Withdrawal/Redaction Sheet
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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. letter	Eugene Epstein to President Clinton (partial) (1 page)	02/19/1999	P6/b(6)
002a. memo	Lisa Gilmore to Devorah Adler re; phone number (partial) (1 page)	04/09/1999	P6/b(6)
002b. letter	Deborah Maurer to Lisa Gilmore re: phone number (partial) (1 page)	03/31/1999	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20469

FOLDER TITLE:
Organ Donation [Folder 2]

2012-0463-S
rc803

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Withdrawal/Redaction Marker
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cc: Bruce Reed

Sir Eugene Epstein
Lady Marlene Epstein
P6/(b)(6)

[001]

Call

CHRIS-
What's this?
-BR

The White House
President William Clinton
attn;
John Podesta
Chief of Staff
February 19th 1999

Dear John;

P6/(b)(6)
P6/(b)(6)

[illegible] of the [illegible] Department at the University of Pennsylvania hospital. He thanked me and said he would pray for its adoption since thousands of lives would be saved each year.
I know how busy you are and that you were passing it on to Bruce Reed but I have heard nothing. Each day another ten people will die without an organ donor. *

On another subject. With computer technology available today manufacturers of hand guns and rifles should test fire each and computer enter the rifling marks. This will then identify every bullet to its owner. It will then stop those buying guns for others for it will be traced to back to them. There will not be such a great need to find the weapon in homicide cases.

This would be a great idea for the President to claim and push for. What do you think ?

As always my sincerest regards to both of you.

Gene

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Deputy Secretary
Washington, D.C. 20201

FACSIMILE

DATE March 29, 1999

TO: (NAME, ORGANIZATION, CITY/STATE AND PHONE NUMBER):

Ms. Deborah Adler
(202) 456-5707

FROM: (NAME, ORGANIZATION, CITY/STATE AND PHONE NUMBER):

U.S. Department of Health and Human Services
Office of the Secretary

LISA A. GILMORE, MSW, MBA
Special Assistant to the Deputy Secretary

H.H. Humphrey Bldg., Room 614G
200 Independence Avenue, S.W.
Washington, DC 20201

(202) 690-6133
Fax (202) 690-7755
lgilmore@os.dhhs.gov

RECIPIENT'S FAX NUMBER (202) 456-5557

NUMBER OF PAGES TO SEND (INCLUDING COVER SHEET): 8

COMMENTS:

As requested, Thanks!

Lisa

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Deputy Secretary

Washington, D.C. 20201

MAR 29 1999

MEMORANDUM

To: Devorah Adler
Domestic Policy Council

From: Lisa A. Gilmore
Special Assistant to the Deputy Secretary

Subject: Request for information on 1998 donation trends

As you requested earlier today, attached is a draft HHS/UNOS press release on the 1998 donation trends to be issued in conjunction with the proposed event and an analysis by UNOS of the 1998 increase. We will be updating the June 17, 1998 press release on the National Organ and Tissue Donation Initiative to include information on new partners and other HHS activities, including the grant program and the HCFA Hospital Conditions of Participation. As soon as I receive confirmation on our new partners, I will forward the information to you.

The preliminary statistics indicate that the number of cadaveric organ donors increased 5.1 percent in 1998 to 5,759 donors, up from 5,479 donors in 1997. This was the first substantial increase since 1995. Reflecting a trend toward older donors over the past decade, the largest increase in 1998 was in older donors. By region, the central United States had the most substantial increase in donors last year. These are preliminary figures and will be revised in the months to come as the organ procurement organizations submit written forms providing more detailed information. The overall rate of increase is not expected to change significantly, however.

In addition, we are ready to announce preliminary results from a groundbreaking $2.3 million study on why families refuse consent to donate a deceased relative's organs. The study confirms the central focus of the National Organ and Tissue Donation Initiative, namely, that family discussion is critical for increasing consent. Conducted by researchers at Case Western Reserve University and the University of Pittsburgh and funded by HHS' Agency for Health Care Policy and Research, the study is the largest and most comprehensive study of the factors affecting organ procurement to date. It has been conducted in nine hospitals in two states and directly reviews the procurement request process with families and the health professionals who ask for donation.

Initial results indicate that:

- The pattern first observed five years ago is virtually unchanged, with 47.5% of families agreeing to organ donation while 52.5% refuse.

- However, the reasons for refusal and the circumstances that encourage this high refusal rate are becoming clearer. Initial attitudes are key: for example, 82% of the families who were initially pro-donation consented to organ donation, but only a tiny fraction of those who initially believed they did not want to donate (7%) eventually changed their minds and donated organs. Moreover, less than half (40%) of families who reported that they were undecided about organ donation finally decided to donate.

- There's a critical need for family discussions about donation: 95% of families indicated how knowledge of their loved one's wishes would have exerted substantial influence upon their decisions. Unfortunately, only 43% of these families had at least on one occasion explicitly discussed organ donation with their loved ones, and less than 25% even knew if their loved ones carried donor cards.

- The researchers conclude that education campaigns that specifically enhance attitudes toward donation, and disseminate knowledge among the general public before, rather than while they are confronting a stressful situation, promise to greatly improve rates of consent.

Attachments:
(1) Draft Fact Sheet: Organ Donations Increase in 1998
(2) Donation Trends

cc: Campbell Gardett, ASPA
Charlotte Mehuron, HRSA

DRAFT 3/25/99

DRAFT

FOR IMMEDIATE RELEASE
(once cleared)

Contact: HRSA Press Office
301-443-3376
UNOS Press Office
(XXX-XXX-XXXX)

Increase in 1998

ORGAN DONATIONS [redacted]

The U.S. Department of Health and Human Services and the United Network for Organ Sharing announced today that preliminary data shows that cadaveric donors increased 5.1 percent in 1998, the first substantial increase since 1995.

Donations increased from 5,479 cadaveric donors in 1997 to 5,759 cadaveric donors in 1998. As many as ~~15,000~~ organ and tissue transplants are the estimated results from these additional donors.

"More Americans are hearing about the need for organ donation, and more are responding with the gift of life," said HHS Secretary Donna E. Shalala. "But we need to maintain and accelerate this trend. The need for organs is still far greater than the supply, and too many patients still die while waiting for a transplant."

The increase came in the first year following the launch of the Clinton Administration's National Organ and Tissue Donation Initiative. Announced by Vice President Gore December 15, 1997, the initiative brings together dozens of partner groups, along with the nation's organ procurement organizations and the Coalition on Donation, to encourage donation. The special emphasis of the campaign is pointing to the need to tell family and others about the desire to be a donor.

"We're letting people know that signing a donor card is not really enough. You have to tell your family," Secretary Shalala said. "It's families and loved ones who must make the decision to consent to donation, and their decision often is made under the most difficult circumstances. That decision is made much easier if the individual has told them in advance that he or she would want their organs to be offered for transplantation."

Donation increases were substantial for Caucasian (6.2 percent from XXXX to XXXX) and Hispanic (6.3 percent from XXXX to XXXX) donors. The number of African-American

DRAFT

donors remained relatively unchanged (give number), and the number of Asian donors decreased 9.4 percent (106 to 96).

Donors increased for all age ranges, but the largest increase was in older donors age 60 and above (9.9 percent from 706 to 776). Donors age 40 to 59 increased by 8.7 percent (1,782 to 1.935). Donors age 20 to 39 increased by 2.2 percent (1,653 to 1.690) and age 0 to 19 increased only slightly by 1.4 percent (1,339 to 1,358).

At the same time, waiting lists in 1998 climbed to XXXXX from XXXX in 1997, and the gap between supply and demand for organs continued to widen.

"An increase in donations gives us added incentive to find out what works and replicate it across the country," said Claude Earl Fox, M.D., M.P.H., administrator of the Health Resources and Services Administration, the HHS agency with national responsibility for overseeing the organ donation and transplantation system. "Our plan is to evaluate good, creative programs so we'll know where to focus future efforts."

Over the last 3 years, May has had the largest number of donors, and this was true in 1998, with 523 donations. A week in mid-April is traditionally set aside to celebrate National Organ Transplant and Donation Week. This year it is April 18-24. HHS will begin the week with a National Donor Recognition Ceremony in Washington, D.C. April 17-18 where donors and donor families will be recognized for their gifts allowing others to continue healthy, productive lives. Local organ procurement organizations plan special events in all parts of the country to highlight NOTDAW and bring attention to the need to make the choice to donate and tell one's family.

The largest increase in donations occurred in the central region of the U.S. UNOS Region 10 (Michigan, Indiana and Ohio) had the largest increase at 12 percent (numbersXXX). UNOS Region 8 (Iowa, Missouri, Nebraska, Kansas, Wyoming and Colorado) increased by 11.1 percent (numbersXXXX), and Region 4 (Oklahoma and Texas) increased by 9.1 percent (numbersXXXX). ***Note to UNOS: do you have it by state so that we can show which states had the largest increase??***

(Quote from Pfaff for UNOS)

DRAFT

This preliminary 1998 data was produced by UNOS from Organ Procurement and Transplantation Network and Scientific Registry of Transplant Recipients statistics, under its contract with HHS' Health Resources and Services Administration.

(Howard Nathan quote on Coalition on Donation)

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Note: HHS press releases are available on the World Wide Web at : http://www.hhs.gov. (UNOS web site address)

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1998 Donation trends

- Based on *preliminary* 1998 statistics, the number of cadaveric donors increased 5.1% from 1997 to 1998 (5,479 donors to 5,759 donors). This was the first substantial increase since 1995.

- The number of Caucasian and Hispanic donors increased substantially (6.2% and 6.3%, respectively), but the number of African-American donors remained relatively unchanged and the number of Asian donors decreased 9.4% (106 to 96).

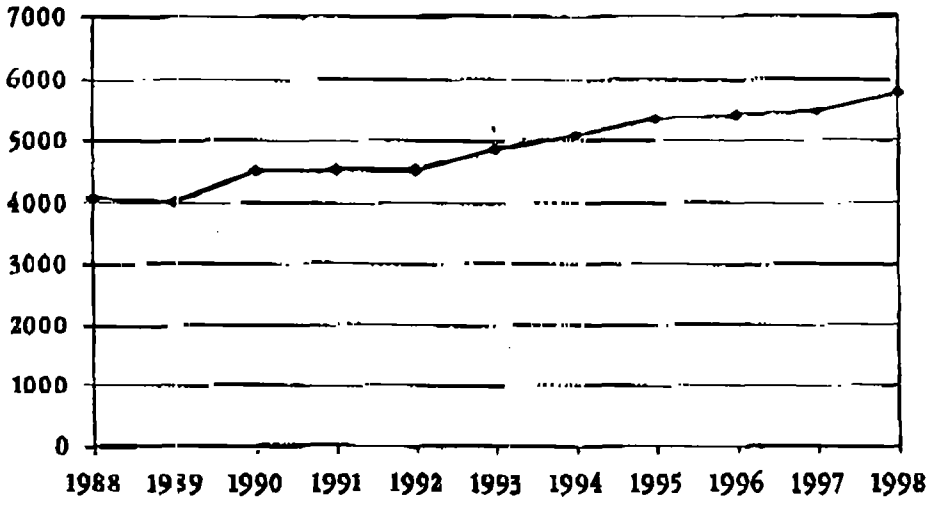
- Male donors increased by 3.3% (3,247 to 3,355) and females increased by 7.7% (2,232 to 2,404).

- While donors increased in all age ranges, the largest increase was in older donors. Donors age 60 and above increased by 9.9% (706 to 776). Donors age 40-59 increased by 8.7% (1,781 to 1,935). Age 20-39 only increased by 2.2% (1,653 to 1,690) and age 0-19 increased by only 1.4% (1,339 to 1,358).

- While donor numbers vary considerably by month, May had the largest number of donors in 1998 with 523. Over the last three years, the highest monthly total of donors has occurred in May.

- The central region of the U.S. had the largest increase in donors. UNOS Region 10 (Michiga, Indiana and Ohio) had the largest increase (12%). UNOS Region 8 (Iowa, Missouri, Nebraska, Kansas, Wyoming and Colorado) and Region 4 (Oklahoma and Texas) were not far behind with respective increases of 11.1% and 9.1%.

U.S. Cadaveric Organ Donation, 1988-1998



DRAFT

Percentage of Cadaveric Organ Donors by Age Range, 1997-1998

Donor Age Range	1997	1998
0-19	24.4%	23.6%
20-39	30.2%	29.4%
40-59	32.5%	33.6%
60 and older	12.9%	13.5%

Percentage of Cadaveric Organ Donors by Race, 1997-1998

Donor Race	1997	1998
White	75.6%	76.3%
Black	11.8%	11.3%
Hispanic	10.1%	10.2%
Asian	1.9%	1.7%
Other/Unknown	0.6%	0.5%

Percentage of Cadaveric Organ Donors by Gender, 1997-1998

Donor Gender	1997	1998
Male	59.3%	58.3%
Female	40.7%	41.7%

Note: percentages may not total to 100 percent due to rounding of decimals.

Based on preliminary UNOS OPTN/Scientific Registry data as of March 19, 1999. Totals subject to change due to future data submission or correction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Deputy Secretary

Washington, D.C. 20201

FACSIMILE

DATE April 9, 1999

TO: (NAME, ORGANIZATION, CITY/STATE AND PHONE NUMBER):

Ms Devorah Adler
(202) 456-5707

FROM: (NAME, ORGANIZATION, CITY/STATE AND PHONE NUMBER):

U.S. Department of Health and Human Services
Office of the Secretary

LISA A. GILMORE, MSW, MBA
Special Assistant to the Deputy Secretary

H.H. Humphrey Bldg., Room 614G
200 Independence Avenue, S.W.
Washington, DC 20201

(202) 690-6133
Fax (202) 690-7755
lgilmore@os.dhhs.gov

RECIPIENT'S FAX NUMBER (202) 456-5557

NUMBER OF PAGES TO SEND (INCLUDING COVER SHEET): 14

COMMENTS:

As we discussed. Thanks!

Lisa

Solidarity House
8000 EAST JEFFERSON AVE.
DETROIT, MICHIGAN 48214
PHONE (313) 926-5000
FAX (313) 823-6016

INTERNATIONAL UNION, UNITED AUTOMOBILE, AEROSPACE & AGRICULTURAL IMPLEMENT WORKERS OF AMERICA—UAW

STEPHEN P. YOKICH, *PRESIDENT* RUBEN BURKS, *SECRETARY-TREASURER*

VICE-PRESIDENTS: ELIZABETH BUNN • RON GETTELFINGER • BOB KING • JACK LASKOWSKI • RICHARD SHOEMAKER

April 1, 1999
Via Facsimile

To: Lisa Gilmore

From: Chuck Gayney, Director, UAW Social Security Department

RE: National Organ and Tissue Donation Initiative

Attached is a copy of Steve Yokich's letter to Kevin Thurm. I trust this is sufficient for your needs.

I've also attached a copy of the UAW Resolution on Health Care which was adopted by our delegates last Tuesday at our Collective Bargaining Convention.

CG:df
opeiu494
Att.
c: Jim Carpenter

NATIONAL DONOR DAY

March 31, 1999

Kevin Thurm
Deputy Secretary
U.S. Department of Health and Human Services
Fax (202) 690-7755

Deputy
Dear Secretary Thurm,

The UAW takes great pride in being founder and a primary force in National Donor Day. This year's drive in February increased both blood donations and bone marrow typings for entry into the National Marrow Donor Registry by nearly 50% over the inaugural 1998 National Donor Day event.

In concert with our National Donor Day commitment, the UAW is pleased to join the National Organ and Tissue Donation Initiative and lend its support to National Organ and Tissue Donor Awareness Week, April 18-24. We will assist by getting the word out to UAW members across America of the critical need for organs for transplantation. We know that at any given time those awaiting organ transplant include union brothers and sisters.

We applaud the efforts of the U.S. Department of Health and Human Services in assisting with National Donor Day, and we recognize that your Initiative is one-in-the-same with National Donor Day in its goal of building public awareness of the need for life-saving organ and tissue donation. Working together, we can make a very real impact in helping the over 60,000 persons who current await organ transplant, and we look forward to the whole of AFL-CIO joining the National Organ and Tissue Donation Initiative as well.

Yours truly,

Stephen P. Yokich
President

6325 Canoga Avenue, Suite 1600 Woodland Hills, CA 91367 USA Telephone: (800) 738-1617 Fax (818) 595-1012

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HEALTH CARE

For almost half a century, the UAW has been at the forefront of progressive change in health benefits coverage. Our efforts at the bargaining table and in the policy arena have helped lead the way to important and cutting edge advances in health care coverages.

The ongoing crisis in health care costs continues to pressure our negotiated benefits and programs while also eating away at wage gains and job security protections. In this round of bargaining, we must continue to work to assure that health protection begins when work begins and continues through layoffs, disability and any other circumstances that cause loss of coverage. That should encompass benefits for new family configurations, including coverages for dependents up to age 25 and domestic partner relationships.

The health care cost crisis is aggravated by employer practices designed essentially to save money through cost-shifting to workers and beneficiaries by means of copayments, deductibles and premium sharing and the elimination of previously covered benefits. Numerous employers are also using changes in Financial Accounting Standards Board rules for post-retirement benefits as an excuse to cut retiree benefits.

Employers are not the only payers seeking to shift costs and cut benefits. Funding for the Medicare program has been substantially cut. Medicare beneficiaries are increasingly confused and unprotected by managed care options and defined contribution plans that have been poorly implemented and inadequately funded. Health Maintenance Organizations are also pulling out of markets or slashing benefits or both. Just last fall, HMOs abandoned over 400,000 seniors because of funding cutbacks in the Medicare program.

As cost pressures push private employers and public payers and conservative policy makers to pursue cost-shifting, benefit cutbacks and a privatization agenda, our tasks are clear: We must vigilantly protect our hard-won gains from employer and government attacks by holding the line on cost sharing and stepping up our demands for improved quality and access.

One critical consumer area largely neglected by the health system is organ donation. Today, thousands of people die and thousands more are on organ donor waiting lists even though, for many conditions, enough organs are available to meet demand. Though the government has recently taken tentative steps in this area, our bargaining efforts can promote awareness and education on this issue among UAW members and families as well as in the broader community.

The UAW helped pioneer the development of quality standards for managed care plans. These standards have been largely adopted by the major managed care accreditation bodies and form the basis for UAW HMO qualification status. Today, the UAW is raising the quality bar even further. We are working to assure that HMOs, and other delivery systems, implement evidence-based guidelines that eliminate inappropriate variation in care so that, for example, a woman diagnosed with breast can-

Resolution adopted March 31, 1999 at UAW Collective Bargaining Convention.

cer in Los Angeles will not face a different set of treatment options than a woman with the same diagnosis living in Buffalo. We are working to put reliable consumer information about physicians, facilities and outcomes into the hands of UAW members and families through various report card projects. And we are developing voluntary wellness programs for patients with, or at risk for, certain chronic conditions such as diabetes, heart disease and asthma. Affected members and their families can access information and resources to help them manage and improve their health status.

Over the past several years, pharmaceutical research has resulted in some truly important and remarkable technological advances in the biomedical sciences. Not only are new drugs leading to more effective, less invasive treatment and reduced hospitalizations, but they are also proving to be powerful agents of prevention. As costs and utilization are shifted from the hospital care sector to the pharmaceutical component, many employers are using higher drug costs as an excuse to raise copays and deductibles in our prescription drug programs, thereby shifting those costs to workers while ignoring the cost savings and benefits of shorter hospital stays. Such shell games must be resisted.

Improving the quality of health care for UAW members and families requires vast quantities of data and sophisticated information technologies for interpreting such data. But while health information technology promises quality and cost improvement, it also threatens privacy and confidentiality. The same information that identifies an individual for improvement in care, can also potentially identify a person for other purposes. Limited data is needed for audit purposes. All other patient-identifiable data must remain in the clinical care setting, and severe penalties must be established for its misuse.

The UAW has pioneered a program that links evidence-based medical science to community health status improvement: the "Community Health Care Initiatives." This program is coordinated by the UAW Center for Community Health Care Initiatives. Together with employers, government, purchasers, providers, consumers and other interested parties, the UAW has been encouraging and initiating collaborative community activity and organization to bring health care resources into balance with a community's needs. Focusing on quality and access to care, a community working together can reform the delivery system to provide a better quality of life, enhance access, and encourage cost-effective use of resources for the benefit of the entire community.

Pilot projects have been initiated by CHCI in six communities with major UAW represented employers. It is anticipated that these community initiatives will stimulate reform of the entire health care delivery system at the place health care services are actually delivered — in the community — and help achieve the goal of high quality, cost-effective health care for all.

Though the health care scene changes daily, we must continue to pay attention to what matters most. We must protect the health care coverage of retirees and working families and we must continue to protect our hard won gains from employer attacks by negotiating programs that improve quality, control costs, assure access

to care and hold the line on cost sharing. High quality care, delivered in an appropriate and timely manner, on the basis of scientific evidence, is the best way to contain costs.

Areas of focus for this round of bargaining will include:

- Updating and expanding coverages to include new developments and health care technologies, closing gaps in existing coverages and adjusting benefit entitlements for increases in inflation.

- Resisting employer efforts to shift additional costs to workers and restoring wages and benefits lost from past cost shifting.

- Continuing and expanding of the Community Health Care Initiative activities in the pilot sites, establishing of new CHCI sites, and including all UAW employers within the CHCI program.

- Expanding efforts to collect and disseminate easily understood information about health plans, professionals and facilities.

- Establishing in all UAW collective bargaining agreements the right to confidentiality of health information, including the right to review and amend records.

- Establishing organ donation committees at each UAW facility.

- Assuring access to pharmaceutical innovation and drug therapies while promoting appropriateness, effectiveness and affordability.

- Increasing to 25 the age for which health care coverage is extended to dependents.

- Extending health care coverage to domestic partners.

- Addressing the issue of AIDS in the workplace and the community, providing safe workplaces for those workers most often exposed to the virus, and assuring health coverages keep up with technology and the changing nature of the disease.

- Expanding and improving benefits at nonmajor employers to include the full array of benefit plans and financing and delivery options as found at major employers.

- Providing continuing health care coverage in the case of full or partial plant/workplace closings as a benefit in all UAW collective bargaining agreements.

- Preserving the right to a choice of health care providers that assures access to appropriate, high-quality health care.

Organ & Tissue
COALITION ON DONATION
Share your life. Share your decision.®

Fax

To:	Lisa Gilmore	**From:**	G. David Fleming
Fax:	202-690-7755	**Pages:**	2
Phone:		**Date:**	03/30/99
Re:		**Phone:**	804-330-8540

☐ **Urgent** ☐ **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

• Comments:

Dear Lisa:

To follow is the letter of commitment from MBNA Bank America. They are very excited about the opportunity and the opportunity to work with the Initiative.

For your information, the partnership with MBNA has not been announced to the public, nor have they started marketing the Organ & Tissue Donor Visa. I think the event will be a great way to announce the card, and MBNA's commitment to increasing donation through joining the National Initiative.

Please call with any questions.

MBNA Marketing Systems, Inc
11337 McCormick Road
Hunt Valley, Maryland 21031

March 30, 1999

Hon. Donna E. Shalala
Secretary of Health and Human Services
Washington, D.C. 20101

Dear Secretary Shalala:

In the fall of 1998, MBNA America Bank and The Coalition on Donation joined forces to help raise awareness about the need for organ & tissue donation and to help benefit the more than 60,000 Americans waiting for life saving organ transplants.

Our commitment to the cause of organ and tissue donation led to the joint development of The Coalition on Donation Visa credit card program. By having supporters use The Coalition on Donation Visa card, MBNA America Bank contributes a portion of the purchases to fund efforts to educate the public about the critical need for organ & tissue donors.

As a member of The Coalition on Donation, MBNA America Bank is honored to join the National Organ and Tissue Donation Initiative. We look forward to being a part of the solution to solving this national health crisis.

Sincerely,

Michael J. Flynn
Senior Vice President

Organ & Tissue
COALITION ON DONATION
Share your life. Share your decision.®

Fax

To:	Lisa Gilmore	**From:**	G. David Fleming
Fax:	202-690-7755	**Pages:**	4
Phone:		**Date:**	04/06/99
Re:		**Phone:**	804-330-8540

☐ **Urgent** ☐ **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

• Comments:

To follow is the letter of commitment from Aetna U.S. Healthcare. I have spoken with David Murphy, Director of Corporate Advertising, and they are extremely excited about this opportunity. They are currently in the process of working out the details for how they might include a designation for organ & tissue donation on their insurance cards. It will most likely be a sticker that the card-holder can affix.

I am scheduled to meet with them in the next week to finalize their participation with the U.S. Sports Council on Donation. It looks as if they will be joining as the first corporate partner and it will be in time to announce at the press conference.

I have also spoken with Jeff Marx and he is confident that we will be able to get Carl Lewis to participate in the press conference as a representative from the Sports Council if desired.

Thanks again for all the hard work! Please call with any questions.

980 Jolly Road
P.O. Box 1180
Blue Bell, PA 19422

Tim Nolan
215-775-5190 Fax: 215-775-6401

April 6, 1999

Donna E. Shalala
Secretary of Health and Human Services
Washington, D.C. 20201

Dear Secretary Shalala:

As the nation's leading health and related benefits organization, Aetna U.S. Healthcare recognizes our responsibility to provide education on key health issues to our members and the public at large.

Our company has been actively involved with the California Transplant Donor Network in educational efforts over the past year. Through this sponsorship we have helped to reach many Californians, heightening their awareness of the importance of organ and tissue donation. This year we are expanding our sponsorship into Southern California and Washington State.

We believe that, in conjunction with the Department of Health and Human Services, we can help to extend these efforts nationally. We have discussed the possibility of embarking on a program to provide educational information about organ and tissue donation to our constituents across the country: including more than 200,000 participating doctors, hospitals and other health care providers in our network; the plan sponsors we serve; and the approximately 16 million members and 25,000 employees we reach. Indeed, we authorized coverage for approximately 2,000 solid organ and bone marrow transplants for members last year, attesting to our commitment to organ donation and transplants. Targeting these audiences with the message of the importance of organ and tissue donation can give impetus to a campaign to spread this important information throughout the country.

We would be honored to join the National Organ and Tissue Donation Initiative, and look forward to a partnership with both the Department of Health and Human Services and the Coalition on Donation. We plan to meet with the Coalition on Donation in the near future to clarify how we might work collaboratively on this project.

Sincerely,

Timothy Nolan
Head of Field Organization

Withdrawal/Redaction Marker
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
002a. memo	Lisa Gilmore to Devorah Adler re; phone number (partial) (1 page)	04/09/1999	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20469

FOLDER TITLE:
Organ Donation [Folder 2]

2012-0463-S
rc803

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Deputy Secretary

Washington, D.C. 20201

MEMORANDUM

APR - 9 1999

To: Devorah Adler, DPC

From: Lisa A. Gilmore, HHS

Subject: New partners for the proposed Administration Organ Donation Event

Attached are statements from UAW, MBNA America Bank, Aetna U.S. Healthcare, and Kaiser Permanente confirming that each has joined as a partner of the National Organ and Tissue Donation Initiative and has made a commitment to promoting organ and tissue donation. The four organizations are willing to take part in the proposed Administration announcement and would send a senior official to the event. We also are optimistic of a confirmation from the AFL-CIO shortly. We've gotten positive signals so far, and Kevin Thurm is waiting for a final reply from the organization.

In addition, attached is a letter from the American Hospital Association applauding the efforts of the National Organ and Tissue Donation Initiative. I also have attached information on the newly-expanded Sports Council. It is very likely that Olympic champion Carl Lewis, the founding member of the Sports Council and a featured speaker in our federal employee education video, would participate in the Administration event if invited. The Coalition on Donation also has put in a request to Michael Jordan's agent for him to join the Sports Council and would appreciate it if the White House would invite Mr. Jordan to participate in the proposed event and on the Sports Council. The Coalition on Donation has recently released the second phase of its Michael Jordan campaign, and HHS distributed 15,000 Michael Jordan posters to federal agencies earlier this year. Finally, the National Education Association and United Airlines have expressed initial interest in being partners, and we hope they commit in time for the event.

Given the upcoming First Family Pledge Congress with the American Society of Transplant Surgeons on April 14, the Congressional hearing on April 15, the National Donor Recognition Ceremony on April 18, and the eagerness of the transplant community to promote our news during National Organ and Tissue Donor Awareness Week (NOTDAW, April 18-24), we hope we can release our announcements regarding new partners, the 1998 organ donation increase, and the $5 million extramural support program as early as possible. We are in the process of putting together a video news release for NOTDAW which could focus on the Administration event and be used to amplify our messages to local media nationwide.

I look forward to hearing from you soon. I can be reached at work at (202) 690-6133 or at P6/(b)(6) and at home at P6/(b)(6) Thank you. [002a]

Attachments: (1) Statements from UAW, MBNA America Bank, Aetna U.S. Healthcare, Kaiser Permanente, American Hospital Association

(2) Description of the U.S. Sports Council on Donation

cc: Liz Summy

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
002b. letter	Deborah Maurer to Lisa Gilmore re: phone number (partial) (1 page)	03/31/1999	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20469

FOLDER TITLE:
Organ Donation [Folder 2]

2012-0463-S
rc803

RESTRICTION CODES

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P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
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RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
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b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

KAISER PERMANENTE

National Health Services Contracting

March 31, 1999

Lisa Gilmore
Special Assistant to the Deputy Secretary
Co-Chair, National Organ and Tissue Donation Initiative
U.S. Department of Health and Human Services
Office of the Deputy Secretary
H.H. Humphrey Bldg., Room 614G
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Ms Gilmore,

In response to your request to have Kaiser Permanente partner with the Administrations' National Organ and Tissue Donation Initiative, we are pleased to accept this invitation. In addition, we would also be interested in having this partnership highlighted in any upcoming events.

Kaiser Permanente is committed to communicating within our organization the message of this life saving effort and the critical shortage of available organs for transplantation. We intend to identify systems and processes within our organization that will enable us to educate our members, their families and our employees on the importance of organ and tissue donation. As you noted in your letter, we are taking the first step in demonstrating our commitment to this issue by sponsoring a Kaiser Permanente family to attend the National Donor Recognition ceremony April 16-18th.

Again, thank you for this invitation to partner with you on such an important issue. Please feel free to call me at P6/(b)(6) so we may discuss the next steps with this project.

[0026]

Sincerely,

Deborah A Maurer, RN
Manager, National Transplant Network

Cc: Richard Froh, Government Relations
Beverly Hayon, National Media Relations
Christy Edwards, National Health Services Contracting

April 2, 1999

The Honorable Donna Shalala
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Shalala:

As National Organ and Tissue Donor Awareness Week approaches, the American Hospital Association would like to take this opportunity to applaud the President's and your efforts to heighten awareness of the critical need for increased organ donation. Your willingness to use your resources to reach out to the communities involved in organ donation has sparked a new and positive discussion on the best strategies for encouraging more donations.

Those who work in hospitals witness first hand the miracle of successful donation and the tragedy and frustration of families whose loved ones do not receive organs in time. Because of these experiences, our members work hard to ensure that all potential donors or their families are identified and given the opportunity to donate. In addition to their own individual efforts, hospitals collaborate with their organ procurement organization partners to develop even better methods for increasing organ donations.

However, the efforts of those directly involved are not enough. Your efforts to increase public understanding and awareness through the National Organ and Tissue Donation Initiative are critical. Thank you for your leadership on this issue. We look forward to a continuing partnership.

Sincerely,

Rick Pollack

Rick Pollack
Executive Vice President
Government and Public Affairs

Washington, DC Center for Public Affairs
Chicago, Illinois Center for Health Care Leadership

Liberty Place, Suite 700
325 Seventh Street, N.W.
Washington, DC 20004-2802
(202) 638-1100

National Sports Council

Understanding that approximately 90% of Americans read about, watch, or participate in organized sports on a daily basis, we are enthusiastic about utilizing sports and sports icons to positively influence potential donors.

Instead of recreating the wheel, the Coalition is partnering with the Wendy Marx Foundation (the "Foundation") to increase the reach and effectiveness of the U.S. Sports Council on Organ Donation that was founded by the Foundation in 1992. This volunteer network of professional athletes and other prominent sports figures was established for the single purpose of increasing awareness for the desperate need for organ donations. The initial programs of the Sports Council have been very successful, thanks in large part to the commitment of Olympic champion Carl Lewis, co-founder and board member of the Foundation.

Other charter members of the Sports Council include: U.S. Senator Bill Bradley(former N.Y. Knicks all-star); NBC sportscaster Bob Costas; NFL coach David Shula; and Phyllis George, former CBS sportscaster and Miss America. Recent additions to the sports council include: Leroy Burrell, Olympic gold medallist and world-record holder; Bert Jones, former all-pro quarterback for the Colts; Tom Landry, former coach of the Dallas Cowboys; and the Mickey Mantle Family. We are now in the process of officially adding Michael Jordan; Tony Dungy, head coach of the Tampa Bay Buccaneers; Jerry Rice, all-time NFL leading receiver; Ken Griffey, Jr., Seattle Mariners; Mike Gardner, San Francisco Giants; Rich DeVos, owner of the Orlando Magic and President of Amway Corporation; and Carol Shelby, owner of Shelby Motor Company.

Each of the members of the Sports Council have authorized the use of their name and image for approved use in public awareness activities for the purpose of increasing organ and tissue donations. Please note that their services will be provided free of charge. Current and planned future utilization of the members of the Sports Council include:

- serve as witnesses at celebrity donor card signings;
- guest appearances at special events;
- creation of public service announcements; and
- inclusion in corporate campaigns.

One of the primary strategic objectives of the Coalition and the Sports Council is to recruit corporate partners that wish to participate in a cause marketing campaigns with the members of the Sports Council. These campaigns will be localized by geography, matching the region with a representative member of the Sports Council. Creative elements to such a campaign might include posters, billboards, radio and television spots, brochures and other electronic media elements. Each campaign will be customized. Current corporate partners outside of the transplant community include: Aetna U.S. Healthcare; and Moose International.

FACSIMILE

From the Immediate Office of the Secretary
Executive Secretariat

To: Sena

Fax#: 395-5631

Re:

Date: 7/15/99

Pages: including this cover sheet 25

From the desk of:

- ___ LaVarne Burton
- ___ Sandy Bart
- ___ Kimberly Harold
- ___ Christy Quigley
- ___ Mirtha Beadle
- ___ Scott Boule
- ___ LaJuana Caldwell
- ___ Carlos Cano
- ___ Sean Donohue
- ___ Neleen Eisenger
- X Lorraine Fishback 690-7699
- ___ Johnathan Friebert
- ___ Jackie White
- ___ John Gallivan
- ___ Carlos McCormick
- ___ Martina Varnado
- ___ Ann White
- ___ Melvin Whitfield
- ___ Other ___

Comments: Background information for meeting at 2pm today

U.S. Department of Health and Human Services
Immediate Office of the Secretary- Executive Secretariat

200 Independence Avenue SW
Washington, DC 20201
Fax: 205-8870 or 205-2135

February 26, 1998

The attached letter was sent today by HHS Secretary Donna E. Shalala to 89 members of Congress who have signed letters to her this year concerning the development of regulations on the Organ Procurement and Transplantation Network.

An identical letter went to each of the members.

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

The Honorable
United States Senate
Washington, D.C. 20510

Dear Senator:

Thank you for your recent letter concerning the Department of Health and Human Services' (HHS) consideration of final regulations for the Organ Procurement and Transplantation Network (OPTN). Many members of Congress have written to me to communicate a variety of viewpoints on this topic, and I wish to respond as fully as possible. While I am constrained from discussing details of the regulation prior to publication, I think it is important to share with you the principles which are guiding our development of these rules. In particular, I want members of Congress to understand that I am committed to vigorous efforts to increase organ donation; to all patients having equitable access to organs to the extent medically feasible; and to the leadership of the OPTN in establishing medical criteria for organ allocation.

As you know, organ transplantation provides life-saving and life-enhancing benefits to thousands of Americans every year. American medicine has been a world leader in delivering these benefits, and during the past two decades, patient and graft survival rates have improved markedly. In 1996, some 20,000 transplants were performed -- about 55 each day. This record is a tribute to transplant surgeons and other medical personnel, as well as our organ procurement organizations, and indeed all those who work or volunteer in the field of organ transplantation.

At the same time, however, we have not fully realized the goals of the National Organ Transplant Act of 1984 (NOTA), nor of the report of the Task Force on Organ Transplantation which was developed in response to the Act. NOTA was passed to create a national system in which an adequate supply of organs

would be available on an equitable basis to patients throughout the Nation. On both counts -- the adequacy of organ supply as well as equity in distribution -- I believe we are falling short of the law's expectations.

We continue to have a serious shortage of organs for transplantation, and indeed in recent years, the shortage has grown worse. Some 55,000 persons are on the national organ transplant waiting lists today, up from 16,000 in 1988. More important, about 4,000 Americans died in 1996 -- almost 11 each day -- while awaiting an organ transplant. It is estimated that we are achieving only about a third of our total potential for cadaveric organ donation. Improvement in bringing about organ donation would substantially reduce the number of Americans who die while awaiting a transplant, and that must be our first goal in improving our organ procurement and transplantation system.

In addition, we have not yet achieved many of the important benefits of a national organ-sharing network that were envisioned by NOTA. In particular, we have not achieved equitable distribution to those with greatest medical need. The most visible short-coming is the wide span in average waiting times for those on transplantation waiting lists. In some areas of our Nation, patients wait 5 times longer or more for an organ than in other areas. Less visible but more important are the resulting inequities in who receives organs. Where waiting times are shortest, organs may go to patients who are less ill; while at the same moment, in areas where patients wait longer, organs often are not offered to patients with greater medical need. In the worst case, patients die in areas where waiting times are long, while at the same time organs are being made available to less ill patients in areas with shorter waiting times.

It seems clear to me that in passing NOTA, Congress did not intend for patients in some areas of the Nation to be disadvantaged in this way. NOTA envisioned a national network which would help bring about the most medically effective use of organs and the most equitable treatment of patients possible within the bounds of available technology. Unfortunately, even as technology has improved, making it possible to preserve organs longer and hence offer them over a wider geographic area, the allocation scheme of the OPTN has continued to give preference to local use of organs even if such organs could be used to save the lives of sicker patients located nearby.

For example, in 1996 over 60 percent of livers were used in the local area where they were procured, instead of being used outside the local area. Over 50 percent of these livers went to patients who were not sick enough to be hospitalized, while during the same year almost 400 of the 953 patients who died awaiting transplant were hospitalized at the times of their deaths. Thus, even though technology has increased our capability to share organs over a wider geographic area and thereby give more preference to patients with the greatest medical need, the OPTN allocation scheme has so far failed to take full advantage of that opportunity.

Today, almost 15 years since the passage of NOTA, I believe the time has come to reassess our performance across the board in the area of organ procurement and transplantation, and to bring about the improvements that are so conspicuously needed. In doing so, my purpose is to fulfill the purpose of NOTA while respecting the role of the various players, especially the OPTN. In particular, I fully concur that the transplantation network must be operated by professionals in the transplant community, and that the policies (including allocation policies) of the OPTN should be determined by transplant professionals, in an open environment that includes the public, particularly transplant patients and donor families.

At the same time, I also believe that the Department has an important and constructive role to play, particularly on behalf of patients. Human organs that are given for donation are a public resource and a public trust. It is the responsibility of HHS to ensure that this resource is made available equitably, subject to sound medical practice. Also, as you know and as we made clear both in our Federal Register Notice of 1989 and our Notice of Proposed Rulemaking in 1994, policies determined by the OPTN must be subject to approval by HHS before they can be considered binding on member transplant centers for Medicare and Medicaid participation.

Our first goal, as I stated above, must be to increase the donation of organs for transplantation. While this task is not within the realm of the OPTN regulation, it is nonetheless the most important and productive work that can be done now to save and improve more lives through transplantation. As I hope you are aware, Vice President Gore joined with a large number of national organizations last December to launch a National Organ and Tissue Donation Initiative. Among our partner organizations are the American Medical Association and American Academy of Family Physicians, which will encourage physicians to make donation materials available in their offices and discuss donation with patients; the American Bar

Association, which will encourage members to discuss donation wishes during the preparation of wills and estate planning; the American Association of Health Plans, which will help provide educational materials; and the American Red Cross, which will use its community network to expand public awareness. More than a dozen other national organizations are also committed to help reach particular audiences.

As part of the donation initiative, HHS has also proposed new provisions in the Medicare Conditions of Participation for Hospitals which would enhance the process by which hospitals notify an organ procurement organization (OPO) of those deaths that could potentially result in organ donation. The proposal was suggested by approaches that have already been successful in several states. Based on these experiences, HHS estimates that the number of donors nationwide could increase 20 percent within two years. This would substantially reduce the number of deaths which occur among patients waiting for an organ transplant.

The Department's role is not limited to increasing organ donations. In keeping with the policy announced by the Department in December 1989 and further defined in the 1994 NPRM, the Department's role is also to set a framework for the operation of the OPTN and to provide federal oversight of the processes by which the OPTN allocates organs for transplantation. In developing our policies, we have been guided by a number of principles.

While NOTA provided the broad structure and goals for a national organ transplant network, and while day-to-day operational responsibility was assigned to a private contractor under HHS, there has been too little attention given to defining the expectations that are inherent in the law and applying those expectations to the work of the contractor. This is the role HHS should play. HHS should not seek in the first instance to define specific policies, including organ allocation policies, of the OPTN. But HHS should indeed establish broad performance standards and make clear the desired outcomes which will best serve the Nation. In preparing the regulation, we are developing performance and outcome standards which would be applied to the policies developed by the OPTN. This is the same approach the Department adopted in implementing the organ procurement organization provisions. This approach has had widespread support.

The goal of the performance standards would be to make it possible for patients with the greatest medical need for transplantation to be more accurately identified by the national network and to be put at the head of the list for a

suitable organ. In particular, this means the development of standard patient listing criteria and medical urgency categories that would enable our transplant network to reliably assess the medical condition and need of all patients awaiting transplantation. Our approach would help assure that those who receive organs are those with greatest medical need and that organ allocation policies would result in more equal waiting times (adjusted for severity of illness) across the country.

It is not the desire or intention of the Department to interfere in the practice of medicine. Decisions about who should receive a particular organ in a particular situation involve a subtlety and an urgency which must be dealt with by transplant professionals. The proper HHS role is, instead, to assure that the policy framework within which those decisions are made is one that serves the ends that the law intended. Thus, for example, it may be necessary for the OPTN to construct more uniform medical criteria for the appropriate listing of patients at transplant centers, as well as more uniform criteria for the definition of patient status.

Uniform criteria among centers would help assure equitable treatment for all patients, a clear goal of NOTA that HHS should help achieve. But the Department would look to the OPTN to develop those criteria. Likewise, it may be necessary for the OPTN to develop allocation policies that would make waiting times more equal in the various regions of the Nation. Again, this clearly serves the goals of NOTA. But our regulation would look once more to OPTN to develop the specific, medically-sound policies for achieving this goal. The OPTN is fully capable of developing policies which would advance these goals. HHS does not seek to develop the policies and would not do so unless the OPTN failed to develop satisfactory policies of its own.

Further, in order to inform patient choice and monitor the quality of care at transplant centers, information about transplants and the performance of individual transplant centers needs to be available to patients and physicians in a form that is current and comprehensible. Recently, HHS and the OPTN contractor have experienced disagreements over the release of transplant center data. HHS intends to make data disclosure requirements clearer.

I believe it is time to move forward on these issues. As you know, the policies pertaining to the OPTN have undergone an unusual period of development and an unusual degree of public comment. When the NPRM was published in 1994, a comment period of 90 days was provided, and the Department received comments from 121 individuals and organizations.

In December 1996, an additional three days of hearings were convened, and 110 persons testified. Additional written comments were also received and considered. I am fully committed as we move forward to ensure additional opportunities for comment and Congressional dialogue.

I thank you again for your interest in this important subject. I believe we have made remarkable progress in the field of organ transplantation, and I believe we can keep building and do even better. We can increase organ donation, not only through public awareness but by bringing about better performance by hospitals and OPOs. We can help the Organ Procurement and Transplantation Network operate more effectively by establishing clearer expectations through performance standards that serve the goals embodied in NOTA. And, with the leadership and expertise of the transplant community, we can assure Americans that organ allocation policies are equitable, and that those who need organ transplants will be treated according to medical need, no matter where in the country they may be hospitalized, or at what center they may be listed. I believe we owe them no less.

Sincerely,

Donna E. Shalala

HHS FACT SHEET

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

March 26, 1998

Contact: HRSA Press Office
(301) 443-3376

IMPROVING FAIRNESS AND EFFECTIVENESS IN ALLOCATING ORGANS FOR TRANSPLANTATION

Background

Since the enactment of the National Organ Transplant Act of 1984, American medicine has been a world leader in organ transplantation. More people are benefiting from organ transplants and their survival rates are steadily improving. In 1996, some 20,000 Americans--about 55 each day--gained a new lease on a better life through transplantation. At the same time, the rapid development of transplant procedures and growth in the organ transplant system have brought new challenges:

- *The demand for organs for transplantation far exceeds the supply. Some 4,000 people--10 people every day--die in the U.S. while waiting for a donated kidney, liver, heart, lung or other organ.*
- *In March 1998, approximately 54,500 people were on the national transplant waiting list, and the list grows by about 500 each month.*
- *Despite technological advances in preserving organs, the system for allocating scarce organs (especially livers) remains weighted to local organ allocation, instead of broader regional or national allocation according to medical need. A patient who is less ill in one geographic area with a short waiting list may get a matching organ before a patient whose condition is more medically urgent in another area with a longer waiting time.*
- *Medical criteria for listing patients and assessing their status vary from one transplant center to another, making it difficult to objectively compare the medical need of patients awaiting organ transplantation in different centers and different areas of the country.*
- *While much data is available today, there is still a need to provide for more current and usable data collection and dissemination to help patients and doctors in measuring quality and making transplant decisions.*

The Regulation

The National Organ Transplant Act of 1984 envisioned a national transplant system to be operated by transplant professionals, with oversight by HHS to ensure an equitable allocation system in the public's interest. The Act created the Organ Procurement and Transplantation Network, a non-profit private sector network to be operated by a contractor to HHS. Originally, OPTN membership and policies were voluntary. But with enactment of the Omnibus Budget Reconciliation Act of 1986 adding Section 1138 of the Social Security Act, all hospitals that perform transplants and all organ procurement organizations (OPOs) were required to abide by the rules and requirements of the OPTN in order to receive Medicare and Medicaid reimbursement.

In December 1989, HHS issued a Federal Register notice indicating that all OPTN rules and requirements would remain voluntary until the Secretary promulgated regulations to define the roles and policy-making procedures of the OPTN and HHS. A Notice of Proposed Rule Making containing these definitions was published on September 8, 1994.

After two extensive comment periods, including three days of special hearings in December, 1996, HHS today announced a final rule providing a framework for the operation of the OPTN, and aimed at assuring that the Nation's organ procurement and transplantation system operates for the greatest benefit of transplant patients. The regulation builds on medical technology advancements; it looks to the medical community for leadership in policy development, with participation by patients, donors and their families; and it sets performance goals for fair and effective use of donated organs.

The rule, to be published in the Federal Register in March 1998, with a 60-day opportunity for additional public comment, provides the framework within which the OPTN, its members, and other participants in organ procurement and transplantation will operate. The rule, which becomes effective 90 days after publication, sets requirements for the structure of and membership in the OPTN; the OPTN policy making process, including the Secretary's oversight role; standardized criteria for placing transplant candidates on a national waiting list; identification of organ recipients; equitable organ procurement and allocation; designation of transplant programs; review and evaluation of OPTN activities; and record maintenance and reporting by the OPTN, OPOs and transplant hospitals.

Key Principles

Important principles underlying the final regulation include:

- The Department's responsibility is to assure that the goals of the National Organ Transplant Act are being realized for patients. The Department's role is to provide broad oversight and performance goals to ensure an equitable allocation system that operates in the best interest of patients.

- The rule does not dictate medical practice, but provides a broad framework for the OPTN's operation and activities. Within that framework and the goals of the law, the OPTN has the freedom and flexibility to determine the most effective ways to put the policies into practice nationwide. Individual physicians will continue to make decisions regarding individual patients.

- As far as medically feasible, there should be a "level playing field" in organ allocation. Organs should be allocated based on patients' medical need and sound medical judgment, with less emphasis on keeping organs in the local area where they are procured. Patients should have an equal chance to receive an organ based on their medical need, not the accident of geography. Efforts should be made to equalize waiting times among different regions of the country.

- Standardized medical criteria should be used to determine the status of a person's illness and when the person can be placed on a waiting list. The same medically objective criteria should be used by all transplant centers. Uniform criteria can help reduce regional variations and will help build trust among centers, physicians and patients.

- Patients, their physicians and the public should have timely, accurate and user-friendly center-specific data on the performance of transplant programs to measure quality and make transplant decisions.

- Transplant decisions should always be based on sound medical judgment to avoid wasting organs and ensure an efficient and effective system.

- HHS policies must be guided by the interests of patients and the purposes of the law, not the sometimes conflicting interests of different transplant centers

Major Provisions

The final regulation establishes a framework within which both the OPTN and the Department will operate. It delineates the roles of each, providing a basis for the OPTN to act and the Department to monitor and review these actions to ensure an equitable allocation system that operates for the public's benefit. Major provisions include:

- **Policy Development**--The OPTN Board of Directors is responsible for developing organ allocation policies, with the advice of patients, families and the public. Proposed policies may be reviewed by the Secretary, and if determined appropriate, published in the Federal Register for public comment. Entities objecting to OPTN or Secretarial policies may submit appeals to the Secretary in writing. In addition to policies for the equitable allocation of organs, the OPTN's policy making role includes: policies on the training and experience of transplant surgeons and physicians; policies for nominating OPTN Board members; and other policies as directed by the Secretary.

- **Allocation of Organs**--The OPTN Board of Directors is responsible for developing organ-specific policies (including combinations of organs, such as for heart-lung transplants) for equitable organ allocation among potential recipients. The rule sets three broad performance goals for organ allocation:

  -**standardized listing criteria** for placing patients on waiting lists, using objective and measurable medical criteria;

  -**standardized criteria for determining medical status**, also based on objective and measurable medical criteria, sufficient to differentiate patients from least to most medically urgent

  -organ allocation **policies that give priority to those whose needs are most urgent**, with the result that differences in **waiting times** for patients of like medical status will be reduced;

All of these goals, of course, are subject to considerations of **practicality and sound medical judgment** to avoid futile transplants and wasted organs, and to promote the efficient management of organ placement.

The rule requires the OPTN board to focus first on appropriate revisions to its current liver-allocation policy and propose a new liver allocation policy to the Secretary within 60 days of the regulation's effective date. Other organ-specific policies must be provided to the Secretary within one year of the regulation's effective date.

- **Transition to New Policies**--When the OPTN initially revises organ allocation policies, it must propose transition policies so that people who are already on the national waiting list for transplantation do not receive less favorable treatment than under previous policies.

- **Board Composition**--The rule modifies the composition of the OPTN Board of Directors. At least six public members must come from fields such as behavioral science, computer science, economics, ethics, heath care financing, law, policy analysis, sociology, statistics or theology. Another eight members--at least 25 percent of the board--must represent transplant candidates, transplant recipients, organ donors and family members. No more than 50 percent of the members are to be transplant surgeons or transplant physicians.

- **Public Access to Data**--The rule pays special attention to public access to data. When the Secretary determines that information will serve the public's interest, the Secretary may release it. The rule requires that outcome data be updated every six months and be available no more than six months later than the period to which they apply. The data shall include the characteristics of individual transplant programs as well as rates of non-acceptance of organs and waiting times, and other data useful to patients, their families and physicians in making transplant decisions.

- **Review and Evaluation**--The Secretary or her/his designee may review and evaluate member OPOs and transplant hospitals where there is evidence of non-compliance with the OPTN rule or actions that risk patients' health or compromise public safety. Sanctions may include removal of transplant program designation, termination of the transplant hospital's participation in Medicare or Medicaid, or termination of an OPO's Medicare and Medicaid reimbursement.

EFFECTIVE DATE--These regulations are effective 90 days after publication in the Federal Register. Comments on this rule are invited. To assure consideration, comments must be received within 60 days after date of publication in the Federal Register.

ADDRESSES: Written comments should be addressed to Jon L. Nelson, Associate Director, Office of Special Programs, Health Resources and Services Administration, Parklawn Building, 12420 Parklawn Drive, Rockville, MD 20857. All comments received and referenced background materials will be available for public inspection and copying at the above address, weekdays (Federal holiday excepted) between 9 a.m. and 4 p.m.

A copy of this rule and selected background materials will be posted on the Health Resources and Services Administration's Division of Transplantation Web site at http://www.hrsa.dhhs.gov/bhrd/dot/dotmain.htm.

WHAT OTHERS HAVE SAID

"In principle, and to the extent technically and practically achievable, any citizen or resident of the United States in need of a transplant should be considered as a potential recipient of each retrieved organ on a basis equal to that of a patient who lives in the area where the organs or tissues are retrieved. Organs and tissues ought to be distributed on the basis of objective priority criteria, and not on the basis of accidents of geography."

--L.G. Hunsicker, quoted from public testimony in the *Report of the Task Force on Organ Transplantation*, April 1986 *(Dr. Hunsicker is currently president of the United Network for Organ Sharing)*

"Organs should be considered a national, rather than a local or regional resource. Geographical priorities in the allocation of organs should be prohibited except when transportation of organs would threaten their suitability for transplantation."

--American Medical Association, Code of Medical Ethics *(See "Ethical Considerations in the Allocation of Organs and Other Scarce Medical Resources Among Patients," 1996-97 Current Opinions and Annotations, Code of Medical Ethics)*

"What should the Department of Health and Human Services do?

"First, stay above the fray. Demonstrate that good medicine and policy drive decisions, not politics. Insist on sound data -- subjected to an independent review -- on the effects of proposed modifications of the system. The conflicts among medical centers are about money and prestige, as well as the welfare of patients.

"Second, build on the incremental changes that have been made. It is reasonable to apply strict and standardized rules for placing patients on the waiting list and to set priorities on the basis of objective, verifiable criteria for the urgency of transplantation and the likelihood of a benefit. Standards for the outcomes of transplantation and greater regional distribution of organs are also reasonable.

"Third, make it clear that the allocation of a scarce resource on the basis of explicit criteria can work only on a level playing field. For example, gaming the system by placing patients on the waiting list early so that they can accumulate more points or representing them as sicker than they really are may help some patients, but such practices undermine overall confidence in the system of allocation. Although billions of dollars are spent on organ transplantations in the United States each year, the allocation system is built on trust among physicians, hospitals, procurement organizations, patients, and families of donors ... The system's success hinges on its public and professional credibility and on the perceptions that it plays no favorites and rewards altruism.

"Fourth, promote voluntary organ donation ... Increasing the rate of donation requires broad-based public education, identifying larger numbers of potentially eligible donors, learning from the experience of successful procurement organizations, and addressing the reasons that some families are reluctant to donate."

-- New England Journal of Medicine, editorial, Feb. 6, 1997

HHS FACT SHEET

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

June 18, 1998

Contact: HRSA Press Office
(301) 443-3376

ORGAN TRANSPLANTATION REGULATION

Countering Misinformation – Seeking Fairer Treatment for Patients

Overview: On April 2, HHS published a final regulation concerning operation of the nation's organ transplantation network. It gives responsibility to the private sector organ network to develop policies for allocating organs for transplantation. Within those policies, individual transplant decisions are made on a case-by-case basis by physicians and patients.

A special focus of the regulation is to help assure fair treatment of patients by using objective medical criteria when making organ allocation decisions. Another goal of the regulation is to make waiting times for organs more equal, so that patients in different parts of country will have more equal opportunity to receive organs for transplantation.

The regulation gives to the organ network the responsibility for developing all these policies, and for assuring that the policies are consistent with sound medical practice. The regulation does not dictate an allocation policy, but rather states broad goals for equity and medical effectiveness. It looks to the transplant professionals of the organ network to develop policies that will work.

On June 3,, HHS Secretary Donna E. Shalala responded to 181 members of Congress concerning misinformation about the regulation which has been disseminated by the United Network for Organ Sharing. "It is regrettable that since we issued our regulations, UNOS has launched a campaign that factually misrepresents the Department's intent in issuing the rule and mischaracterizes its provisions," she wrote.

Specifically, the regulation:

1. ***Does not take over decisions about who should get organs***
2. ***Does not require a new single national patient waiting list***
3. ***Does not require that organs go to the very sickest patients***
4. ***Does not result in organ wastage or poor medical use of organs***
5. ***Does not result in allocation to a few large transplant centers***
6. ***Does not result in closure of smaller transplant centers***
7. ***Does not require patients to travel long distances for transplants***
8. ***Does not disadvantage minorities or the poor***
9. ***Does not reduce organ donation***
10. ***Does not result in fewer patients getting transplants, nor fewer lives saved.***

maintained by UNOS, and lists all persons seeking transplants. That list does not now function as a priority wait list, and the regulations do not require that it ever do so.) The notion of a national allocation-controlling list is purely fictional.

UNOS' own Liver Committee has in the past recommended alternatives to the present system that involve approaches other than a national list. And UNOS' own computer modeling, which is cited in the preamble to the regulations, shows that the removal of artificial barriers to organ sharing results in essentially the same number of people receiving transplants under at least two of the options considered by the Liver Committee – and more, not fewer, lives saved under all three of the UNOS-modeled options to the current policy.

3. *UNOS claim: The regulations will result in "... forcing doctors to transplant livers into the very sickest patients..."*

The regulations do not mandate transplants to the "sickest" first, without regard to consequences. Doctors will not be forced to treat patients in any respect contrary to their medical judgment.

UNOS' current liver allocation system already ranks patients in order of medical urgency and generally aims at allocating organs to sicker patients. The regulation would not upset this principle, but would require that allocation policies be designed to reduce geographic disparities in waiting times, with doctors continuing to make the medical judgment as to who should be transplanted.

4. *UNOS claim: "Under the new regulations, we project increased wastage of precious organs due to excessive transit time – organs that could have saved a life if used promptly in a local setting."*

The regulation explicitly prohibits allocation policies that would result in such wastage of organs. In the words of the preamble: "Broad geographic sharing should not come at the expense of wasting organs through excessive transportation times." And in the language of the regulation itself: organ allocation policies will be designed by the organ network in such a way as "to avoid futile transplantation, to avoid wasting organs, and to promote efficient management of organ placement."

5. *UNOS claim: "The new system would allocate donated organs away from patients at the vast majority of the country's transplant centers and shift those organs to the largest centers."*

When organs are allocated in the future with an emphasis on medical need, then small and medium-sized centers will receive organs because they also serve patients with the greatest medical need. Saving lives by serving patients with greatest medical need is a desirable goal, and it is already accomplished by small as well as large centers.

10. UNOS claim: *"The impact of the regulations would be to lengthen the amount of time sick people must wait for transplants, and reduce the number of people who get them."*

Assertions about how long people will wait for transplants, or the number of people who will get them, are without foundation since the allocation policies have yet to be established by the organ network. Until the policies exist, it is not possible to estimate what their effects will be. It is hard to imagine that the organ network would develop policies whose disadvantages outweigh their advantages. Modeling by the organ network itself indicates that a variety of policy alternative exist which would be improvements on the existing situation. It remains only for the network to begin the work of developing the policies.

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THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

OCT 6 1998

The Honorable Arlen Specter
United States Senate
Washington, D.C. 20510-1304

Dear Chairman Specter:

As you know, this week the appropriations committees may be asked to consider a rider that would delay implementation of the Department's April 2 patient fairness rule. The rule is designed to reduce or eliminate current inequities in the policies of the Organ Procurement and Transplantation Network (OPTN). Under these policies, where a patient lives, or at which hospital a patient lists, largely determines whether the patient will live or die. The policies are contrary to the National Organ Transplant Act, which requires a fair national system of organ allocation.

Any additional delay for the patient fairness rule is unjustified. The rule has already been the subject of extraordinary public review and comment. The rule was originally published for comment in 1994. The public comment period was extended in 1996, and additionally, the Department conducted three days of public hearings in December of that year. On April 2 of this year, HHS published the rule, but provided yet another public comment period, which was then extended in the most recent emergency supplemental appropriations bill. There have been hearings in the House and Senate on the April 2 rule, as well. All sides have been heard on this issue multiple times; there have been four years of comments and five public hearings on issues contained in the rule.

On June 19, 1998, at the request of the Department's appropriations and authorizing committees, representatives of HHS and the United Network for Organ Sharing (UNOS), which manages the OPTN, began a series of meetings comprising 50 hours of discussion about the intent of the rule. The Administrative Procedures Act prevented an actual negotiation about the regulation. Any changes in the rule, if necessary, will result from the public comment process. During the meetings, HHS staff clarified several issues that had been of most concern to UNOS: specifically, allocation policies will be developed by UNOS, not the Department. HHS also emphasized that the regulation does not require a national list. HHS reiterated that there should not be an arbitrary policy requiring that only the sickest patients be transplanted, but that patients with the greatest medical urgency, based on sound medical judgment, not geography, should be transplanted. HHS made it clear to UNOS that it should not develop policies that adversely affect small transplant centers or unduly benefit large transplant centers.

During the final meeting between HHS and UNOS, the respective parties in the room concurred on draft language that both sides felt could form the basis for a mutual understanding. In the end, UNOS would not agree to the language. It seems that UNOS believes its political interests are best served by suspension of the patient fairness regulation.

Most recently, at the request of Congressional opponents of the rule, HHS staff met with representatives of a coalition of transplant centers that have been most vocal in their opposition to the regulation. While there was general agreement about policy goals for the transplantation network , we were informed that further discussions were pointless because of the coalition's belief that the Federal Government has no authority in overseeing the taxpayer-subsidized transplant system.

In enacting the National Organ Transplant Act, Congress clearly provided for a governmental role in ensuring accountability and fairness in the transplant system. The Federal Government is the Nation's largest payer for transplant services. HHS alone pays for more than half the transplant surgeries in the United States. Patients, whom we represent, must have a larger voice in policy decisions that affect their lives. I urge you again to reject any actions that would compromise patient well-being and the authority of the Federal Government to approve policies that determine substantial expenditure of tax dollars.

Thank you for your attention to this matter. Please let me know if I can provide you with further information.

Sincerely,

Donna E. Shalala

Aug 11, 1998

THE LANCET

Volume 352, Number 9122

Changing the US transplant system

In the USA, where you live can determine whether or not you receive an organ transplant. That is because the US organ allocation system is broken up into 11 regions and operates a "locals first" policy in which organs are first offered to patients in the area where the organs were obtained, then to patients in the surrounding region, and finally to patients in the rest of the nation. As a result, a patient living in one part of the country may receive a transplant before another patient with greater medical need living in another part of the country.

To try to reduce such geographical disparities, US Secretary of Health and Human Services, Donna Shalala, has proposed new regulations that will require the national Organ Procurement and Transplantation Network (OPTN), a private sector system of organ procurement organisations and transplant centres established by the 1984 National Organ Transplant Act, to revise its allocation policies so that eligible patients are not denied a transplant because of where they live.

Precisely how the OPTN is to attain this goal is left to the network to work out, but the policies must satisfy three performance goals. They must establish standardised criteria for determining which patients are medically eligible to be put on transplant waiting lists and for determining the medical status of patients, so that the medical needs of different patients can be compared; and they must set up allocation protocols that will reduce the influence of geographical factors so that organs will first go to those with the highest medical urgency. In pursuit of these goals, however, the regulations do not require the OPTN to adopt policies which, because they are impractical or are contrary to sound medical judgment, lead to futile transplants and organ wastage.

On the face of it, it is hard to see what is objectionable about Shalala's proposal, but the response of the United Network of Organ Sharing (UNOS), the DHHS contractor that operates OPTN, has been furious. In a letter sent to every US Senator last spring, the outgoing president of UNOS, L G Hunsicker, described the regulations as a "federalization of the current system which takes away control of the transplant system from doctors and patients in almost 300 transplant centers and hands it over to Federal regulators" and forces doctors to give livers "to the very sickest patients", who are likely to require second or third transplants and thus use organs that could have gone to save other patients. Hunsicker predicts that the regulations will make it more difficult for most patients to receive a transplant because organs will be shunted towards a few large transplant centres with the longest waiting lists and the sickest patients.

But it is hard to see how the regulations amount to a "federalization" of the US transplant system, when they merely set performance goals and allow OPTN to develop the policies. The regulations also do not require that transplants be given to the "very sickest" patients but rather that preference be given to those who are "very ill but who, in the judgment of their physicians, have a reasonable likelihood of post-transplant survival" over those who are less medically urgent. Finally, it is hard to predict, before OPTN has formulated the final policies, what impact the regulations will have on smaller transplant centres. However, it can be argued that since where organs will go will depend on the needs of patients and not the size of the transplant centre smaller programmes could fare well under the new rules.

But what is clear is that the rhetoric adopted by UNOS and other opponents of the proposal is not helpful and has already caused mischief. Two states have passed legislation that gives state residents priority for organs donated within those states. Several other states are considering similar laws, which, if they survive court challenge, will further fragment the US organ allocation system.

The new regulations proposed by Secretary Shalala seem to give the network sufficient leeway to move closer to the desired goal without requiring it to adopt policies that will waste organs or force doctors to perform futile transplants. UNOS would better serve the transplant community if it abandoned its stance and began working with DHHS to draw up allocation policies that are practical and fair.

The Lancet

David Hess taking on Walter Graham..... ..

Forward Header

Subject: Fwd: UNOS to protect programs
Author: TranNews@aol.com at INTERNET
Date: 6/11/99 7:35 PM

Analysis: System costs lives, organs
Sunday, June 6, 1999
BY DAVID RESS
Times-Dispatch Staff Writer

On one side of the river, patients can get a transplant after waiting just a few months. On the other side, sicker patients wait for years.

Many die.

The river is the Hudson. It also can be the Ohio, the Missouri, the Red, the San Joaquin. It is one of the boundary lines across which few organs travel.

The Richmond-based United Network for Organ Sharing, which runs the nation's organ allocation system, has said that mainly local use of organs recovered from the dead is the fairest and most efficient way of allocating a lifesaving resource.

But a Times-Dispatch analysis of UNOS statistics and reports shows that:

Relatively healthy people in some states are getting liver and heart transplants while others nearby die.

Hospitals are discarding more livers, hearts and kidneys than they once did.

More adults are receiving livers and hearts from dead children and teen-agers, even as the number of pediatric patients signing up for lifesaving transplants rises.

Patients for whom it is difficult to find matches may be increasingly unlikely to get transplants.

UNOS says its emphasis on local use of organs saves more lives, wastes fewer organs and encourages people to become organ donors by reassuring them their donations will help their neighbors.

"At the outset, it must be acknowledged that there is a dire shortage of organs for transplantation," said Walter K. Graham, UNOS executive director.

That shortage, and the fact that people who need a transplant die if they don't get one, means fairness has to be key goal when allocating organs, Graham said in a recent speech. So does making sure that the most people benefit: The sicker patients are when they have a transplant, the less likely they are to survive.

That means UNOS must "seek a balance of principles that are sometimes in competition with one another," he said.

One thing UNOS is sure of: Local use of donated organs encourages people to agree to become donors and ensures that doctors and nurses identify as many

potential donors among the recently deceased as possible.
"The strength of this rationale can be seen in the dramatic increases of organ recovery in areas where a particular type of transplant had not been performed previously," Graham said.
The shortage of organs is probably what is causing the increase in discards as organ procurement specialists try to close the gap by recovering more organs from older donors, UNOS spokesman Joel Newman said.
UNOS has said that broader sharing would give large hospitals control of a business that can bring in hundreds of thousands of dollars for a single operation -- and it is some of those big hospitals that are pushing hardest within UNOS and with federal officials for a change in allocation policy.
But patient groups say the UNOS policy requiring that organs be offered first to local patients means people are dying needlessly. The local areas, the territory covered by a federally chartered organ procurement organization, can range in size from several states to single cities. Some of the 64 procurement organizations, which are responsible for recovering organs in their territory, are based at a single hospital.
By discouraging sharing, the system is aimed more at protecting small and medium-size hospitals' transplant businesses by ensuring them access to as many organs as possible, patient groups say.
UNOS statistics analyzed by The Times-Dispatch show that in one large city between 1994 and 1997, more than 230 liver patients died while waiting for a transplant; 976 transplants were performed.
Nearby, surgeons performed transplants on 177 liver patients, including 120 relatively healthy ones who waited an average of 60 days each. Eighteen people died while waiting for a transplant, about half the rate in the city.
UNOS would not identify the areas, but cross-checking some of the death and transplant statistics against an earlier report suggested that they were New York City and New Jersey, respectively.
No waiting time could be calculated for New York patients as healthy as the New Jerseyans, because so few received transplants. New Yorkers who were as healthy when they signed up for a transplant but whose chronic liver disease worsened until they required intensive care waited 422 days for a transplant on average.
The same analysis suggested that in Baltimore, 13 patients who went to the hospital needing intensive care for severe liver disease waited an average of 105 days for a transplant. A 100-minute airplane trip away, in Nashville, Tenn., the median waiting time for 14 patients who didn't even need to be in the hospital was 67 days.
The median waiting time nationally for those as sick as the Baltimore patients was 13 days. A national average wait for people as healthy as the Tennesseans cannot be calculated, because such a small fraction of such patients receive transplants.
"It is inevitable that differences in outcomes will exist in situations where multiple local units are involved in the distribution of benefits," UNOS executive director Graham said. Geographic differences may be due to

differences in the incidence of disease, too.
It is tough to do away with all geographic differences, said Dr. Marc Posner, the head of Virginia Commonwealth University's Medical College of Virginia Hospitals' liver transplant team.
"You have to draw the boundary somewhere," he said.
But fewer people would die waiting if organs were offered to the sickest people in a region before they were offered to local people whose needs were less urgent, a consultant's study for UNOS said. That approach, which the UNOS board may consider later this year, would increase deaths after transplant but increase transplants for the sickest patients and for children, a summary of the study shows.
Meanwhile, UNOS statistics also show that nearly one out of every 14 livers donated by families from their deceased children, spouses, siblings or parents is discarded, up from one of every 25 donations a decade ago.
More than eight of every 10 unused livers are discarded locally and not shared. The reasons were not reported.
The number of organs kept locally and not shared has climbed over the past decade from about one of every four donations to more than two of every three. Over the same time, 45 hospitals opened liver transplant programs; since the local-use rule went into effect, nearly two dozen hospitals have entered the business.
Nearly one out of every 10 kidneys donated is discarded, up from about one of every 30 a decade ago, while roughly one of every 50 hearts donated is discarded, up from one of every 200 a decade ago.
The statistics also show that surgeons transplanted 577 livers from dead children and teen-agers into adults in 1997.
More than 1,400 pediatric patients were waiting for transplants at the end of that year.
A total of 555 children and teen-agers received transplants in 1997, 22 fewer than the adults who received organs from child or teen-age donors.
UNOS spokesman Newman said most of the pediatric organs transplanted are from teen-age donors and there are relatively few teen-age transplant candidates.

Organ Network Changes Liver Policy

AP Online
06/24/99, 1:41p

By LAURA MECKLER

Associated Press Writer

WASHINGTON (AP) – More donated livers will be directed to the sickest transplant patients under a new policy approved today by the nation's transplant network.

The United Network for Organ Sharing is also poised to release data about individual transplant centers for the first time, including the survival rates of their patients.

In both cases, the changes represent a retreat for the network after more than a year of defending its current system under pressure from the Department of Health and Human Services.

HHS issued rules last year ordering the network to create a new system that would get more organs to the sickest patients. But the network has insisted on its system, which relies heavily on geography.

The HHS rules also called for the network to release more data, but transplant centers have balked, saying it was unfair to release potentially embarrassing or misleading data about individual hospitals and doctors.

Hoping to stop these rules, the network mounted an intense lobbying effort and persuaded Congress to delay them until the fall.

But, meeting today in Atlanta, the board moved closer to what HHS wants.

In distributing donated organs, the liver policy has engendered the fiercest debate, partially because there is an acute shortage of livers and very few other medical options for patients who need new ones.

The policy adopted today will direct more livers to the sickest patients – those classified as "status 1." These are people who are suddenly struck by liver disease and have a week or less to live.

Under the current system, livers are offered first to status 1 patients in the local area. If there are no medical matches, they are offered to other local patients, in order of medical urgency. If there are still no local matches, livers are offered to patients in the surrounding region, sickest first.

The new policy would kick in if there are no local status 1 matches. In this case, livers would be offered to status 1 patients throughout the region before being offered less urgent local candidates

Under current policy, 9.7 percent of donated livers go to status 1 patients. The network expects that to rise to 14.3 percent under the new policy. The percentages going to less urgent patients – those in status 2A, 2B and 3 – all drop slightly.

The HHS regulation wanted the network to go further, although government officials have said they are willing to compromise. The rule called for the elimination of geographic boundaries, while the new network policy still relies on regional lines.

A liver donated in Cleveland, for instance, might be directed to someone who is relatively healthy even if there is a status 1 patient in nearby Pittsburgh, because the regional line is drawn between Pennsylvania and Ohio.

Nationally, there are 63 local areas and nine regions.