extends overnight.

30-5-156. Scope of physician services for adult medikan program recipients. Coverage shall be limited to:

(a) Nonelective surgery and elective sterilization;

(b) corneal, kidney, *liver* and bone marrow transplants, including related services. However, services related to procurement of the organ shall not be covered; (c) inpatient hospital services which cannot be provided on an outpatient basis;

(d) outpatient hospital services;

(e) twelve office visits per calendar year;

(f) one adult care home visit per calendar month;

(g) twenty-four hours of psychotherapy per calendar year;

(h) laboratory and diagnostic radiology services; and

(i) chemo- and radiation therapy.

Be it further resolved: That the secretary of state be directed to transmit a copy of this resolution to the secretary of social and rehabilitation services.

2-9

RE: PROPOSAL NO. 26 -- ORGAN TRANSPLANTS*

Under the directive set out in Proposal No. 26, the Special Committee on Public Health and Welfare was instructed to: (1) study the state's policy for reimbursing for organ transplants through the Medical Assistance Program; (2) consider whether the state should regulate the number and type of transplant programs in the state; (3) review the system used to determine which potential transplant patients receive available donor organs; and (4) consider the need for legislation concerning the sale of or profiting from organ transplant procedures.

Background

In order to carry out the Committee study on Proposal No. 26, the members met with conferees at meetings held in Topeka and in Wichita, reviewed the provisions of the National Organ Transplant Act of 1984, PL 98-507, and considered the recommendations of the national Task Force on Organ Transplantation. The conferees who met with the Committee included the Director of the American Red Cross Tissue Bank located in Wichita; a Wichita pediatric gastroenterologist; a transplant surgeon; the parents of two liver transplant recipients; the Secretary of Social and Rehabilitation Services; a representative of the Midwest Organ Bank, who was also a member of the Task Force on Organ Transplantation; and the clinical-renal coordinator of the Department of Nephrology at the University of Kansas Medical Center. The Committee received written testimony from the Health Services Coordinator of the Wichita Head Start Program and from a former Kansan whose daughter is the recipient of a liver transplant.

Information supplied to the Committee by conferees indicates the transplantation of human organs has become

* S.B. 18, S.B. 19, S.B. 20, S.B. 21, and S.C.R. 1601 accompany this report.

an effective means of treating many individuals who suffer life-threatening organ failure. The rapid progress made in the development of drugs to suppress the body's immune response and to control rejection of organs transplanted from unrelated donors, along with technical developments in the highly complex field of transplantation, have resulted in organ transplantation being widely available in the United States. The transplantation of kidneys, livers, and hearts has joined well-established programs providing cornea, skin, and bone transplantation as an accepted weapon against life-threatening medical conditions. Less widely accepted procedures are heart-lung and pancreas transplants.

Committee Findings

In spite of the dramatic improvements in transplant technology in recent years, there remain unresolved social, ethical, and economic issues connected with solid organ transplantation. Among the unresolved issues is the allocation of available health care dollars. The high costs associated with solid organ transplantation, along with the expense of life-long medication and medical supervision necessary for transplant patients, raise ethical questions about the allocation of scarce health care dollars for life-saving procedures for a relatively small population at the possible expense of larger populations also faced with life-threatening health conditions that can be prevented or treated at far less cost. (See also the Committee report on Proposal No. 24 in this volume.)

Access. Access to liver and heart transplants is not equally available to all patients who could benefit from such medical intervention. Since the enactment of the Social Security Amendments of 1972, PL 92-603, which established the federal End-Stage Renal Disease Program, patient resources have not been a major factor in determining who receives a kidney transplant because most persons who suffer end-stage renal disease can become

eligible for Medicare coverage for dialysis and transplantation. For such patients, only the cost of immunosuppressive therapy has represented a barrier to needed health care because Medicare did not cover such drug costs. However, there is no comparable federal program for those patients who meet the medical criteria for liver or heart transplantation but who lack governmental or private third-party coverage or the financial resources to pay for the procedure. Thus, some persons who could benefit from transplantation are denied access to heart or liver transplants due to inability to pay. For these patients, there is no alternative medical procedure to sustain life as is the case for those who suffer end-stage renal disease and for whom dialysis may be an alternative.

While a number of state Medicaid programs have funded one or more liver or heart transplants, Medicaid coverage is spotty, often based on a case-by-case decision-making process, or subject to prior authorization, rather than constituting a routine covered service. There is also variation as to the extent of coverage in Medicaid programs. In Kansas, the Medical Assistance Program does not cover liver or heart transplants although cornea, kidney, and bone marrow transplants are covered services as are the services related to such transplants.

Abuse. Although the interstate transfer of an organ for valuable consideration is a felony under federal law, abuses in the procurement, distribution, and use of human organs for transplantation have been reported in the press and in testimony presented to the Task Force on Organ Transplantation. Concerns remain about the potential for commercialization of organ procurement and distribution and, while no testimony presented to the Committee indicated abuses in the Kansas-Missouri region, several conferees recommended that a state law be enacted making the intrastate transfer of organs for commercial purposes a crime. The Task Force also recommends the enactment of state laws prohibiting the sale

of organs from cadavers or living donors within individual state boundaries.

Donor Supply. One of the more serious unresolved issues relating to organ transplantation is the wide gap between the need for solid organs and the donor supply. One source estimates there are roughly three people waiting for transplantation for every donor organ that becomes available. The lack of available donor organs is particularly great for pediatric patients, certain patient subgroups whose prior sensitization requires more specific donor matching, and for minority populations. Kansas, as has every other state, has adopted the Uniform Anatomical Gift Act, which resolves certain legal issues relating to the right of adults or the family of a deceased person to donate organs. Kansas has also adopted the Uniform Determination of Death Act which recognizes brain death, and in 1986, Kansas adopted a required request law. Kansas law does not currently encourage coroners to give permission for organ and tissue procurement from cadavers under the coroners' jurisdiction when families consent to such procedures. The Task Force on Organ Transplantation has recommended that states enact legislation which requires coroners to develop policies that facilitate the evaluation of cadavers for organ and tissue donation and which provides the family of the deceased with the opportunity to make an anatomical gift. Also recommended is legislation that requires coroners to give permission for organ and tissue procurement when families consent, unless medico-legal evidence would be compromised by such procurement.

Organ Allocation and Distribution. Currently, there is no unified national system of organ sharing to coordinate organ allocation and distribution, although the development of such a network has been recommended by the Task Force on Organ Transplantation created pursuant to PL 98-507. There is no nationwide certification of organ and tissue procurement agencies to assure that minimum standards relating to organ procurement, organizational structure, staff training, and fiscal accountability are met by such agencies, although

the Task Force on Organ Transplantation has recommended that the Department of Health and Human Services develop and enforce minimum standards. Concern exists about the proliferation of organ procurement agencies and the potential effect of such proliferation on the equitable allocation of donor organs.

In general, the need for a national system for organ sharing cannot be met by any one state. However, should the recommendation of the Task Force be implemented, a state policy could be adopted that recognizes, for reimbursement purposes, only those organ procurement agencies that meet national standards and that participate in a national organ sharing network. The concept of a national network is supported by the Midwest Organ Bank, whose protocols for organ sharing were reviewed by the Committee.

Transplant Centers. Improvements in the transplantation of organs and the availability of third-party coverage for such procedures have stimulated a rapid increase in the number of institutions in which transplants are performed. The Task Force on Organ Transplantation, for example, reports that between 1981 and 1985 the number of heart transplant centers in the United States increased from eight to 71, and the number of liver transplant centers increased from one to 36. While the total number of transplants increased during the same period, the proliferation of centers raises serious concerns about the potential for diffusing expertise and experience to the point that patient outcome, effective organ use, and cost may be compromised. Federal regulation has been limited to setting conditions for participation in kidney transplants reimbursed under Medicare, while regulation by the states, to the extent that it has occurred, has come about through certificate-of-need programs.

Arguments can be made that the development of more transplant centers will bring about the benefits that

might arise from competition. Equally compelling arguments can be made for regulation of the growth in transplant programs. Conferees who met with the Committee stressed the need for multi-discipline support for transplant programs, the apparent relationship between volume and patient outcome, the need to minimize inappropriate use of scarce donor organs, and the importance of performing a minimum number of procedures in order for a transplantation center to maintain the experience and skill necessary to achieve desirable transplant success rates. There may also be benefits in terms of cost-effective care arising from the concentration of transplantation resources at institutions that serve as regional resources. The Task Force on Organ Transplantation has recommended that regulation of the proliferation of transplant centers be carried out at the federal level through limiting reimbursement for organ transplants to institutions that meet criteria relating to minimum volume, transplantation experience, the availability of graduate medical education, survival rates, facilities, access to donor organs, recipient selection procedures, transplant surgeon certification, collaborative support, ancillary services, blood bank support, psychiatric and social support services, and the retention of data for evaluation purposes. Additionally, some third-party payers have already adopted policies which limit reimbursement for organ transplant procedures to specified facilities.

Costs. The estimated cost of liver and heart transplants given to the Committee varies according to the source of the information. The Task Force on Organ Transplantation identified costs ranging from $135,000 to $250,000 for liver transplants and from $60,000 to $120,000 for heart transplants. The Department of Social and Rehabilitation Services estimates the total one-year cost of care for one heart-transplant patient will range from $170,000 to $200,000, with $120,000 to $150,000 of the cost related to the hospitalization and procedure itself and the remaining $8,000 to $22,000 allocated to physician care and immunosuppressant drug costs. The Department's estimate of the total cost of

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covering a liver transplant under Medicaid is $215,000, of which $96,320 is estimated to be state dollars. A pediatric gastroenterologist who met with the Committee estimated the total first-year costs of liver transplantation as ranging from a low of $68,000 to a high of $238,000, with an average first-year cost of $130,000. The same conferee estimated the need for pediatric liver transplants in Kansas as being from 8.7 to 12 each year. The estimates of cost are difficult to compare because they may include different factors, i.e., the Task Force estimates concern only the transplant procedure itself and do not include first-year, follow-up medical care and drugs. In addition to the first-year costs associated with transplant procedures, there are life-long drug costs which are estimated to range currently from $8,000 to $10,000 per year and life-long medical care costs arising from the organ graft.

In order to develop costs for the purpose of Medical Assistance coverage in Kansas, one could assume that those persons with no insurance or minimal health insurance coverage who are in need of organ transplants would become eligible for Medical Assistance prior to or at the time of the transplant. Others who have insurance coverage may become eligible through the spend-down procedure for coverage of all or a part of transplant-related costs. The Secretary of Social and Rehabilitation Services told the Committee the Department was aware of three liver transplants that would have been eligible for funding through the Medicaid Program in fiscal year 1985 had the program covered liver transplants. Using the Department's estimated cost figures, the minimum cost of three liver transplants would have been $645,000 in fiscal year 1985, with $289,960 of the cost representing state funds. It is probable that, had Medicaid and MediKan coverage been available, more cases which would have been eligible for assistance would have been brought to the Department's attention. It should be noted that the cost estimates are for routine, uneventful liver transplantation and do not reflect any costs associated with complications arising during surgery, after surgery, or from rejection of the

donor organ. In specific known cases, additional costs resulting from complications have been as high as $1,000,000.

Conclusions and Recommendations

The Special Committee on Public Health and Welfare, after reviewing the issues examined under Proposal No. 26, has reached several conclusions and recommendations.

The Committee has concluded that the proliferation of solid organ transplant centers has implications for escalating the cost of an already costly medical procedure and raises serious concerns about assuring a high-quality outcome for transplant patients. The Committee believes there are many reasons that lead medical care facilities to consider the development of transplant programs, including viewing such programs as an advantage in a competitive environment and viewing such programs as adding prestige to the facility. Unless transplant programs are developed only when rigid criteria are met and only when such programs are not otherwise available on a regional basis, a proliferation of programs may reduce the quality of care and increase the costs of organ transplantation available to Kansans.

Recommendation. The Special Committee recommends that any agency of the state that reimburses providers for solid organ transplantation confine such reimbursement to transplant centers that meet any national criteria that may be developed or, in the absence of national criteria, develop policies that follow the recommendations of the Task Force on Organ Transplantation. Further, the Committee recommends that transplant centers be considered a regional resource and that the state refrain from adopting any policies that would lead to duplication in Kansas of facilities and services that are available in the surrounding states.

The Committee found that the current policies followed by the Midwest Organ Bank in allocating donor

organs among the transplant programs served by the Bank generally follow the recommendations of the Task Force on Organ Transplantation and result in a reasonable allocation of valuable resources. No examples of abuses in this allocation system were reported to the Committee by conferees.

The Committee believes there is a potential for abuse in the procurement and distribution of human organs for transplantation purposes. The members concluded that the critical nature of the medical conditions that lead to transplantation could result in commercialization of organ procurement and distribution outside of established systems developed for these procedures. Further, there is a potential for exploitation of individuals, including foreign nationals, who may see the sale of an organ as a means to secure money. Thus, the Committee concluded that legislation should be enacted to make the sale of organs for commercial purposes a crime in Kansas.

Recommendation. The Special Committee on Public Health and Welfare has drafted S.B. 21 which makes it a crime to knowingly buy or sell or assist another in buying or selling a human body or any part of a human body for purposes set out in the bill. S.B. 21 also sets out exceptions to the prohibited practices created by the bill. The Committee recommends that S.B. 21 be enacted by the 1987 Legislature.

Recommendation. The Committee believes that, inasmuch as donated organs are a scarce resource, the recommendations of the Task Force on Organ Transplantation should be adopted, and a national organ procurement and transplantation network should be established. Therefore, the Committee recommends that any state agency reimbursement for organ transplantation should recognize any national procurement and transplantation network that is established and limit reimbursement to those transplant centers and organ procurement agencies that participate in such a national network.

The Committee concluded that every effort should be made by agencies of the state to increase organ donations. In this regard, the Department of Revenue, the health care provider licensing agencies, the State Department of Education, and the Department of Health and Environment could develop programs to educate and motivate the public about organ donation. Particular efforts should be directed to minority populations who currently participate at a low level in organ donation and to correcting misconceptions about organ donation.

The Committee also recommends that legislation be enacted that will encourage coroners to permit the donation of anatomical gifts from cadavers under the coroners' control when family consent has been obtained and when no interference with the medico-legal investigation would result. S.B. 19 has been introduced to implement this recommendation.

An issue that arose during Committee hearings was brought to the members' attention by the Director of the American Red Cross Tissue Bank, who noted that Kansas is one of only 15 states that do not exempt tissue products from liability as is done with blood banking products pursuant to K.S.A. 65-3701. It was suggested that such an exemption would aid in containing costs associated with tissue banking. The Uniform Anatomical Gift Act, in K.S.A. 65-3209, defines "bank or storage facility" to mean a "facility licensed, accredited or approved under the laws of any state for storage of human bodies or parts thereof." (Emphasis added.) Because such facilities are not licensed, accredited, or approved under the laws of this state or of most other states, this term has little meaning as used in the Uniform Anatomical Gift Act. The term appears in K.S.A. 65-3213, which authorizes certain persons or facilities to become donees of gifts of bodies or parts thereof, and in K.S.A. 65-3213, which authorizes the deposit of a document making an anatomical gift in such facility. In order to obtain the benefits of relief from liability afforded under the Uniform Anatomical Gift Act, it is necessary to amend the definition of the term "bank or storage facility" to

reflect current practice or to enact some form of state accreditation or approval of such facilities.

Recommendation. The Special Committee on Public Health and Welfare has prepared legislation which amends the Anatomical Gift Act to delete the language in the definition of "bank or storage facility" which currently makes the relief from liability arising from the Act inapplicable to tissue and organ banks operating in Kansas. The Committee recommends that S.B. 20 be considered by the appropriate committees of the 1987 Legislature.

Additionally, the Committee has prepared S.B. 18 to amend K.S.A. 65-3701, a statute which now defines certain activities relating to blood and blood products as constituting a service rather than a sale and limits the liability arising from such service. S.B. 18 expands the provisions of K.S.A. 65-3701 to include a "human body part," a term defined in the bill to mean an organ, tissue, eye, bone, artery, whole blood, plasma, blood products, blood derivatives and products; other fluids, and any other portions of the human body. The Committee recommends that S.B. 18 be considered by the Judiciary committees of the 1987 Legislature in light of the need to facilitate organ, tissue, and blood banking services. The provisions of S.B. 18 are coordinated with the provisions of S.B. 21.

At the present time, the Kansas Medicaid and MediKan programs do not include liver transplants as a covered service. According to the Secretary of Social and Rehabilitation Services, such coverage has not been extended through the Kansas Medical Assistance program because of the potential cost. Absent specific legislative consideration of the issue of liver transplants and an appropriation to cover the anticipated liabilities for such transplants, any coverage under Medicaid or MediKan would result in reduced services for persons who are eligible for medical services under Medical Assistance -- a program in which services have already been

cut to meet budget restrictions. (See report on Proposal No. 24 in this volume.)

Recommendation. The Special Committee on Public Health and Welfare has determined that liver transplantation is no longer an experimental procedure for children and some adolescents. Currently, liver transplantation is seldom recommended for adults. Because a liver transplant may literally represent an opportunity for life for children and adolescents and because no alternative procedure is presently available to those who suffer organ failure, the Committee recommends that liver transplantation be a covered service under Medicaid and MediKan.

In making this recommendation, the Committee is aware that the state will incur substantial costs in connection with reimbursement for liver transplantation and that such costs will be shared in most instances between the state and federal governments. If six liver transplants were to be eligible for Medicaid coverage in a fiscal year, total costs for routine, uncomplicated transplants could exceed $1,000,000, with the state's share in excess of $500,000. It is not the Committee's intent that such costs be incurred at the expense of other program recipients. Therefore, the Committee recommends that the Secretary of Social and Rehabilitation Services prepare a separate budget request for presentation to the 1987 Legislature that covers liver transplants only. Any appropriation for liver transplantation should represent a new expenditure and should result in no reduction in other covered services. Further, the Committee recommends that the costs of organ transplantation be set out separately in future Medical Assistance budgets in order that the Legislature may consider the policy of including organ transplants under the Medical Assistance program in light of the total program. The Legislature should also be aware that coverage of liver transplants will include long-term commitments for necessary drugs and medical supervision.

The Committee also recommends that, if appropriations are made to include liver transplants as a covered service, the Secretary of Social and Rehabilitation Services adopt rules and regulations setting out the specific diseases or conditions that are medically accepted as criteria for transplantation. The Secretary should also designate those transplant centers that meet adopted criteria as eligible for reimbursement. Nothing contained in this recommendation should be construed as offering any inducement for the development of a liver transplant program in Kansas since the University of Nebraska program already meets accepted standards and is available to Kansas residents as a regional resource.

The Committee has introduced S.C.R. 1601 which requests the Secretary of Social and Rehabilitation Services to amend three regulations which now preclude liver transplants as covered services under the Medicaid and MediKan programs.

Recommendation. Although the Committee did not have an opportunity to determine the feasibility of bulk purchase of those drugs most often prescribed for recipients of organ transplants, it does recommend that the Department of Social and Rehabilitation Services investigate the possibility of purchasing such drugs in bulk in order to reduce the cost to the Medicaid Program and to other persons who require such drugs.

Respectfully submitted,

November 24, 1986

Sen. Roy Ehrlich, Chairperson
Special Committee on Public Health and Welfare

Rep. Marvin Littlejohn, Vice-Chairperson
Rep. Gary Blumenthal
Rep. Jessie Branson
Rep. Frank Buehler
Rep. Elaine Hassler
Rep. Melvin Neufeld

Sen. William Mulich
Sen. Joseph Norvell
Sen. Ben Vidricksen
Sen. Jack Walker

MINORITY REPORT

The information presented to the Special Committee on Public Health and Welfare regarding organ transplants is not in dispute. However, at a time when the state faces a severe revenue shortfall, it behooves us to be more prudent in our recommendations as to how scarce tax dollars are spent in the Medical Assistance Program.

The facts presented in the majority report clearly indicate that any liver transplant program will be costly in the first year it is implemented and will increase in costs in every subsequent year. This is the case because the recommendation of the majority includes payment not only for the initial operation but for medications that will be necessary from the time of the transplant until the death of the recipient. Since successful transplant patients can be expected to live nearly normal lives, the accumulative effect of continued payment for medications will be a heavy burden on the General Fund to sustain.

While the financial ramifications of the majority's recommendation are sufficient in themselves to cause us to dissent, a second and human rationale leads us to disagree with the majority. Specifically, we believe that it is grossly unfair to potential liver transplant patients and to their families for the Legislature to create a statutory program of financial assistance for liver transplants and then leave all those who seek assistance from the law in despair because the Legislature could not fund the program. What the majority proposes to give hope to those in need of financial assistance may, in the end, add only frustration and suffering for those intended to be helped by the program.

Respectfully submitted,

Rep. Frank Buehler
Rep. Melvin Neufeld
Senator Ben Vidricksen

Midwest Organ Bank

4006 Central • Kansas City, Missouri 64111 • Phone: 816-531-3763

February 16, 1987

Senator Erlich, Members of the Committee:

I am the Director of Education for the Midwest Organ Bank in Kansas City. Our Organ Procurement Agency is responsible for coordinating organ donation in all of the hospitals in the state of Kansas.

We have been asked to address the proposed Senate Bill 144 which deals with Medicaid funding for liver transplants.

Since 1985, at least thirteen Kansas residents have gone outside of the state to obtain a liver transplant. The average cost of these procedures was $ 125,000. While this may seem very expensive, there are several important points to consider.

1) Liver transplantation is not an experimental procedure. Some liver transplant programs report a 60 - 80% 1 year survival rate.

2) These proceedings are life saving. There is no alternative therapy for end-stage liver disease patients.

3) The Federal Government has committed millions of dollars to kidney transplantation, and will soon begin paying for selected heart transplants. The success rates for these procedures is no higher than the success rate for liver transplants.

4) I was a member of the U.S. Department of Health and Human Resources National Task Force on Organ Transplantation. The Task Force deliberated for fifteen months prior to publishing its report in regard to payment for extra-renal (heart and liver) transplants.

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attachment 3

Only forty people per million would qualify for a liver transplant. Therefore, the costs, in the total national health care budget, would be relatively small: 2.9 to 4.1 million dollars per year. * (See handout Table I)

Many private insurers are covering liver transplants so that the entire financial burden would not be borne by state agencies. There are those people who fall through the cracks, however, and many of them are being denied a transplant - in effect a death sentence - because of inability to pay. Because of this inequity, the Task Force made the following recommendation:

> "Private and public health benefit programs, including Medicare and Medicaid, should cover heart and liver transplants, including outpatient immunosuppresive therapy that is an essential part of the post-transplant care."

Of the thirteen Kansas residents who were transplanted, we know that at least eight of their liver transplants were paid for by third party payers. We are not talking about funding for a great number of procedures; only funding in those cases where no other mechanism exists.

I have included in your packets exerpts from the Task Force's reports on the subject of liver transplant funding to give you further information for your deliberations.

In conclusion, the Task Force and the Midwest Organ Bank absolutely support Medicaid funding of liver transplants for those patients who have no other payment mechanism.

Sincerely,

Jane Warmbrodt

Jane Warmbrodt
Director
Professional Education
Midwest Organ Bank

*(Appendix to the Report of the Task Force on Organ Transplantation, April 1986, Ch. V)

ORGAN TRANSPLANTATION

Issues and Recommendations

Report of the Task Force on Organ Transplantation

April 1986

U.S. DEPARTMENT OF
HEALTH & HUMAN SERVICES
Public Health Service
Health Resources and Services Administration

Executive Summary

In response to widespread public interest and involvement in the field of organ transplantation, the Congress enacted the National Organ Transplant Act of 1984 (PL 98-507). In addition to prohibiting the purchase of organs, the act provided for the establishment of grants to organ procurement agencies (OPAs) and a national organ-sharing system. This act also established a twenty-five member Task Force on Organ Transplantation representing medicine, law, theology, ethics, allied health, the health insurance industry, and the general public. The Office of the Surgeon General of the Public Health Service, the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Health Care Financing Administration (HCFA) were also represented.

The mandate given to the Task Force was to conduct comprehensive examinations of the medical, legal, ethical, economic, and social issues presented by human organ procurement and transplantation and to report on these issues within one year. In addition, we were asked to assess immunosuppressive medications used to prevent rejection and to report on our findings within seven months; this report also was to include a series of recommendations, including recommending a means of assuring that individuals who need such medications can obtain them.

During the twelve months following its organizational meeting on February 11, 1985, the Task Force met in public session on eight occasions and held two public hearings. We were supported by staff from the Office of Organ Transplantation and by consultants from HCFA and other agencies and organizations. Data were obtained through surveys, literature reviews, commissioned studies, consultations, and public testimony. Five workgroups were established within the Task Force to address each of the mandated issues identified by Congress and to prepare presentations and recommendations for consideration by the full membership.

As required by the act, the Task Force completed an assessment of immunosuppressive medications and the costs of these therapies, and submitted its report and recommendations to the Secretary and the Congress on October 21, 1985. Briefly, we found that the new immunosuppressive regimens, although

expensive, proved to be cost-saving due to improvement in outcome; for this reason, and in order to ensure equitable access, the Task Force recommended that the federal government establish a mechanism to provide immunosuppressive drugs to recipients otherwise unable to pay for these drugs, when Medicare paid for the transplantation procedure.

In this final report, the Task Force summarizes its arguments on the issues identified as major concerns by the Congress, and presents a series of recommendations for consideration of federal and state legislators, public health officials, the organ and tissue transplantation community, organized medicine, nursing, and the federal government.

ORGAN AND TISSUE DONATION AND PROCUREMENT

The serious gap between the need for organs and tissues and the supply of donors is common to all programs in organ transplantation, as well as to tissue banking and transplantation. The Task Force believes that substantial improvements in organ donation would ensue through new, innovative, and expanded programs in public and professional education and the coordination of efforts of the many organizations and agencies that engage in these activities. In particular, we support both the enactment of legislation in states that have not clarified determination of death based on irreversible cessation of brain function (the Uniform Determination of Death Act), and the enactment of legislation requiring implementation of routine hospital policies and procedures to provide the next-of-kin with the opportunity of donating organs and tissues. In addition, we found both a serious lack of uniform standards of accountability and quality assurance in organ and tissue procurement and a spectrum of effectiveness of procurement activities. Therefore, the Task Force supports the development both of minimum performance and certification standards, and of monitoring mechanisms.

RECOMMENDATIONS

1. To facilitate organ donation the Task Force recommends:

- **The Uniform Determination of Death Act be enacted by the legislatures of states that have not adopted this or a similar act.**

- **Each state medical association develop and adopt model hospital policies and protocols for the determination of death based upon irreversible cessation of brain function that will be available to guide hospitals in developing and implementing institutional policies and protocols concerning brain death.**

- States enact legislation requiring coroners and medical examiners to give permission for organ and tissue procurement when families consent unless the surgical procedure would compromise medicolegal evidence. Further, the legislation should (1) require coroners and medical examiners to develop policies that facilitate the evaluation of all nonheart-beating cadavers under their jurisdiction for organ and tissue donation, and (2) provide the next-of-kin with the opportunity to consider postmortem tissue donation. The Task Force further recommends that coroners develop agreements with local tissue banks to help implement these policies.

2. To facilitate the identification of potential donors and to provide the next-of-kin with appropriate opportunities to donate organs and tissues, the Task Force recommends that:

- All health professionals involved in caring for potential organ and tissue donors voluntarily accept the responsibility for identifying these donors and for referring such donors to appropriate organ procurement organizations.

- Hospitals adopt routine inquiry/required request policies and procedures for identifying potential organ and tissue donors and for providing next-of-kin with appropriate opportunities for donation.

- The Joint Commission on the Accreditation of Hospitals develop a standard that requires all acute care hospitals to both have an affiliation with an organ procurement agency and have formal policies and procedures for identifying potential organ and tissue donors and for providing next-of-kin with appropriate opportunities for donation.

- The Department of Defense and the Veterans Administration require their hospitals to have routine inquiry policies.

- The Health Care Financing Administration incorporate into the Medicare conditions of participation for hospitals certified under subpart U of the Code of Federal Regulations, a condition that requires hospitals to have routine inquiry policies.

- All state legislatures formulate, introduce, and enact routine inquiry legislation.

- The Commission for Uniform State Laws develop model legislation that requires acute care hospitals to develop an affiliation with an organ procurement agency and to adopt routine inquiry policies and procedures.

3. In regard to living donors and the donor pool, the Task Force recommends that:

- A study of the potential donor pool be conducted using data available through the National Hospital Discharge Survey, supplemented by regional retrospective hospital record reviews.

- Living donors be fully informed about the risks of kidney donation. Health care professionals must guarantee that the decision to donate is entirely voluntary. In the case of all living donors, special emphasis should be placed on histocompatibility.

- A national registry of human organ donors not be established.

4. To improve public education in organ and tissue donation, the Task Force recommends that:

- Educational efforts aimed at increasing organ donation among minority populations be developed and implemented, so that the donor population will come to more closely resemble the ethnic profile of the pool of potential recipients in order to gain the advantage of improved donor and recipient immunologic matching.

- At the regional level, single consortia, composed of public, private, and voluntary groups that have an interest in education on organ and tissue donation should develop, coordinate, and implement public and professional education to supplement, but not replace, activities undertaken by local programs.

- A single organization, such as the American Council on Transplantation, composed of public, private, and voluntary groups that are national in scope and have an interest in education for organ and tissue donation, should develop and coordinate broad scale public and professional educational programs and materials on the national level. This umbrella organization would both develop and distribute model educational materials for use by national and local organizations and plan, coordinate, and develop national efforts using nationwide electronic and print media.

- A national educational program should be established, similar to the High Blood Pressure Education Program of National Institutes of Health's National Heart, Lung, and Blood Institute, aimed at increasing organ donation. This program should include development both of curricula and instructional materials for use in primary and secondary schools throughout the nation, and of programs directed to special target populations, e.g., minority groups, family units, and churches.

5. To improve professional education in organ and tissue donation the Task Force recommends that:

- Medical and nursing schools incorporate organ and tissue procurement and transplantation in the curriculum.

- The Accreditation Council of Graduate Medical Education, the body responsible for accrediting residency programs, include requirements for exposure to organ and tissue donation and transplantation in relevant programs in graduate medical education, such as emergency and critical care medicine and the neurological sciences.

- Each appropriate medical and nursing specialty require demonstration of knowledge of organ and tissue donation and transplantation for certification.

- All professional associations of physicians and nurses involved in caring for potential organ and tissue donors (especially neurosurgeons; trauma surgeons; emergency physicians; and critical care, emergency room, and trauma team nurses), establish programs to educate and encourage their members both to participate in the referral of donors and to cooperate in the organ donation process.

- Organizations of physician specialists who frequently come in contact with organ and tissue donors should establish mechanisms, such as a committee on transplantation, to facilitate communication and cooperation with physicians in the transplantation specialties.

6. The Task Force recommends that organ procurement agencies and procurement specialists be certified:

- Professional peer group organizations, e.g., the North American Transplant Coordinators Organization, should establish mechanisms for certification of nonphysician organ and tissue procurement specialists and standards for evaluation of performance at regular intervals.

- The Department of Health and Human Services should certify no more than one Organ Procurement Agency in any standard metropolitan statistical area or existing organ donor referral area, whichever is larger.

- The Department of Health and Human Services should use the criteria developed by the Association of Independent Organ Procurement Agencies as a guideline to develop consistent certification standards for Independent Organ Procurement Agencies and Hospital-Based Organ Procurement Agencies.

- The Department of Health and Human Services should establish minimal performance productivity standards as part of a recertification process that could be conducted at regular

intervals. Such standards should address procurement activity, organizational structure and programs, staff training and competence, and fiscal accountability.

- Appropriate peer organizations should develop standards for certifying tissue banks and for conducting performance evaluations at regular intervals. Such standards should include assessment of quality and quantity of performance, organizational structure and programs, staff training and competency, and fiscal responsibility.

7. The Task Force recommends that the Department of Health and Human Services collect uniform data on organ procurement activities of all Organ Procurement Agencies, including, at a minimum, the number of kidneys procured, kidneys transplanted, kidneys procured but not transplanted, kidneys exported abroad, and relevant cost data. (The data could be collected through the Organ Procurement and Transplantation Network or from each Organ Procurement Agency.)

- The Department of Health and Human Services require all Organ Procurement Agencies to have, as a minimum, a form of governance that would be similar to that described for the national Organ Procurement and Transplantation Network, i.e., it should include adequate representation from each of the following categories: transplant surgeons from participating transplant centers, transplant physicians from participating transplant centers, histocompatibility experts from the affiliated histocompatibility laboratories, representatives of the Organ Procurement Agencies, and members of the general public. Representatives of the general public should have no direct or indirect professional affiliation with the transplant centers or the Organ Procurement Agency. Not more than 50 percent of the Board of Directors may be surgeons or physicians directly involved in transplantation, and at least 20 percent should be members of the general public. Where the governing boards of existing Organ Procurement Agencies differ from this composition, it is desirable that those boards be modified over a maximum of two years to achieve this distribution. The Task Force believes that all Organ Procurement Agency boards should consider immediate steps to include public representatives.

8. To facilitate more effective collaboration between organ and tissue banks, the Task Force recommends that formal cooperative agreements be established among eye, skin, and bone banks.

- All Organ Procurement Agencies evaluate all potential donors for multiple organ and tissue donation.

- Organ procurement agencies and tissue banks enter into formal agreements for collaborative programs to educate the public and health professionals and to coordinate donor identifications, discussions with next-of-kin, and the procurement process.

ORGAN SHARING

The Task Force believes that establishment of a unified national system of organ sharing that encompasses a patient registry and coordinates organ allocation and distribution will go far in assuring equity and fairness in the allocation of organs. In addition, a national network organization, through adoption of agreed upon standards and policies, may serve as the vehicle both for improving matching of donors and recipients and for improving access of groups at special disadvantage (the sensitized and small pediatric recipients); thus, the outcome of organ transplantation in this country will surely improve. The development of a national network will permit the gathering and analysis of comprehensive data and, through the establishment of a scientific registry, will facilitate the exchange of new information vital to progress in the field. We assisted the Office of Organ Transplantation in developing specifications for a model network, and urge that the National Organ Procurement and Transplantation Network be established promptly; in addition, we urge Congress to appropriate the funds necessary to initiate the development of the scientific registry.

RECOMMENDATIONS

1. The Task Force recommends that a single national system for organ sharing be established; that its participants agree on and adopt uniform policies and standards by which all will abide; and that its governance include a broad range of viewpoints, interests, and expertise, including the public.

- The national network establish a method to systematically collect and analyze data related to both kidney and extrarenal organ procurement and transplantation. Further, to provide an ongoing evaluation of the scientific and clinical status of organ transplantation, a scientific registry of the recipients of kidney and extrarenal organ transplants should be developed and administered through the national network, and the Task Force urges the Congress to appropriate funds to initiate this activity.

- Organ sharing be mandated for perfectly matched (HLA A, B, and DR) donor-recipient pairs and for donors and recipients with zero antigen mismatches (assuming that at least one antigen has been identified at each locus for both donor and recipient).

- A system of serum sharing and/or allocation of organs based on computer-determined prediction of a negative crossmatch, be developed to increase the rate of transplantation in the highly sensitized patient group by increasing the effective size of the donor pool.

- Blood group O organs be transplanted only into blood group O recipients.

- Because of the limited local and regional donor pools available to small pediatric patients, the national organ-sharing system should be designed to provide pediatric extrarenal transplant patients access to a national pool of pediatric donors.

- The national organ-sharing network, when established, should conduct ongoing reviews of organ procurement activities, particularly organ discard rates, and develop mechanisms to assist those agencies and programs with high discard rates. In the meantime, we recommend that the Department of Health and Human Services conduct a study to identify why procured kidneys are not transplanted and why the discard rates vary widely from one organ procurement program to another.

2. The Task Force recommends regional centralization of histocompatibility testing where it is geographically feasible, and standardization of key typing reagents and crossmatching techniques.

3. The Task Force recommends that the Congress appropriate funds to establish a national ESRD registry that would combine a renal transplant registry with a dialysis registry. The Task Force further recommends that the national organ-sharing network be represented on any committee responsible for management and data analysis of a national ESRD registry.

EQUITABLE ACCESS TO ORGAN TRANSPLANTATION

The process of selecting patients for transplantation, both in the formation of the waiting list and in the final selection for allocation of the organ, is generally fair and for the most part has succeeded in achieving equitable distribution of organs. However, the Task Force believes that these processes must be defined by each center and by the system as a whole, and that the standards for patient selection and organ allocation must be based solely on objective medical criteria that are applied fairly and are open to public examination. Moreover, as vital participants in the process, the public must be included in developing these standards and in implementing the policies. We recognized the complex conflict between need for an organ (medical urgency) and the probability of success of the transplant, and did not presume to make recommendations in this sphere; rather we believe that a thoughtful process of development of policies for organ allocation, which takes into

account both medical utility and good stewardship, must take place within a broadly representative group.

The Task Force condemns commercialization of organ transplantation and the exploitation of living unrelated donors. The Task Force also addressed the difficult problem of offering organ transplantation to non-immigrant aliens. Because transplantable organs are scarce, we have recommended that no more than 10 percent of all cadaveric kidney transplants in any center be performed in non-immigrant aliens and that extrarenal transplants be offered only when no suitable recipient who is a resident of this country can be found.* The Task Force also concluded that equitable access of patients to extrarenal organ transplantation is impeded unfairly by financial barriers, and recommends that all transplant procedures that are efficacious and cost effective be made available to patients, regardless of their ability to pay, through existing public and private health insurance or, as a last resort, through a publicly funded program for patients who are without insurance, Medicare, or Medicaid who could not otherwise afford to obtain the organ transplant.

RECOMMENDATIONS

1. The Task Force recommends that each donated organ be considered a national resource to be used for the public good; the public must participate in the decisions of how this resource can be used to best serve the public interest.

2. In order that patients and their physicians be fully informed, the Task Force recommends that:

- **Health professionals provide unbiased, timely, and accurate information to all patients who could possibly benefit from organ transplantation so that they can make informed choices about whether they want to be evaluated and placed on a waiting list.**

- **Information be published annually for patients and physicians on the graft and patient survival data by transplant center. A clear explanation of what the data represent should preface the presentation of data. A strong recommendation should be made in the publication that each patient discuss with his or her attending physician the circumstances of medical suitability for transplantation and where that patient may best be served.**

3. The Task Force recommends that selection of patients both for waiting lists and for allocation of organs be based on medical criteria that are publicly stated and fairly applied.

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*See page 137 for a minority opinion and statement of exception from this recommendation.

- The criteria for prioritization be developed by a broadly representative group that will take into account both need and probability of success. Selection of patients otherwise equally medically qualified should be based on length of time on the waiting list.

- Selection of patients for transplants not be subject to favoritism, discrimination on the basis of race or sex, or ability to pay.

- Organ-sharing programs that are designed to improve the probability of success be implemented in the interests of justice and the effective and efficient use of organs, and that the effect of mandated organ sharing be constantly assessed to identify and rectify imbalances that might reduce access of any group.

4. The Task Force recommends that non-immigrant aliens not comprise more than 10 percent of the total number of kidney transplant recipients at each transplant center, until the Organ Procurement and Transplantation Network has had an opportunity to review the issue. In addition, extrarenal organs should not be offered for transplantation to a non-immigrant alien unless it has been determined that no other suitable recipient can be found.

5. The Task Force emphatically rejects the commercialization of organ transplantation and recommends that:

- Exportation and importation of donor organs be prohibited except when distribution is arranged or coordinated by the Organ Procurement and Transplantation Network and the organs are to be sent to recognized national networks. Even then, when an organ is to be exported from the United States, documentation must be available to demonstrate that all appropriate efforts have been made to locate a recipient in the United States and/or Canada. The Task Force has every expectation that these international organ sharing programs will be reciprocal.

- The practice of soliciting or advertising for non-immigrant aliens and performing a transplant for such patients, without regard to the waiting list, cease.

- Transplanting kidneys from living unrelated donors should be prohibited when financial gain rather than altruism is the motivating factor.

- To the extent federal law does not prohibit the intrastate sale of organs, states should prohibit the sale of organs from cadavers or living donors within their boundaries.

- As a condition of membership in the Organ Procurement Transplantation Network (OPTN), each transplant center be required to report every transplant or organ procurement procedure to the OPTN. Moreover, transplantation procedures should not be reimbursed under Medicare, Medicaid, CHAMPUS, and other public payers, unless the transplant center meets payment, organ-sharing, reporting, and other guidelines to be established by the OPTN or another agency administratively responsible for the development of such guidelines. Failure to comply with these guidelines will require that the center show cause why it should not be excluded from further organ sharing through the OPTN.

- In order to insure that patients in need of an extrarenal organ transplant can obtain procedures regardless of ability to pay, the Task Force recommends that private and public health benefit programs, including Medicare and Medicaid, should cover heart and liver transplants, including outpatient immunosuppressive therapy that is an essential part of post-transplant care.

- A public program should be set up to cover the costs of people who are medically eligible for organ transplants but who are not covered by private insurance, Medicare, or Medicaid and who are unable to obtain an organ transplant due to lack of funds.

DIFFUSION OF ORGAN TRANSPLANTATION TECHNOLOGY

The number of organ transplant centers in this country is rapidly increasing. As the technical aspects of the procedures have been mastered and patient management has become better understood and standardized, it is not surprising that diffusion of this technology has taken place. The issue of designating centers for reimbursement purposes requires careful consideration of many factors, including cost, criteria for facilities, resources, staffing, and the training and experience of personnel. After lengthy debate, the majority of the Task Force agreed with the widely accepted principle within surgery that the volume of surgical procedures performed is positively associated with outcomes and inversely related to cost and believe that this principle applies to organ transplantation procedures as well. Therefore, we recommend that a minimum volume criterion be enforced, together with other criteria defining the minimal requirements for both institutional and professional support and outcome of transplantation procedures.* In the context of scarcity of donor organs, we strongly support regulating diffusion of transplantation technology.

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*See page 139 for a minority opinion and statement of exception from this recommendation.

Recommendations

1. The Task Force recommends that transplant centers be designated by an explicit, formal process using well-defined, published criteria.

2. The Task Force recommends that the Department of Health and Human Services designate centers to perform kidney, heart, and liver transplants, and that the centers be evaluated against explicit criteria to ensure that only those institutions with requisite capabilities are allowed to perform the procedures.

3. The Task Force recommends that the Department of Health and Human Services adopt minimum criteria for kidney, heart, and liver transplant centers that address facility requirements, staff experience, training requirements, volume of transplants to be performed each year, and minimum patient and graft survival rates.

RESEARCH IN ORGAN TRANSPLANTATION

Organ transplantation continues to evolve and improve at a fast pace. Strong research programs in basic and applied clinical sciences have been vital to this fortunate development. As is clearly evident in the concerns of the public that resulted in the enactment of the National Organ Transplant Act, research also is needed in the social, ethical, economic, and legal aspects of organ donation and transplantation. The Task Force acknowledges the important role played by the NIH in transplantation research, and encourages the NIH to coordinate the free flow of information regarding transplant-related research through an interinstitutional council on transplantation. Moreover, we strongly urge that research on all aspects of transplantation be fostered and encouraged and that funding for this vital effort be increased. Therein lies the future of transplantation.

Recommendations

1. The Task Force recommends that basic research continue to receive high priority.

2. The Task Force recommends that both laboratory and clinical research of an applied nature directly related to transplantation also be fostered, encouraged, and increasingly funded. For the immediate benefit of patients, the Task Force further recommends that research be aggressively pursued in organ preservation and optimal immunosuppression techniques. The Task Force also wishes to emphasize the importance of sponsoring prospective clinical trials, involving multiple institutions, to solve certain problems in patient management.

3. The Task Force recommends that continuing attention be devoted to collecting complete information on the status and efficacy of transplantation treatments.

4. The Task Force recognizes that the interaction and exchange of information between the agencies involved in transplantation research and its funding must be encouraged. Therefore, we recommend that the National Institutes of Health be provided with resources to establish an interagency and interinstitute Council on Transplantation that will serve as a focus for this activity.

ESTABLISHMENT OF AN ADVISORY BOARD ON ORGAN TRANSPLANTATION

At the final meeting of the Task Force, where this report was adopted, a recommendation was made to establish a National Organ Transplantation Advisory Board. The Task Force agreed in concept that a national group to advise the Secretary of Health and Human Services would continue to be needed to monitor implementation of the Task Force's findings and serve in an advisory capacity on organ procurement and transplantation issues. Therefore we adopted the following recommendation:

The Task Force recommends that a National Organ Transplantation Advisory Board be authorized and funded to review, evaluate, and advise with regard to the implementation of the recommendations of the Task Force on Organ Transplantation, to serve in an advisory capacity to the Office of Organ Transplantation and to other transplant-related activities of the Department of Health and Human Services, and that this board be established in the Office of the Secretary.

A proposed model for legislation to implement this particular recommendation is appended (see Appendix A). The inclusion of the proposal is meant only as an example and does not imply that the Task Force endorses this model nor the mandate of the Advisory Board.

Midwest Organ Bank

4006 Central • Kansas City, Missouri 64111 • Phone: 816-531-3763

February 16, 1987

Senator Erlich, Members of the Committee:

Since we were unaware of the hearings held previously for Senate Bills 18, 19, 20 and 21, we would like to officially endorse all four bills, in particular Senate Bill 19. I cannot emphasize strongly enough the passage of this piece of legislation.

We are aware of several cases where a patient has died, has been a suitable organ donor, and yet the coroner has refused to give consent for organ retrieval. These cases occured despite the fact that next-of-kin consent had been obtained for organ donation, and that organ retrieval would in no way compromise medio-legal evidence.

The Required Request legislation (HB 3157) passed in Kansas last year has helped increase hospital participation in offering families the option of organ donation. However, if these hospitals obtain permission, and then the coroner subsequently refuses to allow the donation to take place, we have not accomplished our objective.

Passage of Senate Bill 19 will ensure that the intent of Required Request legislation, making more organs available for Kansans who need them, is carried out.

Sincerely,

Jane Warmbrodt

Jane Warmbrodt
Director
Professional Education
Midwest Organ Bank

SP&LW
2-17-87
Attachment 4

TABLE 1

Estimates of the Cost of Coverage for Heart and Liver Transplants
by Private Insurers, Medicare, and Medicaid

Transplant Procedures	Payer	Number of Potential Beneficiaries (in Millions)	Need for Transplantation*	Number of Transplant Procedures Likely to be Performed** Low Est./High Est.		Cost of Coverage (in million) Low Est./High Est.	
Heart	Medicare	30.0	1,800	63	166	$ 6.9	$18.3
	Medicaid	5.6	336	12	31	1.3	3.4
	Private	11.6	696	24	64	2.7	7.0
	Total	47.2	2,832	99	261	10.9	28.7
Liver	Medicare	30.0	1,200	222	318	30.6	43.9
	Medicaid	2.8	112	21	30	2.9	4.1
	Private	11.2	448	83	118	11.5	16.3
	Total	44.0	1,760 (924)***	326 (171)	466 (245)	$45.0 (23.6)	$64.3 (33.8)
					Total costs	$55.9 (34.5)	$93.0 (62.5)

*Estimates of need for heart and liver transplants are based on the incidence of conditions for which such transplant procedures are indicated as derived from national morbidty and mortality data. These estimates are: sixty people per million for heart transplants and forty people per million for liver transplants.

**Estimates of the number of transplant procedures likely to be performed are based on donor organ availability and past experience with organ procurement and suitability of donated organs for transplantation.

***Figures in parentheses represent estimate exluding patients with alcoholic cirrhosis or hepatocellular carcinoma. Estimate of need for this group is twenty-one people per million.

represent "interstate commerce." Therefore, the Task Force adopted the following position on this issue:

> Title III of PL 98-508, prohibits the transfer of any human organ for "valuable consideration that affects interstate commerce." The Task Force urges the appropriate federal officials to strictly enforce this provision. **To the extent that federal law does not prohibit the intrastate sale of organs, the Task Force recommends that states prohibit the sale of organs from cadavers or living donors within their boundaries.** The Task Force also opposes insurance policies that guarantee policy holders priority in receiving human organs for transplantation.

PAYMENT FOR ORGAN TRANSPLANTATION

Costs

The cost of heart and liver transplantation procedures is a major factor in the decision whether or not to seek this treatment. The average cost of a heart transplantation procedure is $95,000 (range: $57,000-$110,000); the average cost of a liver transplantation procedure is $130,000 (range: $68,000-$238,000).[8] Meeting these high costs is a major source of financial and emotional strain for many patients and their families. Unless they are covered by adequate health insurance or by public programs, only the wealthy or those who can raise sufficient funds through public appeals can receive a heart or liver transplant.

Existing Payment Mechanisms

Virtually all kidney transplantation procedures are paid for by Medicare, Medicaid, or private insurance. Medicare also pays for corneal and bone marrow transplants, as well as liver transplants for Medicare eligible children younger than eighteen with biliary atresia or other forms of end-stage liver disease. Medicare does not pay for drugs that are self-administered or given on an outpatient basis, such as the immunosuppressant medications that prevent organ rejection. The Task Force addressed this issue in its October 1985 Report to the Secretary and the Congress on Immunosuppressive Therapies, and recommended coverage of immuno-suppressive therapy. Although HCFA commissioned a major technology assessment of heart transplantation and received the report in May 1985, no decision on Medicare coverage of heart transplantation had been made at the time this report was prepared.

Although state Medicaid programs traditionally have followed Medicare policies in determining what procedures to pay for, this has not necessarily been the practice with organ transplantation. Many states pay for transplantation procedures that Medicare does not cover, usually on a case-by-case, or exception, basis. Thus,

while a state may "cover" a transplantation procedure, in the absence of a formal policy with stated criteria specifying conditions under which such coverage will be provided, there is no assurance that an agreement to reimburse will be either consistently or fairly applied. States without formal policies regarding payment for heart and liver transplants have been reluctant to develop any in the absence of more definitive information regarding long-term costs. In those instances where transplants are paid for, the federal government provides matching funds. Medicaid pays for liver transplants in thirty-three states, heart transplants in twenty-four states, heart-lung transplants in thirteen states, and pancreas transplants in three states. (See Appendix G).

CHAMPUS provides health care benefits for active military personnel, their dependents, and retired military personnel, and pays for kidney, liver, and bone marrow transplants. The medical programs of each of the uniform services either pay for or provide kidney, heart, and bone marrow transplants.

As heart and liver transplantation have become accepted treatments, private insurance programs have begun to offer coverage for these procedures. In general, coverage for extrarenal organ transplantation by private insurers exceeds that provided by the public sector. Private sector coverage is summarized in Table V-1.

Table V-1
Summary of Surveys: Percentage of Respondents Providing Coverage by Transplant Procedures, 1985

	Heart	Heart-lung	Liver*	Pancreas
BC/BS	80	72	84	53
HIAA	85	69	80	57
GHAA (HMOs)	30	23	74	18

*Data on liver transplant coverage include some members who provide coverage only for children younger than eighteen with biliary atresia.

Source: Spring, 1985, membership surveys on organ transplantation issues: the Blue Cross and Blue Shield Association (BC/BS); Health Insurance Association of America (HIAA); and the Group Health Association of America (GHAA).

However, this coverage is not universal and many people do not have policies that pay for organ transplantation procedures. Also, coverage varies considerably among payers. This uneven coverage is the result of a number of influences affecting reimbursement for almost all evolving health care technologies,

including the need for the procedure, the supply and distribution of resources, precedents set by other payers, and public demand. Because these are complicated factors to evaluate, it is difficult for all third-party payers to reach timely or uniform decisions.

The need for a particular transplant procedure is determined by the incidence of disease leading to organ failure and by the effectiveness of the treatment procedure. With improvements in the outcome of the transplant, the indications for the procedure broaden and the number of contraindications are reduced. For example, as transplantation becomes safer, older patients may become eligible to receive an organ, thus greatly increasing the potential pool of recipients. Given that the determinants of need are so dynamic, it is not possible to accurately project the reimbursement risks of third-party payers.

However, transplantation is unique among advanced medical technologies because, in addition to the institutional resources, it also requires a supply of organs. It is the supply of donor organs, rather than institutional or professional resources, that limits the number of transplant procedures that can be performed. Consequently, the costs and reimbursement requirements associated with transplantation are also limited. As long as this limitation exists, third-party payers can have some confidence that, as a whole, reimbursement risks will remain manageable, or at least predictable. Indeed, private insurers have noted that, because of the small volume of transplant procedures performed relative to the number of insured beneficiaries, the incremental increases in insurance premiums due to including transplant coverage have been small, especially when the carrier's risk has been shared through reinsurance. If the supply of organs significantly increases, the effect on reimbursement costs and coverage by third-party payers could be substantial.

Most payers have cited the experimental status of the procedure as the justification for not covering certain transplant procedures. Whether a particular procedure is experimental or is an accepted medical treatment is a professional judgment regarding safety, efficacy, and the long-term outcome of the procedure and is usually determined by peer review. Peer review may be informal and unstructured, such as the gradual accumulation of evidence in the medical literature leading to "conventional wisdom" about the status of a procedure, or it may be a part of a formal, explicit technology evaluation, conducted by an agency such as the National Center of Health Services Research and Health Care Technology Assessment. The major third-party payers each have a process for evaluating health care technology and medical procedures. These processes differ in detail, but all incorporate peer review by medical professionals. These different processes contribute to the lack of uniform coverage for evolving health care technologies, such as transplantation.

For the most part, cost-effectiveness considerations have not been an important factor. The most important factor in determining whether a procedure is covered by either public or private payers is whether it is medically necessary or "reasonable and necessary." An individual policyholder or employee preference or interest could also determine whether a procedure is covered. Once a procedure is determined to be an accepted or necessary medical treatment, it becomes difficult to deny that treatment to beneficiaries on the grounds of cost.

Many medical procedures become eligible for reimbursement by third-party payers as a result of gradual accumulation of ad hoc, unrelated decisions by individual insurers rather than through a formal, directed process. Precedents set by other payers, especially competitors in the private sector, may play an important role in determining whether a procedure is covered. As the largest single payer, Medicare has often been regarded as the most important precedent setter for major coverage decisions. This has not been true for extrarenal transplants however. Private insurers and state Medicaid programs have opted to pay for transplants that Medicare will not cover.

The high public visibility of organ transplantation has exerted considerable pressure on both third-party payers and public officials to find ways of paying for these procedures, particularly when patients have inadequate insurance coverage or no coverage at all. The public perception of transplantation as an acceptable, last-resort treatment for certain end-stage diseases has been a considerable force in increasing reimbursement coverage for these procedures.

ACCESS AND ABILITY TO PAY

Since the passage of the Social Security Amendments of 1972 (PL 92-603), which established the End-Stage Renal Disease Program, patient wealth has not been a major factor in determining who obtains a kidney transplant, except to the extent that immunosuppressant therapy has not been available. However, some patients who meet medical eligibility criteria but lack third-party payer coverage are denied access to heart or liver transplantation because of inability to pay. The Task Force believes that the federal government should ensure that all patients have access to all efficacious organ transplantation procedures, regardless of ability to pay. There are two arguments that support this position. Each is briefly discussed below.

The Commitment of Society to Meet Basic Health Needs

The question of providing extrarenal transplants to those who are unable to pay for them, like questions of funding other health needs, concerns the obligation of society to meet the basic health care needs of its citizens. There is a widespread recognition that the government should ensure access to a decent

minimum or adequate level of health care. The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research held that a standard of "equitable access to health care requires that all citizens be able to secure an adequate level of health care without excessive burdens."[15] Although opinions may differ over what constitutes an "adequate level of care" and "excessive burdens," life-saving procedures that are comparable in cost and efficacy to other procedures that are routinely funded would seem to qualify.

The Task Force believes that heart and liver transplants belong in this category. These procedures are neither experimental nor unproven, but produce outcomes in terms of longevity and quality of life that are equivalent to treatments that are covered by public and private insurance (e.g., treatment of patients with AIDS, certain malignancies, or serious burns). The National Heart Transplant Study found that 80 percent of heart recipients survive one year, and 50 percent are alive at the end of five years, with a good quality of life applying both objective and subjective criteria.[16] Comparable results have also been achieved for liver transplants in several centers.[17]

Given the nonexperimental, established status of heart and liver transplantation, denying coverage under existing private and public health insurance programs has the effect of denying one group of patients the support of society while granting it to others. At a time when treatment for other life-threatening health conditions is paid for without question, it would be anomalous to deny funding for heart or liver transplantation when it is comparable in cost and efficacy.

The recognition that society is obligated to meet the basic health needs of those unable to pay for themselves has been the linchpin of federal policy for the past twenty years. Medicare and Medicaid programs are the result of the federal commitment to eliminate wealth disparity in access to health care. These programs are committed to funding those services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the function of a malformed body member."[18]

The question of wealth discrimination in heart and liver transplantation thus arises in the context of a system that is already strongly committed to meeting basic health care needs, regardless of ability to pay. A strong precedent exists in the 1972 decision to end wealth discrimination in kidney transplantation by funding it through the ESRD program. At that time, the outcome of kidney transplantation was considerably poorer than the outcome of heart or liver transplantation is today. Given this context, and the fact that transplantation of the heart or liver is a "necessary" treatment for certain end-stage diseases in certain patients, it would seem clear that these procedures should be paid for by public and private insurance.

The Task Force is cognizant of the need to conserve health funds and recognizes that it may no longer be possible for public funds to be used to meet the health needs of everyone who qualifies. But the Task Force believes that the burden of conserving public health funds should be spread equally, not borne by one disease group alone. The lack of consistent public and private health insurance coverage for heart and liver transplantation may cause some people with end-stage heart and liver disease to bear the burden of the need to economize in health care costs. A person who has end-stage renal disease would receive treatment, while a person who contracts end-stage liver or heart disease would not. The latter patient therefore is denied equitable access to a life-saving procedure.

The Task Force wishes to emphasize that the recommendation to end wealth discrimination in heart and liver transplantation is not based on a belief that society is obligated to fund every health or medical procedure that might benefit someone. Rather, this recommendation is based on the fact that our society is already committed to funding a wide variety of basic health care needs. Given this commitment, it is arbitrary to exclude one life-saving procedure while funding others of equal life-saving potential and cost. If a transplant or other procedure is not shown to be "reasonable and necessary . . . for the treatment of illness," there is no obligation to fund it. Once a therapy is determined to be medically effective, there would be compelling reasons to fund it under existing public and private insurance programs, providing its cost effectiveness is equivalent to other comparable therapies that are funded. However, it is recognized that private insurers must also consider market forces and demand, including selective offerings and customer willingness to pay for such costly services.

The Special Nature of Organ Transplantation: Organs as a Public Resource

A separate argument for eliminating wealth discrimination in extrarenal transplantation derives from the special nature of organ transplantation--organs are donated by individuals for the good of the public as a whole. Whether or not there is an obligation to provide equal access to health care, it seems unfair and even exploitative for society to ask people to donate organs if those organs will then be distributed on the basis of ability to pay. This argument connects organ procurement with organ distribution and focuses attention on the nature of the gift of a donated organ. Organs are a public resource and all members of the public who need a transplant should have equal access to an organ. This argument offers an independent justification for the societal funding of organ transplants, without building on a general right to health care or on what the society already funds.

When the President's Commission held that there is a "societal obligation" to provide equitable access to health care,

It referred to "society in the broadest sense--the collective American community," which consist of "individuals, who are in turn members of many other, overlapping groups, both public and private; local, state, regional, and national units; professional and workplace organizations; religious, educational, and charitable organizations; and family, kinship, and ethnic groups." Within this pluralistic approach, the President's Commission cited the federal government as the institution of last resort; it held that the "ultimate responsibility" rests with the federal government "for seeing that health care is available to all when the market, private charity, and government efforts at the state and local level are insufficient in achieving equity."[15]

The Task Force concludes that equitable access to extrarenal transplantation means access regardless of wealth. Because of the social commitment to meet basic health needs and the special status of donated organs as a community resource, the Task Force believes that donated organs should be distributed to medically eligible recipients regardless of their ability to pay for the transplant.

Accordingly, the Task Force makes the following recommendations:

Private and public health benefit programs, including Medicare and Medicaid, should cover heart and liver transplants, including outpatient immunosuppressive therapy that is an essential part of post-transplant care. The estimated costs to public and private payers of providing this coverage are summarized in Appendix H.

A public program should be set up to cover the costs of people who are medically eligible for organ transplants but who are not covered by private insurance, Medicare, or Medicaid and who are unable to obtain an organ transplant due to lack of funds. The cost of such a program is estimated in Appendix H.

LIVER TRANSPLANTATION

SINCE THE INTRODUCTION OF CYCLOSPORIN-STEROID THERAPY IN MARCH 1980, THE PITTSBURGH AND NOW THE NEBRASKA LIVER TRANSPLANT TEAMS HAVE AN OVERALL ONE YEAR SURVIVAL RATE OF 69.7% AND A FIVE YEAR SURVIVAL RATE OF 62.8%. LIVER TRANSPLANTATION OFFERS THE POTENTIAL OF A COMPLETE CURE.[1]

INDICATIONS FOR LIVER TRANSPLANTATION:[1,2]

Biliary Atresia
Inborn Errors of Metabolism
Postnecrotic Cirrhosis
Chronic Active Hepatitis
Primary Liver Malignancy
Hepatic Vein Thrombosis
Alcohol-related Cirrhosis (special cases)
Sclerosing Cholangitis

Estimated Need for Pediatric Liver Transplantation in Kansas
(based on 40,000 live births per year)

	Incidence[3]	Cases per year
Biliary Atresia	1:8000 to 1:14000	3 to 5
Metabolic Disease (alpha-1-antitrypsin deficiency most common)	1:1714 to 1:5000	1.2 to 2.5
Neonatal Hepatitis (cirrhosis 50% of cases)	1:8000	2.5
Other		2 (estimated from my practice)
TOTAL		8.7 to 12

Existing Insurance Coverage for Liver Transplantation:[4]

Blue Cross/Blue Shield	Commercial Insurers	State Medicaid Plans
84%	80%	66%

Estimated Total First Year Costs of Liver Transplantation:[4]

Low	High	Average
$68,000	$238,000	$130,000

Cost of Treating End-Stage Liver Disease Without Transplantation:[4]

$35,000 estimated cost per patient for medical and surgical therapy of bleeding esophageal varices

SP&HW
2-17-87
attachment 5

1. Gordon, R., et al: Indications for Liver Transplantation in the Cyclosporine Era. Surg. Clin. N.A., 66:541-556, 1986.

2. National Institutes of Health Consensus Development Conference Statement: Liver Transplantation - June 20-23. Hepatology, 4(Suppl. 1):107s-110s, 1984.

3. Silverman, A. and Roy, C.: Pediatric Clinical Gastroenterology. The C. V. Mosby Co., St. Louis, 1983.

4. Evans, R.: Cost-effectiveness Analysis of Transplantation. Surg. Clin. N.A., 66:603:616, 1986.

State Department of Social and Rehabilitation Services
Testimony Regarding Senate Bill No. 144
Liver Transplantation
Senators: Anderson, Francisco, Hayden, Karr, Martin, Mulich, Parrish and Strick

Mr. Chairman, members of the Committee. My name is John Schneider, Commissioner for Income Maintenance and Medical Programs the State Department of Social and Rehabilitation Services. I am appearing today to express my concerns about adopting Senate Bill No. 144. This legislation, if adopted, would require the Department to reimburse for the performance of liver transplantation for all Kansas Medicaid recipients.

Currently, the Medical Assistance Program does not reimburse for liver transplantation. This is because of the exceedingly high cost involved, and because liver transplantation is a complex medical procedure with frequent complications following surgery.

To reimburse for liver transplantation for one Medicaid recipient would cost the state approximately $96,320 in state funds. This is if there were no complications requiring further medical care. The most costly part of liver transplantation is the follow-up care and the frequent complications. The immunosuppressive drug used for this costs $51,000 annually for one individual. This drug cannot be competitively bid so as to reduce costs because there is only one manufacturer. Every individual having a transplant must take the immunosuppressive drug the rest of his or her life. The life expectancy of an individual receiving a transplant is unknown. It is rare that complications do not occur. You may recall the child in Chicago that recently had three liver transplants. One Medicaid recipient in another state incurred expenditures of over $1 million following the transplantation.

Kansas could expect to have a statistical average of six liver transplantations per year if the Medicaid Program is expanded to cover this procedure. $96,320 (the cost for one individual) multiplied by six is $557,920 (in all state funds if there were no complications). This amount to $1,290,000 per year if the state share is federally matched. This is detailed as follows:

	State	Federal	Total
Surgeon	$ 67,200	$ 82,800	$ 150,000
Hospital	107,520	132,480	240,000
Assistant Surgeons	29,568	36,432	66,000
Anesthesiology & Other Physicians	40,320	49,680	90,000
Immunosuppressive Drugs	137,088	168,912	306,000
Other Drugs	40,320	49,680	90,000
Laboratory & Radiology	67,200	82,800	150,000
Medical Evaluation - Post Operative	48,384	59,616	108,000
Other Costs	40,320	49,680	90,000
Total Cost Per Year	**$577,920**	**$712,080**	**$1,290,000**

S PH & W
2-17-87
attachment 6

The Department could support coverage of liver transplantation for children and adolescents twenty-one years of age and under and who are in the Early & Periodic Screening, Diagnostic & Treatment Program, and for whom the procedure is no longer experimental, if there was not such a tremendous shortage of funds for the rest of the Medicaid Assistance Program. Many needed services for some recipients are no longer covered. Other services are virtually unavailable because providers are discontinuing participation in the Medical Assistance Program due to inadequate funding.

If liver transplantations were to be reimbursed, coverage should be confined to transplant centers that meet national criteria. One such center is at University of Nebraska in Lincoln. These centers have established criteria for determining which transplants should be approved and which ones should be denied. This is a decision that can only be made with the expertise of the surgeons and other physicians involved.

Because of the exorbitant cost of this procedure, and because it is still fraught with problems and complications, the Legislature is encouraged to not cover liver transplants at this time, unless it is able to sufficiently fund other needed services of the Medical Assistance program for Kansas elderly, disabled and poor.

John A. Schneider
Commissioner
Social and Rehablitation Services
296-3271
February 13, 1987

JAS:LKK:plk

6-1

KANSAS DEPARTMENT OF CORRECTIONS

JOHN CARLIN — GOVERNOR • • MICHAEL A. BARBARA — SECRETARY

KANSAS STATE PENITENTIARY
P.O. BOX 2 • LANSING, KANSAS • 66043
• 913-727-3235 •

HERB MASCHNER - DIRECTOR

February 12, 1987

Senator Roy Ehrlich
Box 35
State Capitol
Topeka, Kansas 66612

Dear Sir:

Per our conversation this date, the Penitentiary contracts with two local optometrists. They are governed by the same rules and regulations as elsewhere. Basically they perform optical examinations and write optical prescriptions for glasses. They also test for glaucoma. If they recommend a prescription medication, the doctor receives the referral and he will prescribe as needed. All inmates in need of ophthalmological treatment are referred to Kansas University Medical Center. The referrals are made both by the optometrists and our own physicians.

I hope this answers your questions. If I can be of further assistance, please contact me.

Sincerely,

Marilyn Belshe

Marilyn Belshe
Infirmary Administrator

MB:jal

cc: Dave McKune DDSS

SP&W
2-17-87
attachment 7