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October 1, 1998

New Organ Transplant Rules Delayed

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Filed at 5:36 p.m. EDT**By The Associated Press**

WASHINGTON (AP) -- A fight over how to allocate scarce organs for transplant has shifted to a Louisiana court in a new setback for the federal government, which has been trying to force a change in policy for six months.

"We are disappointed in the last-minute ruling," the Department of Health and Human Services said Wednesday in a statement after a federal court delayed rules set to take effect Thursday.

Congress already had postponed the rules once and many lawmakers want to push them back again. Now, a federal judge in Louisiana has blocked them until an Oct. 14 hearing.

Louisiana points to a state law, which says all organs donated in Louisiana must be given to someone in the state, if possible.

By contrast, HHS wants to send organs to the sickest patients no matter where they live. It has ordered the United Network for Organ Sharing, which runs the nation's transplant system under an HHS contract, to develop a new policy.

Under the current system, organs first are offered locally, to the sickest person first. If there are no local matches, organs are offered regionally, then nationally.

Defending that system, the network fought HHS with aggressive lobbying to a receptive Congress. Talks this summer between the two sides went nowhere.

HHS argues that a new system is needed to equalize waiting times, which are five times longer for transplant patients in some parts of the country than others.

The network counters that a change would threaten smaller programs, which could see locally donated organs siphoned off to larger hospitals.

Furthermore, the network worries that giving priority to sicker patients would mean more deaths, because relatively healthy patients are more likely to survive surgery.

HHS insists the new rules would be flexible, noting they say that any policy should follow sound medical judgment and avoid wasting organs.

But the network does not trust HHS and has asked the department to make changes in the regulation itself to reflect that flexibility.

As the fight drags on, the transplant system will continue to function. But all sides fear the battle could jeopardize support for organ donation if people see negative news about transplants. Also, HHS officials believe the new system is needed now to start saving more lives.

Some 17,000 transplants are performed every year, but about 4,000 people die each year while waiting for organs. The list of patients who need new hearts, lungs, livers, kidneys and pancreases now tops 50,000.

The battle is the culmination of years of tension between the network and HHS and centers on whether the government has the power to veto network decisions.

The new rules give the network 60 days to adopt a new liver allocation policy, the source of most controversy, and a year to develop new policies for other organs.

But the clock will not start until the rules officially take effect.



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DEPARTMENT OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

Executive Secretariat

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FROM: Jackie White

FAX NUMBER: (202) 205 2135
OFFICE NUMBER: 640 5027

February 26, 1998

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

An identical letter went to each of the members.



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

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

Dear Senator:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sincerely,

Donna E. Shalala

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**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Office of the Secretary

Washington, D.C. 20201

June 2, 1998

The attached letter was sent today by HHS Secretary Donna E. Shalala to 181 members of Congress who have an interest in the Department's April 2, 1998, regulation governing the Organ Procurement and Transplantation Network.

An identical letter went to each of the members.



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

JUN 1 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.

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

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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.

Page 3 -- Member of Congress

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 has

Page 4 -- Member of Congress

decided 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 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

Page 5 -- Member of Congress

leadership and expertise of the transplant community, we can assure Americans that organ allocation policies are equitable, and that those who need organ transplants will be treated according to medical need, no matter where in the country they may be hospitalized, or at which center they may be listed. I look forward to working closely with you to achieve this important goal.

Sincerely,

/s/

Donna E. Shalala

Enclosure

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

**Health Resources and
Services Administration
Rockville MD 20857**

JUN 1 1998

**L.G. Hunsicker, M.D.
President, United Network for Organ Sharing
Suite 500, P.O. Box 13770
Richmond, VA 23225-8770**

Dear Dr. Hunsicker:

Secretary Donna E. Shalala has asked me to respond to your letters of April 17 and April 27, 1998. I address both letters, and focus particularly on the issues raised in the April 27th one which comments on the alleged effects of newly implemented national guidelines governing liver urgency status and allocation.

As you know, the shortage of organs available for transplantation in our country is so severe that approximately ten people die every day while waiting for a transplant. Many of these people die because the current allocation system is geographically biased and does not distribute organs on the basis of medical urgency. This policy violates the requirements of the National Organ Transplant Act, which calls for a system, equitable across the nation, for distributing organs. It also breaches the American Medical Association's Code of Medical Ethics, which states:

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.

The Department of Health and Human Services (HHS) is charged by statute with overseeing the Organ Procurement and Transplantation Network (organ network). In meeting this obligation, our greatest challenges are facilitating organ donation and reducing geographic access disparities for patients in need of transplants. We are addressing the first challenge by joining with public and private sector partners to implement the Administration's organ donation initiative and have taken steps to meet our goal of increasing organ donation by 20% within two years.

Our second challenge is addressed by HHS' organ network regulations which ask the transplant community to formulate new policies to eliminate the unfairness caused by the existing allocation systems. The regulations require the organ network, in devising the policies, to meet three broad performance goals: 1) standardization of listing criteria; 2) standardization of determining medical status of patients; and 3) that medical urgency, determined by the exercise

Page 2 - L.G. Hunsicker, M.D.

of sound medical judgment, not geography, be the main criterion for allocating organs. All three elements are necessary in our effort to achieve the best results for patients.

The regulations, which we first proposed in 1994, reflect substantial written public comments as well as testimony received during three days of public hearings in December 1996. UNOS responded to the published rule in writing and testified about the issues addressed by the rule at the 1996 hearings. You have a third opportunity for formal input, now on the newly-published final rule.

Your comments are welcome and should include any honest disagreement your organization may have with the final rule. But thus far, your response reflects a disappointing strategy of fostering conflict rather than cooperation. UNOS has lobbied to block the rule in a campaign not grounded in truth, and has used tactics that have frightened transplant patients and risk negatively affecting organ donation.

In fact, the UNOS campaign disregards your own precept. I remind you of the March 13, 1997, statement of former UNOS President, James Burdick. In reaction to the debate about allocation policies, Dr. Burdick provided the following admonition to the transplant community:

"...the community must generally understand the likely impact of a new or revised policy. In recent months, there have been conflicting accounts in the news media of the potential effects of revisions to liver allocation policy. While diverse views are held within the community, we must realize that contradictory or inaccurate statements about the policy's effect can needlessly confuse or frighten those with the most at stake -- patients desperately awaiting transplants."

Despite Dr. Burdick's statement, UNOS has responded to HHS' regulations by providing inaccurate or otherwise misleading information to patients, transplant surgeons and Members of Congress. UNOS has created a "legislative action kit," as you know, and has advised patients and the professional transplant community to use the kit to block the regulation. ("We urge you to prevent these regulations from being implemented." UNOS Sample Letter to Congress, UNOS Legislative Action Kit.) The kit includes a form letter to be sent to Members of Congress by its recipients. Among the unfounded claims issued by your organization are the following, cited as examples, not a complete catalogue, of your misleading assertions.

1. UNOS claim:

"[T]he impact of the regulations would be to lengthen the amount of time sick people must wait for transplants and reduce the number of people who are able to get them. The proposed federalization of the current system would take away control of the transplant system from doctors and patients in almost 300 transplant centers and hand it over to Federal regulators." March 30, 1998, letter from L.G. Hunsicker, M.D. to every Senator in the 105th Congress, included in UNOS' Legislative Action Kit.

Page 3 - L.G. Hunsicker, M.D.

The facts:

This statement is patently false. The regulations do not contain a new allocation system. The organ network itself will devise allocation policies. The regulations explicitly state that the organ network "... Board of Directors shall develop and propose policies for the equitable allocation of organs..." and empower the organ network to "[u]pdate policies developed in accordance with this section to accommodate scientific and technological advances."

Assertions about how long people will wait for transplants and/or the number of people who will get them are without foundation since the allocation policies have yet to be established by the organ network. Until the policies exist, it is not possible to observe what their effects will be. And it is hard to imagine that the organ network will develop a policies whose disadvantages outweigh its advantages.

2. UNOS claim:

"A single national list, which is what would be created, would result in more patients' deaths and longer waits for all patients..." UNOS letter [undated] from Donna Henry Wright, J.D. to Health Care Legislative Staff Members of the Congressional Black Caucus.

The facts:

The regulations do not require that organs be allocated from a priority ranked national waiting list. In fact, a directory of patients throughout the nation is currently maintained by UNOS, and lists all persons seeking transplants. That list does not now function as a priority wait list, and the regulations do not require that it ever do so. The notion of a national allocation-controlling list is purely fictional.

UNOS' own computer modeling, which is cited in the preamble to the regulations, shows that the removal of artificial barriers to organ sharing results in essentially the same number of people receiving transplants under at least two of the options considered by UNOS' liver committee, and more, not fewer, lives saved under all three of the UNOS-modeled options to the current policy.

The regulations do require that "... neither place of residence nor place of listing shall be a major determinant of access to a transplant." This simply means that fairness will be required for patients, and it means that patients will no longer die because of where they happen to live or list for a transplant.

Page 4 - L.G. Hunsicker, M.D.

3. UNOS claim:

The regulations will result in "...forcing doctors to transplant livers into the very sickest patients...". March 30, 1998 letter of L.G. Hunsicker, M.D. to every Senator in the 105th Congress, included in UNOS' Legislative Action Kit.

The facts:

Doctors will not be forced to treat patients in any respect contrary to their medical judgment. The regulations do not mandate transplants to the "sickest" first. As the preamble to the regulations state, "...those who are very ill but who, in the judgment of their physicians, have a reasonable likelihood of post-transplant survival - receive preference in organ allocation over those who are less medically urgent."

UNOS' current liver allocation system (with patients in Status 1, 2A, 2B or 3) ranks patients in order of medical urgency, recognizing that those in Status 1 are likely to die within a week or less if not transplanted. The regulations merely require that when the organ network establishes allocation policies, those policies take into account reducing geographic disparities as doctors continue to make the medical judgments they now do about who shall be transplanted.

4. UNOS claim:

"[C]losing down centers is likely to cause a decrease in donations as the efforts of transplant doctors and nurses to increase local donations cease. History shows that organ donation is a local phenomenon...". March 30, 1998, letter from L.G. Hunsicker, M.D., to every Senator in the 105th Congress, included in UNOS' Legislative Action Kit.

The facts:

We repeatedly note in the rule that nothing dictates, and no evidence supports, the conclusion that the rule would result in fewer organ donations. Indeed, the preamble to the regulations reference a 1994 organ network survey, among other supporting evidence, that shows that "... the overwhelming majority of donor families state as their preference that organs go to the neediest patients, regardless of geography, so long as organs are not wasted."

The Administration, with dozens of partners, has initiated a national organ and tissue donation initiative. Under conditions of participation regulations for hospitals, proposed in a separate rule, hospitals will be required to engage in activities to increase organ donation, or risk losing eligibility for Medicare and Medicaid. We have every expectation that, with your collaboration, and that of others, this initiative will be successful.

Page 5 - L.G. Hunsicker, M.D.

5. UNOS claim:

"[I]t is especially important that Congressional Black Caucus members are aware of the negative consequences of these regulations on minorities and the poor." UNOS letter [undated] from Donna Henry Wright, J.D. to Health Care Legislative Staff Members of the Congressional Black Caucus.

The facts:

Our regulation does not disadvantage minorities or the poor, though the current system does. A 1991 HHS Inspector General report, as well as soon to be released UNOS data, show that minorities wait longer under the current system. The UNOS data show that women wait longer as well. And, at our 1996 public hearings, several witnesses testified to the prohibitive costs to poor people should they need to travel to or list at several hospitals in order to get needed organs. With these facts as a predicate, our regulations state specifically that socioeconomic barriers to transplantation must be reduced.

6. UNOS claim:

"[T]he new system would allocate donated organs away from patients at the vast majority of the country's transplant centers and shift those organs to the largest centers. This in turn would...force many small and medium sized transplant centers (like mine) to shut their doors." "Sample Letter" in UNOS' Legislative Action Kit to be sent to Members of Congress.

The facts:

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

The regulations specifically reject the imposition of volume standards that would cause smaller centers to close. Any effects on the operations of transplant centers will depend on policies developed and implemented by the organ network. Moreover, in the preamble to our regulations, we specifically commit to monitoring any impact on the centers of new policies designed by the organ network.

7. UNOS claim:

"The regulations will have a particularly harsh impact on individuals who will have to travel great distances..." March 30, 1998 letter of L.G. Hunsicker M.D. to every Senator in the 105th Congress, included in UNOS' Legislative Action Kit.

Page 6 - L.G. Hunsicker, M.D.

The facts:

The opposite is the case. For those patients fortunate enough to live near a transplant center and who choose to list there, reforms in the current allocation policies would mean that organs would be more likely to reach them and their centers because there would be a larger pool of donated organs from which to draw. By eliminating the current incentives for patients to travel to areas with shorter waiting times, the rule is actually less likely than the current situation to require unnecessary and expensive travel.

The guiding principle of our regulations is that the formulation of policies requiring medical judgment, such as the design of a more equitable allocation process, is the responsibility of the organ network. The preamble to the regulations state this point quite clearly.

"The Department believes that the transplantation network must be operated by professionals in the transplant community, and that both allocation and other policies of the ...[organ network] should be developed by transplant professionals, in an open environment that includes the public, particularly transplant patients and donor families. It is not the desire or intention of the Department to interfere in the practice of medicine. This rule does not alter the role of the ...[organ network] to use its judgment regarding appropriate medical criteria for organ allocation nor is it intended to circumscribe the discretion afforded to doctors who must make the difficult judgments that affect individual patients. At the same time, the Department has an important and constructive role to play, particularly on behalf of patients. Human organs that are given to save lives are a public resource and a public trust."

The principle is firmly grounded in the organ transplant statute. The original law required the organ network to assist in the distribution of organs "which cannot be placed within the service areas of the [organ procurement] organizations [P.L. 98-507, title II, Sec. 201]." This language was removed in a 1988 amendment to the law, "so as to remove any statutory bias respecting the important question of criteria for the proper distribution of organs among patients," according to the Senate report on the amendment. In 1990, the statute was again changed, to require that the organ network "assist organ procurement organizations in the nationwide distribution of organs equitably among transplant patients." Without a doubt, Congress intends for the organ network to operate across the nation through a system that is free of any discrimination, whether it be the result of geographic bias or another form of prejudice.

Throughout the development of our regulations, this Department has created many opportunities for UNOS, the transplant community and the public to participate in the process. At this Department's 1996 public hearings on donation and allocation, UNOS was the first organization to present its views. More recently, the Department's Science Advisor and I met on several occasions with Dr. Burdick, then President of UNOS' Board and other UNOS staff to keep them informed of the Department's preliminary thinking and to receive feedback. On the day the

Page 7 - L.G. Hunsicker, M.D.

regulation was announced, HHS staff met at length with and briefed you and your staff on the particulars of the regulation and committed, yet again, to working with you and others in the transplant community to develop policies that treat patients fairly.

Though you disagree with provisions of the regulations, I ask that you or Dr. Bollinger, Chair of UNOS' Ad Hoc Advisory Committee, accept my offer to meet with me and other Departmental representatives. Through our discussions and during the public comment period, I urge you to offer constructive suggestions on how we can get this job done so that our main and shared goal of treating patients fairly is realized.

Sincerely,

A handwritten signature in black ink, appearing to read "Claude Earl Fox", written in a cursive style.

Claude Earl Fox, M.D., M.P.H.
Administrator

BUTZ



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

JUL 23 1998

The Honorable [Name]
U.S. House of Representatives
Washington, DC 20515

Dear [Name]:

Thank you for your letter regarding the Final Rule for the Organ Procurement and Transplantation Network (OPTN), which was published in the Federal Register on April 2, 1998, after extensive public comment and consultation. In issuing this rule, we paid close attention to the basic fairness of the system and sought to fulfill the responsibilities assigned to the Department of Health and Human Services (HHS) by Congress through the National Organ Transplant Act (NOTA), as amended.

This Rule preserves the OPTN's critical role in developing and implementing organ procurement and allocation policies. The preamble to the Final Rule states: "It is not the desire or intention of the Department to interfere in the practice of medicine." In the Rule, the Department calls on the transplant professionals of the OPTN itself to develop medically sound organ allocation policies.

Our goal in issuing this Final Rule was to ensure that the system of allocating these scarce resources is as fair as possible. Therefore, the regulation calls upon the OPTN to develop standardized medical criteria and to ensure that, no matter where patients live or in which transplant center they are awaiting treatment, they have a fair chance of receiving an organ, based on their medical condition and the judgment of their physician. 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 far away transplant centers simply to improve their chances of getting an organ.

We are aware that significant concerns have been raised by what has been referred to as the "sickest first standard" in the Final Rule. I would like to take this opportunity to reassure you, as I said during the June 18th Congressional Hearing, that nothing in the Rule should be construed as direction from HHS to the OPTN

Page 2 - The Honorable Anne M. Northrup

to waste organs by transplanting them to patients who are too ill to be viable transplant candidates. The Rule directs the OPTN to develop allocation policies based upon medical urgency and sound medical judgment. 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.

At present, medical urgency is not always the main factor in deciding who lives or dies. The current system often gives more weight to geography than to medical urgency with the result that patients in one part of the country wait as much as five times longer than patients in other parts of the country who have the same severity of illness. Policies of the OPTN should be based on medical criteria, as developed by the transplant community itself. Non-medical criteria, such as where you live or list, should not drive policy anymore than a person's wealth, celebrity, religion, ethnicity or race should be a factor. I am enclosing a copy of my testimony for the recent Congressional Hearing which discusses this and other points in more detail.

We recognize that the shortage of donors plays a major role in the tragic reality of Americans dying while on waiting lists for organ and tissue transplants. This Administration, with dozens of partners, is committed to increasing the rate of organ donation by 20 percent within two years. 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.

I look forward to working closely with you, the constituencies of the transplantation community, and other interested groups to achieve our shared goals of increased organ donation and more equitable access to the public trust which donated organs represent.

Sincerely,



Donna E. Shalala

Enclosure



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

FOR RELEASE UPON DELIVERY

TESTIMONY OF
DONNA E. SHALALA
SECRETARY OF HEALTH AND HUMAN SERVICES

BEFORE THE
SENATE LABOR AND HUMAN RESOURCES
AND
HOUSE COMMERCE COMMITTEES

JOINT HEARING ON ORGAN DONATION ALLOCATION

JUNE 18, 1998

Good Morning, Chairmen Jeffords and Bliley, Senators Kennedy and Frist, Representatives Dingell, Bilirakis, Brown, and other distinguished members, it is an honor to appear today before this joint hearing of the Senate Labor and Human Resources and House Commerce Committees. My testimony concerns one of the most important medical breakthroughs of the century, and perhaps the most wondrous: organ transplantation. Until the first half of the century, people routinely died of diseases of the liver, heart, lungs, kidneys and pancreas. The notion that patients with such diseases could be saved by transplanting organs from one human being to another was once beyond our imagination. In the short span of our lifetimes, organ transplantation has evolved from the impossible, to the conceptual, to the experimental, and now, nearly to the routine.

It is an odd notion, thinking of miracles as routine, yet the stunning survival rates of transplant recipients show that extraordinary surgical outcomes are a regular event. These successes are made possible by courageous and dedicated surgeons, physicians and nurses. A member of this heroic profession, one of America's great transplant surgeons, Senator Bill Frist, is cochairing this hearing.

There is much to celebrate about organ transplantation. There is much to celebrate because individuals like Senator Frist did not give up in the face of adversity. As a result of their tenacity and flexibility, the biggest obstacles to successful organ transplant surgery were gradually overcome. Today, donated organs can be preserved for longer periods of time, tissue typing is more accurate and immunosuppressant drugs are much more effective.

We must also remember the patients. Many of them, long forgotten except by friends and family, died during the evolution of transplant surgery. Because of their sacrifices, thousands more live today.

Just as medical professionals struggle to perfect transplant surgery, Federal policymakers also must grapple with difficult issues. These include finding new methods to increase organ donation and balancing our reliance on the medical judgment of the transplant community with statutory requirements to ensure fairness for transplant patients.

There was a time that transplant surgery was grossly unfair. Organs were sold to the highest bidder, often a wealthy foreign national. There were few transplant centers, with loose affiliations, which operated without national standards. As surgical accomplishments mounted, so did abuses and excesses. Eventually Congress intervened by passing the National Organ Transplant Act of 1984.

The Act made the buying and selling of organs a criminal offense. It created the Organ Procurement and Transplantation Network, commonly known as the OPTN. The Act now requires the OPTN to "assist organ procurement organizations in the nationwide distribution of organs equitably among transplant patients." Congress charged the Department of Health and Human Services with implementation of the Act.

We have come a long way from the pioneering days of organ transplantation. The Organ Transplant Act, and related changes to the Medicare law, provided for national policies and required transplant hospitals to abide by the rules of the national network. The network's primary goal is to ensure that all Americans in need have an equal opportunity to receive an organ transplant, consistent with sound medical judgment, regardless of who they are or where they live and choose to list.

Just as the pioneers of transplant surgery had to change their techniques and tinker with their approaches before they reached their goals, we must be prepared to adjust Federal policies to meet the intent of the Organ Transplant Act. Organ transplant policies are not yet fair to all Americans, and there is much that must be done before that aim is achieved.

There are about 55,000 people on waiting lists for organ transplants. Every day, more than ten of them die. They die because of a shortage of organs, and as the gap between the demand and supply of available organs grows, they may die in even greater numbers.

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, about one half to one third of all potential donors, contribute organs for transplantation. While the number of cadaveric organ donors has increased by 30 percent, the number of deaths on the waiting lists has also grown, by nearly 177 percent during the same period.

Increasing organ donations must be our number one policy priority. Last December, we announced a nationwide initiative to increase organ donations. A national partnership of public, private and volunteer organizations is working together to identify and overcome known barriers to organ donation. The centerpiece of the initiative is a new regulation, which was proposed in December and issued in final form yesterday. This regulation requires hospitals participating in Medicare or Medicaid to report to organ procurement organizations all deaths so that medically suitable donors can be more readily identified. The rule is based on the effective Pennsylvania State law that requires the reporting of deaths to State organ procurement organizations. Our goal is for the new rule, combined with other work being accomplished by the partnership, to result in a twenty percent increase in organ donation within two years.

Increasing organ donation is our most important policy goal, but not the only one. We also must do a much better job of meeting the central goal of the National Organ Transplant Act, which is to ensure an equitable nationwide system for the distribution of transplantable organs. Under existing policies, where a patient lives and which transplant hospital a patient chooses are often the primary determinants of whether the patient receives an organ. In other words, where you live and where you list can determine whether you live or die.

Medical urgency - how badly a patient needs the transplant - is not always the main factor in deciding who lives and who dies. I believe that the emphasis on geography instead of medical judgment is the reason that patients in one part of the country wait as much as five times longer than patients in other parts of the country who have the same severity of illness. Policies of the

Organ Procurement and Transplantation Network should be based on medical criteria, as developed by the transplant community itself. Non-medical criteria, such as geography, should not drive policy anymore than a person's wealth, celebrity or religion ethnicity or race should be a factor.

The current policies appear to be particularly unfair to minorities, many of whom wait on lists at large urban transplant hospitals that have long waiting lists. African Americans wait twice as long as white Americans for kidney transplants. Certainly, part of the reason for this inequity has to do with biological matching factors. But I am convinced that geographic inequities also have a role in the disparity.

The National Organ Transplant Act was intended to reduce such inequities. The law's insistence on fairness is echoed by the American Medical Association's Code of Medical Ethics, which states:

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 found that the national Organ Procurement and Transplantation network was inequitable, particularly with respect to race and geography, and that it did not meet the intent of the 1984 Act. As you know, the Office of Inspector General is an

independent organization. Earlier this year, a House panel examining this issue asked the Inspector General to update its findings. Last week, the Inspector General issued its updated report, which found that the inequities identified in 1991 remain in the network, and in some cases have worsened, particularly for African Americans. Let me read you the conclusion reached by the Inspector General last week:

Our brief review of these data lead us to reaffirm the importance of the central message we presented in our 1991 report — that the national organ allocation system should focus on equity among patients, not among transplant centers, and on common medical criteria, not the circumstances of a patient's residence or transplant center affiliation. We continue to believe that the April 2, 1998 HHS rule moves in that direction.

Under the current policy, less ill patients receive transplants while more severely ill patients, perhaps only a few miles away, die. We all have friends and relatives who live in different parts of the country. Should any one of them have a better chance of living than the other if they needed an organ transplant? Is it fair that patients with virtually identical medical needs are treated differently solely because of where they live?

The unfairness exists, not only between different parts of the country, but even within States. For example, the median waiting times for the two major liver transplant centers in the State of Kentucky are vastly different. One recent report found that the median waiting times for livers at

one of the centers was 38 days while it was 226 days at another. In Louisiana, the median waiting time at one center was 18 days, while it was 262 days at a different center. In Michigan, one center had a waiting time of 161 days while another major center in the State had a waiting time of 401 days. And so it goes across the country, inequity within States, and unfairness from one State to another.

These waiting list disparities are the most visible shortcoming of the current system. 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.

The April 2 rule does not actually contain any allocation policy. Instead, it calls on an HHS contractor, the United Network for Organ Sharing, or UNOS, to develop an allocation policy that will reduce current inequities in the network. I want to be clear about this, because there appears to be misunderstanding about the rule. The April 2 rule contains no allocation policy. It calls on UNOS to develop the policy. The rule is consistent with the Department's long-standing position that the development of any policies requiring medical judgement be left to the transplant community. We will rely on the judgement of transplant professionals to establish policy reforms.

The rule contains three common sense goals which are consistent with the equity requirements of the National Organ Transplant Act. The first goal requires that criteria for placing patients on waiting lists be standardized and be based as much as possible on objective medical criteria. The network cannot be truly fair if the standards for placing patients on waiting lists differ across the country. UNOS agrees with this goal and is working toward it.

The second goal requires that criteria for determining the medical status of patients be standardized, again on the basis of objective criteria. Uniform criteria for determining medical status will prevent gaming of the system. UNOS also agrees with this goal and is working toward its accomplishment.

The third goal requires that medical urgency, not geography, be the main criterion for allocating organs. This goal also meets the intent of the Organ Transplant Act for an equitable nationwide organ transplant network. UNOS objects to this goal. In disregard of the Act, UNOS insists on maintaining the current inequitable system.

There is a central purpose to the performance goals, which is to ensure, to the maximum possible extent, that all patients, regardless of where they live, are treated the same. Because there are not yet enough organs to save everyone on the waiting lists, I believe we must, at a minimum, guarantee fairness, while we continue to strive to increase donation.

I recognize that there are legitimate diverse views in the transplant community about the third performance goal, which requires reform of allocation policies. Small transplant centers worry they will be swallowed by large transplant centers. Organ Procurement Organizations that have worked hard to obtain transplantable organs are concerned that organs will flow from their State, leaving a shortage. Such concerns must be debated by the transplant community and they should strive to reach consensus on the best policies for patients.

Unfortunately, to this point, UNOS has failed to seize the opportunity offered by the rule to develop consensus about policy improvements. In fact, UNOS has gone to great lengths to preserve the current unfair system. It has launched a cynical political lobbying campaign against the April 2 rule. This campaign has been characterized by misinformation and outright falsehoods. The essence of the UNOS campaign has been to create phantom policies and use scare tactics that have hospital administrators and patients around the country up in arms. UNOS has sent form letters, part of a self-described "legislative action kit," to surgeons and patients across the country. UNOS has been loud and vociferous in its lobbying and is working with some of the highest priced public relations and lobbying firms in town. As a result of their slick lobbying campaign, you are hearing protests about the April 2 rule.

I am deeply concerned about these efforts to misrepresent the provisions of the regulation. I have received numerous letters from Members of Congress, transplant professionals, patients, and the public that reflect inaccuracies published by UNOS. I am especially distressed that UNOS is needlessly frightening transplant patients. I appreciate having the opportunity today to set the record straight about the intent and effect of this important rule.

UNOS has claimed that the rule creates a single national waiting list for patients that would result in more patients' deaths and longer waits for all patients across the country. This claim is completely false. As I have said, the rule asks UNOS to develop the allocation policy. There is no requirement for a national waiting list anywhere in the rule. The rule calls for fairness. How the fairness is achieved in terms of allocation policy is primarily up to UNOS. Leading members of the transplant community have presented proposals to UNOS to remedy the current system's unfairness with very little, if any, adverse impact on local transplant centers. There have been several experiments in allocation policies involving broader sharing of organs that have been sanctified by UNOS. These experiments are interesting and worthy of consideration. But instead of consideration, UNOS has resorted to frightening patients and surgeons. The scare tactic of the national waiting list is a central theme of the phantom policy created by UNOS.

I reiterate that the Department does not have a preconceived notion of any allocation policies. We are relying on the transplant community to develop the policy. Any policy that is sensible, is based on sound medical judgment, and reduces geographic inequity, will be taken seriously by the Department.

UNOS has claimed that the rule will force doctors to transplant livers into the very sickest patients, contrary to sound medical judgment. This claim is also false. We know that transplanting the sickest patient is not always the best course. We believe that transplants should be performed on the basis of medical urgency, the definition of which includes viability and chances of survival. Further, it is up to UNOS to develop policies on medical urgency.

UNOS claims the rule will force transplant centers to close. There is nothing in the regulation that would force any centers to close. On the contrary, a fairer distribution of organs should enhance the ability of all centers to have better access to matching organs for transplantation.

UNOS has claimed that organ procurement areas with excellent donation rates will lose organs to areas with poorer donation records. This is another false assertion. Already, over 35 percent of donated organs are used outside the local area. Our organ donation initiative should result in increased organs for every procurement area. Also, broader sharing will mean that patients will benefit from a wider pool from which to draw. Again, UNOS will set the policy.

I think the most outrageous UNOS claim is that the regulation would hurt minorities and the poor. In the first place, the current system is not fair to minorities, as the Inspector General has reported. Minorities can only benefit from the fairer policies the regulations attempt to encourage. As for UNOS claims about the poor, the truth is that Americans who cannot afford to pay for transplant surgery do not even get on the waiting list. So the opposite of UNOS's allegation is true: it is the current unfair system that has negative consequences for minorities and the poor. We are trying to change the system. UNOS is trying to preserve it.

Finally, I would like to comment on the UNOS claim that the Department lacks the authority to issue any rules governing the Organ Procurement and Transplantation Network. As I have said, the National Organ Transplant Act gives the Department the authority to oversee the network. The primary reason the Act was passed in the first place was because the unregulated network was rife with abuses. Also, the Department, through Medicare and Medicaid, pays for more than

half the transplant surgeries in the United States. Taxpayers pay for most of the listing fees charged by UNOS. To say we have no basis to issue regulations when our authority is clear is a disservice to Congress, which created the network, and to the patients, whose transplant bills are paid by taxpayers.

I regret that UNOS has frightened patients and perhaps jeopardized organ donation in some areas of the country. Only a year ago, a former President of UNOS, Dr. James Burdick, warned against such scare tactics. Dr. Burdick sent a statement to all UNOS members. It said:

"...the community must generally understand the likely impact of a new or revised policy. In recent months, there have been conflicting accounts in the news media of the potential effects of revisions to liver allocation policy. While diverse views are held within the community, we must realize that contradictory or inaccurate statements about the policy's effect can needlessly confuse or frighten those with the most at stake — patients desperately awaiting transplants."

What has been the response to Dr. Burdick's warning? There have been charges that the April 2 rule will kill people. There have been charges that the April 2 regulation discriminates against minorities. There have been charges that patients will have to travel great distances for transplants. There have been charges that transplant centers will be shut down. All these charges come from UNOS and all of them are false. Dr. Burdick's responsible policy was flatly rejected.

Many of you have expressed reservations about the April 2 rule. I know your concerns are legitimate and I take them very seriously. I want to respond to every one of them. I know that members of both committees, and the Congress in general, are fair and agree that the debate should be based on facts and what is best for patients.

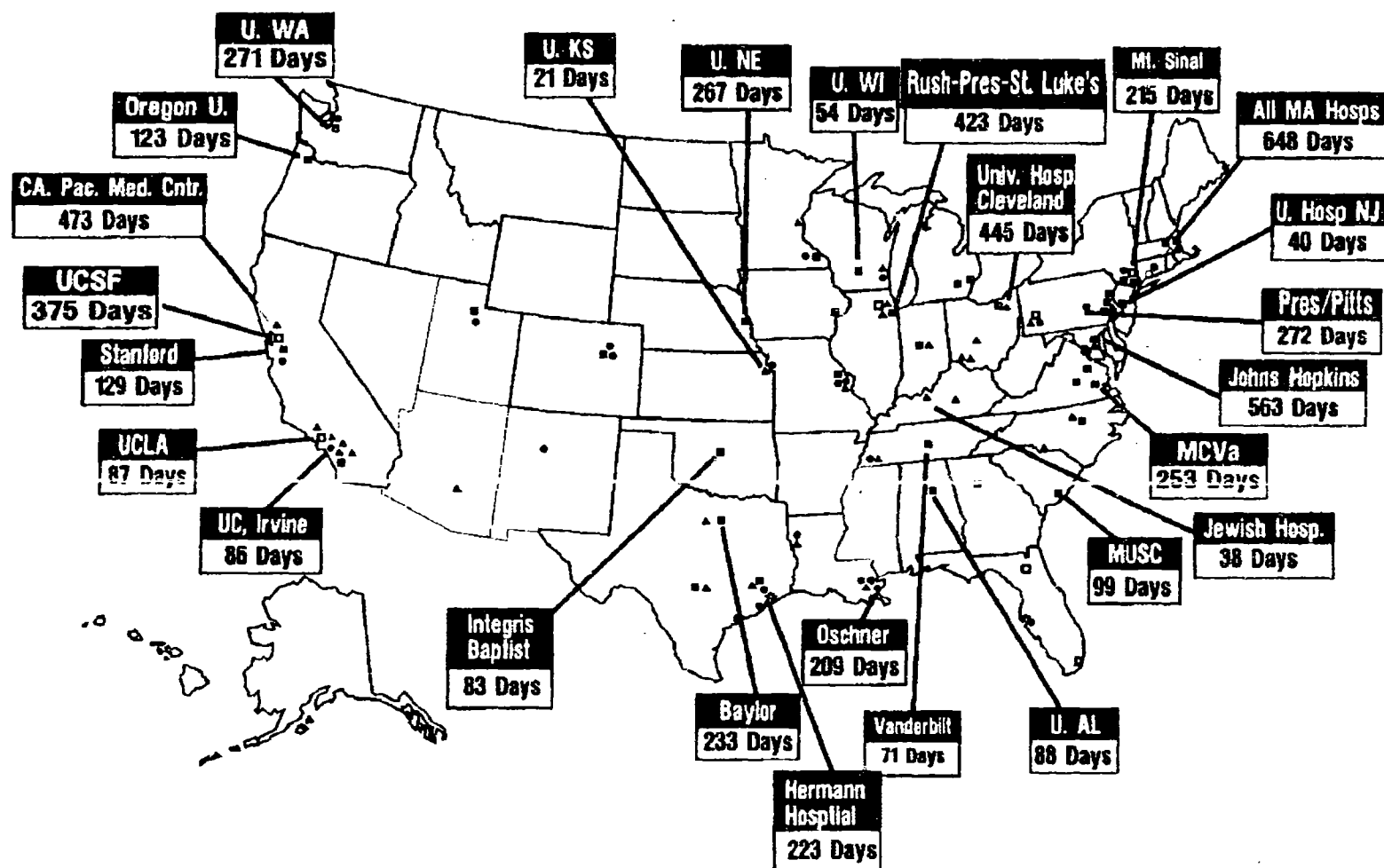
My fervent hope is that the polarization created by the UNOS lobbying campaign is the result of a misunderstanding of the rule and its intent. I say this because I believe that all of us - the Department, UNOS, and Members of Congress, want what is best for patients. Department representatives met with UNOS before the rule was issued to explain our intent. Meetings have occurred since the rule's publication and I hope that we will continue to meet so that UNOS has a complete understanding of the rule and what the Department hopes to accomplish.

I want you to ask the Department tough questions and examine the regulation from every angle. One of the reasons we delayed the implementation of the rule is so that there would be time for additional public comment as well the opportunity for Congress to have hearings on these issues. I am hopeful that you will conclude, as I do, that the April 2 rule is our best chance of meeting the goals of the National Organ Transplant Act.

Thank you for the opportunity to testify and set the record straight. I will be happy to answer any questions that you may have.

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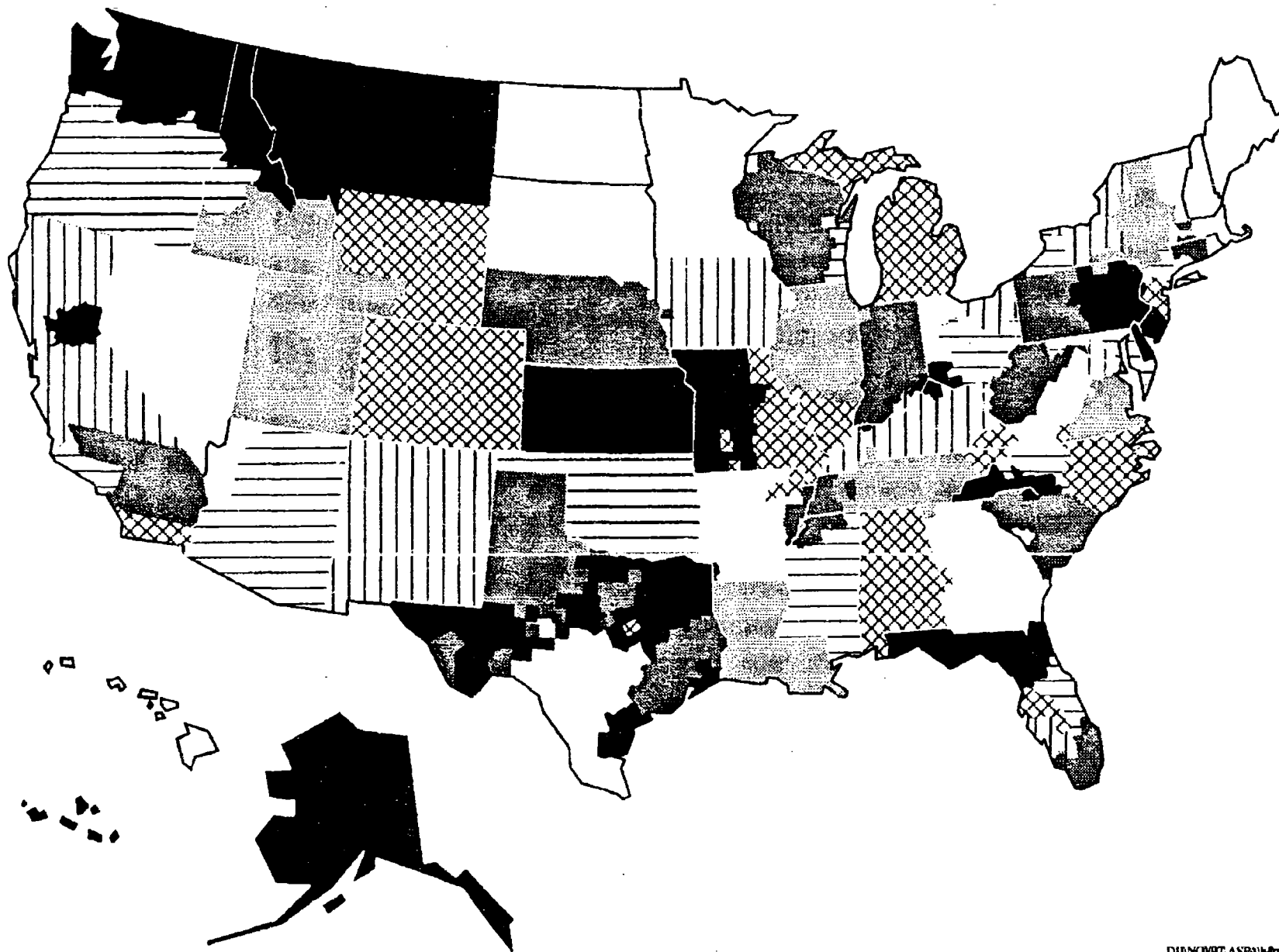
Waiting Times for Liver Transplants Vary Widely by Hospital



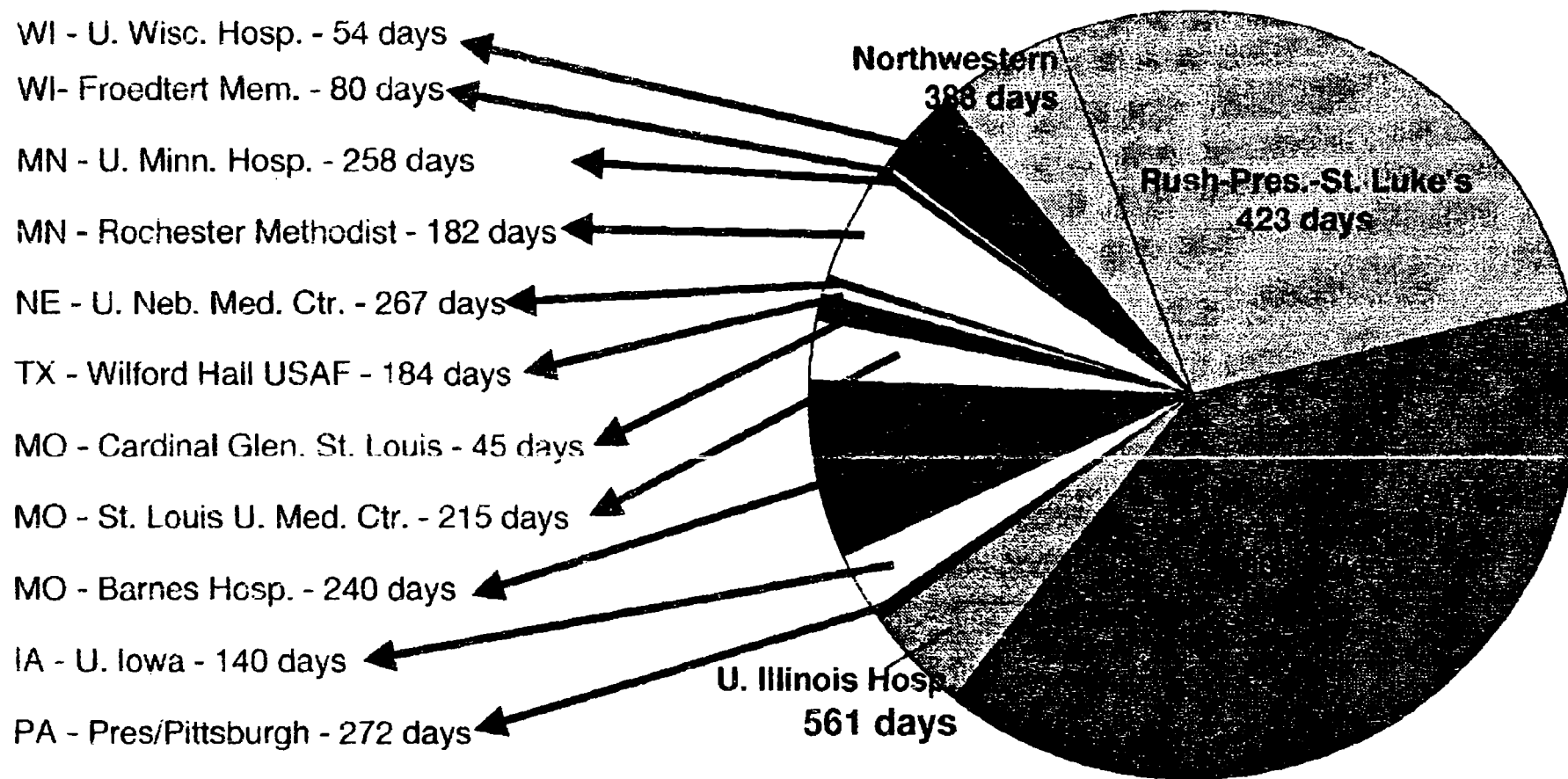
Source: UNOS Scientific Registry data as of September 15, 1997.

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Arbitrary Geographic Non-Medical Boundaries are Used to Allocate Organs



How Long Patients from Illinois Wait for a Liver Depends on Where They List



Source: UNOS data. Waiting time compiled by CONSAD.

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BUTZ

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR RELEASE: 10 a.m.
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

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."

- MORE -

- 2 -

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.

- MORE -

- 3 -

- 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.

- MORE -

- 4 -

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/bhrd/dot.main.htm>.

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HHS FACT SHEET

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

March 26, 1998

Contact: HRSA Press Office
(301) 443-3376

IMPROVING FAIRNESS AND EFFECTIVENESS IN ALLOCATING ORGANS FOR TRANSPLANTATION

Background

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

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

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The Regulation

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

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

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

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

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Key Principles

Important principles underlying the final regulation include:

- The Department's responsibility is to assure that the goals of the National Organ Transplant Act are being realized for patients. The Department's role is to provide broad oversight and performance goals to ensure an equitable allocation system that operates in the best interest of patients.
- The rule does not dictate medical practice, but provides a broad framework for the OPTN's operation and activities. Within that framework and the goals of the law, the OPTN has the freedom and flexibility to determine the most effective ways to put the policies into practice nationwide. Individual physicians will continue to make decisions regarding individual patients.
- As far as medically feasible, there should be a "level playing field" in organ allocation. Organs should be allocated based on patients' medical need and sound medical judgment, with less emphasis on keeping organs in the local area where they are procured. Patients should have an equal chance to receive an organ based on their medical need, not the accident of geography. Efforts should be made to equalize waiting times among different regions of the country.
- Standardized medical criteria should be used to determine the status of a person's illness and when the person can be placed on a waiting list. The same medically objective criteria should be used by all transplant centers. Uniform criteria can help reduce regional variations and will help build trust among centers, physicians and patients.
- Patients, their physicians and the public should have timely, accurate and user-friendly center-specific data on the performance of transplant programs to measure quality and make transplant decisions.
- Transplant decisions should always be based on sound medical judgment to avoid wasting organs and ensure an efficient and effective system.
- HHS policies must be guided by the interests of patients and the purposes of the law, not the sometimes conflicting interests of different transplant centers

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Major Provisions

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

- o **Policy Development**--The OPTN Board of Directors is responsible for developing organ allocation policies, with the advice of patients, families and the public. Proposed policies may be reviewed by the Secretary, and if determined appropriate, published in the Federal Register for public comment. Entities objecting to OPTN or Secretarial policies may submit appeals to the Secretary in writing. In addition to policies for the equitable allocation of organs, the OPTN's policy making role includes: policies on the training and experience of transplant surgeons and physicians; policies for nominating OPTN Board members; and other policies as directed by the Secretary.
- o **Allocation of Organs**--The OPTN Board of Directors is responsible for developing organ-specific policies (including combinations of organs, such as for heart-lung transplants) for equitable organ allocation among potential recipients. The rule sets three broad performance goals for organ allocation:

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

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

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

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

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

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

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

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

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

WHAT OTHERS HAVE SAID

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

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

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

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

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

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

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

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

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

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

AGENCY ATTENDEES

Jacqueline White	Deputy Executive Secretariat
Beverly Dennis	Deputy General Counsel
William Raub	Science Advisor to the Secretary
Walt Francis	ASPE Staffer
Mark Smolonsky	ASL Staffer
Lorraine Fishback	Exec. Sec. Staffer
Judy Braslow	Director of the Division of Transplantation Policy, HRSA

Brief Synopsis of UNOS Liver Allocation Modeling, 1994-1996

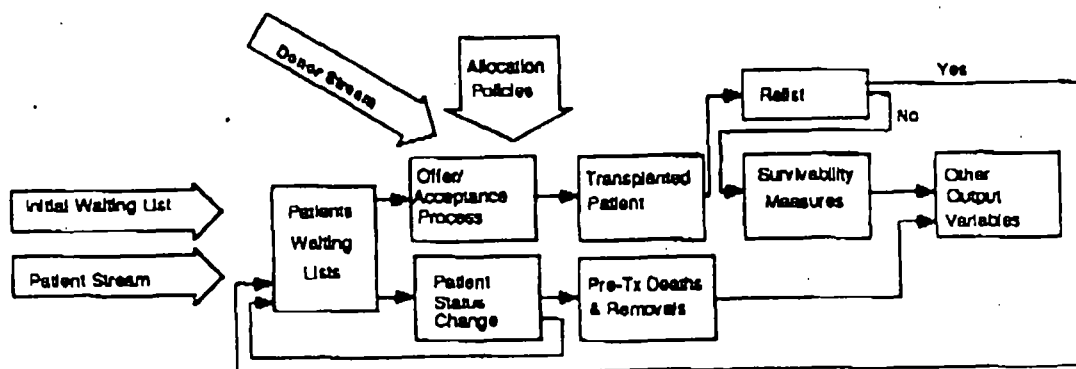
UNOS

Simulation modeling for policy comparison and evaluation.

In 1994, UNOS began compiling the data necessary to construct a computer simulation model for use in comparing alternative liver allocation policies. In November 1994, UNOS President Margaret Allen placed computer modeling at the top of her list of priorities for her 1994-1995 tenure. In December 1994, UNOS began to search for an outside expert in the field of computer simulation and modeling. In January 1995, UNOS contracted with the Pritsker Corporation to develop a computer simulation model for liver allocation to be used in evaluating alternative policy scenarios. An *ad hoc* Modeling Oversight Committee provided medical and scientific direction for development of the UNOS Liver Allocation Model (ULAM). The model specification was approved in March of 1995, and a phase I model was developed by June, 1995. The ULAM was demonstrated at the June 1995 Board of Directors meeting, and results for 8 initial policy alternatives were presented.

ULAM was designed to simulate the liver allocation process in the United States. Thus, it must include all the elements that are present in the existing system, such as donors, recipients, an offer/acceptance process, and so forth. The seven major components of the model are:

1. Initial Waiting List
2. Recipient Stream
3. Patient Medical Urgency Status Change Process
4. Donor Stream
5. Allocation Policy
6. Liver Offer/Acceptance Process
7. Post-transplant Relisting/Mortality



Schematic of UNOS Liver Allocation Model (ULAM)

Brief Synopsis of UNOS Liver Allocation Modeling, 1994-1996

UNOS

ULAM (Cont'd)

- The ULAM is *modular*, consisting of these components. Each component may be modified to accommodate new data or to reflect changes in the technology of transplantation. For example, new data may suggest that post-transplant mortality is a function of waiting time to transplant. Alternatively, a new immunosuppressive drug may emerge that promises a dramatic increase in post-transplant survival rates. In either case, model components may be modified to reflect estimated or hypothetical changes in the field of liver transplantation.
- ULAM uses either *historical data* or *generated data* for policy simulation. Historical donor and recipient data streams use actual OPTN data collected during 1992-1995. The generated donor and recipient data streams are modeled based on the patterns found in the historical data, and can be used to model the 1992-1995 time period or to forecast the effects of the policy over the 1996-1998 time period.

Brief Synopsis of UNOS Liver Allocation Modeling, 1994-1996

UNOS

Model Verification/Validation

The ULAM was validated extensively by comparing the output of each component model as well as the overall model output to actual results from the 1992-1995 time period. The component models were developed and validated using data from the same period. Particular effort was directed to the validation of the patient status change probabilities, which determine each patient's movement between medical urgency status codes or to death or removal. Estimates of these transition probabilities were obtained for the period 1992-1995. Three-year survival and relist rates were calculated using data from patients transplanted in 1991-1993; these components required analysis of this cohort due to the need for sufficient post-transplant follow-up. Using input data from 1992-1995, the model simulation should produce results that are similar to the actual results from the same period.

In general, the ULAM predictions are extremely close to the actual 1992-1995 results. For those output measures that are absolute values (e.g., number of transplants, number of removals), no measure was more than 12%; several measures were within 1% of the actual value. For those measures expressed as percentages (e.g., percent of transplants by status), no measures were more than 5% from the actual percentage. Due to the lag time in patient follow-up, it was not possible to validate post-transplant death or survival measures.

Validation of the model using historical donor and recipient streams was performed by comparing results from the model to actual data for the period from 1992-1995. Validation of the generated data is done prospectively. For example, donor procurement data from 1991-1994 were used to project 1995 donor arrivals, which were compared to 1995 actual data once it had been collected and verified. The projected number of 1995 donors was similar to the actual number of donors with only a 5.6% discrepancy between actual and predicted.

A comparison of the predicted versus actual numbers of registrations by transplant center revealed that the estimation technique used was a strong predictor of patient registrations at the center level. The very few deviations between actual and predicted patient registrations by transplant center were easily explained by key personnel changes at those centers, or, in one case, closure of a transplant center.

A complete description of the ULAM components and methodology can be found in Organ Transplantation Policy Evaluation (Pritsker, et al) in: *Proceedings of the 1995 Winter Simulation Conference*, ed. C. Alexopoulos, K. Kang, W.R. Lilegdon, and D. Goldsman, p. 1314-1323.

Brief Synopsis of UNOS Liver Allocation Modeling, 1994-1996**UNOS****POLICY EVALUATION*****Policy Types Evaluated***

- Variants of the current distribution system; examples:
 - Redefinitions of local (i.e., state) or region (i.e., "Super-Region")
 - Single National List/Modified Single National List
 - Residence-based distribution
- Population-Grouped Distribution System: distribution unit based on size (percentage) of waiting list rather than geographic boundaries
 - Local = 5%, Regional = 20%
- Combinations of current/PGDS:
 - Local = OPO, Region = 20% circle

Over 30 policy proposals were formally evaluated by UNOS' Committees and Board during this process

- In general, the same sequence of allocation of liver within the distribution unit remained the same: Status 1s, Status 2s, Status 3/4s.
- 9 Policy types presented to the UNOS Liver and Intestinal Transplantation Committee in May, 1996, including: Current policy, UPMC proposal, several PGDS variations. Each policy was modeled with the current status codes and the proposed status codes (preference to acutes/primary non-function).

Final Policies Considered

- Liver Committee proposal (5-96)
- Allocation Advisory Committee proposal (6-96)
- UNOS Board Proposal (6-96)
- Final Board-approved Policy (approved by Liver Committee, 9-96, accepted by Board 11-96)

Brief Synopsis of UNOS Liver Allocation Modeling, 1994-1996

UNOS

ULAM MODELING OUTPUT

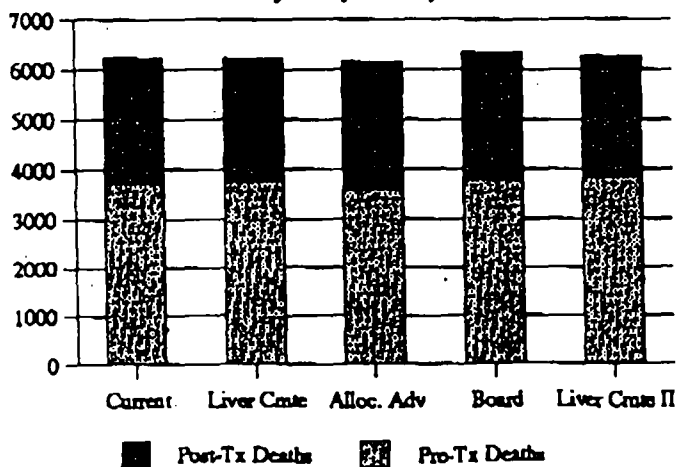
The "most pertinent data" is in the eye of the beholder: better survival, fewer retransplants, fewer pre- or post-transplant deaths, higher pre- or post-transplant life-years, less variation in regional waiting times, etc.

The ULAM produces a wide array of outcome measures for policy comparison: 10 pages of output are produced for each individual policy, and an 8-page spreadsheet is created for policy comparison. A sample of ULAM's policy comparison capability is shown below.

Measure	Current Policy	Liver Cmte (5-96)	Alloc. Adv. Cmte (6-96)	Board Proposal (6-96)	Final Board-Approved Policy (11-96)
Total Patients Transplanted	10992	11147	10998	11141	11194
Retransplants	1663	1509	1659	1516	1463
3-year Survival (%)	74.9	75.8	74.8	75.9	76.0
Distribution of Transplants					
Local	77.5	74.8	44.1	74.4	77.9
Regional	80.0	8.0	27.7	18.4	17.9
National	4.0	17.1	28.2	7.2	.2
Relists	2297	2211	2254	2213	2191
End Waiting List	11534	11500	11789	11463	11308

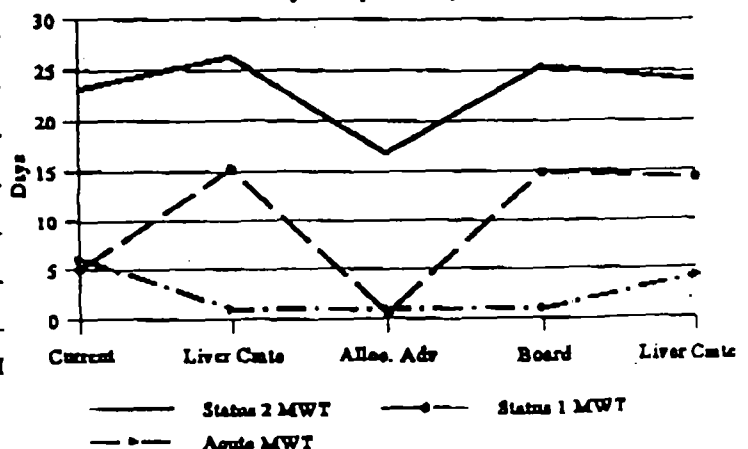
Pre- and Post-Transplant Deaths

ULAM Policy Comparisons, 1996-1996



Median Waiting Times to Liver Transplant

ULAM Policy Comparisons, 1996-1998



An Assessment of Liver Allocation Options:
Results from the CONSAD Liver Allocation Simulation Model

CONSAD Research Corporation
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December 5, 1996

The attached table contains a summary of the results produced by the CONSAD liver allocation simulation model in six analyses. The analyses evaluate the consequences for patients from applying three alternative liver allocation policies within the context of two different specifications of health status categories.

In the table, the specifications are labeled "Original Health Status Categories" and "Revised Health Status Categories". The original categories correspond to the set of categories that UNOS currently uses in liver allocation, and the revised categories correspond to the set recently approved for use by the UNOS Board of Directors. In the two specifications, the categories are numbered from 1 to 3 or 4, in decreasing order of medical severity. In the original category specification, chronically ill patients with short life expectancies are included in health status 1; in the revised category specification, such patients are included in health status 2.

The alternative allocation policies are labeled "Current UNOS Policy", "Priority to Inpatient Proposal", and "Local-first National Proposal". The policies differ in the way that geographic restrictions affect the allocation of donor livers among patients in the specified health status categories. Allocation may be restricted to a **local** area consisting of the service area of the Organ Procurement Organization (OPO) in which the liver was donated, or to a **regional** area consisting of the UNOS Region containing that OPO. Otherwise, allocation is **national**. The order in which each alternative policy offers donor livers to transplant candidates is summarized below:

Current UNOS Policy		Priority to Inpatient Proposal		Local-first National Proposal	
Health Status	Area	Health Status	Area	Health Status	Area
1	Local	1	Local	1	Local
2	Local	2	Local	1	National
3,4	Local	1	Regional	2	Local
1	Regional	2	Regional	2	National
2	Regional	1	National	3,4	Local
3,4	Regional	2	National	3,4	National
1	National	3,4	Local		
2	National	3,4	Regional		
3,4	National	3,4	National		

In the Current UNOS Policy, geographic considerations outweigh health status in the allocation of donor livers among patients; whereas in the Local-first National Proposal, health status outweighs geography. In the Priority to Inpatient Proposal, health status outweighs geography in the allocation of livers to inpatients (patients in health status 1 or 2) rather than outpatients (patients in health status 3 or 4), but geographic considerations outweigh health status in the allocation of livers among inpatients.

The Simulation Model

To evaluate the differences among alternative liver allocation policies, CONSAD has developed a computer model that uses a Monte Carlo (probabilistic) simulation approach to estimate organ donations, patient registrations, waiting lists, and outcomes for any allocation policy. The patient outcomes of primary concern are deaths of transplant candidates while on the waiting list, deaths of patients after transplantation, years of life that patients experience, and the time patients wait between registration and transplantation. The model contains representations of the flows of donor livers to transplant centers, the flows of candidates to transplant centers, the progressive degradation of health status for patients as they wait for transplantation, the deaths of some candidates while waiting, the matching of donor livers with candidates on waiting lists, the transplantation of livers into patients, and the subsequent survival, relisting, or death of the patients who receive liver transplants.

The model operates with a daily time increment. On each simulated day, transition probabilities are consulted to determine the types of events (e.g., registrations, changes in health status, transplantations, and deaths) that occur that day. The model can be used to simulate any year, or group of years, for which data exist to describe registrants, candidates on waiting lists, and donor livers. All data used in the computer model have been obtained from UNOS sources.

Consequence Measures

For each of the six combinations of an alternative allocation policy and a specification of health status categories, the attached table contains estimates for eight measures that we believe are most important to patients. The first four measures relate to the medical efficacy of the option in achieving specific goals, and the last four relate to its equity or fairness to patients. The measures of medical efficacy are:

- (1) the percentage of donor livers allocated to patients in each health status category. This measure describes how well the option distributes livers in accord with the medical priorities established by the specified health status categories.

- (2) the percentages of donor livers that are allocated to patients at transplant centers in different proficiency classes. Statistical studies conducted by UNOS have consistently found that, in general, risk-adjusted post-transplant survival rates are significantly higher in centers that have large annual volumes of liver transplants than in centers that have small annual volumes.
- (3) the number of patients who die during the simulation. Separate estimates are provided for the number who die while waiting for transplants, the number who die after transplantation, and the sum of those values.
- (4) the number of years of life realized by patients in the aggregate. Separate estimates are reported for years experienced before transplantation, years experienced up to two years after transplantation, and the sum of those values.

The measures of equity or fairness include two that relate to a patients who obtain transplants and two that relate to candidates who die while waiting for transplantation. They are:

- (5) the average amounts of time patients wait, between the time they register as candidates and the time they obtain transplants, at centers that have different annual volumes of liver transplants.
- (6) the average amounts of time patients wait at centers in different UNOS regions.
- (7) the percentages of patients at centers that have different annual volumes of liver transplants who die while waiting for donor livers.
- (8) the percentages of patients at centers in different UNOS regions who die while waiting for transplantation.

For each of the last four measures, the equity or fairness of the option is indicated by the standard deviation of the set of values produced for the measure. Total equity or fairness would be realized if all values in the set were equal, and hence the standard deviation was zero. Larger standard deviations indicate lower degrees of equity.

Results

Comparing the results obtained for all three alternative liver allocation policies in combination with the original and the revised health status categories reveals that the recent revision of health status categories approved by the UNOS Board of Directors will have the following effects:

- Fewer livers will be allocated to chronically ill patients with short life expectancies, and more will be allocated to healthier inpatients.
- Pre-transplant deaths will increase, and post-transplant deaths will decrease by roughly the same amount. The net effect on the mortality of patients will be small.
- The total number of years that patients live will increase, primarily as a result of allocating more livers to healthier inpatients.
- Equity will stay the same or decrease slightly (as indicated by the comparative values of the standard deviations).

Thus, the aggregate effect of the recent revision of health status categories on medical efficacy will be small, and the effect on equity will be negligible or slightly adverse.

In marked contrast, comparing the results obtained for the three alternative policies in combination with either of the specifications of health status categories reveals that relaxing the geographic restrictions on the allocation of livers among patients yields:

- Greater achievement of the medical priorities established by the specification of health categories.
- Decreases in pre-transplant deaths that substantially exceed the corresponding increases in post-transplant deaths, resulting in sizable decreases in total mortality.
- Increases in the total number of years that patients live, consisting primarily of substantial increases in life-years before transplantation, with small changes in life-years after transplantation.
- Substantial improvements in all equity measures (as indicated by the uniformly large decreases in their standard deviations).
- Performance of more transplants by the centers in the most proficient class, and fewer transplants by centers in the less proficient classes.

In summary, the results clearly show that, using either the existing health status categories or the recently revised categories, broad geographic sharing of donor livers both saves and extends lives and improves fairness, when compared with the current liver allocation policy.

Summary of Estimated Consequences of Alternative Policies for Allocating Donor Livers Among Registrants on the Basis on the Original and Revised Health Status Categorizations for the Period from 1996 to 1998

Health Status Categorization		Original Health Status Categories			Revised Health Status Categories		
Policy Description		Current UNOS Policy	Priority to Inpatient Proposal	Local-First National Proposal	Current UNOS Policy	Priority to Inpatient Proposal	Local-First National Proposal
Percent of All Transplants*	Health Status 1 (1)	0.7%	1.0%	2.3%	0.8%	1.3%	1.8%
	Health Status 2 (1)	22.5%	34.3%	65.6%	9.3%	13.2%	12.1%
	Health Status 2 (2)	42.9%	64.8%	32.0%	55.3%	85.5%	86.1%
	Health Status 3 (3)	31.7%	0.0%	0.0%	32.3%	0.0%	0.0%
	Health Status 3 (4)	2.3%	0.0%	0.0%	2.2%	0.0%	0.0%
Percent of All Transplants**	Small-volume Centers	24.4%	19.3%	17.9%	24.1%	19.3%	18.9%
	Medium-volume Centers	37.1%	31.8%	29.6%	37.1%	31.8%	30.0%
	Large-volume Centers	38.6%	48.9%	52.5%	38.8%	48.9%	51.0%
Deaths**	Pre-transplant	4,443	4,060	3,664	4,571	4,196	4,216
	Post-transplant	2,612	2,734	3,067	2,468	2,549	2,527
	Total	7,055	6,794	6,731	7,039	6,745	6,743
Patient Life-years**	Pre-transplant	16,032	17,861	18,556	17,093	17,312	18,683
	Post-transplant	35,742	35,520	35,134	36,107	36,270	36,465
	Total	51,774	53,381	53,690	53,200	53,582	55,148
Average Waiting Time Until Transplant***	Small-volume Centers	52.68	94.09	115.10	52.24	97.87	110.37
	Medium-volume Centers	61.59	95.54	115.42	62.70	99.64	114.13
	Large-volume Centers	128.71	119.00	115.61	140.88	124.60	126.04
	Overall	90.50	109.57	115.26	97.63	114.60	121.61
	Standard Deviation	41.56	13.98	0.26	48.44	14.95	8.18
Average Waiting Time Until Transplant***	UNOS Region 1	107.12	110.31	110.96	102.41	108.48	105.36
	UNOS Region 2	104.36	121.15	112.91	126.43	133.58	123.94
	UNOS Region 3	23.74	80.78	114.79	23.03	80.87	109.16
	UNOS Region 4	89.38	99.72	111.82	91.26	102.13	112.76
	UNOS Region 5	112.36	108.77	111.55	120.72	115.28	119.34
	UNOS Region 6	56.81	93.57	111.03	55.98	94.85	106.84
	UNOS Region 7	114.33	104.76	110.59	118.13	112.04	109.97
	UNOS Region 8	103.19	106.41	112.59	110.29	113.91	122.50
	UNOS Region 9	113.01	107.34	110.48	118.59	111.96	114.79
	UNOS Region 10	89.45	92.78	113.29	87.59	96.04	109.70
	UNOS Region 11	73.91	88.15	109.04	69.90	89.95	122.87
Standard Deviation		28.36	11.55	1.59	32.24	14.53	6.81
Percent Dying Pre-Transplant***	Small-volume Centers	12.17%	13.92%	13.66%	12.30%	14.33%	14.62%
	Medium-volume Centers	12.48%	13.78%	13.29%	12.82%	13.79%	14.91%
	Large-volume Centers	19.66%	15.97%	13.35%	20.24%	16.63%	15.92%
Standard Deviation		4.24%	1.23%	0.20%	4.44%	1.51%	0.68%
Percent Dying Pre-Transplant***	UNOS Region 1	15.71%	15.41%	14.45%	15.77%	16.68%	13.66%
	UNOS Region 2	20.51%	17.48%	13.26%	21.16%	18.34%	16.35%
	UNOS Region 3	4.67%	10.29%	14.01%	4.91%	9.73%	14.85%
	UNOS Region 4	16.67%	13.79%	13.36%	16.06%	14.87%	14.91%
	UNOS Region 5	16.84%	14.75%	13.71%	17.64%	15.81%	16.08%
	UNOS Region 6	10.34%	14.58%	13.89%	11.89%	14.29%	14.92%
	UNOS Region 7	18.06%	15.33%	12.95%	18.30%	15.70%	14.39%
	UNOS Region 8	19.76%	16.15%	13.48%	20.09%	15.91%	15.76%
	UNOS Region 9	16.04%	16.08%	13.00%	17.09%	15.33%	15.22%
	UNOS Region 10	14.52%	13.64%	13.14%	14.25%	13.62%	14.45%
	UNOS Region 11	10.92%	12.94%	12.65%	11.56%	13.08%	15.79%
Standard Deviation		4.64%	1.92%	0.53%	4.59%	2.23%	0.81%

* 1996-1998, revised (original) health status categories.

** 1996-1998.

*** 1998.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

Executive Secretariat

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

SUMMARY: This notice sets forth the final rule governing the operation of the Organ Procurement and Transplantation Network (OPTN) and requests comments on possible changes to that rule. The regulation establishes requirements related to the following aspects of organ procurement and transplantation: structure of and membership in the OPTN; the OPTN policy-development process, including the role of Secretarial oversight; listing of transplant candidates on a nationwide computer system; organ procurement; identification of organ recipients; allocation of organs; designation of transplant programs; review and evaluation of OPTN activities; and record maintenance and reporting by Organ Procurement Organizations (OPOs) and transplant hospitals. These regulations provide the framework within which the OPTN, its members, and other participants in organ procurement and transplantation must operate. By this notice, the Secretary also is providing an additional opportunity for public comment and will consider revising this rule based on those comments.

The rule has three primary features. First, it outlines a policy-development process for the OPTN that relies heavily upon the medical expertise and cooperative endeavors of OPTN members while providing for oversight by the Secretary as necessary to protect the interests of patients, donors and their families, and the general public. The Secretary will review significant OPTN policies prior to their promulgation with a view toward ensuring that they are equitable across the national community of patients, that they place reasonable requirements upon health-care providers and payers, and that they otherwise are consistent with the goal of establishing and maintaining a national organ allocation system. The Secretary is ultimately accountable for making proper public-policy choices of this nature.

Second, the rule establishes a performance goal for organ allocation and, for each organ type, charges the OPTN to develop policies that direct organs to patients on the basis of decreasing medical urgency (beginning with those most in need) and without regard to the patient's place of residence. The OPTN is to define medical urgency in terms of objective medical criteria (such as blood tests commonly used to assess organ function) and to focus first on appropriate revisions to its current liver-allocation policy.

Third, the rule provides for substantial improvement in the availability to the public of data regarding transplant programs. The resulting ready access to center-specific performance data will be of unique help to both physicians and patients as they attempt to judge whether particular transplant programs can meet the patient's needs.

I. Background

A. Overview

Human organs that are donated for transplantation are a public trust. Advances in medical science and technology have made organ transplantation an increasingly successful and common medical procedure.

The National Organ Transplantation Act of 1984 (NOTA) created the Organ Procurement and Transplantation Network (OPTN). The Congress envisioned a national system that would be operated by the transplantation community — including physicians and officials of transplant facilities as well as other specialists and individuals representing transplant patients, their families, and the general public. In this way, advances in medicine and transplantation technology as well as changes in physicians' and patients' viewpoints can be accommodated readily in OPTN policies.

At the same time, NOTA vested in the Secretary oversight of the OPTN and responsibility for ensuring public benefit. Amendments to the Social Security Act in 1986 underscored the Secretary's role. Thus, working in partnership with the transplant community, the Secretary has final authority over OPTN policies and procedures. In particular, the Secretary has statutorily mandated responsibility to ensure that the OPTN distributes organs "equitably" and fulfills other statutory objectives, to obtain and act upon "critical comments relating to the manner in which (the OPTN) is carrying out the duties of the Network", and to issue regulations for the purpose of ensuring that the system is operating effectively and efficiently to meet its goals.

Six principles underlie this regulation:

- o transplant patients are best served by an organ-allocation system that functions equitably on a nationwide basis;
- o 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;
- o the OPTN must have the capability to adapt its policies and procedures quickly to changes in medical science and technology;
- o organs should be allocated in such a way as to favor those in most urgent medical need of transplantation without regard to place of residence — except as limited in particular cases by the time period of the organ's usefulness or the patient's likelihood to benefit;
- o 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 available

readily to help patients and physicians in choosing among transplant centers;

o potential conflicts of interest should be minimized for those who are responsible for operation of the OPTN.

In addition, the Secretary is taking steps to increase organ donation and procurement, for only with a substantial increase in both the number of organ donors can the difficult task of organ allocation be made easier. The initiative includes a wide range of partnering activities to encourage increased organ donation, intensified efforts to educate families about organ donation, and research and evaluation focused on alternative approaches to encouraging donation. The initiative also includes proposed changes in Medicare Conditions of Participation for Hospital to the effect that hospitals be required to report all appropriate deaths to their affiliated OPOs (thereby giving OPOs increased opportunities to decide which cases may be appropriate for donation) and to enlist them to work directly with the families of the potential donors.