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## CONGRESSIONAL OPPONENTS OF FAIRER ORGAN TRANSPLANT SYSTEM THREATEN BIPARTISAN AGREEMENT ON HHS RULE

Background: Congressional opponents of the HHS rule to encourage a fairer organ transplant system are attempting to overturn a bipartisan agreement reached last week between the Administration and congressional negotiators designated by the Republican leadership. The vetoed Labor-HHS bill contained an unacceptable policy rider that prohibited the HHS rule from going into effect for 90 days, and established a duplicative public comment and republication process designed to delay the rule even further. The bipartisan agreement reached last week greatly shortened and simplified the process by permitting the rule to go forward immediately after a six week consultation process with the transplant community. Congressional opponents of the rule, led by Senate Republican leaders, are now renege on that agreement and adding the original vetoed language to the Work Incentives Act.

First proposed in 1994, the HHS organ transplant rule sets out broad guidelines for the Organ Procurement and Transplantation Network (OPTN) to establish a fairer and more uniform organ allocation system. Between 1994 and 1998, there were three public comment periods on the rule, three full days of public hearings conducted by HHS, four congressional hearings, and extensive direct consultation between HHS and the transplant community. In April 1998, HHS published a final rule.

In October 1998, Congress enacted a one-year moratorium on implementation of the final rule and asked the Institute of Medicine to conduct a study of related issues. The IOM report broadly validates the goals and requirements of the rule, including the importance of strong federal oversight of the transplant system; broader sharing of organs; and the importance of transplanting organs into the most medically urgent patients. HHS published an amended final rule in October 1999 that is fully consistent with the IOM report and includes other changes recommended during hundreds of hours of additional discussions over the last year between HHS officials and representatives of the transplant community.

### Congressional Opponents of Fairer System Renege on Final Agreement for HHS Rule:

Administration representatives worked in good faith with leadership-designated congressional negotiators last week to reach agreement on the six week delayed effective date for the HHS rule. House Appropriations Committee Chairman Young, Labor-HHS Subcommittee Chairman Porter and other key members were directly involved in what was understood to be a final agreement. Last minute efforts to renege on the agreement are clearly inconsistent with the spirit of the negotiations and raise serious questions about the finality of other negotiated agreements. These efforts also are inconsistent with commitments made last year that the one-year moratorium imposed at the time would be the final congressional delay.

### Extended Moratorium Part of Calculated Strategy to Delay HHS Rule Indefinitely:

The bipartisan agreement reached last week includes report language expressing the intent of Congress to impose no further delay in the rule beyond the six week consultation period.

However, opponents of the rule in the transplant community and the Congress consider congressional moratoria to be their "ace-in-the-hole" and intend to continue pursuing a series of delays until authorizing legislation or outside litigation can achieve their long-term goal of preventing HHS from requiring a fairer organ allocation system. The new 90 day moratorium is designed to block the rule until Congress can return next year and delay the rule again, either through supplemental appropriations legislation or through a reauthorization of the National Organ Transplantation Act (NOTA). NOTA reauthorization legislation sponsored by Representative Bliley, whose district includes the OPTN's headquarters, would block the rule permanently and has already been reported by the House Commerce Committee.

In addition, the language imposing the 90 day delay creates a duplicative public comment and republication process designed to bury the rule in red tape and expose it to further litigation. The rule has already been published three times with three separate public comment periods. This provision establishes a presumption that further changes will be made in response to yet another comment period, and exposes HHS to litigation if changes are not made because the Department determines that earlier revisions have addressed the concerns.

#### Extended Delay will Prevent Congress from Making Informed Decision on NOTA

Reauthorization: The HHS rule provides the OPTN with three months after the rule becomes effective to develop a proposed allocation policy for livers. This process, setting policy for the scarcest organ, is widely considered to be a key test of whether and how the transplant community will develop a fairer and more uniform allocation system. In considering legislation to reauthorize NOTA, it is critical that Congress be informed by this process.

However, under the new 90 day moratorium, it would be a minimum of six months – late May 2000 at the earliest - before the OPTN is required to come forward with a new allocation policy. Additional congressional riders or litigation brought about by the duplicative comment and republication language would likely delay the process further. This would delay the network's production of a liver policy beyond congressional NOTA hearings, and perhaps beyond the passage of a NOTA reauthorization bill as well. Conversely, under the bipartisan agreement reached last week, the network would be required to produce a liver policy no later than April 1, 2000.

#### Extended Moratorium is Fundamentally Inconsistent with Sound Policy and Health Concerns:

Given that almost 5,000 patients die each year while awaiting an organ transplant, it is inappropriate for the Congress to continue to block responsible federal guidelines that can help to establish a fairer organ allocation system. The IOM, charged by Congress with reviewing the HHS rule, strongly supported the core concepts of broader sharing to better serve the most medically-urgent patients, and strong federal oversight to ensure accountability in the system. Congress should let the process move forward and then exercise appropriate oversight and timely reauthorization of the NOTA statute.

Organ Transplants  
File

THE WHITE HOUSE

Office of the Vice President

For Immediate Release:  
September 24, 1999

Contact: (202) 456-7035

**VICE PRESIDENT GORE LAUNCHES NEW EFFORTS TO INCREASE ORGAN DONATION NATIONWIDE**

Today, in an event with families who have donated and received life saving organs, Vice President Gore unveiled a series of new Federal and public-private initiatives to increase the rate of organ donations nationwide. They include: the enactment of the Organ Donor Leave Act; a new \$13 million grant program to provide funds to community based organizations implementing strategies to increase organ donation; a series of new television ads and corporate partnerships designed to inform the public about the importance and process of organ donation; and new Federal efforts to educate health care providers nationwide about best practices in working with the families of potential donors.

"The steps we are taking today will not only enable many more people to understand the need for organ donation," said Vice President Gore. "It will help people meet that need -- and to share the gift of life and health."

**THOUSANDS DIE EACH YEAR WAITING FOR ORGAN TRANSPLANTS.** This year, of the 65,000 patients on the national organ transplant waiting list, almost 5,000 will die while waiting for a donated organ. Less than one-third -- about 20,000 -- are likely to receive transplants. Only 8 percent of the tissue needed for surgery is available. Most Americans say they support donation and would carry out their loved one's wishes if they knew them, but only about half of families asked give consent because they don't know what their family member would have wanted.

**NEW ACTIONS TO INCREASE ORGAN DONATION NATIONWIDE.** Today, the Vice President will:

**Announce the enactment of the Organ Donor Leave Act.** Today, President Clinton will sign the Organ Donor Leave Act, which was introduced by Congressman Elijah Cummings (D-MD) and Senator Daniel Akaka (D-HI) and sponsored by a bipartisan coalition of 25 members, including Senator Bill Frist (R-TN), into law. Because the current seven-day limit on leave for Federal employees for organ donation is insufficient for recovery, this important legislation quadruples the amount of paid leave available in addition to sick or annual leave to Federal employees who donate organs for transplants. As the country's largest employer, this new law will help the Federal government set the example for the private sector as well as other public organizations. Under this new law, Federal employees serving as organ donors would receive up to 30 days of paid leave in addition to sick or annual leave.

**Launch a \$13 million grant program to improve local organ donation efforts.** Today, the Vice President will release the first \$5 million in grant funds to 18 grantees nationwide to improve the donation request process, increase outreach to minority communities, and implement school based and workplace donor education programs designed to educate families about the importance of organ donation. For instance, grantees will use internet based services to support donation; develop easy to access computer centers in public areas where they can record their wishes on organ donation at the same time they renew their drivers' licenses; provide information on organ donation to teenagers in drivers education classes; and utilize parents of organ donors as counselors to other donor families.

**Announce new public service announcements to educate families about organ donation.**

Today, the Vice President will release new television public service announcements to promote organ donation and encourage families to share their decisions on donation. These advertisements, which will be distributed to all major networks and cable stations, are expected to receive \$10 million worth of donated air time for the advertisements. They include a toll-free number (1800 355 SHARE) that provides families with information on the importance of organ donation and helps them discuss this difficult subject with their loved ones.

**Announce a series of regional conferences to promote best practices in working with the families of potential donors.**

The Vice President will announce that, beginning in early December, the Department of Health and Human Services (HHS) will hold four regional conferences to bring together health care providers and transplant professionals from hospitals and organ procurement organizations to share successful strategies for communicating with potential donor families. A new resource guide developed by HHS, *Roles and Training for the Donation Process*, will be used to educate conference attendees. This guide, developed in cooperation with hospitals and transplant professionals, will also be distributed to every hospital participating in the Medicare program by the end of the year.

**BUILDS ON AL GORE'S LONG STANDING COMMITMENT TO INCREASING ORGAN DONATION.**

- Vice President Gore has a longstanding commitment to increasing organ donation nationwide. As a representative, together with Senator Orin Hatch, he cosponsored the National Organ Transplant Act of 1984, established a computerized network to match donated organs with the patients who need them, outlawed the buying and selling of organs, and called for a study of the ethical issues surrounding transplants.
- The Clinton-Gore Administration launched the National Organ and Tissue Donation Initiative in December 1997 to involve public and private partners to educate providers and consumers about the importance of organ donation.
- During 1998, HHS issued a new regulation requiring hospitals to notify organ procurement organizations (OPOs) of all deaths and imminent deaths in order to ensure that opportunities for donation are not overlooked. In 1998, organ donation increased 5.6 percent, resulting in approximately 600 additional organ transplants and up to 14,000 more tissue transplants – the first substantial increase since 1995. HHS continues to work with health care organizations, faith organizations, educational organizations, state partners, and donor and recipient groups to educate the public about the importance of organ donation.

- The Federal government is educating its employees about donation, in order to serve as a model for other employers. With assistance from the Office of Personnel Management, HHS has provided donation materials to over 100 Federal agencies for employees, including donation messages on pay stubs and full-page donation ads in the federal health plan catalog for the past two years.

# Roundtable Discussion on Organ Donation

Old Executive Office Building, Room 450

Washington, DC

Friday, September 24, 1999 -- 11:15am - 12:00pm

**Briefing prepared by Sarah Bianchi (202) 456-5585**

## EVENT

You are hosting a roundtable discussion on the issue of organ donation. You are having a discussion with four people who received a life saving organs, donated an organ, or have family members who donated an organ. (Some of the participants will also have family members on the stage).

**This event is OPEN PRESS**

## LOGISTICS

Off-stage announcement of **the Vice President**;

**The Vice President** proceeds onto stage and takes seat, joining the organ donor/recipient families;

**The Vice President** makes brief remarks and opens the discussion with organ donor/recipient families;

**The Vice President** moderates the discussion with four organ donors and recipients and some of their family members;

**The Vice President** closes the discussion and departs.

## YOUR ROLE AND CONTRIBUTION

This event provides you an opportunity to highlight your longstanding commitment to organ donation. You are announcing some new steps the Administration is taking to promote this issue, including (1) the enactment of the Organ Donor Leave Act; (2) a new \$13 million grant program to provide funds to community based organizations implementing strategies to increase organ donation; (3) a series of new television ads and corporate partnerships designed to inform the public about the importance and process of organ donation; and (4) new Federal efforts to educate health care providers nationwide about best practices in working with the families of potential donors.

## NEW ORGAN DONATION INITIATIVES

**Background on organ donation.** This year, of the 65,000 patients on the national organ transplant waiting list, almost 5,000 will die while waiting for a donated organ. Less than one-third – about 20,000 – are likely to receive transplants. Only 8 percent of the tissue needed for surgery is available. Most Americans say they support donation and would carry out their loved one's wishes if they knew them, but only about half of families asked give consent because they don't know what their family member would have wanted.

Specifically, the Vice President announced:

**The enactment of the Organ Donor Leave Act.** Today, President Clinton will sign the Organ Donor Leave Act, which was sponsored by Congressman Elijah Cummings (D-MD) and Senator Daniel Akaka (D-HI), into law. Because the current seven-day limit on leave for Federal employees for organ donation is insufficient for recovery, this important legislation quadruples the amount of paid leave available in addition to sick or annual leave to Federal employees who donate organs for transplants. As the country's largest employer, this new law will help the Federal government set the example for the private sector as well as other public organizations. Under this new law, Federal employees serving as organ and tissue donors would receive up to 30 days of paid leave in addition to sick or annual leave.

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used to educate conference attendees. This guide, developed in cooperation with hospitals and transplant professionals, will also be distributed to every hospital participating in the Medicare program by the end of the year.

### **THE VICE PRESIDENT'S LONG STANDING COMMITMENT TO INCREASING ORGAN DONATION.**

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- The Clinton-Gore Administration launched the National Organ and Tissue Donation Initiative in December 1997 to involve public and private partners to educate providers and consumers about the importance of organ donation.
- During 1998, HHS issued a new regulation requiring hospitals to notify organ procurement organizations (OPOs) of all deaths and imminent deaths in order to ensure that opportunities for donation are not overlooked. In 1998, organ donation increased 5.6 percent, resulting in approximately 600 additional organ transplants and up to 14,000 more tissue transplants – the first substantial increase since 1995. HHS continues to work with health care organizations, faith organizations, educational organizations, state partners, and donor and recipient groups to educate the public about the importance of organ donation.
- The Federal government is educating its employees about donation, in order to serve as a model for other employers. With assistance from the Office of Personnel Management, HHS has provided donation materials to over 100 Federal agencies for employees, including donation messages on pay stubs and full-page donation ads in the federal health plan catalog for the past two years.

### **BACKGROUND ON EVENT PARTICIPANTS**

**Oscar Robertson** (the Big O) is generally considered the greatest all-around player in basketball history and international ambassador for the game 24 years after retirement. He has been an all-time all-star at every level- high school, college, the Olympics and the National Basketball Association, which recently named him one of the greatest players of all time. During his pro career he served from 1963 to 1974 as President of the NBA Players Association and today is President of the Retired NBA Players Association.

Since his retirement, Mr. Robertson has been active as a broadcaster, author, clinician and entrepreneur. One of the nation's leading small business owners, he is founder and President of Cincinnati-based Orchem, Inc. and Orpack-stone Corporation.

One of Mr. Robertson's proudest achievements was his 1997 donation of a kidney to his daughter, Tia, who had suffered a kidney failure as a result of lupus. He has since become

active with the National Kidney Foundation, serving as an ambassador for organ donation and as Honorary Spokesperson for the 1998 U.S. Transplant Games, where Tia participated with fellow transplant athletes and won a gold medal in doubles tennis.

**Tim Thompson** a 42 year old telecommunications expert for United Postal Service, lost his wife Harriet, aged 32, to a brain aneurysm three years ago. Because of the recent death of a close relative, Tim and his wife had discussed organ donation and he knew that she wanted to be a donor. Because he was overwhelmed trying to cope with the reality of his wife's sudden death and the impact it would have on their two children, Anne-Hamilton (aged 11) and David (aged 7), he doesn't think that he would have remembered that Harriet wanted to be an organ donor. Even if he had remembered, Tim thinks that he would have had an extremely difficult time bringing it up with hospital staff. When a nurse asked him about the possibility of donation, he remembers feeling "pure relief" at the idea that someone was there to help him carry out his wife's wishes. Harriet's organs went to seven different people, all of whom are doing well. Tim, who now serves on the Kentucky Organ Donation Affiliates' Board of Directors, is working with UPS to develop a workplace donation education initiative. His project has been selected as one of the first HHS Model Programs to Increase Organ Donation, and will receive almost \$140,000 of the \$5 million in grant funds that the Vice President is releasing today.

**Jose Torres** received his donated liver in July of 1997. A few months before that, he developed debilitating pains in his abdomen. He thought that it was food poisoning, and his wife Maria rushed him to the hospital – where he ended up staying for almost a month. Jose was diagnosed with a rare liver disease, and he and his family learned that without a transplant, he had less than a year to live. Those months were stressful ones for the family; Jose was forced to leave his job as a homicide detective and stay at home. Maria was forced to work extra hours and worried about the family's financial future; their six children all spent more time at home to try and help as much as they could instead of playing sports after school and taking up extracurricular activities. Jose calls his transplant a "gift from God" – he and his family now appreciate every day they have together. He speaks whenever he can about the importance of organ donation.

**Sarah Lee Beck** and her husband Mark donated their three year old daughter Anna's heart valves, corneas, liver, and kidneys after she died of a brain aneurysm in February 1998. Sarah said that the decision to donate Anna's organs was not a difficult one; although the day her daughter died was the worst one of her life, there was never any question about what they would do. She and her husband Mark have both pledged to donate their organs, and she speaks with pride of the people Anna helped. Sarah is extremely thankful for the support and guidance her local transplant organization provided her when they made their decision. Sarah and Mark have two children, David (aged 6 months) and Lily (aged 3).



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

OCT 5 1998

**MEMORANDUM TO THE HONORABLE ERSKINE BOWLES**

As you know, the Department of Health and Human Services issued a final regulation on April 2 to bring about improvements in the Nation's organ transplantation system. In particular, this regulation is aimed at ensuring that allocation of scarce organs would be based on common medical criteria, medical need and medical judgment, not accidents of geography. Under the current system, less ill patients may receive transplants while more severely ill patients, perhaps only a few miles away, die. Organs should be allocated to patients who are medically judged to need them most, no matter where they live, or at which transplant hospital a patient chooses to list.

Opponents of our regulation, led by transplant centers in Louisiana and Wisconsin, worked with Chairman Livingston and Congressman Obey earlier this year to include in the supplemental appropriations bill language to delay implementation of the rule until Oct. 1; and subsequently, in the House FY 1999 Labor/HHS bill, to delay the rule by another year. Senator Specter, the chairman of our Senate appropriations subcommittee, plans to fight with us against the House rider. This could be one of the most contentious policy rider issues during negotiations on the omnibus appropriations bill.

I want to urge that the Administration very strongly defend our current position in this matter. The reason for doing this is in large part, of course, because of its positive impact on patients. The regulation fundamentally shifts the focus of organ allocation policy from transplant center benefit to patient benefit.

In addition, however, I believe the most fundamental question of Executive Branch responsibility is at stake. The Federal Government, on behalf of Medicare and Medicaid beneficiaries as well as veterans, is the Nation's largest payer for transplant services. Medicare and Medicaid alone pay for more than half the transplant surgeries in the United States. However, organ allocation policies, which ultimately determine who shall receive organs, are set by an HHS contractor, the United Network for Organ Sharing (UNOS), not by HHS itself. Insofar as Congress wants independent medical guidance, UNOS' policy-making role is desirable, and we at HHS respect it. At the same time, however, it seems clear that Congress does not intend for the Federal Government to be without any oversight role in the determination of organ allocation policy, since without federal oversight, the expenditure of these substantial funds is essentially steered by those receiving the funds, and patient interests are far under-represented.

These are the issues at stake in ensuring that Congress allows our regulation to be implemented: the core authority of the government over policies that dictate substantial Federal spending, in addition to the well-being of the patients for whose care we are paying. In our view,

Page 2 - The Honorable Erskine Bowles

the law clearly established the national transplant system as one that is intended to benefit patients by treating donated organs as a public trust. Yet over the years, UNOS allocation policies have increasingly strayed toward choices that are made to benefit the interests of transplant centers rather than benefiting patients with greatest medical need. UNOS, which de facto represents the interests of the majority of transplant centers, maintains that it believes Congress meant HHS to have no oversight role in organ allocation policy. We maintain that the law clearly intends for the Secretary of HHS to have final approval authority for policies that are appropriately devised by the transplant community.

Let me make clear that in our regulation, the Department specifically chose not to mandate any specific organ allocation system, but rather to set broad performance goals for the transplant community. This entirely respects the appropriate UNOS role. Under the goals set out in the regulation, the private sector transplantation network is to develop medically sound allocation policies to improve fairness and establish uniform medical criteria. As of the date the final regulation takes effect, the transplantation network will have 60 days to develop a proposed allocation policy for livers, and one year to develop proposed policies for other organs. But no new system of organ allocation goes into effect until these proposals developed by the network are published for public comment, considered by the network and accepted by HHS. We are making the same point in litigation filed in Louisiana. Although a District Court judge has temporarily stayed the effective date of the regulation, the Justice Department is preparing to immediately appeal.

The work done by HHS on this regulation is based on the law passed by Congress to ensure fairness in our organ transplant system (the National Organ Transplant Act, for which Vice President Gore had a substantial guiding role.) HHS published its proposed rule in 1994, and three extensive comment periods have been provided, including three days of special hearings. Congress has also held several hearings on this subject. This regulation has had exceptionally broad consideration and comment.

I cannot overemphasize the time, thought, and good faith that has gone into the development of this regulation. Because we recognize that core questions of Executive authority are involved, we have been scrupulous in honing this regulation to one that is responsive to the governing statute, places the focus on patient benefit, and protects the right of the Federal Government to approve policies that direct its spending.

For these reasons, I would urge you to reject any actions by Congress to delay implementation of this regulation. Such a delay would compromise patient well-being and the authority of the Federal Government to approve policies that determine substantial expenditure of tax dollars.



Donna E. Shalala

**DRAFT APPROPRIATIONS AMENDMENT ON O.P.T.N RULE**

No sums may be expended to implement or enforce the final rule setting governance policy for the Organ Procurement and Transplantation Network published April 2, 1998 by the Health Resources and Services Administration of the Department of Health and Human Services unless and until the Secretary certifies in writing to the appropriations committees of both Houses of Congress that the following conditions have been met.

The regulation will not require that organs be allocated from a priority ranked national waiting list and does not mandate a system based on any primary geographic distribution unit.

The regulation will require that patient need and medical urgency be given appropriate priority in the establishment of allocation policies; however, organs will not be allocated on a sickest patient first basis without regard to other factors such as sound medical judgment and consistency with efficient organ utilization.

The regulation will allow that different allocation policies may be established for different types of organs.

HHS will evaluate the impact of any proposed policies on small, regional, and large transplant centers.

The Secretary will rely on the transplant community to develop any new policies in consultation with patients and medical professionals.

No patient currently on a waiting list for a transplant will have their status disadvantaged as a result of any new policies established pursuant to the rule.

### Talking Points for Appropriations Amendment on Certification

This amendment would address the major concerns of Chairman Livingston and those in the transplant community. It would require the Secretary of HHS to certify to the Appropriations Committees in both Houses of Congress that the regulation does not mandate a national or centralized waiting list for patients. The amendment also requires the Secretary to certify that only sound medical judgment will be used in transplant decisions; that there can be different allocation policies for different organs; that HHS will evaluate the impact of any proposed policies on small, regional or large transplant centers; and that no current patients be disadvantaged by new policies. Importantly, the amendment requires certification that the transplant community, not the Secretary, develop any new policies required by the rule.

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ONE HUNDRED FIFTH CONGRESS

W.J. BILLY TALBOT, LOUISIANA  
MICHAEL G. O'DLEY, OHIO  
MICHAEL BURRIS, FLORIDA  
DAN BONNER, COLORADO  
JOE BARTON, TEXAS  
J. DENNIS HASTERT, ILLINOIS  
FRED LUTTEN, INDIANAH  
CLIFF STEARNS, FLORIDA  
BILL PALDOR, NEW YORK  
PAUL E. GALLAGHER, OHIO  
JAMES C. GIBBS, PENNSYLVANIA  
MICHAEL D. FEARNS, IOWA  
CHRISTOPHER COX, CALIFORNIA  
NATHAN DEAN, GEORGIA  
STEVE LARGENT, OREGON  
RICHARD BURR, NORTH CAROLINA  
BRIAN P. BLURAY, CALIFORNIA  
ED WHITFIELD, KENTUCKY  
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RICK LAZIO, NEW YORK  
BARBARA CUBBER, WYOMING  
JAMES C. ROGERS, CALIFORNIA  
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TED STRICKLAND, OHIO  
DIANA DRYETTE, COLORADO

**U.S. House of Representatives**  
**Committee on Commerce**  
Room 2125, Rayburn House Office Building  
Washington, DC 20515-6115

October 5, 1998

JAMES C. DERDEGNA, CHIEF OF STAFF

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

Dear Secretary Shalala:

I am writing to request your immediate response to a matter of serious concern to me because it could affect the ability of your Department to pay the costs of organ transplantation for Medicare or Medicaid patients. As you know, there will be an attempt in Congress to use the appropriations process as a vehicle to block implementation of the Department's April 2 rule intended to reduce inequities in the Organ Procurement Transplantation Network (OPTN) and ensure the accountability of the government's contractor, the United Network for Organ Sharing. In addition, the State of Louisiana has sued the Department in a separate attempt to block the rule and enforce a State law limiting the sharing of organs outside the State.

The Department's discussion of the April 2 OPTN regulation stated that "in order to be a rule or requirement of the OPTN and therefore mandatory or binding on OPOs [organ procurement organizations] and hospitals participating in Medicare or Medicaid, the Secretary must have given formal approval to the rule or requirement. Violations of section 1138 could result in withholding of reimbursement under Medicare or Medicaid." I want to know as soon as possible whether there are any circumstances that could arise if the language found in section 213 of H.R. 4274 is enacted that would result in Medicare or Medicaid funds not being available to reimburse transplant operations for persons who are participants in those programs. Medicare and Medicaid are the primary payers of transplant surgeries and I want to know whether blocking the April 2 rule could be a death sentence for thousands of patients in need of a transplant.

I request that the Department promptly evaluate its responsibilities under section 1138, should Congress or the Federal Courts remove your authority to issue enforceable guidelines for the OPTN. I know you share my concern about any action, legislative or judicial, that would adversely affect those who may depend on Medicare or Medicaid for their very survival.

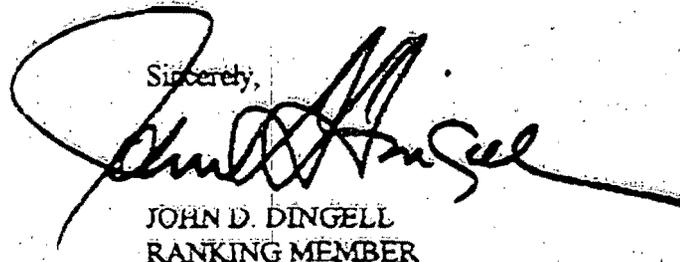
The Honorable Donna E. Shalala  
Page 2

Please respond in writing to the following questions as soon as possible:

1. If section 1138 is violated, is the withholding of Medicare and Medicaid funds discretionary or mandatory?
2. If enacted, would language such as that found in section 213 of H.R. 4274 ("the rider") either require or authorize the Department to withhold Medicare or Medicaid funds from any hospital?
3. If not, are there any other scenarios that could arise during the time the rider is in effect that would require or authorize the withholding of such funds? Examples of such scenarios include, but are not limited to, enactment of state laws on organ sharing similar to Louisiana's as well as changes by the OPTN in its rules and requirements applicable to OPOs and hospitals.
4. A court in Louisiana has temporarily enjoined the April 2 regulation from taking effect. What impact could this or any other litigation have on section 1138 and the withholding of Medicare or Medicaid funds?
5. Does the Department have authority to give formal approval to a rule or requirement of the OPTN if the rider is in effect or if the Department is enjoined from enforcing the April 2 regulation? Could the Department otherwise promulgate and enforce allocation regulations other than the April 2 regulation in order avoid a violation of section 1138?

Thank you for your prompt attention to this matter.

Sincerely,



JOHN D. DINGELL  
RANKING MEMBER

cc: The Honorable Tom Bliley  
The Honorable Michael Bilirakis  
The Honorable Sherrod Brown

File Organ  
4-27-98  
Donor

**OCHSNER CLINIC**  
1514 JEFFERSON HIGHWAY  
NEW ORLEANS, LA. 70121

98 APR 27 21:05

**DEPARTMENT OF SURGERY**

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April 20, 1998

The Honorable William J. Clinton  
President  
The White House  
Washington, DC

Dear Mr. President:

As the Chief of Surgery at the Ochsner Medical Institutions, I have worked over twelve years with hundreds of people to develop a regional center for liver transplantation in the Gulf South. Our program, begun in 1985, represents the tireless efforts of surgeons, physicians, nurses, administrators, clinical coordinators, patients, patients' families, philanthropists, and other supportive citizens. Literally millions of dollars have been invested in the future of the program which is designed solely to benefit the people we serve, patients with end-stage liver disease, most of whom live in the Gulf South, and for whom their only hope of survival is a liver transplant.

This program, with all the time, effort and money it represents, is now threatened with extinction by the proposed changes in organ allocation promulgated by the Secretary of Health and Human Services. I can't help but believe that if you knew the facts, as I do, that you would lend your support to the continued development of our program and those like ours, and prevent the proposed changes in organ allocation.

Mr. President, it is simply a reality of today that all patients in our country with a life-threatening illness as common as liver failure cannot be treated with compassion and precision in only a half dozen medical centers. The regulations about to be promulgated by the Secretary will, in effect, change the present system of organ allocation (UNOS) in such a way that most of the smaller regional centers will have to

close and our patients will be forced to travel to a distant transplant center to be placed on a waiting list. There are several major fallacies and deficiencies in this plan:

1. Organs become available throughout the country and must be transported to the transplant center. This process requires time (the shorter the better) and trained transplant personnel to evaluate and harvest the organs. As organ donor criteria are extended to take advantage of as many organs as possible, it is imperative that the available organ be inspected and harvested by a surgeon who is readily available, properly trained and experienced, and involved with the success of the transplant. This cannot be done efficiently over large distances. Under the reallocation plan promoted by Mrs. Shalala, regional centers will no longer be able to retain transplant specialists because of declining organ availability. Critical technical skills and special training will be lost for both transplanting and harvesting of organs at the regional level creating a disconnection between available organs and waiting recipients.
2. Organ donations are dependent on the communities we serve. The families who make these decisions are influenced by the belief that a neighbor may benefit from the donation. Removing the potential for an organ to be used near home will negatively impact organ donations and greatly depersonalize the decision. The result will be fewer available organs.
3. Regional centers will lose their ability, under the Secretary's proposal, to provide a seamless array of services for all patients. The decision to refer for liver transplantation will be much more difficult and complex for doctors, patients, and insurers, leading to a delay in referrals and higher cost of care for sicker patients. This will force a return to an outdated pattern of practice that will set back medical progress.
4. The issue raised by the larger centers regarding their patients' waiting period for livers is a bogus one. The fact is that several of the most vocal centers are seeing their transplant volumes decline as more regional centers gradually increase their volumes. The elitist attitude promoted by these centers is not supported by the facts, and is self-serving. They have trained hundreds of transplant professionals who are now spread across the nation in regional centers to perform these services with the same efficiency and outcomes. Market forces and regional needs have led to decentralization of transplant services, and, in my opinion, this trend should continue. It is important to remember that to move an organ across country is more expensive, time consuming, and there is no net gain in lives saved. If there is any effect, it will be to reduce lives saved by producing poorer outcomes. Therefore, the solution for long waits in a few transplant centers is to allow natural forces to more evenly distribute waiting patients among regional centers producing a closer proximity of donor organ to recipient.

5. Having to move potential recipients from regional centers to a few national centers will cause a redistribution of organs benefiting the more affluent and well-educated, and disenfranchising low income and poorer educated people. Why? It takes considerable resources and support to relocate in another city and state, await transplantation for weeks or months, and then return home for on-going treatment. Anyone who has had to travel and remain away from home while sick can understand the difficulty. Furthermore, a person with liver failure requires the support of family and friends that may not be available, and even if available would cause unnecessary hardship on the patient's family. After regional centers have lost their transplant capability and expertise as a result of this new policy, patients with major complications will need to be transported back to the distant center at more expense, with further disruption of family, and with possible compromise of livelihood. The more likely scenario is that patients will have to be treated locally and necessary specialized care will not be readily available, thereby endangering the transplant and marginalizing its benefit.

In summary, Mr. President, the solution to the organ allocation debate is to continue to permit distribution of organs first to patients in the same region. This results in better overall utilization of available organs and more personalized and humane care for our patients. The transplantation process is not just a single event. The evaluation for transplant, the wait for a donor organ, and on-going post-operative care, including management of organ rejection and immunosuppression, is critical to long-term success. These functions, as well as the procedure itself, can best be carried out on a regional basis in relatively close proximity to the population served. To me this approach makes good, common sense that is borne out in practice.

Therefore, I implore you to instruct Secretary Shalala to reopen the debate on the subject of organ allocation in liver transplant. A fresh look, with consideration for the concerns I have enumerated, is needed before irreversible damage is done to many fine transplant programs. To transfer the responsibility for determining organ allocation policy from the private sector (UNOS) to HHS will politicize the organ allocation process that should remain consensus-based among healthcare professionals. I stand ready to assist you in any way possible to clarify these issues and to bring balance to the debate.

Sincerely yours,



John C. Bowen, M.D.  
Chairman, Department of Surgery

JB/dgs

### **Talking Points on Organ Transplant Rule Compromise**

- I. Delay implementation of regulation for six months.**
  - II. Data reporting requirements of the regulation implemented immediately.**
  - III. No independent study required.**
- ◆ **Livingston gets six month delay while Louisiana's judicial challenge to Secretary's authority to go forward.**
  - ◆ **Tantamount to one year delay before Secretary actually approves any organ allocation policy. Gives Congress ample time to reimpose moratorium.**
    - \* Regulation requires policy to be developed from two months (livers) to one year (all other organs) after moratorium ends. By the time the moratorium ends, policy is developed, and public comment is received, one year from October 1998 will pass.**
  - ◆ **Secretary pledges to continue working with Livingston to allay his concerns during the moratorium.**



DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Office of the Deputy Secretary

Washington, D.C. 20201

FACSIMILEDATE April 14, 1997

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

Mr. Chris Jennings

Ms. Sarah Bianchi

DPC

202/456-5560

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

Lisa Gilmore  
 Special Assistant to the  
 Deputy Secretary  
 DHHS

202/690-6133  
 202/690-7755 (Fax)

RECIPIENT'S FAX NUMBER (202) 456-5557NUMBER OF PAGES TO SEND (INCLUDING COVER SHEET): 3

COMMENTS:

FYI: HHS statement and Q & A's on non-heartbeating organ donors and use of vasodilators following Sunday's 60 Minutes story. We strongly advise the Vice President not to make a statement or comment on this sensitive issue.

Thanks. Lisa

STATEMENT BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

Organ donation truly constitutes the gift of life. For the recipient, a donated organ means a chance to overcome disease that in prior times would have been fatal. And for those who have lost a friend or family member, organ donation can be important in another way, providing solace and meaning in the often senseless death of a loved one.

Encouraging organ donation is a high priority for HHS, and assuring the integrity of the nation's organ donation system is an important element in supporting donation. Public faith in this system is the foundation of all the benefits of this lifesaving technology.

Our organ transplantation system is fundamentally sound. It provides safeguards for donors and for the families who must make decisions that are very sensitive and difficult. It is designed to address the many medical, legal and ethical issues that surround organ donation, to accommodate choices that need to be made by donors and their families, and to provide the proper context for making them.

At the same time, new issues will always arise that require special review. One such issue today is appropriate use of vasodilators in patients who may be potential organ donors. In order to help clarify this issue for the transplant community and for the public, HHS has asked the Institute of Medicine, a part of the independent National Academy of Sciences, to conduct a review. The IoM will make any needed recommendations to HHS.

Most important, however, we need to continue encouraging Americans to take time to consider organ donation and to agree to be potential organ donors. It would be tragic if our organ donation efforts were needlessly impeded by fears not grounded in fact.

Q and A - Non-Heartbeating Protocol and Regitine

*Do Americans need to be concerned that organs might be taken before a patient dies?*

No. Doctors know how to determine death, and organs are not taken until death has been determined. We have no reason to believe that organs have been taken improperly from patients who have not died. To the contrary, we have a system in place that is designed to protect patients, and we have every reason to believe it is working.

*What is your comment on media stories that suggest patients may be in danger of receiving less than thorough care if they might be candidates for organ donation?*

People need facts, not fear. It would be tragic if organ donation efforts were impeded by media stories based on unexamined reports. Our medical profession and our organ transplantation system are designed to protect patients. Americans can feel confident that they will get the care they need.

(For potential use AFTER broadcast of "60 MINUTES")

*What is HHS' reaction to the "60 MINUTES" report that the use of Regitine might hasten death in patients who are potential organ donors?*

Vasodilator drugs are used successfully and without harm to patients in many situations. However, it is prudent to review the use of these drugs specifically to preserve organs in patients who have not yet died. In order to clarify this issue, HHS has asked the Institute of Medicine, part of National Academy of Science, to conduct a review. The IoM will make any needed recommendations to HHS.

(The review should be completed in a matter of months. Cost: about \$50,000.)

Page 2

*Why is this review needed?*

The lack of consensus between different parties in the Cleveland situation shows that there is conflicting or incomplete understanding of the issue. The medical facts need to be examined in a careful way. Once these facts are established, any legal and ethical implications will be clearer.

*Should Cleveland (or other centers) desist from using Regitine in this way while the review is underway?*

We anticipate that IoM will be able to provide sound guidance when the review is complete. Until then, we do not have any basis to make a specific recommendation.

# HHS NEWS

## DRAFT

Organ Allocation File

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE  
( Revised D R A F T )

Contact: HRSA Press Office  
(301) 443-3376

### **HHS RULE AIMS AT FAIRER ORGAN TRANSPLANT SYSTEM Calls on Private Transplant Network to Develop Medical Criteria**

HHS Secretary Donna E. Shalala today announced a new regulation to improve the nation's organ transplantation system, providing for a more equitable system of organ allocation and better access to transplant center data.

The new rule calls on the Organ Procurement and Transplantation Network, the private sector system created by the National Organ Transplant Act of 1984, to develop revised organ allocation policies that will reduce the current wide geographic disparities in the amount of time patients wait for an organ. The rule also calls on the OPTN to develop uniform criteria for determining a patient's medical status and eligibility for placement on a waiting list. The criteria are aimed at assuring that patients with greatest medical need will receive scarce organs, no matter where they live or in what transplant center they are awaiting treatment.

"Transplant technology now enables us to do a better job in making organs available first to those with the greatest medical need," Secretary Shalala said. "Patients should not have to gamble that an organ will become available in their local area, nor should they have to travel to transplant centers far from home simply to improve their chances of getting an organ. Instead, patients everywhere in the country should have an equal chance to receive an organ, based on their medical condition and the judgment of their physicians. That's what the law intended, and that's what this regulation is about."

In addition to today's action, the Clinton Administration last year launched a new National Organ and Tissue Donation Initiative with public and private sector partners, aimed at increasing organ donation by 20 percent within two years.

"The real answer to the problem of scarce organs is to increase the number of organ donations," Secretary Shalala said. "Human organs for transplantation will always be scarce, and we need to allocate them in as fair and effective a way as possible. But we can also do much better in encouraging Americans to agree to be organ and tissue donors. Our national initiative is a serious new effort to bring about more organ donation."

Under the regulation announced today, the OPTN would be required to modify existing organ allocation policies. Under the current policies, matching organs are usually made available to all listed patients in a local organ procurement area before they are made available to other patients outside the local area. This means less ill patients in the local area may receive a transplant while patients with more urgent medical need in another area continue to wait.

"While current OPTN policy does recognize the need to make organs available first to those with greatest medical need, it too often confines the availability of the organ within arbitrary geographic areas," Secretary Shalala said. "With today's technology, we make organs available over a wider area and reach those with most urgent need."

Under today's regulation, three new sets of criteria for organ allocation would be developed by the OPTN, whose members include transplant centers and other transplant organizations. Development of the criteria would include public input and comment and final HHS approval. "We want medically sound criteria, developed by transplant surgeons and others who know most about transplantation," Shalala said.

The three sets of criteria to be developed by the OPTN are:

- Criteria aimed at allocating organs first to those in the highest medical urgency status, with reduced reliance on geographical factors. This should reduce disparities in waiting times for patients at different transplant centers in different areas of the country. Today, there is a wide variation in waiting times, with patients in some areas waiting five times longer or more for an organ than in other areas. The new criteria would provide for wider sharing to assure organs were made available to patients with greatest medical need.

- Criteria to be followed in deciding when to place patients on the waiting list for an organ. Today, each transplant center establishes its own criteria, with the result that patients listed at one center may not be as ill as patients not yet listed at another center with more stringent medical listing criteria. Under the regulation, the OPTN would develop medically objective criteria to be used by all transplant centers.
- Criteria for determining the status of patients who are listed. Medically objective, uniform criteria would help ensure a "level playing field" in selecting among patients and determining which have the greatest medical need. The OPTN is already developing uniform criteria of this kind.

The final rule includes a new 60-day comment period, and becomes effective 90 days after publication in the Federal Register.

"Together, these new uniform criteria will add up to a fairer and more understandable system, which will serve both patients and the transplant system better," Secretary Shalala said.

Other provisions of today's regulation include enhanced access to center-specific data about transplant centers, measuring outcomes and helping patients and physicians to choose among transplant centers; a broad definition of the composition of the OPTN membership and board of directors; the process for HHS review of OPTN policies before they become mandatory for OPTN members; and approval authority over the fees charged for registration on the OPTN waiting list (currently \$357, usually paid by an insurer, most often Medicare or Medicaid.)

The OPTN includes 281 U.S. transplant centers and 63 organ procurement organizations, as well as other public, medical and professional organizations

The final rule is available on the World Wide Web at <http://www.hrsa.dhhs.gov/bhrd/dot.main.htm>.

###

**DRAFT****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

"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****DRAFT**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

March 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:*

- o 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.*
- o In March 1998, approximately 54,500 people were on the national transplant waiting list, and the list grows by about 500 each month.*
- o 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.*
- o 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.*
- o 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.*

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### 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.

- 3 -

### 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

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### 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:

o **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.

o **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.

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- o **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.
- o **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, health 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.
- o **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.
- o **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>.



DEPARTMENT OF HEALTH & HUMAN SERVICES

**CONFIDENTIAL**

**Melissa T. Skolfield**

Assistant Secretary for Public Affairs

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Date: \_\_\_\_\_ Total number of pages sent: Cover + 13

Comments:

→ THIS IS PACKAGE # 2, OF 2.

→ THESE ARE THE INTERNAL MATERIALS: TP's, Q & A's.

→ Sarah - I'm moving page 8 & 9 of SA, which had some more Q & A's.

**BACKGROUND / TALKING POINTS****OPTN Regulation**

---

**OUR ORGAN TRANSPLANTATION SYSTEM MUST BE FAIR AND EFFECTIVE FOR PATIENTS**

- Fourteen years ago, Congress passed the National Organ Transplant Act. The purpose of the Act was to assure that America would have an organ transplantation system that worked fairly and effectively for patients. In the years since then, we've made great progress in the technology of organ transplantation -- the lives of thousands of patients are saved or improved every year.
- But organs for transplantation are in very short supply, and our policies for allocating these scarce organs have not kept pace with our technological progress.
- We have launched a significant new National Initiative on Organ and Tissue Donation. But in addition, our allocation policies must be as fair and effective as possible for patients.

**TODAY'S SYSTEM PUTS TOO MUCH EMPHASIS ON LOCAL ALLOCATION WITHIN ARBITRARY GEOGRAPHIC AREAS, AND TOO LITTLE EMPHASIS ON PROVIDING FOR PATIENTS WITH GREATEST MEDICAL NEED**

- Under today's system, a matching organ may not reach the patient with greatest medical need. Instead, organs are treated as though they were the "property" of the local procurement area and are offered first to all the matching patients who are listed within that area.
- Thus, an organ that could save the life of a patient who is in more urgent medical need may never reach that patient, because it is used instead for a patient who is less ill but who is located in another area where the organ was procured.

Background/Talking Points - Page 2

**MANY INEQUITIES RESULT FROM TODAY'S ALLOCATION SYSTEM, INCLUDING ENORMOUS VARIATION IN WAITING TIMES FOR DIFFERENT AREAS OF THE COUNTRY**

- Under today's system, a patient's chances of getting an organ can depend more on where the patient lives or is listed than on his or her medical condition. Waiting times for organs can be five times or more longer in some areas of the country than in others.
- This means patients must gamble on a matching organ becoming available in their local area, or must travel to faraway centers to improve their chances of getting an organ. This is clearly not the situation the law intended -- and, with today's technology, it is unnecessary.

**WE CAN DO BETTER TO ASSURE THAT ORGANS GET TO PATIENTS WHO HAVE GREATEST MEDICAL NEED**

- Families who agree to the donation of a loved one's organs expect the donated organs to be used for patients who have the greatest medical need, in accordance with good medical judgment. Technology now permits longer preservation of organs, enabling them to reach those with greatest need.
- Current allocation policies can be modified to assure that all patients will have a more nearly equal chance for a matching organ, based on their medical need, not on the chance of where they live or in what medical center they are receiving treatment.

Background/Talking Points - Page 3

**TO ACHIEVE THE GOAL, THE HHS REGULATION ESTABLISHES PERFORMANCE GOALS TIED TO THE OBJECTIVES OF THE LAW; BUT THE POLICY-MAKING PROCESS IS LEFT IN THE HANDS OF TRANSPLANT PROFESSIONALS**

- The organ transplantation law created a private-sector Organ Procurement and Transplantation Network to operate the nation's transplant network. The OPTN operates under contract to HHS. In its final regulation, HHS requires the OPTN to create criteria that will result in allocating organs first to those in the highest medical urgency status, while reducing the emphasis on arbitrary geographical limits.
- HHS does not seek to create these criteria itself. The Department does not want to interfere in the practice of medicine. HHS wants medically sound criteria, developed by transplant surgeons and others who know most about transplantation.

**THE HHS APPROACH REPRESENTS A MIDDLE-COURSE, GUIDED BY PATIENT WELL-BEING, NOT BY THE COMPETING INTERESTS OF DIFFERENT TRANSPLANT CENTERS**

- The acute shortage of organs for transplantation makes this subject highly-charged and sensitive. Some have urged HHS to take over the process of creating allocation policies in order to make it fairer. Others have urged HHS to take no part at all in these policies. In the regulation, both of these extremes have been avoided.
- The approach adopted by HHS is guided by the well-being of patients; the intent of the law; the premise that patients with greatest medical need should receive available organs, consistent with sound medical judgment; and the desire that allocation policies be designed by those who know most about transplantation.

OPTN REGULATION  
TOP-LINE QUESTIONS AND ANSWERS

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QUESTION 1:

Doesn't this regulation represent government interference in the practice of medicine? Why should government be dictating medical decisions? In fact, why should the government regulate at all in this area?

ANSWER:

This regulation does not dictate medical decisions. It simply carries out the federal responsibility, as required by the National Organ Transplant Act of 1984, to assure that America's organ transplant system works fairly for patients. The regulation specifies transplantation goals that are consistent with the purposes of the law - but it very explicitly leaves medical decision-making to doctors and patients, and medical policy-making leadership to transplant professionals.

Other background:

The National Transplant Act struck a balance, and our regulation preserves that balance:

- The law made it clear that donated cadaveric organs were to be treated as a public trust. The Secretary of HHS was given the responsibility to assure that, as a public resource, organs were allocated fairly. Indeed it was the whole issue of fair allocation that gave rise to the legislation (for example, to assure that organs were not marketed to the highest bidder.) In this regulation, we provide final definition of that appropriate federal role.
- The law also created a private-sector network (the Organ Procurement and Transplantation Network) to administer day-to-day operations and to make the medical decisions - and the regulation also preserves that role for the OPTN.

**QUESTION 2:**

Aren't you injecting politics into the system, where the law wanted politics kept out? Aren't you just responding to lobbying by big centers like Pittsburgh?

**ANSWER:**

Not at all. Our responsibility under the law, and our guiding principle, has been to assure an equitable system for patients. That is the appropriate and necessary HHS role. We look to a continued partnership with the OPTN in translating the goals of the law into effective organ allocation policies.

Other background:

There are indeed strong feelings about this issue, and many different entities have expressed a variety of different viewpoints.

The extensive comment periods and special hearings we have held on these rules reflect the need to air those different viewpoints. That is why we are offering yet another comment period before this regulation becomes effective.

Some entities would want HHS to take over the allocation policy-making process. Other entities want HHS to take no role at all. We have opted for neither of these extremes. Instead, we have adhered to a middle ground, which is the balance struck by the law itself.

**QUESTION 3:**

What will be the results of your regulation?

**ANSWER:**

A more equitable system that works better for patients:

- Organs will reach patients who need them most - There will be more emphasis on medical need, and less emphasis on the accident of geography. The regulation builds on current policies that allocate according to medical need, but confine the initial search to an artificial geographic area, reflecting no medical rationale. The regulation calls for allocation according to medical need, wherever they live or are listed.
- A more level playing field - By requiring objective medical criteria to be used by all transplant centers, the regulation will help reduce uncertainties. There will be less incentive for multiple listing or traveling to distant centers with shorter wait lists.
- Less variation in waiting times - The regulation requires allocation policies that reduce waiting time disparities.
- Greater general perception of fairness in the system, with possible positive impact on organ donation - Families who donate organs of a loved one expect the organs to be provided according to medical need and sound medical judgment.
- Better data for patients and their doctors - Patients and doctors need current, understandable data when choosing a transplant center.
- Continued technological progress - By relying on transplant professionals for policy leadership and day-to-day operation, the regulation continues to provide for the flexibility that enables technological advancement.

**QUESTION 6:**

Why doesn't HHS just go ahead and set the allocation policies?

**ANSWER:**

HHS wants criteria that are medically sound, and we want a policy-setting mechanism that is flexible and responsive to technological progress. The regulation defines a process for policy-making that includes the opportunity for input from all those who are interested. But we look to transplant professionals in the OPTN to lead the policy development process.

**QUESTION 7:**

Will some centers be forced to close as a result of the regulation?

**ANSWER:**

There is absolutely no reason to believe that centers should close just because organs are directed to patients with the greatest medical need. The fact is that the most ill patients would receive organs, wherever they were located. Since all transplant centers serve a mix of patients in various stages of disease, patients in every center would benefit from a change that enabled organs to be directed to those with greatest medical need.

It is true that we will require better and more timely information for patients and physicians to use in selecting centers, and closer monitoring of center performance by OPTN. If this data were to reveal poor quality care at any center, then such a center might be threatened. That would be a completely proper outcome.

**QUESTION 8:**

Won't you be wasting organs by transplanting to sicker patients, who are then more likely to die?

**ANSWER:**

No. In fact, it is already the policy of the current allocation system to transplant those with greatest medical need first, within the local procurement area. Naturally, specific judgments in each case are made on the scene by transplant professionals. That would not change at all under the regulation.

All that would change is that a broader pool of organs would be available for a given patient, making it more likely that this patient will receive an organ when he or she needs it urgently, no matter where he or she is receiving treatment.

**QUESTION 9:**

Why has OPTN failed to make these changes? Why will they be able to make them now?

**ANSWER:**

We don't know why the OPTN has failed to update its allocation policies in significant ways. It has attempted to balance a number of competing objectives, but has not maintained sight of the statute's objective: a national system which treats patients equitably. We believe that with a clear regulatory framework, the transplant community will rise to the challenge

**QUESTION 10:**

Are you taking organs away from local areas to send them to the big centers?

**ANSWER:**

No. The point is to provide organs to patients who need them most. Depending on the matching characteristics of organ and patient, and the amount of time the organ can be preserved, an organ should be enabled to go wherever the patient is found who will benefit the most - no matter which center he or she is in.

Today's system can act to "lock" these organs in arbitrarily-defined geographic areas, preventing them from reaching the patients who need them most. But this is not what the law intended, and it's not what donating families want.

Patients with greatest medical need, should be served, no matter where they are located. Sometimes they will be in one center, sometimes in another. This regulation does not benefit one center, or one class of centers, over another.

Another way of answering:

[The question is not: "Where are organs taken from?" Organs are taken from donors and given in public trust. They do not belong to individual centers or procurement areas.

[The right question is:: "Where are organs to be provided TO?" They are meant to be used, according to the best medical judgment, for patients who need them most. The organs should not be prevented from reaching the patients who need them most, wherever those patients may be.]

**QUESTION 11:**

Under this regulation, will patients have to leave their home transplant centers and go to the big centers?

**ANSWER:**

No, just the opposite. If organs are freed to cross arbitrary boundaries and reach the patients who need them most, then patients will be more able to list at the center of their choice - for example, close to home, in those areas where a center exists nearby.

It is under today's allocation system that patients may feel the need to travel to faraway centers simply to improve their chances of getting an organ. We want a system where patients have both choice of center and an equal chance at getting an organ.

**QUESTION 12:**

Will organ donation be negatively impacted by shipping organs out of local areas?

**ANSWER:**

Bringing organs to the patients who need them most will not impede organ donation. Donating families want the donated organs to be used according to best medical judgment for patients with greatest medical need. That is what the Transplant Act intended, and it's what this regulation is all about.

**QUESTION 13:**

Is there protection for patients on the waiting list now, as a new allocation system is developed?

**ANSWER:**

Yes. The regulation calls for OPTN to develop new criteria, but these new criteria are not due until 60 days after the effective date of the regulation. Therefore there is not an immediate effect. In addition, as part of the new criteria, OPTN is called upon to develop transition rules that will protect patients already on the list, leaving them no worse than under current policies.

**QUESTION 14:**

What will HHS do if the OPTN declines to produce new criteria?

**ANSWER:**

We are confident that the OPTN will want to produce allocation criteria that serve their members and patients in the best way possible. While HHS has the authority to write new allocation policies itself, we would only do so if the OPTN failed to act satisfactorily, and we do not expect that to happen.

**QUESTION 15:**

Do you expect an effort in Congress to intervene and block this regulation?

**ANSWER:**

We are anxious to work productively with Congress. We have built in an additional comment period, both to hear from the public and to give Congress an opportunity to conduct its own review of these regulations.

202 456-5557

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# Mental Health Liaison Group

NOTE: 33 organizations signed on to this letter.

March 18, 1998

Senate Labor and Human Resources Committee  
428 Dirksen Senate Office Building  
Washington, DC 20510

*Parcey Fib*

Dear Members of the Senate Labor & Human Resources Committee:

As providers, consumers, advocates, and family organizations concerned about the confidentiality of medical records we welcome Senator Robert Bennett's and Senator James Jeffords' efforts to produce a comprehensive draft medical records confidentiality bill, (the Medical Information Protection Act). However, we would like to express our strong reservations about the draft in its current form. Key provisions illustrated below need to be changed in order to protect patients from disclosures which invade their privacy and could damage the quality of health care they receive.

We hope it will be possible to work with you to see that important modifications need to be made to allow responsible medical records confidentiality legislation to proceed.

\* We strongly urge that an exception from federal preemption for mental health records be included in your bill. Many state laws have specific provisions protecting the confidentiality of mental health records. These state laws reflect the recognition of the need for special protection for the confidentiality of mental health records due to misconceptions and stigma about mental illnesses which often translates into discrimination against those who are known to suffer from these disorders. Therefore, we strongly urge that an exception from federal preemption for stronger state mental health laws be incorporated into your legislation and that in the future states be allowed to adopt more protective privacy laws.

\* The principle that patient consent to disclosures of medical records be informed, voluntary, and non-coerced is critically important. Under the draft bill patients would have little choice but to provide consent for a broad range of disclosures of their medical record if they wished to receive care. The bill as drafted permits payers to demand all details from a record, if they choose to do so. It also permits health plans to terminate coverage of individuals who do not wish to share so much of their personal information. In addition, employees would have inadequate protection from employers who wished to review their records or from pharmacies which wished to disclose certain information on a patient's medications history. The result of these inadequate privacy protections is that many patients would hold back from providing needed information, and in the case of mental health care many individuals will be less likely to seek mental health treatment and would be more likely to drop out of treatment.

\* We also recommend that limits should be placed on the information which patients must disclose. In particular psychotherapy notes and the most personal information revealed in treatment should not have to be disclosed to insurance companies or health care plans for payment purposes.

In this letter, we are not addressing the issue of consent to disclosures for research purposes because of the particularly difficult tradeoffs involved and the diversity of our views on the issue. We also note that several of our groups have additional important concerns that we will contact you about separately, including the lack of needed protections from searches of medical records by law enforcement personnel.

Thank you for considering our views. We ask and hope that we can work together to address these important issues. For further information, please contact William Bruno of the American Psychiatric Association at (202) 682-6046, Doug Walter of the American Psychological Association at (202) 336-5889, Chris Koyanagi of the Bazelon Center for Mental Health Law at (202) 467-5730, Ron Honberg of the National Alliance for the Mentally Ill, Madeleine Golde of the National Association of Social Workers at (202) 336-8237, Al Guida of the National Mental Health Association at (703) 838-7502, or Janet Shikles of Powers, Pyles, Sutter and Verville at (202) 872-6732.

Sincerely,

American Academy of Child & Adolescent  
Psychiatry  
American Association for Psycho-Social  
Rehabilitation  
American Association of Children Residential  
Centers  
American Association of Marriage and Family  
Therapy  
American Association of Private Practice  
Psychiatrists  
American Board of Examiners in Clinical Social  
Work  
American Counseling Association  
American Family Foundation  
American Group Psychotherapy Association  
American Mental Health Counselors of America  
American Occupational Therapy Association  
American Orthopsychiatric Association  
American Psychiatric Association  
American Psychoanalytic Association  
American Psychological Association  
American Psychiatric Nurses Association  
Anxiety Disorders of America

Association for Ambulatory Behavioral Health  
Association for the Advancement of Psychology  
Bazelon Center for Mental Health Law  
Child Welfare League of America  
Corporation for the Advancement of Psychiatry  
Federation of Families for Children's Mental  
Health  
National Alliance for the Mentally Ill  
National Association of Protection and Advocacy  
Systems  
National Association of Psychiatric Treatment  
Centers for Children  
National Association of School Psychologists  
National Association of Social Workers  
National Council for Community Behavioral  
Healthcare  
National Depressive and Manic Depressive  
Association  
National Federation of Societies for Clinical and  
Social Work  
National Mental Health Association  
Powers, Pyles, Sutter & Verville

File Organ Donation

February 26, 1998

FAX TO:

WH PRESS OFFICE *-Shalala*  
Chris Jennings

Media coverage is likely today on the subject of organ donation and transplantation.

A demonstration is planned at HHS by patient advocates who want the Department to issue its long-awaited regulations on the operation of the Organ Procurement and Transplantation Network.

At the same time, a letter from Secretary Shalala is being sent to each of the 89 members of Congress who have signed letters to her on this subject this year. The letter lays out the principles that are being followed in developing the regulation.

Attached are the letter to members of Congress and some Q's and A's dealing with today's demonstration.

Melissa Skolfield

Questions and Answers - for February 26

*What is HHS' reaction to this demonstration?*

We are sympathetic with those who are demonstrating, and with anyone who faces the need for an organ transplant. We believe this shows how important it is to increase organ donation in our country. We agree that, in a situation of shortage, decisions about who gets organs are extremely difficult to make, and our organ allocation system needs to be as fair as it can be.

*What is the status of the OPTN regulation? Why is it taking so long to produce? Why hasn't it been published?*

The regulation has required extensive work and development. The issues are complex and sensitive. That's why we had additional hearings and comment period. It will be published once we are satisfied that we have struck the right balance and produced the best possible rule.

*What's so complex and difficult about it?*

The letters we have received from members of Congress, which express a variety of viewpoints, reflect the complexities and divisiveness of the issue. We have responded with a letter to all members of Congress who have contacted us recently. Our response acknowledges those complexities and presents the principles that are guiding us.

[If pressed: On the one hand, HHS is responsible for assuring that the Nation's transplantation system works as fairly and effectively as possible for patients. This regulation will be important in carrying out that responsibility. At the same time, we want the private Organ Procurement and Transplantation Network to continue to be responsible for developing medically sound and equitable organ allocation policy. The regulation needs to achieve both these goals.]

Page 2 - Q&A

*Is the present organ allocation system unfair?*

From the standpoint of those awaiting transplants, we have not yet achieved many of the important benefits of a national organ-sharing network that were envisioned by NOTA. Organ donation needs to be increased. And we need to assure the most equitable possible distribution of organs to patients with greatest medical need. See our letter to members of Congress.

[As needed: There is a wide span in average waiting times for those on transplantation waiting lists. And there are geographic disparities in who receives organs. Where waiting times are shortest, organs frequently 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.

[This system can be improved to make the most effective and fairest use of organs, so that patients will have an equal chance for an organ, depending on their medical need, no matter where they are listed.]

*Do you agree that 1,000 patients have died unnecessarily, as symbolized by the flowers presented by the protesters?*

There is no way to know. We really don't need to know any such number in order to be able to see that the Nation's organ allocation system could be better. Even one unnecessary death would be too many, if it resulted from a system that could be improved. With the severe shortage of organs that exists today, our most important task is to increase organ donation and thus increase the supply of organs so that patients will not die while awaiting a transplant. That is why we have launched a national organ and tissue donation initiative. In addition, we want to assure the fairest possible organ allocation system, and that will be a primary goal of the OPTN regulation.

Page 3 - Q and A

[Additional background: Computer models sponsored by private entities have been run to try to determine the effects of the present allocation system (involving livers) and of various alternatives. They have produced differing results. Presumably one of these models was used to produce the result cited by the protesters. While the models produce differing numbers, they do generally support the finding that more lives could be saved if livers were shared more widely.]

*What would you say to the child (Daniel Canal) and to others who are awaiting an organ?*

We would say what anyone would say: We hope he receives a successful transplant soon. [If pressed on what HHS is doing for him: We would say that we have launched a nation-wide effort to increase organ donation so that we can reduce the shortage of organs. And we would say that we want the organ allocation system to work fairly for him and for all other patients. But we can certainly not comment directly on a particular case.]

*Is HHS meeting with Senator Frist to discuss this regulation?*

A letter has been sent to every member of Congress who has written to us recently about this subject. The identical letter of response is going to all these members. It outlines our principles in developing the OPTN regulation. Over time, we have met with several interested members of Congress and their staffs. We are willing to meet with other members and their staffs as requested to discuss these principles enunciated in our letter, but the meetings are private and we will not be announcing them.

*Why didn't Secretary Shalala accept the flowers offered by the demonstrators?*

We made clear to the demonstrators that the Secretary would not be here today. They used her name in their media advisory nonetheless. [The demonstrators' specific request to us was a meeting with Daniel and others, and we agreed to that.]

Page 4 - Q and A

What about the administration's interest in a patients' Bill of Rights? Shouldn't the right to an organ be guaranteed for the sickest patients?

The health care consumers bill of rights has never been intended as a guarantee of specific treatments. [It concerns the rights of patients in dealing with health care providers.]



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

Page 2

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.

Page 3

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

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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

Page 5.

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.

Page 6

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

## MEMORANDUM

April 8, 1997

TO: John

FR: Sarah

The attached note provides a brief description on how major religious organizations can become involved in organ donation. In addition, you should be aware that:

- Some of the educational activities will involve dispelling some of the myths and misunderstandings about organ donation in the context religion. Apparently, organ donation is morally and ethically accepted by the Vatican (see attached quote).
- There is a possibility that there would be some Federal funds available for these activities. (The Union of American Hebrew Congregations received \$6,000 from HRSA.)
- There is an Annual Donor Sabbath in November, which is a time for heightening awareness, doing activities with various congregations. (I am trying to find out more).
- This partnership would be announced at the Vice President's event with organ donors next Sunday. We could most likely get an invitation for a representatives to attend this announcement.

Is this enough information to make a call to CHA? I am trying to get HRSA to produce more formal paper. Please advise. -- Sarah 65585.

**ORGAN DONATION**  
**Partnerships with Major Religious Organizations**

Each year, thousands of Americans die while waiting for the organ or tissue transplants needed to save their lives. Today the waiting list exceeds 50,000 and in 1995, approximately 3,500 people died while waiting for an organ. Religious organizations can play a critical role in encouraging their members to make the decision to be an organ donor and to share that decision with their families. While individual congregations have promoted organ donation, the support of national religious organizations is essential to reaching all Americans with this critical message. The Union of American Hebrew Congregations and the Congress of National Black Churches are partners with the U.S. Department of Health and Human Services in this important effort and can serve as a model for the participation of other religious organizations.

To support organ donation, national religious organizations can:

Educate their respective clergy and congregations through tailored newsletters, brochures, seminars, guest speakers, and sermons.

Counter myths that inhibit organ donation.

Participate in the National Organ Donor Sabbath (November).

Be a model for other religious organizations.