Memo

To: Jennifer Klein
From: Susan Gyeszly
Subject: Transplant Organ Allocation
Date: June 22, 1998

Overview

On March 26, 1998, HHS Secretary Shalala announced a new regulation to improve the nation's organ allocation system. Public comment has been requested until August 31, 1998 with the effective date of the rule October 1, 1998. The regulation sets three broad performance goals for organ allocation. These include:

1. Standardized listing criteria for placing patients on waiting lists, using objective and measurable medical criteria;
2. Standardized criteria for determining medical status, also based on objective and measurable medical criteria, sufficient to differentiate patients from least to most medically urgent.
3. 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.

Background

HHS's Division of Transplantation (DOT) manages the Organ Procurement and Transplantation Network (OPTN), whose primary function is to maintain a 24 hour-a-day national organ placement center to match donors and recipients. Since 1986, the DOT has administered a contract with the United Network for Organ Sharing (UNOS), in Richmond, Virginia, for the operation of the OPTN.

UNOS Analysis of Proposed Organ Transplant Regulations

UNOS agrees with first two parts of the regulation which instruct UNOS to develop national standards that would govern when doctors put patients on the waiting list for a transplant and when patients are moved up in priority on that list. In fact, last year UNOS instituted national guidelines for determining these items. However, the organization disagrees with the third component that eliminates the current local-based allocation system in favor of one national list based on medical urgency, or "sickest first." They believe this will lead to several issues.

1. Longer waits, sicker patients, fewer lives save. UNOS believes that the regulation will require a national list with a "sickest first" criteria, which means patients will become sicker before they receive their transplant. Statistics show

that patients who are extremely ill when given a transplant have a higher rate of failure. However, the HHS argues that while organs should be allocated according to need, they have not devised a rigid directive that would require futile transplants. In fact, they have included a directive stating that organ allocation policies must be designed to avoid organ wastage and poor utilization. The regulation also calls on the organ network, and thus UNOS, itself to develop the new allocation policies.

2. Local centers will close; organ donation will be affected. UNOS believes that by centralizing into a national waiting list, the larger centers that have more patients will perform more transplants, thus leaving smaller, local centers to fail. Also, UNOS believes people are more willing to donate if they know that the organs will stay in the area. However, the HHS feels that there is no evidence of this and instead a 1994 survey found that "an overwhelming majority of donor families state as their preference that organs go to the neediest patient regardless of geography, so long as organs are not wasted.

3. Transplantation access for poor will decrease. If many of the smaller transplant centers close, many transplant patients will be required to travel far from home. This would be an added struggle to patients, one of five that are already on Medicaid.

4. Transporting organ decreases success rates. By abandoning the local system of organ allocation, organs will need to travel farther distances, leading to lower rates of success.

5. Legal uncertainty for UNOS. The National Organ Transplant Act intended to have organ transplantation policy in the private sector and the HHS regulation assert executive branch control over the program without appropriate legislative authorization.

6. Preemption of State Law. The new HHS regulations would preempt many state laws that currently govern organ procurement and distribution. In fact, the Washington Post reported on Jun 16, 1998 that four states (Wisconsin, Oklahoma, Louisiana and South Carolina) have passed "organs-for-state-residents-first" laws.

Letter from Donna Shalala to members of Congress

In response to these criticisms, Secretary Donna Shalala wrote a letter to members of Congress stating that the Department's new regulation does not mandate specific organ allocation policies.

She also stated that the primary objective in issuing regulation is to assure that patients receive organs based on standardized medical judgement and common medical criteria, no matter where they live or in which transplant center they are awaiting treatment. The change in policy stemmed from the fact that one of the current shortcoming of the current allocation system is the wide span in average

waiting times for those on translation waiting lists. In some areas of the nation, patients wait at least 5 times longer for an organ that those in other areas. She also enclosed a letter form Claude Earl Fox, M.D., Administrator of the Health Resources and Services Administration. He stated that the current allocation system is geographically biased and does not distribute organs on the basis of medical urgency which violates the requirements of the National Organ Transplant Act which calls for equitable system to distribute organs.

aged lenient White House treatment of Loral's exports to China—raised the most ire among congressional Republicans.

As a result, the House bill that would bar satellite sales to China passed in two days with very limited debate. The SIA and other business groups have urged the Senate to adopt a go-slow approach.

The industry needs foreign launches to meet the demand for satellite services, the SIA says. "The U.S. is poised to be a great exporter of technology and services," Levin said. "We don't want people to overreact."

The China episode and the PanAmSat satellite's failure have forced the association to rethink how it operates, SIA officials added. Outrage over the pager blackout demonstrated to the group's officials the public's growing awareness of how much it depends on satellite communications.

Given the flurry of Capitol Hill activity, Mowry expects to register as a lobbyist, something neither he nor two other SIA officials did before the recent crises. Historically, the heavy lifting had been done by the SIA's member companies and their hired guns.

The SIA is taking a lead role in trying to block the Federal Communications Commission (FCC) from auctioning off frequencies for satellite communications. The SIA contends that the international nature of satellites means that before the FCC acts, international agreements need to be struck, so that every country does not charge for the same frequencies.

The SIA is claiming a partial victory on the auction issue. The FCC auctioned off some frequencies, but the SIA's lobbying effort, Mowry says, helped "stem the tide" by at least delaying future auctions. Legislation that would prevent future auctions has passed the House. A companion bill has not been introduced in the Senate.

On one hot-button issue—whether the federally chartered company COMSAT should be privatized—the SIA is unable to take a position. Both COMSAT and pro-privatization rivals such as PanAmSat are members. Legislation on the matter has passed the House and is pending in the Senate. ■

■ From the K Street Corridor ■

Organ-Sharing Fight

The nasty battle over which patients should be first to get organ transplants pits doctor against doctor, top research hospitals against regional transplant centers and the Health and Human Services Department (HHS) against its own contractor, the United Network for Organ Sharing (UNOS). At issue is an HHS rule that would provide hearts, kidneys and livers to the sickest people, no matter where they live. Critics say the regulation would cause more deaths, increase costs and force some transplant centers to close. Approximately 55,000 people are on the national waiting list.

The squabble has reached Capitol Hill, and each side is lining up its top guns. The Patient Access to Transplants Coalition, a newly formed group of regional transplant centers, has retained Martha M. Kendrick, a partner at Patton Boggs, and H. Stewart Van Scoyoc, president of Van Scoyoc Associates Inc. Meanwhile, UNOS, which is based in Richmond, Va., has recently hired Black, Kelly, Scruggs & Healey. And the University of Pittsburgh Medical Center, regarded as the nation's premier transplant center, has signed up former House Minority Leader Robert H. Michel, who is at Hogan & Hartson, and Michael [illegible], a name partner at Wunder, Knight, Levine, Kaplan & Fersey.

—W. John Moore

Cheerleading for China

Corporate America's multimillion-dollar advertising blitz that supports renewal of China's most-favored-nation (MFN) trade status and backs the Clinton Administration's policy of engagement with China is getting a boost from former Presidents Bush, Carter and Ford, as well as two dozen top policymakers. The political heavyweights weighed in with an Open Letter to Congress that the United States-China Education Foundation recently had reprinted as an ad in the June 17 editions of *The New York Times*, *The Wall Street Journal* and *The Washington Post*.

What the ad doesn't say is that the two-year-old foundation is supported by a group of companies known in lobbying circles as the "Gang of Six," for their major stakes in China trade. They are the American International Group Inc., the Boeing Co., General Electric Co., General Motors Corp., International Business Machines Corp. and Motorola Inc. The ad also doesn't disclose that some of the ex-government big shots—such as former Secretaries of State Lawrence S. Eagleburger, Alexander M. Haig Jr. and Henry A. Kissinger—have done consulting on China trade issues and investments for several leading U.S. corporations.

Separately, the Business Roundtable reprinted a letter from 119 of its CEOs to Members of Congress calling for MFN renewal in the June 24 editions of *The Post* and *The Washington Times*. The ads were part of a $2 million effort that's expected to last for several weeks.

—Peter H. Stone

An Explosive Issue

Fireworks manufacturers are complaining about what they say is a bewildering array of local, state and federal regulations that govern their industry. Deerfield (Ohio)-based Midwest Fireworks Co., one of the biggest fireworks makers in the country, has hired former Rep. Lyle Williams, R-Ohio, to take the case to Capitol Hill. Williams works with Martha Michael, another lobbyist with International Capital Strategies Inc., in Washington. Both are also working closely with the American Fireworks Association and the American Pyrotechnics Association.

"The regulatory burdens threaten to put all the mom-and-pop fireworks stores out of business," Williams warns. "Fireworks, the Fourth of July, it's all American," he says. "The actual incidents of injury are minimal and most are caused by misuse. Show us where people are getting their fingers blown off. There are more kids injured riding bicycles than using fireworks."

—Shawn Zeller

ERNEST J. ISTOOK, JR
5TH DISTRICT, OKLAHOMA

COMMITTEE
APPROPRIATIONS
SUBCOMMITTEES:
TREASURY, POSTAL SERVICE AND GENERAL GOVERNMENT
LABOR, HHS, AND EDUCATION
NATIONAL SECURITY

AT LARGE WHIP
REPUBLICAN POLICY COMMITTEE

Congress of the United States
House of Representatives
Washington, DC 20515–3605

119 CANNON BUILDING
WASHINGTON, DC 20515–3605
(202) 225–2132
FAX (202) 226–1463

DISTRICT OFFICES
5400 N. GRAND BOULEVARD
SUITE 505
OKLAHOMA CITY, OK 73112
(405) 942–3636
FAX (405) 942–3742

FIRST COURT PLACE
SUITE 205
BARTLESVILLE, OK 74003
(918) 336–5546
FAX (918) 336–5740

5TH & GRAND
PONCA CITY, OK 74601
(405) 762–6778
FAX (405) 762–7049

ISTOOK@MAIL.HOUSE.GOV

To: Debra Wawman, WH Domestic Policy Council

456 287 8

FROM: **Dr. William A. Duncan**
Appropriations Committee Associate
Education, Labor, Health & Human Services

Office Phone: (202) 225-2132 Personal Phone: (202) 226-3454 Fax: (202) 226-1463
E-mail: william.duncan@mail.house.gov

Pages:

Message: Transplant Language

rector of the Office of AIDS Research shall transfer from such account amounts necessary to carry out section 2353(d)(3) of the Public Health Service Act

SEC. 210. Funds appropriated in this Act for the National Institutes of Health may be used to provide transit subsidies in amounts consistent with the transportation subsidy programs authorized under section 629 of Public Law 101–509 to non-FTE bearing positions including trainees, visiting fellows and volunteers.

SEC. 211. None of the funds appropriated in this Act may be made available to any entity under title X of the Public Health Service Act unless the applicant for the award certifies to the Secretary that it encourages family participation in the decision of minors to seek family planning services and that it provides counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities.

SEC. 212. Subsection (b)(1)(H) of section 401 of the Public Health Service Act (42 U.S.C. 281 (b)(1)(H)) is amended by striking "National Institute of Dental Research" and inserting "National Institute of Dental and Craniofacial Research".

SEC. 213 Notwithstanding any other provision of law, the Department of Health and Human Services shall permit the submission of public comments until September

30, 1999, on the final rule entitled "Organ Procurement and Transplantation Network" published by the Department in the Federal Register on April 2, 1998 (63 Fed. Reg. 16295 et seq.), and such rule shall not become effective before November 1, 1999.

SEC. 214. None of the funds made available in this Act may be used to implement or enforce the provisions described in section 482.110(c) or section 482.120(a)(8) of part 482 of title 42, Code of Federal Regulations, as contained in the proposed rule issued on December 19, 1997 (62 FR 66726).

SEC. 215. (a) Section 2003(c) of the Social Security Act (42 U.S.C. 1397b(c)) is amended by striking paragraph (8) and inserting the following:

"(8) $2,299,000,000 for the fiscal year 1998;".

(b) The amendment made by this section takes effect immediately after the amendments made by section 8401 of the Transportation Equity Act for the 21st Century take effect.

SEC. 216. The Consolidated Laboratory Building (Building 50) at the National Institutes of Health is hereby named the Louis Stokes Laboratories.

This title may be cited as the "Department of Health and Human Services Appropriations Act, 1999"

THE WHITE HOUSE

July 4, 1998

Betty Lowe, MD
Medical Director
Arkansas Children's Hospital
800 Marshall Street
Little Rock, AK 72202-3591

Dear Betty:

Thank you for your letter about the new HHS solid organ allocation policy. As you know, I have long admired the transplantation work done at the Arkansas Children's Hospital. The success of your heart transplant program is a testament to the dedication and excellence of the medical staff.

I have asked Jennifer Klein on my staff to look into the issues you raised about the new HHS policy. As you point out, we need to strive to find a balance between creating fair transplantation policies and ensuring that it is practical for patients to get the organs they desperately need. Jennifer will contact you to discuss this further and will continue to update me on this issue.

Sincerely yours,

Hillary

Hillary Rodham Clinton

Memo

To: Jennifer Klein
From: Susan Gyeszly
Subject: Transplant Organ Allocation
Date: June 22, 1998

Overview

On March 26, 1998, HHS Secretary Shalala announced a new regulation to improve the nation's organ allocation system. Public comment has been requested until August 31, 1998 with the effective date of the rule October 1, 1998. The regulation sets three broad performance goals for organ allocation. These include:

1. Standardized listing criteria for placing patients on waiting lists, using objective and measurable medical criteria;
2. Standardized criteria for determining medical status, also based on objective and measurable medical criteria, sufficient to differentiate patients from least to most medically urgent.
3. 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.

Background

HHS's Division of Transplantation (DOT) manages the Organ Procurement and Transplantation Network (OPTN), whose primary function is to maintain a 24 hour-a-day national organ placement center to match donors and recipients. Since 1986, the DOT has administered a contract with the United Network for Organ Sharing (UNOS), in Richmond, Virginia, for the operation of the OPTN.

UNOS Analysis of Proposed Organ Transplant Regulations

UNOS agrees with first two parts of the regulation which instruct UNOS to develop national standards that would govern when doctors put patients on the waiting list for a transplant and when patients are moved up in priority on that list. In fact, last year UNOS instituted national guidelines for determining these items. However, the organization disagrees with the third component that eliminates the current local-based allocation system in favor of one national list based on medical urgency, or "sickest first." They believe this will lead to several issues.

1. Longer waits, sicker patients, fewer lives save. UNOS believes that the regulation will require a national list with a "sickest first" criteria, which means patients will become sicker before they receive their transplant. Statistics show

that patients who are extremely ill when given a transplant have a higher rate of failure. However, the HHS argues that while organs should be allocated according to need, they have not devised a rigid directive that would require futile transplants. In fact, they have included a directive stating that organ allocation policies must be designed to avoid organ wastage and poor utilization. The regulation also calls on the organ network, and thus UNOS, itself to develop the new allocation policies.

2. Local centers will close; organ donation will be affected. UNOS believes that by centralizing into a national waiting list, the larger centers that have more patients will perform more transplants, thus leaving smaller, local centers to fail. Also, UNOS believes people are more willing to donate if they know that the organs will stay in the area. However, the HHS feels that there is no evidence of this and instead a 1994 survey found that "an overwhelming majority of donor families state as their preference that organs go to the neediest patient regardless of geography, so long as organs are not wasted.

3. Transplantation access for poor will decrease. If many of the smaller transplant centers close, many transplant patients will be required to travel far from home. This would be an added struggle to patients, one of five that are already on Medicaid.

4. Transporting organ decreases success rates. By abandoning the local system of organ allocation, organs will need to travel farther distances, leading to lower rates of success.

5. Legal uncertainty for UNOS. The National Organ Transplant Act intended to have organ transplantation policy in the private sector and the HHS regulation assert executive branch control over the program without appropriate legislative authorization.

6. Preemption of State Law. The new HHS regulations would preempt many state laws that currently govern organ procurement and distribution. In fact, the Washington Post reported on Jun 16, 1998 that four states (Wisconsin, Oklahoma, Louisiana and South Carolina) have passed "organs-for-state-residents-first" laws.

Letter from Donna Shalala to members of Congress

In response to these criticisms, Secretary Donna Shalala wrote a letter to members of Congress stating that the Department's new regulation does not mandate specific organ allocation policies.

She also stated that the primary objective in issuing regulation is to assure that patients receive organs based on standardized medical judgement and common medical criteria, no matter where they live or in which transplant center they are awaiting treatment. The change in policy stemmed from the fact that one of the current shortcoming of the current allocation system is the wide span in average

waiting times for those on translation waiting lists. In some areas of the nation, patients wait at least 5 times longer for an organ that those in other areas. She also enclosed a letter form Claude Earl Fox, M.D., Administrator of the Health Resources and Services Administration. He stated that the current allocation system is geographically biased and does not distribute organs on the basis of medical urgency which violates the requirements of the National Organ Transplant Act which calls for equitable system to distribute organs.

Return to Breaking News

Transcript of UNOS President Dr. Larry Hunsicker's Speech At UNOS Meeting of The Executive Board June 23, 1998

DR. HUNSICKER: Well, it's been a quiet week in Lake Woebegone. (Laughter.)

DR. HUNSICKER: With that comment, Garrison Keeler narrates all of the major and minor crises and triumphs of his little town in either southern Minnesota or northern Iowa, depending upon where you come from.

It has not been a quiet week in Lake Woebegone. I would also like to begin this by remembering an ancient Chinese curse. May you live in interesting times. (Laughter.)

DR. HUNSICKER: I've spent the last year in large measure speaking for UNOS and the transplant community, speaking to the public about UNOS and what we try to do in my role as your president and your representative to the public.

Today, I am grateful to have the opportunity to pass this onto my successor, Bill, and as I do this, I want to speak from myself to you, to my group in transplantation, to give you some of the thoughts that I have had this past year.

In many ways, I might have preferred to say all of what I have to say in private, but it is not appropriate for me to do that. I want to say that I accomplished nothing of what I had intended to accomplish when I started my term. I had well defined plans for the year. I knew exactly what I was going to accomplish.

I wanted to improve access to and use of UNOS data, and I spent the first part of the year confronted with the PTR turn down controversy. I have been concerned about the public image of UNOS, and I wanted in my year to improve the public image and to improve the sense that UNOS was swirlingly surrounded by controversy. I haven't succeeded in that.

I wanted to be, as I think each of the presidents before me has wanted to be, the first UNOS president to succeed in focusing on donation rather than allocation. I have spent the last part of my term dealing with issues largely of allocation. We have heard already this morning from Watson where we should be spending our time. I know Dr. Pfaff, like every prior president of UNOS, wants to spend the predominate amount of his time dealing with donation issues, and I want to join Watson and the other people who spoke to this, to ask that this community can finally turn from the issues of allocation to the issues of donation.

We must turn from our rancorous debate about allocation to the only thing which we can all join in and in the only thing that has the potential for solving our problems.

I'm pleased that yesterday the board of directors endorsed the resolution of the Council on Organ Availability to support strongly the HCFA conditions for participation, which would institutionalize required referral, something which I believe we all feel has the potential to make a real difference in donation.

We are pleased, Dr. Fox, to offer that support to HHS unequivocally.

Now, what you all want me to talk about is the UNOS/HHS business, the relationships and other things related to the regulations. I'm commenting here, since this is a public meeting, both to the community and to the Government.

I want to tell you there are two paths that we can take, and the first is the path of confrontation. I'm a classic scholar. Some of you who may know me well enough know this.

I will refer you to the story of the House of Atreus, in which the curse on that

house went back so far to an original grievance that nobody could remember what it was, but because of that grievance as it came down through the generations, Clytaemnestra was bound in honor to kill her husband, Agamemnon, and then Orestes and Electra, their children, were ordered by the gods to avenge Agamemnon by killing their mother, Clytaemnestra.

Because of the matricide, Electra had to die and Orestes went mad, and so it goes on. In a less classical tone, we could talk about the Hatfields and the McCoys. Nobody remembers where it started. It's all lost in the mists of history, but it determines where we are today.

This path leads from whatever ancient mythic distrust started between UNOS and HHS, to regulations announced largely unilaterally, to outraged response, to counter response and wound up at a congressional hearing.

A wiser head than mine observed those hearings, spoke with praise of Secretary Shalala's dignity in handling her side, and had nice things to say about the way UNOS handled its side. He concluded who won, no one won, neither side won, transplantation lost.

That road is still open before us. There are congressional actions. There are other things going on, and the road down that way lies to mutual assured destruction or what has been known in the community as MAD.

Now, from the beginning, it has been my position that if the HHS leadership and UNOS and the transplant community leadership could meet and talk things over, we could find a way to come to work together.

We now have that opportunity, and we must use it wisely. The latest letters of Dr. Fox and Secretary Shalala and what Secretary Shalala said at the testimony on the 18th had lots of things to say but the central and only important part of what these have had to say include the following comments:

Specific rules for allocation of organs should be made by and come from the community, not from the Department. There will be flexibility about what the final rules might be. Our system must strive to achieve fairness as much as possible and as much as prudent, given medical realities, and the Secretary explicitly said at the hearings that she wants to re-build the relationship between HHS and the OPTN contractor or UNOS. These are certainly our objectives, too.

How do we go from here? The images that came to me as I was thinking about this were two. First is the dance, again, a classical thing, the tarantella, which is a classic dance which is actually in its origins, supposedly the acting out by dancers of the engagement between a male and a female spider, trying to decide whether to kill and eat each other or to make love.

The other was the famous question about how porcupines make love, maybe a little bit more vegetarian and a little bit less aggressive, and the answer is very, very carefully.
(Laughter.)

DR. HUNSICKER: On the 8th of May, we had our first meetings with HHS since the release of the regulations. Dr. Fox and some of his associates met with Walter and me in a meeting that was at times very angry, but we came out at the end with a conclusion that we absolutely just had to begin meeting ith one another.

On the 8th of June, for the first time, senior leadership from HHS met with the UNOS Executive Committee for a session in which UNOS expressed its spectrum of concerns about the regulation, so that all of the HHS leadership would be able to hear from our communities what our concerns were, and a beginning of a response came. This was not designed as a negotiation session, but just an exchange of views.

On the 19th of June, the day after the hearings in which neither side won and transplantation lost, HHS and the UNOS team began to discuss how we were going to proceed now with our discussions.

If I had them in my hand, I would have distributed the letters that we have both written. They are still, I think, pending final approval. These letters will express three things on both sides.

First, that what we have heard from the politics, from the hearings, from our own community, is that we should work this out together, not in the political but in the direct route, that we are in fact meeting to work this out and that both sides are committed in good faith to see if these problems can be resolved.

We are going to be meeting frequently in July and August, and this may be part of a subsequent discussion.

I want to make it clear that neither side in this negotiation is capable of speaking unilaterally for everybody on its side. The HHS people clearly will have to go back and clear whatever they say or review whatever they hear or want to propose with the Secretary and with the President, and it is equally clear on our side that the people who are discussing for UNOS well recognize that we cannot speak unilaterally for the entire community.

I have suggested that there are two kinds of issues that will be coming up. One are what I would call structural or relationship issues, which deal with how HHS and the transplant community work with one another.

These are things that UNOS, even if I had the board of directors there, couldn't speak for unilaterally because UNOS is not just an organization, it is the crystallization of the transplant community, and it is perfectly clear that we cannot give our assent to things until the surgeons, the physicians, the patient groups, the OPO groups and the other groups know what's there and have signed onto this.

We are your representatives. I believe this is well understood by HHS.

With respect to the allocation issues, I have argued strongly that it makes no sense for us to try to save UNOS' allocation system by destroying it, and therefore, I do not believe it is appropriate for me as the president or any negotiating group to usurp the process for formation of allocation policy from what has been established.

I will argue strongly that the allocation systems and the changes that will be proposed or whatever should come through the usual UNOS process, which means that what goes on in the other committees of UNOS will be part of this tarantella, this negotiation, this coming to mutual understanding between the transplant community and HHS.

I expect that all people representing UNOS will follow our commitment, your leadership's commitment, that we will approach this in good faith to see if these issues can be resolved.

I want to speak on three specific issues. One is the issue of fairness, equity. A lot turns on this question, of what is fair. I am extremely proud as a member of UNOS to be able to have behind me the ethical principles for organ allocation developed over many years by UNOS. I would like to think that this should serve as a template for how we proceed.

It is clear in our discussions with HHS and in our reading what is there that we have not operationalized these principles. We have general principles but we don't yet know how we as a community want to measure the question of fairness.

I have asked Bill whether he would be willing to charge the organ specific communities, this is his term now coming up, so it's not for me to say, but I would like to see as a personal request, the organ specific committees commit themselves, amongst other things, to discussion of how they would operationalize the definitions of justice and utility.

This is well under way in the area of liver, where we have the leadership of the liver committee that has gone a long way to saying these are the things we should be looking at, but we need to do this in a very thoughtful way to make certain that we have captured what we as a community believe constitutes both

justice and utility, so that we agree in advance on the measures that we are going to use, so that we can go to HHS and say, look, we need to broaden these things, we have the consensus of the community that these factors should be considered.

Waiting time. This is part of the same issue. Clearly, waiting time is not an unique measure of equity. This has been part of our concern with HHS. They know this. I think I'm not saying anything that worries them, particularly in one hotly controversial area, which is liver status three patients.

It can be argued that waiting time doesn't have any direct relationship in large measure because of the rolling in of status four patients, when we changed our rules, because of different paces and all sorts of things.

It doesn't seem clear to me that waiting time under no circumstance is a legitimate measure and we have to understand what is the proper role of waiting time.

I asked what about kidneys. Well, kidneys are a very confusing situation. We have highly sensitized patients and patients who may be listed prior to renal failure, but we can correct for those things. Is waiting time not an issue? We need to decide this as a community and we need to communicate these kinds of things to HHS and to the community.

Caveats. We are concerned about keeping the smaller centers with shorter lists open. There are lots of ways to do this. We can perpetuate a current system where we can look for ways to phase changes in that would protect that. Both UNOS and the United States have made it clear that they have no intention of undercutting our regional system for organ transplantation. We need to find a way to do this.

I want to emphasize in this respect that all of us, both UNOS and HHS alike, are under political judgment. None of us are given the authority to speak for transplant or the community unilaterally from on high. We only have insofar as the public, the broader public, understands that we are acting properly in the interests of the broader public.

A derivative issue from the issue of justice is the issue of whether we are hearing appropriately from all parts of our community. I have had in my time two concerns, one largely now met and one which I hope is well on the way to being met.

The one that's being met is that we now have enfolded the OPO community largely into the leadership of UNOS. That has been a success and I'm grateful to see that.

We now have to also make certain that our patient and public and donor family representatives are heard, not only at the board of directors. We have a third of our Board of Directors representing that community.

We have to figure out how at the regional meetings and at the committee meetings, the voice of the public can be heard, the voice of the patients, the voice of the donor families, can be heard more clearly.

I personally have asked each of our public members and the leadership of the public group to make certain that they recognize they have an equal obligation as trustees of this corporation to speak out clearly on the issues of allocation or whatever.

I would remind my medical breathren of the comments of Jim Childress who says that while it may be that the medical realities belong especially to the medical profession to understand, the allocation of organs is a resource allocation issue in which we doctors have no special competence, but we must in fact turn to the entire community to hear what we have to do.

One final thing, which is not related, and this is the area in which I have had my most intense personal discomfort. That has to do with motivations attributed on both sides to donor families in their willingness to donate.

None of us has stood where the donor family -- well, many of us have stood where the donor families have stood. Neither side in this debate has the right to claim for their side the ethical strength of what those families have done.

At this point, to the extent that I have contributed to this, I want to apologize personally to Thea as a living donor, to Margaret, Arlene, Ken, Lynn and Scharleen for any way in which I have contributed to preempting for my side what the donor families have done. We must not do this. We must not speak of ownership of kidneys or organs or whatever. That's just simply not fair on either side of this debate.

What I've heard from the donor families is that they want us to use these organs with the love and wisdom, do a gift of love, which comes with astonishing grace from unfathomable pain.

I spoke before about the political judgment that we all live under. I think we live under, as we operate in this area, a much more awful kind of judgment.

As we deliberate how we are to use these gifts, we have to realize that we are dealing with something truly holy. We all must keep this greater judgment before us as we deliberate.

That's what I want to tell you. I want to say thank you to the community for its bittersweet gift of the opportunity to represent you this year. I want to thank my Executive Committee. I have been told I should not say "my" Executive Committee, but I felt it as my family, my executive committee, who have shored me up and helped me know when I was right and when I was wrong.

I want particularly to thank Bill, who has been staunch throughout this year, and to whom I am now in the process of transferring both the responsibility and the burden.

I want to thank the UNOS staff. I may not mention everybody here because I did this literally between 2:00 and 4:00 this morning.

I want to thank John Persons, who is a man of iron, who stands quietly behind the people at the head of the table here and keeps us from doing wrong things.

Doug Heiney and Sally Aungier, who led me through a year as chair of the Membership and Professional Standards Committee when I came to that first committee meeting not having the foggiest idea what was going on, as its chairman.

I want to thank Cindy Sommers for her smile and her wisdom. Dave Burroughs, who has yielded to almost every request I have made of him and said, yes, we can find a way to do these things. Berkeley Keck, who stands quietly also in the background and keeps us out of trouble with the year 2000 and in the process of totally re-doing our computer system.

The regional personnel, and particularly Chris Williams, who really got started with me in Region 8 and has now moved up to the Organ Center.

Juanita, who kept -- because I don't have to do it any more -- Walter and I together, the Travel Department at UNOS who never tired of my repetitive changes of schedules time and time again. In particular, my scientific folks. Pat, who I still count in the scientific area. Mary D., Eric, and all the rest of you. You know who you are and I can't go through all the names.

The whole crowd, from whence I came and where I hope to return when I finish this term, Walter, who didn't want these things to happen in his time any more than I wanted these things to happen in my mind, and who doesn't get to get off the train this afternoon.
(Laughter.)

DR. HUNSICKER: Last year as he was winding up, Jim thanked his colleagues, and I thought that was sort of nice. I must thank my colleagues. I have been an absentee landlord. They have filled in for me, uncomplainingly, taken my schedules, done my work for me back home so that I could be up here doing this. I owe them and you owe them a remarkable debt. Of course, my

family, and in particular, my wife, who is the still point in my turning world.

That's the news from Lake Woebegone, where men are strong and women are good looking and where all of the children are above average.
(Applause.)

DR. HUNSICKER: We have the opportunity this morning to hear directly from Dr. Fox, who in concordance with our agreement that we are going to work this out, has interrupted his schedule. He should be today in Geneva, in a much nicer place, not subject to attack by a potentially hostile crowd, but amongst his cohorts at the International AIDS Conference. He broke that schedule to come here and be with us this morning.

I have asked him to come here so he can speak to everybody, and there are chairs up here for his team, so that if he needs to consult, he can do that.

He has agreed to speak for a few minutes and then answer questions, both from the board of directors and from the entire community.

Health Resources and Services Administration
News Room

House Testimony: National Organ Transplantation Policy

Prepared Testimony of **Claude Earl Fox, M.D., M.P.H.**
Acting Administrator, Health Resources and Services Administration

Before the Human Resources Subcommittee
United States House of Representatives

April 8, 1998

Mr. Chairman and members of the Subcommittee, thank you for inviting the Department of Health and Human Services to participate in this very important hearing on national organ transplantation policy. I am **Doctor Claude Earl Fox**, Acting Administrator of the Health Resources and Services Administration. I am accompanied by **Doctor William Raub**, the Secretary's Science Advisor and **Marc Smolonsky**, Senior Policy Advisor in the Office of the Assistant Secretary for Legislation.

We are delighted to be here in Wisconsin, a State with an outstanding record of organ donation. Wisconsin has some of the finest transplant surgeons in the country. And one of the great breakthroughs in transplant technology, the Belzar UW solution, was developed in Wisconsin. This is an appropriate issue for discussion here or anywhere else in the United States, because organ transplantation policy affects all Americans, regardless of where they live.

As you know, the National Organ Transplant Act of 1984 created the national Organ Procurement and Transplantation Network, commonly known by its acronym, OPTN. The OPTN is managed under a contract with the Department by the United Network for Organ Sharing, or UNOS. The Act was amended twice, in 1988 and 1990, each time with language clarifying that the OPTN should direct an equitable nationwide distribution of organs. In the construction of a national organ allocation network, Congress recognized that there is a shortage of organs available for transplantation, and that the shortage was likely to continue into the foreseeable future. Congress further recognized that medical urgency and equity should be the main criteria for access to available organs and that no one should be allowed to unfairly game the system.

Prior to passage of the National Organ Transplant Act, the distribution of organs was often unfair. Wealthy people or persons with special connections reportedly were able to manipulate the system so that they received organ transplants instead of people who were sicker and had been waiting far longer. Patients from foreign countries sometimes received life-saving transplants while Americans died. After hearings and media reports had confirmed many of these allegations, Congress acted swiftly to establish a national system.

HHS has the responsibility to oversee the OPTN to ensure that its policies conform to technological advances and are consistent with the intent of the statute. Our reviews indicate that there are still many challenges to optimal patient care. The greatest challenge is the shortage of organs available for transplantation. About 4,000 people died in 1996 while waiting for a transplant that probably would have saved their lives. The gap between the demand and supply of available organs for transplantation is growing, and will continue to expand as medical innovations make transplantation an option for more and more patients.

Approximately 10,000 to 15,000 deaths in the United States each year could result in viable organ donation. But only 5,500 cadaveric donors, one half to one third of potential organ donors, contribute organs for transplantation. While the number of cadaveric organ donors has increased, from 4,084 in 1988 to 5,417 in 1996, the number of deaths among people on organ transplant waiting lists has also grown. There were 1,507 deaths on the waiting list in 1988, a number that jumped to 4,022 in 1996.

Some 20,000 Americans received organ transplants in 1996, but more than 55,000 people were on the waiting lists. Of those on the waiting lists, ten people will die every day, mainly because there are not enough organs to meet their needs.

The Nation's failure to obtain optimal donation rates for transplantable organs is unquestionably the biggest problem facing the transplant community. Addressing the shortage of organs is a priority of this Administration. Last December, the Vice President announced a nationwide initiative to increase organ donations. The initiative is focused on known barriers to donation by creating a national partnership of public, private and volunteer organizations. The partnership emphasizes the need to share personal decisions on organ donation with one's family. Even if an individual agrees during his or her lifetime to be an organ donor, the agreement is not always honored without family consent. As part of the initiative, HHS convened a conference on best practices last week, with experts from throughout the country discussing successful solutions for increasing organ donations.

The initiative also includes proposed Medicare regulations designed to ensure that deaths are reported to organ procurement organizations whenever there is potential for donation. HHS is working with providers, consumers, organ procurement organizations, eye and tissue banks and hospitals to develop a final regulation. The proposal is based on approaches that have been successful in other areas. For example, organ donations increased dramatically in Pennsylvania as the result of a state law that requires the reporting of deaths to organ procurement organizations. The Department estimates that the number of donors nationwide could increase by 20 percent within two years of the publication of a final rule.

Organ procurement is one of the most sensitive issues in American society. Asking a family to donate an organ from a loved one who just died is a wrenching task, which is done most effectively by people who are trained organ procurement specialists. There are many heroic individuals who are in the business of saving lives every day by convincing people to donate organs. But as a nation, we must do a better job.

Although the country's mixed record on organ donation is our primary concern, there are other problems that pose vexing questions for the Department. How do we ensure that organs are allocated fairly and with sufficient efficiency that available organs are used to prolong the lives of people in the greatest need? How do we guarantee that the OPTN operates primarily in the interests of patients? Our best answers to these questions are contained in the new regulations for the OPTN, which were published last week.

Six principles underlie the regulations:

1. Transplant patients are best served by an organ allocation system that functions equitably on a nationwide basis.

2. The Secretary of Health and Human Services should represent the public interest by setting broad goals for the OPTN and by overseeing OPTN policy development and operations with a view toward ensuring that the goals are being addressed in a reasonable manner.

3. The OPTN must exercise leadership in performing its responsibilities under the National Organ Transplant Act, in particular by devising the specific policies assigned under the regulations, and by adapting its policies and procedures to changes in medical science and technology.

4. Organs should be equitably allocated to all patients, giving priority to those patients in most urgent medical need of transplantation, in accordance with sound medical judgment.

> 5. Thorough, timely, and easy to use information about transplant centers, including center-specific performance data, is essential for measuring quality of care and should be readily available to help patients and physicians in choosing among transplant centers.
>
> 6. Potential conflicts of interest should be minimized for those who are responsible for operation of the OPTN.

The statute that created the OPTN requires the Secretary of Health and Human Services to provide timely information to patients, their families, and physicians about transplantation. Current OPTN policies make it impossible to fulfill this requirement because the Department has been denied current and thorough information. Under existing policies, for example, we cannot provide Americans with the current one-year survival rates of patients and organ grafts. We cannot compare the performance of transplant programs. Data available to patients today is four years old, so it is out of date. Given that the data made public is outdated and incomplete, patients cannot review the performance of respective transplant programs. We find this situation unacceptable and seek to obtain timely useful data for patients through the pending regulation.

The pending regulation also addresses the issue of the broader sharing of organs and intends to spur debate within the OPTN about the suitability of the current local-first policy for the allocation of organs. We believe there is solid evidence that the current system is unfair and that patients may be dying unnecessarily because they happen to live in the wrong place at the wrong time. Secretary Shalala believes that everyone in need of a transplant should have equal access to an organ, regardless of where they live or list.

We believe broader sharing of organs will reduce current geographic inequities in the OPTN. Our view is supported by numerous prominent medical authorities and experts who have proposed broader sharing of donated organs. For example, Dr. Lawrence Hunsicker, the current President of the United Network for Organ Sharing, said in 1986:

> "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."

According to the American Medical Association's Code of Medical Ethics:

> "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."

In 1991, the HHS Inspector General reached the following conclusion:

> "...current organ distribution practices fall short of congressional and professional expectations," and that "there has been substantial progress in developing a national organ distribution system grounded in uniform policies and standards. However, organ distribution remains...confined primarily within the individual service areas of the...Organ Procurement Organizations."

In passing the National Organ Transplant Act, Congress clearly intended that the OPTN act as a nationwide system, free of geographic bias. In 1990, when Congress amended the statute to emphasize the importance of a truly national allocation system, the Senate reported, "because the demand for transplantable organs is expected to continue to be considerably greater than the supply, a fair and equitable organ sharing system is critical to the future of a national transplant program that the public

will support."

The OPTN has not met the mandate of the statute that created it. The allocation system is not fair, nor is it a national network. By allocating organs primarily at the local level, OPTN policies give the sickest patients a substantially lower chance of being promptly matched to a suitable organ. Current OPTN policies create enormous geographic disparities in the time patients must wait to receive transplants. For example, based on the latest data, if you live in New England and need a kidney transplant, you will wait as long as three years. But in the upper portion of the southeast, a patient in need of a kidney transplant will wait as little as 231 days.

We find the disparity in waiting times across the country to be unacceptable. Americans in need of organ transplants will live or die on the basis of where they live. The policy that allows this to happen is contrary to the intent of Congress and in violation of the American Medical Association's Code of Ethics.

It would be illegal to deny an organ to patients solely because of their race, gender, or age. Yet organs are denied to patients because of where they live. Geographic discrimination is no better than any other sort of discrimination. It is flat out wrong and should no longer be tolerated.

The Department recognizes that there is tremendous controversy over the subject of organ allocation. We understand that there is division in the transplant community about the distribution of organs, and that while many want the current system changed, others do not. The OPTN must not be so paralyzed by controversy and division that it does not act to change a system that is unfair to patients, and that may be allowing patients to die unnecessarily. Through the pending regulation, the Department is putting patients first. What is best for patients, in our view, overrides concerns about the individual needs of transplant centers, whether they be large or small.

In its pursuit of justice for patients, the Department does not intend to substitute its own medical judgment for the judgment of members of the OPTN-. Although the pending regulation requires changes in current allocation policy, the regulation does not contain a specific policy. The regulation leaves it to the OPTN to reform the policy and present its recommendations to the Secretary. I reiterate, HHS will not be setting any new allocation policy; it is up to the medical experts of the OPTN to set the new policy. We ask only that the policy conform to three basic performance goals: One, that criteria for placing patients on waiting lists be standardized; two, that criteria for determining medical status of patients be standardized; and three, that medical urgency, not geography, be the main criterion for allocating organs.

The OPTN agrees with the first two performance goals. In fact, the network is already working toward those aims. It is the third performance goal, the one that is designed to end discrimination in the allocation system, with which the OPTN is struggling. But I am confident that if the OPTN puts patients first, it will accomplish this goal as well.

I have described what the pending regulation will do. Now let me tell you what it will not do. The regulation will not adversely affect patients who are on waiting lists at the time it takes effect. The regulation states that no one currently on a waiting list will be disadvantaged by changes in the allocation policy. The regulation will not deprive any locality of organs. Broader sharing will mean that patients have more access to organs, not less. Our goal is that all patients be better off as a result of policy reforms.

I will conclude by saying that the Department has solicited widespread public comment on this regulation. It was published as an NPRM in 1994, and we received extensive public comments in response. In December 1996, the Department conducted three days of public hearings on issues pertaining to the regulation. Everyone connected to the transplant community, from patients to surgeons, was invited to testify. The pending regulation has a 60-day public comment period and a delayed effective date. Should the Department learn anything during the public comment period that requires change, the effective date of the regulation can be delayed further to accommodate the changes. We encourage public debate on the regulation, whether it be at a hearing like this one or within the confines of the OPTN.

Thank you for the opportunity to testify. I will be pleased to answer any questions you may have.

Go to: **Top** | **Speeches and Testimony** | **HRSA News Room** | **HRSA** | **HHS**

Questions/comments to HRSA's Office of Communications
Last Updated May 01, 1998

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

HHS to Congress

June l, 1998

The Honorable _____
House of Representatives/United States Senate
Washington, D.C. 20515-3601

Dear Member of Congress:

Thank you for your interest in the Department's April 2, 1998, regulation governing the Organ Procurement and Transplantation Network (organ network). I am deeply concerned about recent efforts by the contractor that manages the network, the United Network for Organ Sharing (UNOS), to misrepresent the provisions of the regulation. I have received numerous letters from Members of Congress, transplant professionals, patients, and the public that reflect the inaccuracies published by UNOS. I am especially distressed that UNOS is needlessly frightening transplant patients about the HHS regulation. I appreciate having the opportunity to set the record straight about the intent and effect of this important rule.

First, let me assure you that the Department's new regulation does not mandate specific organ allocation policies. We believe strongly that policies requiring medical expertise and judgment should be formulated by the organ transplant professionals who comprise the organ network. Our regulation simply asks that the organ network establish new policies that will be fairer to patients than the current system, especially to assure that allocation of organs will be based on common medical criteria, not accidents of geography.

UNOS claims:

Certain specific claims made by UNOS must be challenged at the outset:

For example, UNOS maintains that we would require a new single national waiting list for transplant patients. This is not true. To the contrary, we allow the organ network wide latitude as it devises new policies that are both fair to patients and medically sound. Indeed, a variety of alternatives have already been presented to UNOS by some of its own members.

UNOS also maintains that our regulation requires organs to be allocated to the very sickest patients first, leading to poor utilization of organs. This is also untrue. While organs should indeed be allocated with a primary emphasis on medical need, the regulation does not make any rigid directive that would require futile transplants. In fact, the regulation explicitly requires that organ allocation policies must be designed to avoid organ wastage and poor utilization. Likewise, the regulation is quite clear in leaving to physicians and to the organ network the difficult but necessary decisions that must be made when a patient may be too ill to be successfully transplanted.

Finally the UNOS claim that fewer patients will be transplanted and fewer lives saved is simply specious. The most important fact to understand is that the HHS regulation calls on the organ network, and thus UNOS itself, to develop the new allocation policies. Therefore, when UNOS predicts that negative consequences will result from the regulation, the truth is

that such negative effects could only occur if UNOS itself chose an unsound policy. HHS does not want such policies; our regulation does not call for such policies; in some instances, the regulation actually prohibits policies with the consequences that UNOS is predicting; and finally, when UNOS actually develops its allocation policies, I am certain that it will adopt approaches that will serve patients, physicians and its own member transplant centers.

A primary objective in issuing our regulation is to assure that patients receive organs based on standardized medical judgment and common medical criteria, no matter where they live or in which transplant center they are awaiting treatment. Patients who need an organ transplant should not have to gamble that an organ will become available within a particular arbitrary geographic area, nor should they have to travel to faraway transplant centers simply to improve their chances of getting an organ. Instead, patients throughout the country should have a more equal chance of receiving an organ, based on their medical condition and the judgment of their physician.

To achieve this result, the rule calls on the organ network to develop uniform medical criteria for determining the severity of a patient's medical status and eligibility for placement on a transplant waiting list. The rule also calls on the organ network to develop organ allocation policies that will reduce the current geographic disparities in patients' access to transplantable organs.

We have proposed these changes because we believe the current system is fundamentally unfair. Consider the recent case of a Maryland child who was transplanted in Florida within a week of listing there, though the child had been waiting for one year on the organ transplant list at a California hospital, and then four years on the organ transplant list at a hospital in Pennsylvania. No one -- especially those who cannot afford it -- should be required to list at several transplant hospitals and fly long distances for surgery that could be provided closer to home.

The most visible shortcoming of the current allocation system is the wide span in average waiting times for those on transplantation waiting lists. In some areas of the nation, patients wait at least 5 times longer for an organ than those in other areas. Less visible are the resulting inequities among those who receive organs. Where waiting times are the 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 cases, 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. And, for many reasons, virtually all patients are on the waiting list of only one transplant center.

UNOS has not published a hospital-specific waiting time report, although one newspaper, using UNOS data, computed these times. The results illustrate that disparities in waiting times exist not only between different parts of the country, but also between transplant centers within the same State. For example, the median waiting times for the two major liver transplant centers in Kentucky were vastly different -- 38 days at one center, 226 at the other. Similarly, in Louisiana, the median waiting time at one center was reported to be 18 days, while at another, it was 262 days. In Michigan, the numbers were 161 days and 401 days. Although these numbers do not tell the whole story, they certainly reflect that unacceptable disparities in waiting times exist, even within States. I believe that basic fairness to patients demands that these disparities be substantially reduced and that the transplant community should ultimately develop the means to this end.

It is regrettable that since we issued our regulations UNOS has launched a campaign that factually misrepresents the Department's intent in issuing the rule and mischaracterizes its provisions. As the organ network contractor, UNOS has a special responsibility to help develop policies that reflect sound medical judgments concerning organ transplantation. Now is the time for UNOS to be working productively to design policies to implement the rule that incorporates the views of patients, the transplant community and the public. Instead, UNOS has embarked on a misleading lobbying campaign that has confused the public and caused fear among transplant patients and their families.

There is no doubt that the issues we are grappling with as we pursue equity in organ allocation are complex and difficult. Members of Congress, and the public at large, have important contributions to make as we seek to get it right. Unfortunately, rather than engage in a fair and thoughtful debate, UNOS hasdecided to craft a set of fictional facts and choices in order to make plausible the dire scenarios that are necessary for their lobbying campaign to succeed. Perhaps most inappropriate has been the decision by UNOS to develop a hypothetical allocation policy and dub it the "HHS policy." UNOS then modeled computer runs on this hypothetical, using outdated 1991 transplant data, in order to predict undesirable results. This effort merely creates a fiction and a distraction. It is not credible.

UNOS Claim:

UNOS also has claimed, without any factual support, that the rule will somehow reduce the rate of organ donation. Simply put, there is no evidence that our regulation would have this effect. A 1991 HHS Inspector General report, cited in the preamble to our regulation, notes that "Americans do not think that keeping a [donated] organ in a specific locality is an important goal in and of itself." And a 1994 survey by UNOS itself showed, again as stated in our regulation's preamble, that "...the overwhelming majority of donor families state as their preference that organs go to the neediest patient regardless of geography, so long as organs are not wasted."

This Administration, with dozens of partners, is committed to increasing the rate of organ donation by 20 percent within two years. Indeed, the urgency could not be greater. As you know, some 55,000 persons are on organ transplant waiting lists today, up from 16,000 in 1988. More importantly, about 4,000 Americans died in 1996 -- more than 10 each day -- while awaiting organ transplants. Increased organ donation is an absolute priority for all of us, and we will work very hard to achieve our commitment.

A final point of special importance is the need to improve the availability of transplant data. Useful, current transplant center-specific information needs to be available so that patients and health care providers can make informed choices. Likewise, good data must be available to HHS and to Congress in order to successfully carry out our oversight functions. The organ network contractor needs to perform better in this area, and our regulation makes this a requirement.

To offer a more detailed response to these and other issues that UNOS has raised, I am enclosing a letter from Claude Earl Fox, M.D., the Administrator of the Health Resources and Services Administration. I trust that you will find this information helpful.

Thank you again for your interest in this important subject. I believe we have made remarkable progress in the field of organ transplantation. But, we can do even better. We can help the organ network operate more effectively by establishing clear expectations through

performance standards that serve the goals embodied in the National Organ Transplant Act. And, with the 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 which center they may be listed. I look forward to working closely with you to achieve this important goal.

Sincerely,

/Donna E. Shalala

Enclosure

Go to home page for: DOT || OrganDonor.gov || HRSA|| HHS

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

OPTN

FOR IMMEDIATE RELEASE
Thursday, March 26, 1998

Contact: HRSA Press Office
301-443-3376

HHS RULE CALLS FOR ORGAN ALLOCATION BASED ON MEDICAL CRITERIA, NOT GEOGRAPHY

Calls on Private Transplant Network to Develop Policies

NOTE: The public comment ~~period~~ for the Final Rule for the Organ Procurement and Transplantation Network (OPTN) has been **extended from June 1, 1998 until August 31,1998**. Similarly, the effective date of the Rule will be October, 1, 1998. These actions are based on Section 4002 of the Fiscal Year 1998 Supplemental Appropriations Act (Public Law 105-174).

HHS Secretary Donna E. Shalala today announced a new regulation to improve the nation's organ transplantation system, to assure that allocation of scarce organs will be based on common medical criteria, not accidents of geography.

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 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 will be aimed at assuring that patients with greatest medical need will receive scarce organs based on medical judgment and common medical criteria, no matter where they live or in what transplant center they are awaiting treatment.

"Patients who need an organ transplant 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," Secretary Shalala said. "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.

"HHS does not want to choose which patients receive scarce organs. Those choices must be made by transplant professionals," she said. "But this regulation will help assure that organs are allocated on the basis of medical need, and that availability of organs will not be impeded by arbitrary geographic lines."

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. "Our national initiative is a serious new effort to bring about more organ donation."

Under the regulation announced today, performance goals would be established to guide the

OPTN as it modifies 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 area. This means less ill patients in the local procurement may receive a transplant while patients with more urgent medical need in another area continue to wait.

Under today's regulation, three new sets of criteria for organ allocation would be developed by the OPTN. Development of the criteria would include public input and comment and final HHS approval. Secretary Shalala emphasized that the regulation looks to transplant professionals in the OPTN to develop the revised policies. "We are not substituting our judgment for the judgment of medical professionals," she said. "We are asking them to make the system fairer, and we are setting clear performance goals to guide their work." The 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. The OPTN would have another 60 days to propose new criteria for livers, and a year for development of criteria for other organs.

"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," 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.)

In 1996, some 20,000 Americans – about 55 each day – gained a new lease of a better life through transplantation. However, more than 55,000 people are on the transplant waiting list

nationwide, and some 4,000 people – 10 every day – die in the U.S. while awaiting a donated organ.

The OPTN includes transplant centers and 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/osp/dot/dotmain.htm.

# # # #

Go to: News Releases | HRSA News Room | HRSA | HHS
Last updated: 05/29/98

HRSA NEWS

U.S. Department of Health & Human Services
Health Resources and Services Administration
5600 Fishers Lane, Rm. 14-45
Rockville, MD 20857
Tel: 301-443-3376
Fax: 301-443-1989

FACT SHEET

Thursday, March 26, 1998

Contact: HRSA Press Office
301-443-3376

IMPROVING FAIRNESS AND EFFECTIVENESS IN ALLOCATING ORGANS FOR TRANSPLANTATION

The Regulation || Key Principles || Major Provisions || Effective Date

Background

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

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

The Regulation

The National Organ Transplant Act of 1984 envisioned a national transplant system to be operated by transplant professionals, with oversight by HHS to ensure an equitable allocation system in the public's interest. The Act created the Organ Procurement and Transplantation Network, a non-profit private sector network to be operated by a contractor to HHS. Originally, OPTN membership and policies were voluntary. But with enactment of the

Omnibus Budget Reconciliation Act of 1986 adding Section 1138 of the Social Security Act, all hospitals that perform transplants and all organ procurement organizations (OPOs) were required to abide by the rules and requirements of the OPTN in order to receive Medicare and Medicaid reimbursement.

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

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

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

Key Principles

Important principles underlying the final regulation include:

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

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

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

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

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

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

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

Major Provisions

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

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

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

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

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

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

problem

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

efficient management of organ placement.

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

- **Transition to New Policies**--When the OPTN initially revises organ allocation policies, it must propose transition policies so that people who are already on the national waiting list for transplantation do not receive less favorable treatment than under previous policies.
- **Board Composition**--The rule modifies the composition of the OPTN Board of Directors. At least six public members must come from fields such as behavioral science, computer science, economics, ethics, heath care financing, law, policy analysis, sociology, statistics or theology. Another eight members--at least 25 percent of the board--must represent transplant candidates, transplant recipients, organ donors and family members. No more than 50 percent of the members are to be transplant surgeons or transplant physicians.
- **Public Access to Data**--The rule pays special attention to public access to data. When the Secretary determines that information will serve the public's interest, the Secretary may release it. The rule requires that outcome data be updated every six months and be available no more than six months later than the period to which they apply. The data shall include the characteristics of individual transplant programs as well as rates of non-acceptance of organs and waiting times, and other data useful to patients, their families and physicians in making transplant decisions.
- **Review and Evaluation**--The Secretary or her/his designee may review and evaluate member OPOs and transplant hospitals where there is evidence of non-compliance with the OPTN rule or actions that risk patients' health or compromise public safety. Sanctions may include removal of transplant program designation, termination of the transplant hospital's participation in Medicare or Medicaid, or termination of an OPO's Medicare and Medicaid reimbursement.

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

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

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

# # # #

Return to OPTN Regulation News

UNOS Analysis of Proposed Organ Transplant Regulations

The federal government's proposed organ transplant regulations would direct UNOS to make three significant changes in transplant medicine. UNOS agrees with two of those, and in fact has already made them. The third, though well intended, would do more harm than good.

To ensure that all patients have a fair chance at getting a transplant, the regulations instruct UNOS to develop national standards that would govern (1) when doctors put patients on the waiting list for a transplant and (2) when patients are moved up in priority on that list. Historically, different doctors in different areas have made different judgements about these matters.

> these are OK

In fact, UNOS recognized the need to address these two issues some time ago and has already acted. UNOS last year instituted national guidelines for determining when someone goes on the waiting list and when the person moves up on the list. Transplant doctors have already begun reviewing each other's cases to ensure that these guidelines are being observed unless there are sound medical reasons not to.

The lawyer who heads the American Bar Association's biomedical ethics coordinating group, Robyn Shapiro, has told Congress that these two steps should help ensure that patients in every part of the country have equal access to transplants. And Ms. Shapiro has urged the federal government to determine what effect these guidelines have over time before making radical changes in the transplant system.

But the proposed federal regulations demand another severe step, eliminating the current locally-based organ allocation system in favor of one national list based on medical urgency, or "sickest first." The transplant community fears this new policy will result in several disturbing realities:

* problem AGAINST b/c:

Longer waits, sicker patients, fewer lives saved. The HHS regulations will require a national list with a "sickest first" criteria. This means that patients will become sicker before they receive their life-saving transplant. Statistics show that patients who are extremely ill when given a liver transplant have a higher rate of transplant failure and may need a second or third transplant to survive. The transplant community believes, and statistical studies verify, the current system of giving priority to the most urgent patients locally, maximizes both the number of patients who have the opportunity for transplantation and long-term survival rates.

Local centers will close; organ donation will be affected. By centralizing the system into a national waiting list, the new regulations will reallocate donated livers away from the vast majority of the country's 120

transplant centers and shift them to about a half-dozen regional surgical centers. This would force many smaller transplant programs to close their doors, depriving their communities of life-saving medical technology and highly skilled doctors. Because the current system is locally based, many transplant centers and community activists have been able to build local awareness and initiatives that have increased organ donation. If the system is converted to a national system, this local incentive and personal exposure to the benefits of organ donation will be lost. Under the current system, the sickest patients receive a transplant in 2-6 days no matter where they live.

Transplantation access for poor will decrease. Almost one of every five transplant patients is on Medicaid. If, as a result of this new policy, a large percentage of the country's smaller transplant centers close, many transplant patients and their families will be forced to travel far from home during an already traumatic time. While families who have the means to have one spouse quit work or make arrangements for child care, may not be affected, these additional travel expenses and logistical nightmares could make it impossible for some poorer patients to get liver transplants.

Transporting organs decreases success rates. As the number of hours a liver goes without a blood supply is increased, the likelihood of a successful transplantation significantly decreases. By abandoning the local system of organ allocation, the amount of time it takes to transport organs from one region of the country to another will be significantly increased. Medical technology has not yet advanced to the point where transport time can be ignored as a factor in the success of transplantation.

take the organ to where needed

Legal Uncertainty for UNOS. The clear intent of NOTA was to have organ transplantation policy development and implementation based in the private sector. The HHS regulations assert executive branch control over the program without the appropriate legislative authorization. If Congress wishes to change NOTA and the role of HHS it should be done through the regular legislative process.

Preemption of State Law. The new HHS regulations

would preempt many state laws governing organ procurement and distribution. For example, Louisiana law states that organs donated or acquired in the state shall not leave the state for transplantation.

In sum, the government's proposed transplant regulations could result in potentially tragic human consequences. UNOS has demonstrated its eagerness to work with the government to improve transplant medicine and to rectify serious problems in the proposed regulations. But UNOS cannot concur with policies that are not in the best interest of patients.

HRSA HEALTH RESOURCES AND SERVICES ADMINISTRATION - HHS
OFFICE OF SPECIAL PROGRAMS

background info

Description of Services

The Division of Transplantation's (DOT) principal responsibilities include the management of the Organ Procurement and Transplantation Network (OPTN), the Scientific Registry of Transplant Recipients (SRTR), and the National Marrow Donor Program (NMDP) contracts, public education to increase organ/tissue donation and technical assistance to organ procurement organizations (OPOs).

DOT maintains working relationships with professional organizations in the field of transplantation and fosters relationships with public and private organizations to promote the concept of donation. Such relationships have led to contracts targeted toward minority populations; national meetings bringing together a cross-section of transplant professionals; coordination of a national exhibit program; a recognition program paying tribute to America's organ donors; adoption of resolutions by private sector groups in support of organ/tissue donation, and a Surgeon General's Workshop on Increasing Organ Donation.

Through its contract with NMDP, DOT supports the recruitment of minority volunteer marrow donors, maintenance of the Donor Registry, patient advocacy, and professional education on marrow transplantation.

Organ Procurement and Transplantation Network (OPTN)

Since 1986, DOT has administered a contract with the United Network for Organ Sharing (UNOS) in Richmond, Virginia for the operation of the OPTN. The primary function of the OPTN is to maintain a national computerized list of patients waiting for organ transplantation and a 24 hour-a-day computerized organ placement center to match donors and recipients. Its purpose is to ensure equitable access to organs by critically-ill and medically-qualified patients and to guarantee that scarce organs are recovered and used safely and efficiently. The computer currently maintains the status of more than 54,000 potential recipients. In 1996, about 19,000 transplants were performed on patients on this waiting list.

OPTN membership includes all 275 transplant centers, 63 organ procurement organizations, 156 histocompatibility laboratories, and other members representing the general public, voluntary health organizations and related medical and professional organizations.

Scientific Registry of Transplant Recipients

DOT also has a contract with UNOS to maintain the Scientific Registry of Transplant Recipients. The Registry includes information on all recipients of kidney, heart, liver, heart-lung, lung and pancreas transplants since October 1, 1987. The Registry also tracks all transplant patients from the time of transplant through hospital discharge, and then annually until graft failure or death

Education

DOT has responsibility for conducting public and professional education initiatives to improve awareness of organ and tissue transplantation as a successful treatment option and, ultimately, to increase donation in the United States. Often in collaboration with private sector groups related to transplantation, DOT conducts a variety of activities such as exhibits, seminars, and special events to inform the public at large about the critical need for organ donors and to apprise professionals about ways they can help promote the concept of donation. DOT also collaborates with organizations such as the American Association of Motor Vehicle Administrators to promote the concept of donation. DOT expands its educational impact by collaborating with numerous other private sector organizations and assisting them in conducting organ donor awareness activities.

National Marrow Donor Program

DOT oversees the National Marrow Donor Program (NMDP), a nonprofit organization headquartered in Minneapolis, MN. NMDP began search operations in 1987 with 49 donor centers, 10 transplant centers and fewer than 10,000 donors listed on the Registry. The first two transplants facilitated by the NMDP took place in December 1987.

Currently, NMDP is a network of 106 (8 foreign) donor centers, 109 (13 foreign) collection centers, 95 (20 foreign) transplant centers, 11 recruitment groups and a Coordinating Center that helps patients suffering from Leukemia or other blood diseases find matching volunteer unrelated marrow donors for transplants. The NMDP also is a research organization, studying the effectiveness of unrelated marrow transplants and related treatments. It currently has relationships with transplant centers and/or donor registries in Argentina, Australia, Austria, Brazil, Canada, Denmark, France, Germany, Great Britain, Hong Kong, Israel, Italy, Japan, the Netherlands, Norway, Russia, Spain, Sweden and Switzerland.

As of 1996, there are 1,946,824 potential donors registered with the NMDP, and at any given time, an average of 2,500 active searches is under way. On average, 81 transplants are performed monthly, and more than 4,052 patients have received NMDP-facilitated transplants since 1987.

NMDP has undertaken a national effort to increase the number of potential donors from four ethnic groups: African Americans, Asian/Pacific Islanders, Hispanics and Native Americans.

Go to home page for: HRSA|| HHS

Send all questions, comments and suggestions to RDean@hrsa.dhhs.gov
Return to the DOT Homepage

HRSA HEALTH RESOURCES AND SERVICES ADMINISTRATION • HHS
OFFICE OF SPECIAL PROGRAMS

Quickfacts!

Solid Organ Transplantation

The United Network for Organ Sharing national patient waiting list for organ transplant contains over 58,000 registrations. On **March 18, 1998** there were:

- 38,760 registrations for a *kidney* transplant.
- 10,059 registrations for a *liver* transplant
- 367 registrations for a *pancreas* transplant.
- 88 registrations for a *pancreas islet cell*
- 1,653 registrations for a *kidney-pancreas* transplant
- 95 registrations for an *intestine* transplant
- 4,020 registrations for a *heart* transplant
- 235 registrations for a *heart-lung* transplant
- 2,756 registrations for a *lung* transplant

58,033 **TOTAL**

NOTE: UNOS policies allow patients to be listed with more than one transplant center (multiple listing), and thus the number of registrations may be greater than the actual number of patients.

Numbers of Transplants Performed, January - December 1996

- 850 *kidney-pancreas* transplants
- 11,099 kidney *alone* transplants (3,173 from living donors)
- 172 *pancreas alone* transplants
- 4,058 *liver* transplants
- 2,342 *heart* transplants
- 39 *heart-lung* transplants
- 805 *lung* transplants.
- 45 *intestine* transplants

19,410 **TOTAL**

Based on UNOS Scientific Registry data as of April 23, 1997. Double kidney, double lung, heart-lung and kidney-pancreas transplants are acounted as one transplant.

Number of Donors Recovered, 1996

- 5,416 cadaveric
- 3,524 living
- 8,940 TOTAL

As of November 12, 1997, UNOS membership included the following:

- 275 Transplant Centers
- 3 Consortium Members
- 54 Independent Organ Procurement Organizations (OPOS)
- 58 Histocompatibility Laboratories
- 12 Voluntary Health Organizations
- 9 General Public Members
- 29 Medical/Scientific Organizations
- 440 TOTAL

NOTE: Of the 275 transplant centers, 12 have in-house OPOs and 102 have in-house histocompatibility labs

---

Currently, 275 medical institutions in the United States operate an organ transplant program. These transplant centers can be separated into organ specific programs that include the following:

- 251 Kidney Transplant Programs
- 124 Liver Transplant Programs
- 124 Pancreas Transplant Programs
- 20 Pancreas Islet Cell Transplant Programs
- 33 Intestine Transplant Programs
- 158 Heart Transplant Programs
- 95 Heart-Lung Transplant Programs
- 91 Lung Transplant Programs

NOTE: Data subject to change due to future data submission or correction.

Go to home page for: HRSA|| HHS

Send all questions, comments and suggestions to RDean@hrsa.dhhs.gov
Return to the DOT Homepage

MEMO

To: Jennifer Klein
From: Susan Gyeszly
Subject: Transplant Organ Allocation
Date: June 22, 1998

Overview

On March 26, 1998, HHS Secretary Shalala announced a new regulation to improve the nation's organ allocation system. Public comment has been requested until August 31, 1998 with the effective date of the rule October 1, 1998. The regulation sets three broad performance goals for organ allocation. These include:

1. Standardized listing criteria for placing patients on waiting lists, using objective and measurable medical criteria;
2. Standardized criteria for determining medical status, also based on objective and measurable medical criteria, sufficient to differentiate patients from least to most medically urgent.
3. 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.

Background

HHS's Division of Transplantation (DOT) manages the Organ Procurement and Transplantation Network (OPTN), whose primary function is to maintain a 24 hour-a-day national organ placement center to match donors and recipients. Since 1986, the DOT has administered a contract with the United Network for Organ Sharing (UNOS), in Richmond, Virginia, for the operation of the OPTN.

UNOS Analysis of Proposed Organ Transplant Regulations

UNOS agrees with first two parts of the regulation which instruct UNOS to develop national standards that would govern when doctors put patients on the waiting list for a transplant and when patients are moved up in priority on that list. In fact, last year UNOS instituted national guidelines for determining these items. However, the organization disagrees with the third component that eliminates the current local-based allocation system in favor of one national list based on medical urgency, or "sickest first." They believe this will lead to several issues.

1. Longer waits, sicker patients, fewer lives save. UNOS believes that the regulation will require a national list with a "sickest first" criteria, which means patients will become sicker before they receive their transplant. Statistics show that patients who are extremely ill when given a transplant have a higher rate of failure. However, the HHS argues that while organs should be allocated according to need, they have not devised a rigid directive that would require futile

transplants. In fact, they have included a directive stating that organ allocation policies must be designed to avoid organ wastage and poor utilization. The regulation also calls on the organ network, and thus UNOS, itself to develop the new allocation policies.

2. Local centers will close; organ donation will be affected. UNOS believes that by centralizing into a national waiting list, the larger centers that have more patients will perform more transplants, thus leaving smaller, local centers to fail. Also, UNOS believes people are more willing to donate if they know that the organs will stay in the area. However, the HHS feels that there is no evidence of this and instead a 1994 survey found that "an overwhelming majority of donor families state as their preference that organs go to the neediest patient regardless of geography, so long as organs are not wasted.

3. Transplantation access for poor will decrease. If many of the smaller transplant centers close, many transplant patients will be required to travel far from home. This would be an added struggle to patients, one of five that are already on Medicaid.

4. Transporting organ decreases success rates. By abandoning the local system of organ allocation, organs will need to travel farther distances, leading to lower rates of success.

5. Legal uncertainty for UNOS. The National Organ Transplant Act intended to have organ transplantation policy in the private sector and the HHS regulation assert executive branch control over the program without appropriate legislative authorization.

6. Preemption of State Law. The new HHS regulations would preempt many state laws that currently govern organ procurement and distribution. In fact, the Washington Post reported on Jun 16, 1998 that four states (Wisconsin, Oklahoma, Louisiana and South Carolina) have passed "organs-for-state-residents-first" laws.

<u>Letter from Donna Shalala to members of Congress</u>

In response to these criticisms, Secretary Donna Shalala wrote a letter to members of Congress stating that the Department's new regulation does not mandate specific organ allocation policies. She also stated that the primary objective in issuing regulation is to assure that patients receive organs based on standardized medical judgement and common medical criteria, no matter where they live or in which transplant center they are awaiting treatment. The change in policy stemmed from the fact that one of the current shortcoming of the current allocation system is the wide span in average waiting times for those on translation waiting lists. In some areas of the nation, patients wait at least 5 times longer for an organ that those in other areas. She also enclosed a letter form Claude Earl Fox, M.D., Administrator of the Health Resources and Services Administration. He stated that the current allocation system is geographically biased and does not distribute organs on the basis of medical urgency which violates the requirements of the National Organ Transplant Act which calls for equitable system to distribute organs.

cc's Jen Klein

AGAINST b/c:

800 Marshall Street, Little Rock, Arkansas 72202-3591, (501) 320-1100 or TDD (501) 320-1184

(1) Only major centers survive
(2) Arkansas residents more willing in-state
(3) Ischemic time
(4) UNOS collaborated with concerned groups

June 11, 1998

Mrs. Hillary Rodham Clinton
The White House
Washington, DC 20500-2000

Dear Hillary:

The new HHS solid organ allocation policy, which directs the removal of regional considerations from organ allocation, is very distressing to the medical staff at Arkansas Children's Hospital. As you know, our cardiology department, including heart transplantation, is one of our largest and most outstanding services. Although the policy refers to livers only, the Secretary has stated that this same perspective (i.e., applying a single rule that organs should go to the sickest patients on a national waiting list) will be applied to heart and kidney allocation as well. We agree that organs should go to the sickest patients, but certain practical aspects of organ transplantation also need to be considered.

Arkansas Children's Hospital and other smaller programs are at risk in a national organ donation environment. Very large centers will compete more effectively for scarce organs because they have more patients on the waiting list at any given time. Only the major centers in large metropolitan areas will survive, resulting in heart transplants only for those able to afford the travel and hotel costs for long periods of time as they wait for an organ. Most of our patients have little or no transportation, finding it difficult to make regular clinic visits even to ACH, a primary reason for our statewide local clinics. Usually, the child's illness has already depleted the family's resources, and the parents would not be able to seek the transplant needed for their child. I know that access to health care for rural citizens has been a concern of yours for a long time, and this action seems to be counterproductive to that goal.

We feel strongly that Arkansas residents would be more willing to donate organs knowing that they would save the lives of Arkansas patients. The notion that organs are going to patients who don't urgently need them is incorrect. No patient is put on the waiting list until their medical condition has reached the acuity that demands a transplant.

A critical issue in heart transplantation is the ischemic time (the time from excision of the organ to transplantation). The ischemic time is even more important in

pediatric patients, many of whom have congenital structural abnormalities, which complicate the transplant surgery and make it more time-consuming. Studies have shown a direct correlation between longer ischemic time, greater risk of death, and later complications.

In cadaver donations, the heart necessarily is the last organ to be harvested. If the patient's other organs are being allocated to centers long distances away, the heart harvest must wait until each transplant team travels for hours to excise the particular organ allocated to them. By the time the heart is harvested, viability of the donor heart is at risk. The delays inherent in this complicated chain of events are a major concern of our heart transplant team.

UNOS has collaborated with all concerned groups (physicians, attorneys, ethicists, donor families, and organ procurement specialists) in establishing equitable policies for organ allocation. Our Cardiology Department Chairman, Dr. Robert Morrow, has served on the UNOS thoracic organ committee, which has spent countless hours trying to determine an equitable distribution system. These policies are constantly under revision in response to both professional and lay input. No policy will be perfect, but we feel that the existing policy and, more importantly, the inclusive UNOS process, is the best for now.

Sincerely yours,

Betty Lowe, MD
Professor Pediatrics, UAMS
Medical Director, ACH
Harvey and Bernice Jones Distinguished
Chair in Pediatrics, ACH

BAL/sam

P.S. The Arkansas Children's Hospital heart transplant program has performed 56 transplants since 1990. Forty-three patients are alive at present and our survival rate since October 1997 is 95%. This service is an extraordinary asset to the health care system of the state and region.

July 4, 1998

Betty Lowe, MD
800 Marshall Street
Little Rock, AK 72202-3591

Dear Betty:

Thank you for your letter about the new HHS solid organ allocation policy. As you know, I have long admired the transplantation work done at the Arkansas Children's Hospital. The success of your heart transplant program is a testament to the dedication and excellence of the medical staff.

I have asked Jennifer Klein on my staff to look into the issues you raised about the new HHS policy. As you point out, we need to strive to find a balance between creating fair transplantation policies and ensuring that it is practical for patients to get the organs they desperately need. Jennifer will contact you to discuss this further and will continue to update me on this issue.

Sincerely,

Hillary Rodham Clinton