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HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE
Monday, Oct. 18, 1999

Contact: HRSA Press Office
(301) 443-3376

STATEMENT BY DONNA E. SHALALA
Secretary of Health and Human Services
Regarding Issuance of OPTN Final Rule Amendments

"Today my Department is issuing an amended regulation to carry out the shared responsibilities under the National Organ Transplant Act. The amended rule includes important changes that reflect the constructive input we received over the past year from the Congress, the Institute of Medicine and representatives of the transplant community. We appreciate the many suggestions we have received, and we look forward to continuing and improving our partnership with the transplant community in making our transplantation system as effective and fair as it can be.

"The Department has worked hard to fulfill the intent of Congress since the legislative moratorium was placed on our Final Rule. The Congress asked for three courses of action: a report by the Institute of Medicine to examine these issues closely; development of improved transplantation data; and renewed discussions between HHS and the various members of the transplant community to improve our understanding of the various points of view.

"Today, those three steps have been taken, and I believe all of us have learned significant lessons as a result of these extra efforts.

"The Institute of Medicine delivered a landmark study in July, using a breadth of data never before available to researchers, and performing enlightened analyses of that information. All of us concerned with transplantation policy are indebted to the IOM committee for its work.

"Likewise, the Department explored new avenues for providing useful, transplant center-specific information for patients, physicians and the entire transplant community. This work was provided to Congress this month, and has also been conveyed to the Scientific Registry of Transplant Recipients for appropriate further development.

"Finally, we have concluded a series of meetings with representatives from all sides of the transplant community. We conducted a dozen meetings with representatives of 11 different groups, and we listened to all concerns. In our final meeting, we invited all these groups to come together to discuss the rule.

"Today, the amendments to our Final Rule rely heavily on the findings of the IOM. They also reflect the concerns we have heard in our discussions with the transplant community.

- More -

"These amendments improve and refine the Final Rule. They make much clearer the separation of roles between the federal government and the transplant professionals who make the medical decisions. They add a significant new element, an independent advisory committee to assure that HHS has the best scientific counsel as it oversees the broad policies of the Organ Procurement and Transplantation Network, consistent with the law. They provide for appropriate representation by transplant physicians and surgeons, and by patient and donor representatives, in the leadership of the OPTN. They envision a more vigorous role for the OPTN in assuring that consistent medical criteria are used, so that we can be assured that organs are being allocated in the fairest and most medically effective manner. And they provide expanded flexibility for development of performance criteria, including modifications in keeping with the IOM's recommendations concerning the use of waiting time as a performance measure.

"As the Final Rule is put in place, we look forward to the establishment of policies by the OPTN that reflect the following core principles

- Organs must be allocated according to uniform medical criteria, which are developed by the transplantation community. Likewise, the transplantation community should design fair and effective criteria by which the performance of the system can be measured.
- Organ sharing must take place over broad enough areas to ensure that organs can reach the patients who need them most, and for whom transplantation is most medically appropriate
- There are appropriate and distinct roles to be played by both the federal government and the organ transplant community. In particular, HHS does not seek to interfere in the practice of medicine, but rather to assume proper responsibility, as specifically reaffirmed by the IOM, for ensuring that the transplantation system as a whole operates in the public interest.
- The best possible information must be made available to physicians and patients, both to help in medical decision-making, and to learn the most successful practices and deliver the highest quality care.

"These principles were reinforced by the findings of the IOM. They are simple and powerful goals that we can all share.

"During the past year, we have gained the important input of the IOM, we have developed some promising new analyses of transplant data, and we have gained greater clarity about our common purposes and how to reach them.

"Now it is time to move forward toward the goals we share: increased donation of organs, and best medical use of every organ that is donated. It is time to take the steps that can make our transplant system work better and save more lives. It is time to translate our words and our intentions into action that benefit patients."

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HHS Rule Responds to Institute of Medicine Recommendations and Public Comments Summary of Major Revisions to Organ Transplantation Rule

"Today my Department is issuing an amended regulation to carry out the shared responsibilities under the National Organ Transplant Act. The amended rule includes important changes that reflect the constructive input we received over the past year from the Congress, the Institute of Medicine and representatives of the transplant community. We appreciate the many suggestions we have received, and we look forward to continuing and improving our partnership with the transplant community in making our transplantation system as effective and fair as it can be." -- Secretary Donna E. Shalala, October 18, 1999

Last year, Congress included in the Omnibus Appropriations Bill for Fiscal Year 1999 a one-year moratorium on implementation of HHS' Organ Procurement and Transplantation Network (OPTN) final rule. Congress asked the Institute of Medicine to independently examine issues related to the rule and current OPTN policies. Congress also asked HHS to conduct discussions with the OPTN to resolve issues raised by the final rule, and required the OPTN to provide data to HHS for analysis.

During the year that the moratorium has been in effect, HHS has worked to fulfill the intent of Congress and has learned much from the IOM's July 1999 report. HHS senior staff conducted a series of meetings with members of the transplant community, and the Department has analyzed hundreds of public comments on the rule. HHS also has analyzed newly available OPTN data that provide important insights.

Highlights of Revisions to HHS Final Rule

- The changes emphasize and strengthen the role of transplant community in policy development.
- An Independent Advisory Committee is established to ensure policies are based on the sound medical judgment of transplant professionals.
- Regional sharing is deemed acceptable, and there is no requirement for a national list.
- Policies that waste organs or encourage inappropriate transplants in sickest patients are prohibited.
- Data provisions are strengthened to better inform patients and the public.
- Equal treatment of patients is required, regardless of place of residence, celebrity, or socioeconomic status.
- A 30-day delayed effective date is included and the network is provided 3 additional months to develop liver allocation policy.

Summary of Changes to HHS Organ Transplantation Rule

Changes in the Amended Rule in Response to the IOM Report

- adopts the IOM recommendations and clarifies that new allocation policies should be based on medically appropriate broader sharing of organs.
- encourages the OPTN to adopt the IOM recommendations regarding the appropriate use of waiting times by revising the rule's language to de-emphasize the use of waiting times for less medically urgent patients.
- adopts the IOM recommendation for appropriate federal oversight by strengthening the use of performance measures to assess transplant program performance and by requiring additional data from the OPTN to enable the public to better assess the OPTN; also adds a strong role for a new Advisory Committee on Organ Transplantation (see below).
- adopts the IOM recommendation that a new Advisory Committee on Organ Transplantation be established to assist HHS "in ensuring that the system of organ procurement and transplantation is grounded in the best available medical science and is as effective and equitable as possible."
- adopts the IOM recommendation to improve data collection and dissemination by requiring the OPTN to provide to HHS data necessary to assess performance and outcomes.

Additional Changes to Respond to Public Comments

- revises the rule to make clear that a so-called "national list" is not required.
- revises the rule to make clear that allocation policies must be tailored to different types of organs so that, concepts of "medical urgency" as used for some types of organ allocation, need not be used for kidney patients because of the availability of life sustaining kidney dialysis.
- strengthens the rule's call for medically-based criteria for putting patients on transplant waiting lists by adding the complementary requirement that the OPTN develop criteria for de-listing patients if transplantation is no longer a medically appropriate option.
- strengthens the rule's discussion of medical urgency to make clear that this concept must be tempered by sound medical judgment regarding whether a patient remains an appropriate candidate for an organ transplant.

- strengthens the rule's acknowledgment of medical factors (most notably organ ischemic time) that affect broader sharing of organs.
- strengthens HHS' ability to monitor the effect of changes in allocation policy on small and medium centers.
- strengthens physician and surgeon involvement in the OPTN's governance, while retaining an increased role for transplant candidates, recipients, organ donors, and families, and providing the OPTN with additional flexibility in its governance.
- provides a greater role for the OPTN in developing performance indicators to assess transplant program performance.
- provides for a smoother transition to the new liver allocation policies, increased data availability requirements, and new OPTN governance requirements.

HHS Amended Rule for Organ Transplantation Is Fully Consistent with IOM Recommendations

IOM RECOMMENDATION	HHS RULE
RECOMMENDATION 1: <i>Establish Organ Allocation Areas for Livers.</i> The committee recommends that the DHHS Final Rule be implemented by the establishment of Organ Allocation Areas (OAAs) for livers - each serving a population base of at least 9 million people (unless such an area would exceed the limits of acceptable cold ischemic time). OAAs should generally be established through sharing arrangements among organ procurement organizations to avoid disrupting effective current procurement activities.	New regulatory provision indicates that organs should be distributed "over as broad a geographic area as feasible" taking into account factors such as: (1) sound medical judgment; (2) making the best use of donated organs; (3) preserving the ability of transplant programs and surgeons to make individual-by-individual difficult medical decisions; (4) taking into account factors unique to a particular organ type (such as the ischemic time for that type of organ); and (5) avoiding wasting organs and futile transplants, promoting patient access, and promoting the efficient management of organ placement (logistical considerations). (§121.8(b)(3), §121.8(a)(1)-(5))

IOM RECOMMENDATION	HHS RULE
RECOMMENDATION 2: <i>Discontinue Use of Waiting time as an Allocation Criterion for [Liver Transplant] Patients in Statuses 2B and 3.</i> The heterogeneity and wide range of severity of illness in statuses 2B and 3 make waiting time relatively misleading within these categories. For this reason, waiting time should be discontinued as an allocation criterion for status 2B and 3 patients. An appropriate medical triage system should be developed to ensure equitable allocation of organs to patients in these categories. Such a system may, for example, be based on a point system arising out of medical characteristics and disease prognoses rather than waiting times	To facilitate the OPTN's adoption of this recommendation, HHS added new regulatory provision (and preamble discussion) to: • indicate that waiting time need not be used for organ allocation (§121.8(b)(4), preamble) • require the OPTN not to use waiting times where medically inappropriate to do so (§121.8(b)(4), last sentence, last clause; preamble explains this is intended to address IOM recommendation) • require the OPTN to develop more homogeneous patient status categories (§121.8(b)(2), last sentence) • authorizes use of "performance indicators" other than (or in addition to) waiting time, as means of assessing transplant program performance (§121.8(b)(4))

IOM RECOMMENDATION	HHS RULE
RECOMMENDATION 3: <i>Exercise Federal Oversight.</i> The Department of Health and Human Services should exercise the legitimate oversight responsibilities assigned to it by the National Organ Transplant Act, and articulated in the final rule, to manage the system of organ procurement and transplantation in the public interest. This oversight should include greater use of patient-centered, outcome-oriented performance measures for OPOs, transplant centers, and the OPTN.	New regulatory provisions: • ensure that oversight of OPTN policies, consistent with the National Organ Transplant Act. Provide for active participation of public and requires consultation with new Advisory Committee on Organ Transplantation. (§121.4(b)(2)) • adopt IOM-recommended performance measures to assess transplant program performance. (§121.8(b)(4)) • provide for HHS review of OPTN compliance and enforcement activity (§121.10(c))
RECOMMENDATION 4: <i>Establish Independent Scientific Review.</i> The Department of Health and Human Services should establish an external, independent, multidisciplinary scientific review board responsible for assisting the Secretary in ensuring that the system of organ procurement and transplantation is grounded on the best available medical science and is as effective and as equitable as possible.	New regulatory provisions: • establish an Advisory Committee on Organ Transplantation (§121.12) • require Secretarial consultation with the Advisory Committee in reviewing proposed OPTN policies (§121.4(b)(2)), or complaints about the operation of the OPTN (§121.4(d))

IOM RECOMMENDATION	HHS RULE
RECOMMENDATION 5: <i>Improve Data Collection and Dissemination.</i> Within the bounds of donor and recipient confidentiality and sound medical judgment, the OPTN contractor should improve its collection of standardized and useful data regarding the system of organ procurement and transplantation and make it widely available to independent investigators and scientific reviewers in a timely manner. The Department of Health and Human Services should provide an independent, objective assessment of the quality and effectiveness of the data that are collected and how they are analyzed and disseminated by the OPTN.	New regulation: • Strengthens requirements for OPTN to submit relevant data to HHS for its assessment of the OPTN (§121.8(b)(3)) • retains strong requirements that OPTN make its data available, with suitable patient confidentiality protections, to independent researches and scientific reviewers in a timely manner. (§121.11(b)(1)(v))



October 27, 1999

MEMORANDUM FOR THURGOOD MARSHALL, JR.

Forwarded herewith is a Memorandum for the President, signed by Secretary Shalala. The memorandum provides the President with background regarding the Department of Health and Human Services' Final Rule to improve the nation's system of organ procurement and transplantation.

In her memorandum, the Secretary urges the President to reject actions by Congress that would further delay implementation of the Final Rule.

If you have questions, please phone me at 202/690-7431.

Mary Beth Donahue

Attachment
Memorandum for the President



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

OCT 27 1999

MEMORANDUM FOR THE PRESIDENT

As you know, the Department of Health and Human Services has been working for a number of years toward improving the Nation's system of organ procurement and transplantation. Our goal is to make the system operate for the greatest possible benefit of patients. We believe improvements in the organ transplant system could result in saving hundreds more lives each year.

Toward the goal of saving more lives, we have moved in two areas. With the Vice President's leadership, we have undertaken a National Initiative to increase organ donation. This effort has produced successful results in its first year. At the same time, HHS developed regulations to carry out the purposes of the National Organ Transplant Act of 1984. These provisions, developed over a period of years with extensive opportunities for comment, were published as a Final Rule on April 2, 1998.

Our Final Rule was supported by patients' groups and many prominent transplant centers and professionals, but was opposed by the HHS contractor which operates the Organ Procurement and Transplantation Network (OPTN) and by others in the transplant community. Last Fall, Congress imposed a one-year moratorium on implementation of the Final Rule, and mandated that a study of the issue be carried out by the National Academy of Science's Institute of Medicine (IOM). Congress also asked for further consultation between HHS and the transplant community. Both of these actions have been completed.

The IOM published its study in July. Its findings strongly validated the concerns and the approach of the HHS Final Rule. In particular, the study reinforced the need for Federal oversight of the Nation's organ procurement and transplantation system -- not to impose government in medical decision-making, but to ensure that the policies of the OPTN were operating fairly and effectively in the public interest. Throughout this year, HHS also continued meeting with the various elements of the transplant community, listening to concerns about the Final Rule and identifying common goals.

On October 20, HHS published amendments to the Final Rule which reflect the findings of the IOM report as well as our discussions with the transplant community. These amendments especially benefit from the input provided by the IOM, and they represent improvements in the

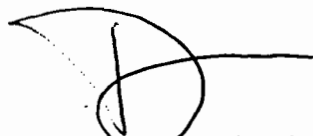
Final Rule. But at the same time, we have preserved the core features of our Final Rule, which are the foundation for improving our system for patients. In particular, this means using standard medical criteria, developed by transplant professionals themselves, to decide which patients will receive organs. This is the only way to ensure that organs will reach patients who need them most.

Opponents of our Final Rule are once again seeking to use the Appropriations process to impose a renewed moratorium on the Final Rule. The Administration is on record as strongly opposing any new moratorium. I want to urge that we remain strong in defending our current position and insist that the regulation go forward as scheduled. Our approach has been validated by the IOM study that Congress ordered, we have listened to the concerns of all elements in the organ transplant community, and we must remain committed to an organ transplant system that saves more lives by serving patients in the fairest and most medically effective way possible.

In addition, both Congress and the Executive Branch should be concerned about the integrity of Federal spending for transplants. Medicare and Medicaid alone pay for more than half of transplant costs in the United States. However, without the Final Rule to define the Federal role in our transplant system, the government has little useable authority to assure that these Federal dollars are being used in a fair and effective manner.

Our goal is to work cooperatively with the transplant community to ensure the best possible transplant system for Americans. We have been careful not to inject government into decisions which must be left to medical professionals. Instead, we have designed a carefully balanced approach in which the Federal Government can carry out the oversight role which the IOM so clearly reaffirmed.

For these reasons, I would urge you to reject any actions by Congress that would further delay implementation of the Final Rule.



Donna E. Shalala

Attachments

Wash. Post; 10-23-99

An End to Organ Games?

THE FIGHT between the federal government and local organ transplant centers over how better to allocate scarce organs has been a strikingly unsavory application of territorial politics to an area where politics should play no role. This week the Department of Health and Human Services (HHS) published a final regulation—to go into effect in 30 days—intended to make organ distribution more equitable. The idea is to even out disparities among the many geographic areas served by the nation's 272 transplant centers, most of which grew up in an era when "harvested" organs needed, for technical reasons, to be used close to home. The varying populations of these regions mean uneven distribution, which, given the shortage of organs, spells death for some 4,000 patients a year for whom an organ cannot be found in time.

Enter HHS, which last year issued a draft regulation calling for the network's contractor, United Network for Organ Sharing, to come up with more equitable criteria based on medical, rather than geographical, status. The organ transplant network, though, fiercely opposed the regulation and persuaded Congress to delay its implementation a year. The network fears the changes would force local transplant centers to close, which in turn would dissuade families from donating loved ones' organs; it also warned of organ wastage

because of failed procedures if the sickest patients were invariably transplanted first.

Behind these concerns—for which a congressionally mandated report from the National Academy of Sciences' Institute of Medicine found no evidence—is the fear that local centers would close, eliminating the substantial income source they represent for the hospitals that house them. That may explain the otherwise remarkable fact that 10 states responded to the proposed rule by passing laws making it more difficult to send organs out of state. The Institute of Medicine report even cites cases where grieving families willing to donate were urged to sign contracts requiring that organs go only to in-state recipients.

In fact, the report's researchers found no evidence that families care whether organs are used nearby; on the contrary, surveys showed they cared most whether the organs would be fairly used. The report recommends that geographical regions be made larger but that any new system make use of existing transplant networks rather than closing them down, a goal HHS Secretary Donna Shalala says could be achieved under the rule. Opponents of the reforms could still hobble and delay the regulation further as part of the budget appropriation for HHS. Such an action would be an extension of a cynical battle that costs patients' lives as it drags on.

MONDAY, OCTOBER 25, 1989

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Ensuring a healthy system

By keeping the details open to doctors' suggestions, feds may produce a better organ donation network

The Clinton administration continues to push for a more rational system of allocating donated organs. That's good for sick people.

But the push leaves a lot of room for input from hospitals and doctors involved in transplant surgery. That's good for all concerned.

Whether the United Network for Organ Sharing, the hospital organization that set up the current system of allocating transplants, can recognize the common good remains to be seen. Thus far, UNOS has been much too intent on defending its methods to acknowledge that patients might be better served by a few changes.

Donna Shalala, secretary of Health and Human Services, has expressed a willingness to lay down the law if UNOS balks at doing its work the way its employer, the federal government, wants it done. But Shalala cleverly has stopped well short of dictating precisely what UNOS must do.

Instead, her department has set forth broad administrative requirements and left the details for the medical professionals at UNOS to decide.

As a result, comments like those of UNOS board member Ronald Ferguson of Ohio State University, couldn't possibly ring more hollow. "I support keeping medical decisions about transplant in the hands of the doctors that are caring for the patients. I oppose the intrusion of the government into the process," Ferguson says in a letter he has been asking his patients to mimic, sign and send to Congress (an actively intrusive arm of the government, last time we checked).

Good for you, Dr. Ferguson. Your argument in favor of keeping doctors in charge of curing patients is right in line with what Secretary Shalala wants, loath though you may be to admit it.

She is asking only that the criteria hospitals use to determine a patient's place on a transplant waiting list be standardized around the country, and that any donated organ be made available to the patient in most urgent need in a region larger than a single state. Further, HHS wants UNOS to establish performance measures so transplant centers' work can be evaluated.

Those broad requirements are fair, sensible and in line with advances in organ transplantation, preservation and transportation. The details of how to meet those requirements are the medical professionals' to decide, which is as it should be.

Unfortunately, the medical professionals at UNOS became used to lax HHS oversight over the years, and rare indeed is the hospital or doctor eager for performance evaluations. So it is no surprise that this government contractor has enlisted allies in Congress to help it become a law unto itself. That should not be allowed to happen.

The small burdens the Clinton administration is asking UNOS to take on hold great promise for improving the treatment of patients. But if the medical professionals best suited to do the job fail to do it, the government will have to step in and do its imperfect best.

July 26, 1999

Improving Access to Organs

Forum

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-

For more than a year the Clinton Administration has been trying to improve the way human organs donated for transplants are distributed to patients around the country. But Congress, responding to intense opposition from transplant centers, has blocked the use of new Federal regulations that aim to broaden organ sharing across arbitrary local lines. A new report by the Institute of Medicine, a branch of the National Academy of Sciences, confirms that changes are needed to make the system more fair and effective.

The current system directs most organs to be used in the local area where they were donated. That can create unfair situations where patients who are less ill may get transplants while more severely ill individuals who happen to live outside the local organ procurement area are made to wait. This has become an increasingly important public health issue, since about 4,000 Americans die each year while waiting for transplants.

The Department of Health and Human Services tried to address the problem by issuing new regulations last year. These direct the United Network for Organ Sharing, a private organization that coordinates organ distribution nationally, to design a new allocation system that puts more emphasis on medical criteria and leaves less to geography. But Congress delayed that directive from going into effect until this October. The network insisted that the rules would force small transplant centers to close and discourage organ donations if donors knew organs would go outside their community.

The Institute of Medicine report, commissioned by Congress, found those fears to be overblown. The report, which focused on liver transplants, said waiting periods for the very sickest patients were actually comparable across the nation. But there were differences in waiting times for patients who were less ill. The report recommends improving distribution by requiring that organs be shared across

wider regions based on population, so long as the regions are not so geographically large as to pose problems in transporting the organs.

The report also affirmed the need for more active Federal oversight and greater scientific review of allocation principles. These recommendations are consistent with the Administration's approach. The transplant community should drop its resistance to Federal regulations that could make the system more equitable for patients everywhere.

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THE LANCET

Volume 352, Number 9122

Changing the US transplant system

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

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

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

On the face of it, it is hard to see what is objectionable about Shalala's proposal, but the response of the United Network of Organ Sharing (UNOS), the DHHS contractor that operates OPTN, has been furious. In a letter sent to every US Senator last spring, the outgoing president of UNOS, L G Hunsicker, described the regulations as a "federalization of the current system which takes away control of the transplant system from doctors

and patients in almost 300 transplant centers and hands it over to Federal regulators" and forces doctors to give livers "to the very sickest patients", who are likely to require second or third transplants and thus use organs that could have gone to save other patients. Hunsicker predicts that the regulations will make it more difficult for most patients to receive a transplant because organs will be shunted towards a few large transplant centres with the longest waiting lists and the sickest patients.

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

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

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

The Lancet

USA TODAY

THE HIT
HOLLYWOOD
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WEDNESDAY



Top 10 sleeper: Grass-roots marketing vaulted biblical 'Omega Code' into a weekend box office hit.

Wednesday, October 19, 1989

'fairer' transplant rules set

HHS policies would reduce inequities in organ cases

By Robert Davis
USA TODAY

Years of debate over how organs are allocated for transplants ended Monday with government rules that will require strict accountability from doctors and establish more uniform criteria for deciding which patients get organs.

The Department of Health and Human Services, which has been concerned about unfairness in patient selection and large regional variations in availability of organs, is requiring a new set of "core policies" that will change the medical community's handling of transplant cases.

The policies are intended to lessen the importance of waiting lists, force hospitals to share more information about more patients and minimize inequities that can lead to heart-breaking medical choices.

Government officials have been concerned that doctors sometimes pick their own relatively healthy patients over very sick patients in a hospital across town or in another state.

The rules are intended to ensure more protection for sicker patients and establish a series of criteria that treat all patients by one set of rules, including survivability.

"We think that this is going to improve (patient) survival overall," said Claude Earl Fox, administrator of the Health Resources and Services Administration.

"We think it is going to be a fairer system."

The transplant community, which has expressed concern about loss of medical independence, reacted cautiously.

"We absolutely believe (Secretary of Human Services Donna Shalala) should exercise oversight, but we do not believe the secretary should be making medical decisions," said a statement from Ronald Busuttil, president of the American Society of Transplant Surgeons.

The private group that runs the transplant system, the United Network for Organ Sharing (UNOS), said it was still reviewing the rules, which take effect in about 30 days.

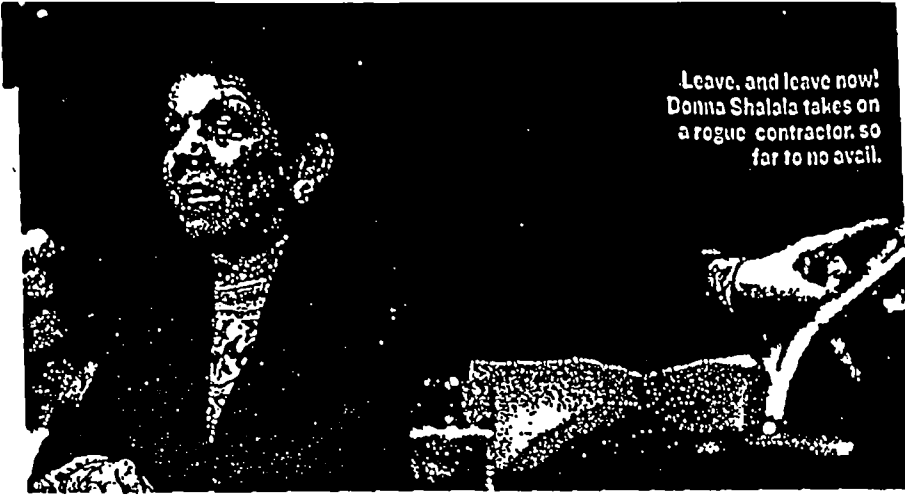
The rules call for UNOS to establish policies that would:

- ▶ Establish the same basic criteria to decide which patients get transplants and when.

- ▶ Expand organ-sharing regions to ensure that organs reach patients who need them most. A recent report found that the wait for organs was 46 days in New York City, 21 days in western Pennsylvania.

- ▶ Reduce information barriers to the public to allow physicians and patients to identify the most

Forbes magazine
October 19, 1999



Leave, and leave now!
Donna Shalala takes on
a rogue contractor so
far to no avail.

The Organ King

An outfit with life-and-death power over patients waiting for transplants has evolved into a heavy-handed private fiefdom.

BY BRIGID MCMENAMIN

EVER SINCE FORBES EXPOSED THE federal monopoly that's chilling the supply of transplantable organs and letting Americans who need them die needlessly (FORBES, Mar. 11, 1996), Health & Human Services Secretary Donna Shalala has been trying to challenge the way United Network for Organ Sharing operates.

But the Richmond, Va.-based cartel will have none of it. Using a heavy-handed mix of litigation, lobbying and bullying of its opponents, UNOS has solidified its position as the federal contractor in charge of deciding which people get new kidneys, livers or hearts.

Under the UNOS system, most organs are shared only within 62 regional territories. A potential recipient in, say, New York, where donations are low, can expect to wait months for an organ to show up, even though there may be so many donors across the river in New Jersey that New Jersey patients are getting transplants after short waits or when they are far from desperate.

Though UNOS has begun to relax the locals-first policy, still, last year 4,855 Americans died while waiting for transplants. (This doesn't even count

people pulled off the list after they became too sick to handle a transplant.) It is a matter of debate how much lower the number of deaths would be if the system for obtaining and allocating organs were more rational. But Consad, a research outfit in Pittsburgh, estimates that at least 1,000 people die needlessly each year.

When Shalala urged that organs be shared over wider regions, UNOS Executive Director Walter K. Graham refused. He decreed, in a memo to his member hospitals and organ banks, that UNOS doesn't have to take direction from the federal government on this point.

UNOS' main source of funding is the \$375 registration fee potential organ recipients must pay to get on the waiting list. That amounts to some \$13 million a year, money that is supposed to be spent mostly to match organs with suitable recipients. In reality, at best half of the money goes to that.

What about the rest? Graham and his 40 board members spend some \$1 million each year on jetting around and on meetings and confer-

ences. A new \$7 million headquarters building is planned. In 1997, some \$1.6 million went for items network officials refuse to explain. "They really never tell you what they're spending money on," says veteran board member John Fung, a liver surgeon at the University of Pittsburgh.

When Shalala tried to exert more control over the rising registration fees, Graham challenged her in a proceeding before the U.S. General Accounting Office, claiming she had no right even to know how he spent the fees. The suit was settled; Shalala backed down.

Why not simply bring in another contractor to ration organs? Good luck. The congressional committee in charge of such matters is headed by Representative Thomas Bliley, from UNOS' home city of Richmond. His cousin Paul S. Bliley is a law partner of UNOS lawyer Malcolm E. (Dick) Ritsch. Last fall, then-Louisiana Congressman Robert Livingston, whose home state includes eight profitable transplant centers, pushed through a bill halting further attempts by Shalala to control the contractor.

After the Senate rejected this moratorium, Livingston got it tacked onto another bill behind closed doors by threatening to hold up funding for the International Monetary Fund. The moratorium ends Oct. 21. But UNOS has already had Wisconsin Congress-



UNOS' hometown congressman, Thomas Bliley, heads up the committee that oversees transplant matters.

UNION AGENT (TOP); ASSOCIATED PRESS / TILER HALLORY (BOTTOM)

UNOS

man David Obey tack another one-year extension onto a bill that was set to go to the full House for a vote in October. His state's four transplant centers stand to lose organs if UNOS loses its grip.

Craig Howe, executive director of the National Marrow Donor Program, recently expressed interest in having his organization bid on the organ contract. After UNOS found out he was interested, his board members, who include 14 physicians, axed him. Although some powerful and prominent surgeons like Fung are an exception, most doctors involved in the business fear offending UNOS lest their organ supply be affected.

In another instance FORBES is aware of, UNOS threatened to retaliate against an outfit it perceived as a rival bidder for the organ allocation job.

Tax-exempt groups like UNOS are supposed to make their financial state-

ments available for public perusal. But UNOS hides significant activity behind two little-known affiliates that aren't required to disclose anything.

The first is the UNOS Foundation, a six-year-old shadow organization run by UNOS staffers. Spokesman Robert

UNOS milks desperate patients to subsidize a stealth for-profit firm.

Spieldenner claims the foundation doesn't have to file tax returns because it brings in less than \$25,000 a year. The UNOS Foundation owns something called the Transplant Informatics Institute, a for-profit company run by organ network staffers. Transplant Informatics is so secret that even some UNOS board members are unaware that it exists.

What does the institute do? The government thinks it markets UNOS-developed software to organ network members. In an audit looking into the use of registration fees for lobbying, the Office of the Inspector General got just that impression. What the institute really does is analyze and sell organ network data to profit-making companies like Fujisawa, the Japanese firm that sells drugs for transplant patients. When the institute has not been able to cover its costs with such sales, UNOS has used

its registration fee income to make up the difference. Prospective organ recipients are therefore effectively funding this hidden business.

You'd think someone on UNOS' board would scream bloody murder about all this. After all, the 40-person board is almost half doctors, dedicated to saving lives. But the directors have little idea what's going on. "The board

is kind of in the dark," sighs patient advocate Charles Fiske, a former board member.

"We received an annual financial report and pretty much accepted it as written," says University of Oklahoma transplant doctor Larry R. Pennington, a board member from 1996 to 1998. They really don't know how to interpret the data. "All I'm familiar with is hospital sort of activity," admits transplant physician William Harmon.

Realizing that UNOS is out of control, Shalala has put out feelers for a replacement. "I hope we have some bidders this time," sighs Claude Fox, a pediatrician who, as administrator of the Health Resources & Services Administration, oversees transplants for Shalala. The only prospect so far is Santa Monica-based Rand.

Determined to see that Rand does not walk off with the contract, UNOS' lobbyists are pushing for a law that

would insure that Graham's group will keep the contract forever. Last month Bliley's committee held hearings on a bill which would require the organ rationing contractor to have experience, something no group but UNOS has. It would also allow UNOS' members to vote on the choice.

"Anything that gives them more of a stranglehold isn't in the public interest," says Fox. "It's like giving the EPA to some land-fill company," says Dr. Fung.

It would be nice if UNOS didn't have a lock on this business. Better still if the federal government stepped out of the process altogether and let doctors come up with creative ways to increase the supply of organs. (How about giving

people who sign up as potential donors when they are young some priority in getting organs when they are older?) Once there are enough hearts and livers to go around, there won't be unaccountable arbiters holding sway over our lives.



Disillusioned patient advocate Charles Fiske.

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FOLDER TITLE:

Organ Allocation [Folder 1]

2012-0463-S

rc801

RESTRICTION CODES

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

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
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- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
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- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

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

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- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Census/Donor -
Fig 1.

Arkansas Delegation Assertions and Responses:

Organ donations should stay in Arkansas to benefit, especially, those who live in rural or impoverished areas.

Forty four percent of Arkansans leave the state for their transplants, in part because there is no liver or lung transplant program in Arkansas, in part because the kidney, kidney/pancreas, and heart transplant programs are small. Of the residents who do receive transplantation services within the state, many of them benefit from donation in other parts of the country (in 1997 alone 30 kidneys and hearts were "imported" from other areas to meet the needs of patients in Arkansas).

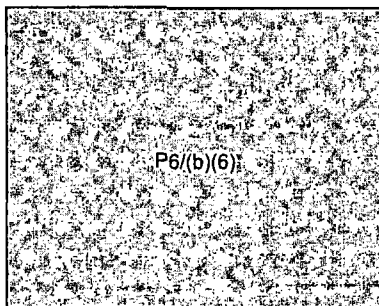
The IOM found that the current system was "reasonably effective and equitable," and that waiting times are not a useful measure for evaluating access or equality.

The IOM looked only at liver allocation and noted that, as Dr. Gibbons reported at the recent hearing, with the broader sharing recently put in place, liver sharing was equitable, but not optimal. Additionally, until implemented as an approved policy of the OPTN, no system, however good, is enforceable.

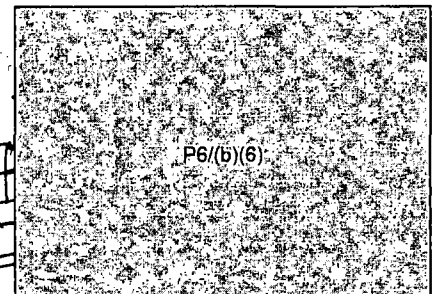
As to waiting times, we agree with the IOM that they are not the best measure, but, if the transplant community continues to use them to allocate organs, they should be a measure which patients can use to select among programs. For the Arkansas transplant programs, the median wait times are short (about one half the national average).

The revised final rule grants the Secretary too much authority.

The IOM recommended greater Secretarial oversight, tempered by reliance on the expertise reflected in an Advisory Committee. We took that recommendation seriously, included the role of the Scientific Advisory Committee in the rule, and have already begun the process to establish that committee.



Brada can
dermatology



[001]

Congress of the United States

Washington, DC 20510



402444

October 21, 1999

President William J. Clinton
1600 Pennsylvania Avenue
Washington, D.C. 20500

Dear Mr. President,

The Arkansas delegation is writing in support of the provision in the House FY 2000 Labor, Health and Human Services, and Education appropriations bill which calls for a continuation of a moratorium of the April 2, 1998, Final Rule issued by the Department of Health and Human Services (HHS) regarding organ procurement and transplantation.

We believe that regions of the country which work hard to generate higher organ donations should be entitled to keep those organs in that region. The number of persons who need organ transplants far exceeds the number of available organs in every region. The moratorium in place on the April 2nd Final Rule expires on October 21, 1999. We believe that Congress and the transplant community deserve time to review any changes or new regulation that HHS publishes regarding organ procurement and transplantation. Unless this moratorium is included in the Labor, Health and Human Services, and Education conference report, we believe Arkansans in need of organ donations will be treated unfairly. We are afraid that those who live in rural or impoverished areas of Arkansas, like the Delta, will not be able to afford to travel outside of Arkansas to obtain the organs they need.

Since the moratorium was put in place last October, the Institute of Medicine (IOM) has released a study regarding specific aspects of organ procurement and transplantation. The IOM report introduced new, important information into the debate. For example, it was determined that the current system of organ transplantation is "reasonably effective and equitable" for the most medically urgent patients, thus dispelling the notion that our current system is harming patients and requires urgent adjustment. In addition, the IOM concluded that the measure of median waiting time, one of the fundamental underpinnings of the HHS final rule, is not a useful measure for evaluating access to or equality of the allocation system.

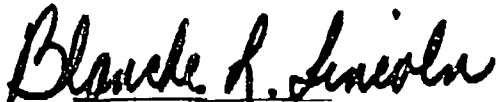
We are also concerned that the revised Final Rule recently issued by HHS grants the Secretary authority beyond that mandated by current law.

We urge you to continue the moratorium on the Final Rule until the National Organ Transplant Act has been reauthorized. Thank you for your consideration of this matter.

Sincerely,

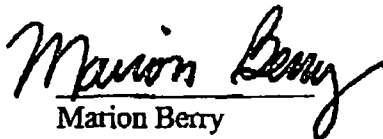
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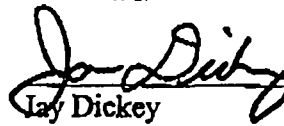

Blanche Lincoln

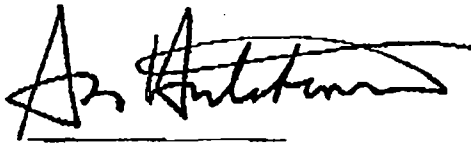

Tim Hutchinson

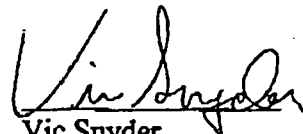
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Marion Berry

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Jay Dickey


Asa Hutchinson


Vic Snyder

BLL/em

ORGAN POLICY NEWS COVERAGE

EDITORIALS

1) "An End To Organ Games?"

The Washington Post, October 23, 1999

"Opponents of the reforms could still hobble and delay the regulation further as part of the budget appropriation for HHS. Such an action would be an extension of a cynical battle that costs patients' lives as it drags on."

2) "Toward Fairer Organ Transplants"

Chicago Tribune, October 28, 1999

"Unless Congress slaps a moratorium on the amended rules, which would be a shame, UNOS will be instructed to make medical need (not just length-of-time on a waiting list) the prime criterion for who gets the next available organ."

3) "Ensuring A Healthy System"

The Plain Dealer, October 25, 1999

"The Clinton administration continues to push for a more rational system of allocating donated organs. That's good for sick people. But the push leaves a lot of room for input from hospitals and doctors involved in transplant surgery. That's good for all concerned."

4) "Organ Delay: Parochialism Again Slows A Sickest-First Policy"

Pittsburgh Post-Gazette, November 2, 1999

"Policymakers, hospital administrators, doctors and patients have been talking for years about how to improve the wretchedly inadequate system by which scarce organs are distributed in this country. Now that the Clinton administration has come up with a reasonable alternative, the last thing that is needed is additional delay."

5) "The Organ Game"

Toledo Blade, November 1, 1999

"And there is other mischief afoot in a bill to be taken up next year to remove from the HHS secretary any authority to regulate transplant policy. This is utter nonsense. UNOS and the hospitals should not be given free rein without any oversight, and the HHS secretary has the resources best suited to the task."

6) "HHS' Regulation Should Be Implemented"

Transplant News, August 26, 1999

"UNOS' ill-advised attempt to spin the findings of the IOM into an endorsement of how well the current organ allocation is working is predictable and blatantly transparent. The Department of Health and Human Services (HHS) is not going to withdraw the regulation and it should not. The overhaul the allocation of organs in the US is needed and should be implemented as scheduled this fall."

REGIONAL NEWS STORIES

1) "Transplant Rules Face Delay"

Toledo Blade, October 27, 1999

"The highly controversial 'local-first' organ transplant system, run for a dozen years by the United Network for Organ Sharing headquartered in Richmond, Va., divides the nation into geographic regions for organ distribution. Critics say the sickest patients don't always get available organs first and that doctors are able to shove healthier patients to the top of the list."

2) "Donor Organ Plan Is Again In The Hot Seat"

The Times-Picayune, October 21, 1999

"Health Secretary Donna Shalala issued revised rules this week as a means of compromise. They said, for example, that organ allocation should be based on 'sound medical judgement' and policies should be designed to ensure that organs aren't wasted in futile transplant attempts. The rules didn't mandate a single national list but said that organs should be disbursed 'over as broad a geographic areas as feasible.'"

3) "Odds Against Apple in Transplant Race"

New York Post, October 20, 1999

"More patients die waiting for heart transplants in New York than in many other parts of the country, a new federal study finds...A new federal rule - guidelines of which were released Monday - would distribute organs over a wider geographic area and may help the city..."

4) "New Transplant Policy May Cut Bay Area Waits"

San Jose Mercury News, October 20, 1999

"Bay Area residents -- who now have one of the longest waits in the nation for healthy organs -- may benefit the most from a Clinton administration overhaul of the nation's transplant policy announced this week."

5) "Organs Will Go To Sickest First "

Richmond Times, October 19, 1999

"Federal officials sought to revise the system because the wait for a transplant varies widely for equally sick people in different parts of the country. In June, a Times-Dispatch investigation of the system found that many healthy patients receive transplants while many patients nearby die."

6) "New Organ Transplant Rules To Alter Allocation Methods"

Chicago Tribune, October 19, 1999

"...[W]hat has evolved is a chaotic system of organ distribution based mainly on local control in which geographic boundaries are deemed more important than medical need. Under this system, organs are distributed in local areas first, even if there are sicker patients elsewhere."

EDITORIALS

ORGAN POLICY NEWS COVERAGE

EDITORIALS

- 1) **"An End to Organ Games?"**
The Washington Post, October 23, 1999
- 2) **"Toward Fairer Organ Transplants"**
Chicago Tribune, October 28, 1999
- 3) **"Ensuring A Healthy System"**
The Plain Dealer, October 25, 1999
- 4) **"Organ Delay: Parochialism Again Slows A Sickest-First Policy"**
Pittsburgh Post-Gazette, November 2, 1999
- 5) **"The Organ Game"**
Toledo Blade, November 1, 1999
- 6) **"HHS' Regulation Should Be Implemented"**
Transplant News, August 26, 1999

A22 SATURDAY, OCTOBER 23, 1999

The Washington Post

AN INDEPENDENT NEWSPAPER

An End to Organ Games?

THE FIGHT between the federal government and local organ transplant centers over how better to allocate scarce organs has been a strikingly unsavory application of territorial politics to an area where politics should play no role. This week the Department of Health and Human Services (HHS) published a final regulation—to go into effect in 30 days—intended to make organ distribution more equitable. The idea is to even out disparities among the many geographic areas served by the nation's 272 transplant centers, most of which grew up in an era when "harvested" organs needed, for technical reasons, to be used close to home. The varying populations of these regions mean uneven distribution, which, given the shortage of organs, spells death for some 4,000 patients a year for whom an organ cannot be found in time.

Enter HHS, which last year issued a draft regulation calling for the network's contractor, United Network for Organ Sharing, to come up with more equitable criteria based on medical, rather than geographical, status. The organ transplant network, though, fiercely opposed the regulation and persuaded Congress to delay its implementation a year. The network fears the changes would force local transplant centers to close, which in turn would dissuade families from donating loved ones' organs; it also warned of organ wastage

because of failed procedures if the sickest patients were invariably transplanted first.

Behind these concerns—for which a congressionally mandated report from the National Academy of Sciences' Institute of Medicine found no evidence—is the fear that local centers would close, eliminating the substantial income source they represent for the hospitals that house them. That may explain the otherwise remarkable fact that 10 states responded to the proposed rule by passing laws making it more difficult to send organs out of state. The Institute of Medicine report even cites cases where grieving families willing to donate were urged to sign contracts requiring that organs go only to in-state recipients.

In fact, the report's researchers found no evidence that families care whether organs are used nearby; on the contrary, surveys showed they cared most whether the organs would be fairly used. The report recommends that geographical regions be made larger but that any new system make use of existing transplant networks rather than closing them down, a goal HHS Secretary Donna Shalala says could be achieved under the rule. Opponents of the reforms could still hobble and delay the regulation further as part of the budget appropriation for HHS. Such an action would be an extension of a cynical battle that costs patients' lives as it drags on.

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October 28, 1999 Thursday, CHICAGO SPORTS FINAL EDITION

SECTION: EDITORIAL; Pg. 24; **ZONE: N**

LENGTH: 418 words

HEADLINE: TOWARD FAIRER ORGAN TRANSPLANTS

BODY:

The Clinton administration is backing away from its veiled threat to nationalize the distribution of transplantable human organs and is instead telling the private organization that runs the program to make the system more fair.

That's progress.

It never made sense to shuttle freshly donated organs from one end of the country to the other in search of the sickest recipient. Cross-country transplants would have degraded organ viability and weakened incentives for states like Illinois to maintain aggressive organ donation programs.

But it will be up to the United Network for Organ Sharing (**UNOS**) to put its house in order and fix the inequities identified not just by the U.S. Department of Health and Human Services but by the academically prestigious Institute of Medicine.

The way it works now, your chances of getting, say, a new liver depend a lot more on where you live than the gravity of your condition or your ability to tolerate a transplant. Chances are, if your local organ bank and medical center take a "charity begins at home" attitude, you won't wait long. If not, you could be among the 4,000 Americans who die each year waiting for an organ that never arrives.

Unless Congress slaps a moratorium on the amended rules, which would be a shame, **UNOS** will be instructed to make medical need (not just length-of-time on a waiting list) the prime criterion for who gets the next available organ. But **UNOS** can continue using its regional system of cross-state organ sharing, so long as there's fairness within regions.

That being the case, **UNOS** had better find a fairer way to settle a nasty dispute here in the Upper Midwest between Illinois and its neighbors to the north, Wisconsin and Minnesota. Those states are trying to limit their export of organs to the Chicago area's advanced medical centers (even though their residents are well-represented on waiting lists here.) To that end, **UNOS** wants Illinois to "pay back" organs imported from those states. This hardly reflects the sickest-first spirit of the new federal rules.

Still missing, moreover, is an adequate national strategy to increase the overall number of donated organs. With all the federal money coursing through hospitals via Medicare, Medicaid and research grants, Washington should put more heat on hospitals to aggressively solicit donors and their families for gifts of life.

In the end, our organ shortage will be overcome not by tinkering with distribution formulas but by increasing the supply.

LANGUAGE: ENGLISH

LOAD-DATE: October 28, 1999

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The Plain Dealer

October 25, 1999 Monday, FINAL / ALL

SECTION: EDITORIALS & FORUM; Pg. 8B

LENGTH: 483 words

**HEADLINE: ENSURING A HEALTHY SYSTEM;
BY KEEPING THE DETAILS OPEN TO DOCTORS' SUGGESTIONS, FEDS MAY PRODUCE A
BETTER ORGAN DONATION NETWORK**

BODY:

The Clinton administration continues to push for a more rational system of allocating donated organs. That's good for sick people.

But the push leaves a lot of room for input from hospitals and doctors involved in transplant surgery. That's good for all concerned.

Whether the United Network for Organ Sharing, the hospital organization that set up the current system of allocating transplants, can recognize the common good remains to be seen. Thus far, UNOS has been much too intent on defending its methods to acknowledge that patients might be better served by a few changes.

Donna Shalala, secretary of Health and Human Services, has expressed a willingness to lay down the law if UNOS balks at doing its work the way its employer, the federal government, wants it done. But Shalala cleverly has stopped well short of dictating precisely what UNOS must do.

Instead, her department has set forth broad administrative requirements and left the details for the medical professionals at UNOS to decide.

As a result, comments like those of UNOS board member Ronald Ferguson of Ohio State University, couldn't possibly ring more hollow. "I support keeping medical decisions about transplant in the hands of the doctors that are caring for the patients. I oppose the intrusion of the government into the process," Ferguson says in a letter he has been asking his patients to mimic, sign and send to Congress (an actively intrusive arm of the government, last time we checked).

Good for you, Dr. Ferguson. Your argument in favor of keeping doctors in charge of curing patients is right in line with what Secretary Shalala wants, loath though you may be to admit it.

She is asking only that the criteria hospitals use to determine a patient's place on a transplant waiting list be standardized around the country, and that any donated organ be made available to the patient in most urgent need in a region larger than a single state. Further, HHS wants UNOS to establish performance measures so transplant centers' work can be evaluated.

Those broad requirements are fair, sensible and in line with advances in organ transplantation, preservation and transportation. The details of how to meet those requirements are the medical professionals' to decide, which is as it should be.

Unfortunately, the medical professionals at UNOS became used to lax HHS oversight over the years, and rare indeed is the hospital or doctor eager for performance evaluations. So it is no surprise that this government contractor has enlisted allies in Congress to help it become a law unto itself. That should not be allowed to happen.

The small burdens the Clinton administration is asking UNOS to take on hold great promise for improving the treatment of patients. But if the medical professionals best suited to do the job fail to do it, the government will have to step in and do its imperfect best.

LANGUAGE: ENGLISH

COLUMN: EDITORIALS

LOAD-DATE: October 26, 1999

Pittsburgh Post-Gazette

November 2, 1999

A12

Organ delay

Parochialism again slows a sickest-first policy

Policymakers, hospital administrators, doctors and patients have been talking for years about how to improve the wretchedly inadequate system by which scarce organs are distributed in this country. Now that the Clinton administration has come up with a reasonable alternative, the last thing that is needed is additional delay.

But thanks to some powerful interests who do well by the status quo, that is exactly what is going to happen. And Pennsylvania Sen. Arlen Specter, who is an advocate of the change and a subcommittee chairman on the all-important Appropriations Committee, has failed to parry the thrust of the opponents.

Most disheartening was the way Sen. Specter defended his impotence. "It's been very important not to handle this strictly as a parochial matter," Specter said. "There are important national interests."

This is unnecessarily defensive. While it is true that Pittsburgh in particular and the region in general would benefit from the rule change, it is in the interest of all Americans to create a system based on fairness that uses the precious resources of donated organs in the most efficient manner possible. Panel after expert panel and study after study validates the logic behind a sickest-first distribution system, rather than the current system that gives preference based on where the organ is donated.

The real parochialism comes from those defending a status quo that keeps small transplant centers propped up at the expense of the sickest patients. Sen. John Breaux of Louisiana makes no attempt to hide his parochial interest, saying that his state's eight organ trans-

plant centers would be better off with a delay of the new regulations.

"The new rule would allow organs harvested in Louisiana to be transferred to transplant facilities anywhere in the country, instead of those most in need in Louisiana."

Small centers do relatively few procedures and they do even fewer on the sickest patients. If organs start going to patients in the most dire need, regardless of where they are in the country, the continued existence of some of the smaller centers would be at risk.

Since such transplant centers are scattered around the nation, they form a sizable interest group and are able to garner the protection of some of the nation's most powerful legislators. So last year, after a series of long and comprehensive hearings held by the Department of Health and Human Services, the Senate blocked implementation of the proposed new rules for 12 months, calling for more study.

The Institute of Medicine experts found that the current system is not a disaster, but that a sickest-first policy would be a better and fairer way to go. Again HHS proposed the new rules, and the Senate again stands ready to delay — this time for three months.

Sen. Specter says he does not believe the delay is intended to buy time in an effort to kill the new rules altogether. But we have a hard time imagining what other motivation could be behind the move.

There is no need for more study, discussion, analysis or research. The evidence provides a powerful and compelling case to change the system. Now all that's needed are some elected representatives capable of getting it done.

A shower in the morning

L 22 H 41

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November 3, 1999

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AD INDEX

THE BLADE

TOLEDO, OH

toledoblade.com
Opinion

Editorial: The organ game

November 1, 1999

Congress, for the most part ill-equipped to practice medicine, is holding up the negotiated rules governing who can get transplanted organs.

United Network for Organ Sharing, based in Virginia, had set up a "local-first" transplant system; organs donated locally were transplanted, to the extent possible, in local patients.

With the burgeoning of transplant centers, this system failed to produce the necessary organs that major transplant centers - which often get the sickest patients - needed. So large centers sought new federal rules that would remove geographic boundaries for available organs, which then could go to the sickest patients.

Negotiations between UNOS and the Department of Health and Human Services, produced a compromise. Under a UNOS policy to have taken effect this month, livers first would go to "status 1" local patients, those suddenly and acutely stricken with liver disease who have less than seven days to live.

When there are no "status 1" patients locally, the liver would go to the sickest people in that UNOS region - there are nine throughout the country - not to a less ill local person, nor, apparently, to an acutely ill person in another region.

The new policy uses one set of medical criteria to decide how organs are allocated. It would benefit the sickest people in a region, and it would address worries of local residents and their politicians that the locals don't lose out on locally donated organs.

Now some congressmen are in a dither, as if they'd heard of the changes for the first time. They want to delay implementation of the new regulations at least until February. And some of the various transplant centers are cool to providing comparable information about the number of their patients and their outcomes.

And there is other mischief afoot in a bill to be taken up next year to



remove from the HHS secretary any authority to regulate transplant policy. This is utter nonsense. UNOS and the hospitals should not be given free rein without any oversight, and the HHS secretary has the resources best suited to the task.

A National Academy of Sciences study of 68,000 people on waiting lists for livers from 1995 to 1999 found the current system working fine for acutely ill liver patients, but in less populous areas the agencies that procure organs may keep what comes their way for less sick people rather than passing them on. It also found no evidence that the proposed regulations will make it harder for minorities, people of low income, or those who reside in remote areas to get a liver if they need one.

We have no confidence that this Congress, which can't fix Medicare, can't fix Social Security, can't reform campaign spending, and can't be nonpartisan, fair, and dispassionate about anything, is equipped to make more than a muddle of organ transplant regulation.

Why is its nose under the tent?

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Transplant News

Vol 9, No. 16
August 26, 1999

Commentary

UNOS' spin on IOM report as support for status quo misguided; HHS' regulation should be implemented

By Jim Warren

Editor & Publisher

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The problem for UNOS and its supporters is simple—the recommendations of the IOM committee for improving organ allocation in the US were spawned by data from 68,000 liver transplants performed over the past 5 years.

Transplant News Commentary

If it's true that it "ain't over until the fat lady sings," then the sound of music produced by the Institute of Medicine (IOM) report on organ allocation in the US should be deafening to the United Network for Organ Sharing (UNOS).

UNOS' ill-advised attempt to spin the findings of the IOM into an endorsement of how well the current organ allocation is working is predictable and blatantly transparent. The Department of Health and Human Services (HHS) is not going to withdraw the regulation and it should not. The overhaul the allocation of organs in the US is needed and should be implemented as scheduled this fall.

The problem for UNOS and its supporters is simple—the recommendations of the IOM committee for improving organ allocation in the US were spawned by data from 68,000 liver transplants performed over the past 5 years. The committee, which was not beholden to the government in any way, arrived at an independent conclusion that a) the system is working relatively well; b) the system will work better if changes are made; c) the federal government must provide increased oversight of the system to see that the changes are made and organ allocation becomes more equitable.

To say that the IOM report amounts to a ringing endorsement of the status quo is disingenuous at best and badly misguided. Even many who disagree with some of the recommendations are saying it is time to call a halt to the destructive public squabbling—primarily on the part of UNOS—and get on with the business of saving lives and increasing donation.

Through its actions over the past year, UNOS has clearly indicated to the government that they are willing and able to make the allocation of organs, particularly livers, more equitable. In a letter to Congress outlining UNOS' position on the IOM report, UNOS President William Payne, MD, proudly pointed out that the board recently approved a more regionalized system of sharing livers. The IOM "recommended a geographically based structure for organ distribution, which is remarkably similar to the regional system by which UNOS currently allocates livers to the most urgent patients," Payne wrote. He added, with no apparent sense of embarrassment, "it is encouraging that UNOS and IOM independently arrived at similar conclusions," a sentence that smacks of being written by a PR agency.

But the change to broader regional sharing has occurred in spite of, not because, of UNOS. Following my coverage of UNOS' most recent policy revision to share livers on a regional basis, I received the following comment from the director of a large OPO: "I think it [the article]

Transplant News -- A twice-monthly newsletter providing up-to-the-minute information on developments in organ, tissue, eye, and bone marrow procurement and transplantation. Editor & Publisher: Jim Warren

did a good job of explaining the new rules, but should have included a comment that half of the UNOS Regions are already sharing livers in this manner. It made it seem too much like a completely new rule enacted by pressure from HHS. It would have been a good opportunity to reflect on the adjustment of some regions and transplant centers to proactively address the need for wider sharing when urgent patients need organs quickly."

The organ sharing alliance being formed by Wisconsin, South Dakota, North Dakota, Minnesota (forget the dispute with Illinois for now) is just the beginning of transplant centers deciding not to wait for reorganization of the UNOS regions to form broader sharing agreements. Look for more such developments in the near future, hopefully with much less public name calling and gamesmanship. The sharing arrangements

are light years ahead of the ill-sinine state laws mandating organs to go to state residents first. The specter of transplant centers fighting for organs has to be having a negative impact on an already skittish public being asked to donate the organs of a loved one.

So what happens now? The HHS regulation will likely go into effect on October 21. There seems to be little passion on Capitol Hill to further extend the moratorium it placed on the measure last year. Also keep in mind that the Republicans pushed through a measure prohibiting riders to be tacked on to this year's appropriations bills. And given the simple fact that they have not done so in 9 years, there is no reason to believe Congress will pass legislation reauthorizing the National Organ Transplant Act (NOTA) with language which would delay the implementation of the HHS regulation.

Which brings us to the courts. Louisiana and Wisconsin have strongly suggested they would reinstitute a legal battle if IOM produced recommendations that left the HHS regulation intact. Is a lawsuit inevitable? I certainly hope not.

This very divisive public struggle has got to stop before it does even more damage to the public's confidence in the national transplant system. Don't let last year's 5.6% increase in donors fool you. The great majority of that was due to the use of expanded, i.e. older, sicker donors. At least 40% of the people who tell pollsters they would likely donate the organ of a loved one, still say no when asked. Distrust of the system has got to be a major reason.

The impasse has also done a great disservice to the nation's organ procurement organizations. They are dealing with transplant centers that don't want their access to organs diminished through any change in allocation policy; they are dealing with a public that is clearly revolted at the sight of transplant centers fighting publicly over organs; and, they are dealing with the Health Care Financing Administration (HCFA) that is constantly looking over their shoulders to see how many organs they are procuring annually as a performance standard of how well they are doing. They will continue to be in a no win situation until the issues are resolved.

Under normal circumstances, IOM studies are requested by a government agency like HHS. However, Congress and the General Accounting Office (GAO) specifically requested the study because of the distrust between HHS and UNOS. As the saying goes, be careful what you wish for because you just might get it.

(Continued on next page)

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Nevada (no extra-renal transplant centers) passes "resident's first" law

Nevada has become the 6th state in the US to pass legislation requiring that an organ procured from a resident of the state must first be offered to any residents in the state on a local waiting list. However, there is one slight oversight, Nevada does not have any extra-renal transplant centers.

HHS regulation should be implemented

(Continued from page 2)

What's next? UNOS has moved steadily towards rapprochement with the HHS on the allocation issue and all indications are that an agreement can be reached. However, UNOS officials have signaled they intend to continue to fight over how much authority the Secretary has in oversight of the OPTN and in setting policy.

Perhaps that's as it should be. People who know that the allocation issue is extremely damaging to transplantation and must be put to rest say that they remain skeptical of HHS because they "just don't trust the government." However, HHS has repeatedly said the opposition to the regulation is based on several myths i.e. that it wants a national sharing list, or that it intends to set medical policy. My response to the "I don't trust" cry is: call HHS' hand. If the agency reneges on what it says it won't do, the transplant community will then have a case to take to Congress and action can and should be taken.

Armed with the IOM study and recommendations, both sides should declare victory and move on. UNOS has had an arduous two years of policy making and has matured as an organization as it addressed these very difficult issues. It has succeeded in getting HHS to clarify its intentions, has received the IOM's commendation for developing an allocation system that works pretty well, and should have made its case to remain the OPTN contractor for the foreseeable future. HHS now has hard data to back up its call for more equitable sharing of organs based on medical urgency, not geography. The stage should be set for a final set of negotiations with UNOS to clarify any remaining issues before the regulation is implemented in October.

Once HHS and UNOS truly form a productive public-private partnership assuring Americans the transplant system is equitable and accessible as possible, donation may begin to increase in numbers meaningful enough to have a major impact on the nation's donor waiting list. The evidence clearly shows they won't in the current climate of confrontation and distrust.

"I don't want to alienate the legislator who introduced the legislation and has an interest in transplantation, but with no extra-renal programs this won't accomplish what was intended," Ken Richardson, executive director of the Nevada Donor Network told *Transplant News*. "We weren't consulted until after the fact. If they had, we would have told them not to do it."

"As a practical matter I don't see how we can comply with the law," Richardson added. "When the list of potential recipients is run by UNOS (United Network for Organ Sharing) it doesn't tell us the residency status of the recipient, just the transplant center where the person is listed."

Because of the size of the population—2 million—Patients in Nevada needing an extra-renal transplant like a liver or heart, are usually transplanted either in Reno, which is served by the California Transplant Donor Network (CTDN) in San Francisco or UCLA Medical Center, which is served by the Regional Organ Procurement Agency of California. Some Nevada patients needing extra renal transplants go elsewhere as dictated by their health insurance.

The surprise provision in Assembly Bill 238 contained the following language: "Except as otherwise required by the specific terms of an anatomical gift, an anatomical gift from a resident of this state must be offered to any residents in this state in need of transplantation or therapy and listed on a transplant list generally recognized in the medical field before the anatomical gift may be used for another person."

Richardson said he doesn't want the bill to create a backlash of ill will from California residents where most Nevadans are transplanted. "We have 2 million people, while California has 33 million people. What if they decided to do the same thing," he noted.

Midwestern states fight over organ sharing pact

An organ sharing agreement hastily put together by Wisconsin, South Dakota, North Dakota and Minnesota has erupted into a nasty dispute with the neighboring state of Illinois. The agreement has not been approved by the United Network for Organ Sharing (UNOS). The 5th state in the region under UNOS' policy, Illinois is complaining loudly and publicly for not being included in the sharing agreement.

A squabble has been brewing for months between Wisconsin and Illinois over the sharing of organs. Charges and countercharges are airing daily in the local press.

Because of the evolving nature of the story, *Transplant News* will provide in-depth coverage in its next issue.

REGIONAL NEWS STORIES

ORGAN POLICY NEWS COVERAGE

REGIONAL NEWS STORIES

- 1) **"Transplant Rules Face Delay"**
Toledo Blade, October 27, 1999
- 2) **"Donor Organ Plan Is Again In The Hot Seat"**
The Times-Picayune, October 21, 1999
- 3) **"Odds Against Apple in Transplant Race"**
New York Post, October 20, 1999
- 4) **"New Transplant Policy May Cut Bay Area Waits"**
San Jose Mercury News, October 20, 1999
- 5) **"Organs Will Go To Sickest First "**
Richmond Times, October 19, 1999
- 6) **"New Organ Transplant Rules to Alter Allocation Methods"**
Chicago Tribune, October 19, 1999

Transplant rules face delay

October 27, 1999

Toledo Blade

BY ANN McFEATTERS
BLADE NATIONAL BUREAU

WASHINGTON - The furor over changing the nation's organ transplant system ratcheted up another notch yesterday, with House and Senate negotiators tentatively agreeing on another delay in new regulations.

When the federal government issued final regulations Oct. 18, claiming that the new rules would make organ transplants more fair, some members of Congress vowed to delay them. Sen. John Breaux (D., La.) said his state's eight organ transplant centers would be better off with a delay.

"The new rule would allow organs harvested in Louisiana to be transferred to transplant facilities anywhere in the country instead of those most in need in Louisiana," Mr. Breaux said.

Sen. Arlen Specter (R., Pa.), a key appropriator who prefers no moratorium, said negotiators on the Labor and Health and Human Services appropriations bill gave near-final approval to a compromise of three months. That would mean the regulations, now slated to take effect Nov. 20, would be delayed until mid-February, he said. That is down from a four-month moratorium under discussion last week.

"It's been very important not to handle this strictly as a parochial matter," Mr. Specter said. "There are very important national interests. When you deal with the kind of people I'm dealing with, you have to satisfy Alaska, you have to satisfy a lot of states."

The highly controversial "local-first" organ transplant system, run for a dozen years by the United Network for Organ Sharing headquartered in Richmond, Va., divides the nation into geographic regions for organ distribution. Critics say the sickest patients don't always get available organs first and that doctors are able to shove healthier patients to the top of the list.

HHS regulations would change the system so that one set of medical criteria would be used although decisions on how organs would be allocated would be left to the contractor that operates the organ network.

The new regulations require the organ agency to make sure organs go to

patients who need them most. Patients in some regions wait two months; patients in other states may wait two years or more. Information on various programs would be released to the public.

Disappointed critics of the system said any delay could be used to provide momentum to pending legislation early next year to take away the secretary of Health and Human Services' authority over organ transplants. "We are not happy with Sen. Specter," said an official with HHS who asked not to be identified.

Craig Irwin of the National Transplant Action Committee, an advocacy group which argues changes are needed, also expressed disappointment with Mr. Specter. "I don't know that Sen. Specter really came through for us," he said.

"A delay essentially gives the opposition more time to try to kill the regulations," Mr. Irwin said. "The possibility we'll never see these regulations implemented is a very real one."

But Mr. Specter, chairman of the Senate subcommittee on labor and HHS appropriations, said there is no reason to believe the regulations will be killed. "Nobody has told me that. I don't think there's any basis for that at all," he said.

Pending legislation touted by opponents of the regulations would reauthorize the National Organ Transplant Act to restrict HHS oversight. The bill is ready to go the House floor but has been put on hold because no action has been taken in the Senate.

Mr. Breaux argues that the goal of getting more organ donations and making sure the system is fair is so important that reauthorization of the law "should be a top congressional priority next year and not relegated to a regulation interpreting an act that expired in 1993."

The University of Pittsburgh Medical Center, which supports the new rules, argues that another delay "would not be in the best interests of the sickest patients."

Spokeswoman Lisa Rossi said, "There have been comments to death on this issue. HHS has held 12 meetings with professional and patient advocacy groups. They made changes in the regulations that were reflective of (comments). What more can be said?"

But Bob Spieldenner, a spokesman for the organ network, , said a delay is good news because more time is needed to study the regulations.

"We had some concerns with some of the regulations with secretarial oversight and over the fees we charge our members, and I think there was some concern the transplant community didn't have much time to look at these (regulations)," Mr. Spieldenner said.

Even if the House and Senate agree to the delay, it is part of a controversial spending bill that President Clinton has threatened to veto for various reasons. But a compromise on a delay of the organ transplant rules probably would hold.

A recent report by the Institute of Medicine, a private, nonprofit part of the National Academy of Sciences, stated the current system works reasonably well for acutely ill liver patients, but that small organ procurement agencies often keep available organs within their communities for less sick patients.

The report, prepared by a 16-member panel of statisticians, bioethicists, and medical professionals from outside the transplant community, was based on 68,000 patients on waiting lists for livers between 1995 and 1999. It found no evidence that government regulation as HHS proposes would make it harder for minorities, low-income Americans, or people living in remote areas to get access to organs.

The nation has 272 transplant centers and 62 organ procurement organizations, covering widely varying populations from 1 million to 12 million. For example, Pittsburgh's Center for Organ Recovery & Education covers 5.6 million people. Toledo's Life Connection of Ohio covers 2.5 million. Those are below the Institute of Medicine's recommended threshold.

Blade National Bureau writer Jack Torry contributed to this story.

Donor organ plan is again on hot seat
Allocation system attacked

By Bill Walsh
Washington Bureau/The Times-Picayune
10/21/99

WASHINGTON -

The political fight over the nation's scarce supply of critical organs for transplant has erupted again in Congress.

With the clock ticking toward the start of what many believe will be a nationwide "sickest-first" organ allocation system, opponents in the House and Senate have launched separate bids to delay or scuttle the plan and preserve the current regional-based system.

On Wednesday, 33 senators launched a campaign to block the Clinton administration initiative, which is set to take effect in about a month. In a letter delivered to key lawmakers, the senators, including Louisiana Democrats John Breaux and Mary Landrieu, asked for a one-year moratorium on changes in the way organs are distributed. They complained that the new rules give the administration's health secretary too much power in deciding which patients should get critical organs. The senators say those decisions need to remain in the hands of doctors.

"We remain seriously concerned that the authority granted to the Secretary under the new rules goes beyond current law," they wrote.

In the House, Rep. Mike Bilirakis, R-Fla., would go even further. His bill would hand over key organ allocation decisions to an independent organization comprised of doctors and other health-care professionals, who would decide how hearts, livers, kidneys and other critical organs are disbursed. The bill passed the House Commerce Committee last week and awaits House floor action.

The contentious debate over organ sharing is fueled by a simple fact no one disputes: There aren't enough organs being donated to meet the need. About 66,000 people are waiting for a transplant and an estimated 4,000 of those die every year.

President Clinton launched an initiative earlier this year to promote donations through a public education campaign. The administration also has sought to make donations easier. One approach being developed in Louisiana would allow people to sign up in shopping malls to be organ donors.

In the meantime, however, the argument over who controls the limited supply of organs continues. While partisanship has marked most issues on Capitol Hill this year, the debate over organ allocation is a strictly geographic feud.

It pits the representatives of states with large transplant hospitals, like Pennsylvania, Texas and California, against lawmakers from states like Louisiana, Arkansas and Alabama, where smaller transplant centers fear losing locally donated organs to the major transplant centers with long patient waiting lists. They prefer the current system in which organs donated in-state are offered locally and then regionally before going on the national list.

Health Secretary Donna Shalala issued revised rules this week as a means of compromise. They said, for example, that organ allocation should be based on "sound medical judgment" and policies should be designed to ensure that organs aren't wasted in futile transplant attempts. The rules didn't mandate a single national list but said that organs should be disbursed "over as broad a geographic areas as feasible."

That was good news to transplant surgeons, like J. Philip Boudreaux of New Orleans, who has opposed the Clinton administration plans. But plenty of important questions remain unanswered, he said.

Boudreaux said that the new rules still vest too much authority in government bureaucrats instead of medical professionals in deciding such key issues as: Should the sickest patients get transplants or those who have been waiting the longest? Should organs be offered first near where they are donated or potentially flown across the country? How should a patient's need be evaluated and how should that system be policed to ensure that doctors aren't overstating the seriousness of their own cases?

"These rules, although well intentioned, set a very uncomfortable precedent that the secretary can interpose her will, and her politics, into the system," Boudreaux said.

He would like to shelve the new rules and have Shalala instead focus her energies on boosting the rate of organ donations. But those who support the new policies say there has been too much waiting already. The rules were to have gone into effect last year, but they were delayed for a year while an independent panel of medical experts studied the matter.

This summer, the Institute of Medicine issued its report which largely tracked the Clinton administration proposal by encouraging more government oversight and wider organ sharing than goes on now.

The administration stepped up its case last week when it released statistics showing that waiting times for organs and post-transplant survival rates differ widely around the nation, suggesting that patients aren't being treated fairly.

"We have had a moratorium for a year and a half. We can't wait any longer," said Lisa Kory, executive director of the non-profit Transplant Recipients International Organization. "It is unfair for people to be transplanted based on where they live. No one owns these organs."

New York Post
October 20, 1999

ODDS AGAINST APPLE IN TRANSPLANT RACE

By SUSAN RUBINOWITZ

More patients die waiting for heart transplants in New York than in many other parts of the country, a new federal study finds.

Mount Sinai Medical Center - a busy transplant hospital, with up to 35 heart operations a year - landed ninth on the list of the 10 worst hospitals nationwide in how long patients wait for a new heart.

Only 35 percent of patients got their transplants within one year of joining the waiting list at Mount Sinai, compared to the national average of 53.7 percent, the Department of Health and Human Services reported.

And 21 percent of patients died within a year of waiting, in contrast to the 16.5 percent nationally, according to the data, made public last week by Rep. Henry Waxman (D-Calif.).

Buffalo General Hospital ranked fourth-worst in waiting time, with just 30.5 percent of heart patients getting new organs in a year, and 28 percent who died waiting.

Local experts blamed delays on the way organs are meted out through a national system. Although organs are assigned on the basis of need, they usually stay in the geographic area they came from.

"The [city] pool of donors isn't big enough," said Dr. Bruce Sommer, chief of transplants at SUNY Health Science Center in Brooklyn.

Body parts from people with HIV, hepatitis or other infections can't be used, noted Dr. Alan Gass, director of transplant cardiology at Mount Sinai.

But it's the sharp drop in the murder rate that's done the most to heighten the organ-shortage problem here, Sommer said:

"It has decreased the donor population in juveniles and adolescents, whose parents would donate their organs."

A new federal rule - guidelines of which were released Monday - would distribute organs over a wider geographic area and may help the city, Sommer

said.

Gass of Mount Sinai insisted that the HHS study - which used data from 1994 through 1997 - doesn't mean that if a patient is still waiting for an organ, he's somehow getting worse care.

Dr. Henry Krakauer, HHS's senior medical epidemiologist, agreed, saying the public should focus more on how well a hospital keeps patients alive than with how fast they'll get new organs.

New medical techniques other than transplants are adding years to the lives of people with heart or liver failure, he said.

Several local hospitals did well on that front.

At NYU, 85.6 percent of liver patients were still alive after 12 months; 81.6 percent at Mount Sinai, and 81.1 percent at Strong Memorial. The national average was 79.6 percent.

San Jose Mercury News
Wednesday, October 20, 1999

New transplant policy may cut Bay Area waits
BY LISA M. KRIEGER
Mercury News Staff Writer

Bay Area residents -- who now have one of the longest waits in the nation for healthy organs -- may benefit the most from a Clinton administration overhaul of the nation's transplant policy announced this week.

In Northern California demand for organs far outstrips supply, and the average wait for a kidney is 3 1/2 years -- more than twice the national average. The new regulations are designed to shift the focus from geography to medical need and help the sickest patients first, wherever they live.

"It will benefit this community because it will broaden access to donors," said Phyllis Weber, executive director of the California Transplant Donor Network based in San Francisco.

The new U.S. Department of Health and Human Services rules also could indirectly help minorities, who have higher incidence of diseases such as hypertension and diabetes that lead to the need for transplants. Because minorities are often among the sickest on the list, the mandates unveiled Monday should improve their odds of getting an organ, experts theorize.

But some physicians close to the situation said the new policy will have a major impact only if it changes the underlying problem -- too few donations.

"A larger regional area would help us," said Dr. Oscar Salvatierra, director of the pediatric transplant program at Lucile Salter Packard Children's Hospital at Stanford. "But the best way it is going to help is by exposing the shortage of donor organs."

Organ distribution is a minor point, said Salvatierra, an architect of the National Organ Transplantation Act of 1984, compared to that shortage.

The long wait in the Bay Area is partially due to the presence of world-class transplant centers such as UCSF Stanford Health Care Center, say experts. These transplant centers attract potential recipients from all over the globe, yet donations come exclusively from local residents.

Under the old distribution plan, when an organ became available, it was offered to the sickest people in an area initially determined by population. For the Bay Area, that meant Northern and Central California -- excluding Sacramento. If there were no local patients, the organ was offered

regionally, then nationally.

Waits have been long in New England, the Central Atlantic region, the northern Midwest and parts of the West, particularly the Bay Area. Waits have been shortest in Florida and Southeast states.

Old rules

Under that old system, according to the administration, more than half the livers transplanted in 1996 were given to patients who were healthy enough to be living at home. Yet at the same time, nearly 400 patients -- much sicker, but living in regions with long lists -- died while awaiting an organ. To avoid a wait, some patients put their name on lists at several transplant centers; others move to states where the wait is short.

Citing those inequities, the federal government first issued new regulations last year. That, in turn, triggered opposition from small and medium transplant centers, such as the Medical University of South Carolina, which opposed a large national list because they feared it would shortchange local residents.

At least five state legislatures also have adopted laws that are intended to block the effort by the Clinton administration to broaden the organ distribution network.

The United Network for Organ Sharing (UNOS), which runs the transplant system and supervises the regional operations such as the California Transplant Donor Network, also had objections to the first set of proposed changes. UNOS said allocation of organs was a medical decision that should be made only by medical experts.

Revised guidelines

Like the original proposal, the revised rules state that organs should be given to the most medically urgent patients first, without regard to where patients live. And Health and Human Services Secretary Donna E. Shalala retains the right to approve or veto any allocation plan developed by UNOS.

But the rules include several clarifications that address some objections. They say that allocation should be based on "sound medical judgment" and that no single nationwide list of patients awaiting transplants is required. Rather, organs are to be distributed "over as broad a geographic area as feasible."

That new policy could expand the Bay Area service area to include all of California, Nevada and perhaps the Pacific Northwest. Further details will not be published until next month.

More than 65,145 Americans now wait for organs, the most in history. Yet only 10,073 organs were donated last year, according to the United Network of Organ Sharing.

Transplant experts blame the shortage on several factors, including seat-belt laws, anti-drunken driving legislation, handgun control and a shortage of nurses to preserve the organs of brain-dead patients. Typically, donors have suffered head injuries in motor vehicle accidents, gunshot wounds to the head or the bursting of a blood vessel in the brain.

Members of minority groups also donate fewer organs because of lack of awareness, religious concerns and a distrust of doctors, according to a study by Dr. Clive Callender, an African-American transplant surgeon at Howard University in Washington.

Enactment of the new rules had been held up by Congress, which imposed a one-year moratorium after complaints. That moratorium is to expire Thursday.

VIRGINIA/METRO RICHMOND
Organs will go to sickest first / U.S. alters transplant policy

Tuesday, October 19, 1999
BY A.J. HOSTETLER
Times-Dispatch Staff Writer

Patients who need transplants the most will get the country's scarce organs under controversial revisions to the nation's allocation system announced yesterday by federal health officials.

The new rules, which attempt to level the playing field by tearing down geographic barriers, will go into effect next month. Health and Human Services Secretary Donna Shalala said they clarify the federal government's oversight role of the 15-year-old network, which is run by the Richmond-based United Network for Organ Sharing.

Although about 20,000 people a year receive organ transplants, almost 66,000 are on the waiting list. About 4,000 people a year die while waiting for transplants.

Federal officials sought to revise the system because the wait for a transplant varies widely for equally sick people in different parts of the country. In June, a Times-Dispatch investigation of the system found that many relatively healthy patients receive transplants while patients nearby die.

The changes reflect many of the recommendations by the Institute of Medicine, which held congressionally mandated hearings on the subject earlier this year.

Yet the Clinton administration's main intent in reshaping the system remains unchanged, that the country's organs should be given to the sickest patients first.

In a statement, UNOS said it "applauds the Department of Health and Human Services for listening to the concerns and recommendations of the transplant community."

Although UNOS representatives have met frequently with HHS officials about the changes, the organization said it was disappointed that it didn't get to review the final plan before it became public. "UNOS does continue to have concerns with certain provisions which are currently under review by Congress," the statement said.

Allocating organs is a question of doling out a national resource in short

supply. The new rules require broader sharing where medically and geographically feasible.

The revisions also call for the network to establish and enforce uniform medical criteria for when and how patients are put in line for a transplant. This is to ensure that hospitals are not unfairly listing their patients as sicker than they are to get organs quicker.

"The federal government is ensuring the effectiveness and fairness of the system," said HHS Deputy Secretary Kevin Thurm.

In addition, HHS officials will appoint members of the transplant community to a new independent advisory committee that will offer guidance for future policies governing organ allocation, Shalala said.

The secretary also asserted the federal agency's right to approve or veto any allocation plan devised by the private contractor that runs the transplant system. UNOS has held the contract for 15 years and recently was granted an extension.

Charlie Fiske of the National Transplant Action Committee, a former UNOS board member who lobbied for the proposed changes, said he was encouraged that the revisions appear to address many of the concerns voiced in the past year.

"The secretary backed down a bit" from her original plan, he said. "It's a case of compromise."

UNOS also has compromised, partially meeting some of the government's demands earlier this year. Even as it defended its turf, UNOS altered its liver allocation policy by establishing regionwide sharing for the most urgent patients and gave the public, for the first time, access to information on survival data and performance of transplant hospitals.

The battle over control of organ allocation began in earnest in April 1998, when the HHS issued a plan to overhaul the system.

UNOS and transplant surgeons lobbied Congress against the new regulations, saying that giving more organs to the sickest would lead to more deaths, since sicker patients are less likely to survive after surgery. Transplant programs also objected, fearing they would lose locally donated organs to larger centers with more patients on waiting lists.

In response, Congress postponed the changes for a year and ordered a panel of experts convened by the Institute of Medicine, which advises Congress on

medical issues, to study the system.

After several hearings, the panel sided with the administration. Its report, released in July, recommended that the government exercise more oversight of the system and concluded that broad sharing of organs was appropriate. The report also said the network should provide more information to the public about transplants.

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NEW ORGAN TRANSPLANT RULES TO ALTER ALLOCATION METHODS

By Peter Gomer
Chicago Tribune Staff Writer
October 19, 1999

One of the visionary ideas of managed health care was that local hospitals would no longer have to fight over the scant supply of organs available for transplant. All transplants would be carried out at specialized "Centers of Excellence" which had the most experience and whose success rates were the best.

The idea never got off the ground.

Instead, what has evolved is a chaotic system of organ distribution based mainly on local control in which geographic boundaries are deemed more important than medical need. Under this system, organs are distributed in local areas first, even if there are sicker patients elsewhere.

On Monday, the U.S. Health and Human Services Department said it would issue controversial new rules aimed at making sure that people who need organ transplants the most get them first, no matter where they live.

But organs should not be wasted, the new rules dictate, by shipping them coast to coast or futilely transplanting them into very sick patients.

And HHS Secretary Donna Shalala retained the right to approve or veto any allocation plan devised by the private contractor that runs the transplant program.

The department issued similar rules last year, but they were put on hold by Congress amid fierce complaints from transplant programs that feared they would lose locally-donated organs to larger centers that have more patients on waiting lists.

The one-year moratorium on the new rules is due to expire Thursday. Congress is trying to decide whether to extend the moratorium for another year.

Also, the National Organ Transplant act is up for reauthorization by Congress. One bill, sent to the House by the Commerce Committee last Wednesday, would greatly reduce the powers HHS has over the current organ-sharing network, the United Network for Organ Sharing, which operates under contract with the Health and Human Services Department.

Transplant surgeons and the organ sharing network have objected to HHS setting the rules, saying allocation policies are medical decisions that

should be made by medical experts.

Shalala said many of the revisions are meant to clarify what the department wanted all along.

"Members of the transplant community read it one way when we actually thought we were pretty clear," she said.

The regulations require that organs be allocated according to medical need, with the sickest patients getting first chance. However, on its own, the United Network for Organ Sharing had already started to move closer to the HHS position.

This year, for instance, it required that donated livers be given to the sickest patients within large regions, bypassing the local level.

But even that modest proposal ran into trouble. Allocation policy can be tricky in a nation bristling with young transplant surgeons and expensive transplant teams; a nation where 66,000 patients await transplants and nearly 5,000 people a year die waiting.

In this case, Wisconsin, Minnesota, North Dakota and South Dakota objected to sharing livers with Illinois, fearing Chicago's large hospitals would grab all available organs because they have so many of the sickest patients.

Shalala, who was in Chicago on Monday for a conference on childhood issues at Loyola University, said the new organ donation rules would not negatively affect people already on the list.

Asked how Illinois would be affected, she said: "These rules make it fairer, so hoarding by certain states, which I won't name, doesn't hurt people in Illinois. People shouldn't die because of where they live or their economics."

Also in line with July recommendations from the prestigious Institute of Medicine, the new regulations no longer require the allocation system to consider the amount of time a patient has been waiting for a transplant. And they establish an expert advisory committee to help guide HHS policy.

Other recommendations include safeguards to ensure that hospitals are not unfairly listing their patients as sicker than they actually are to get organs quicker.

All the fighting over allocation policies seems like an exercise in futility: The demand for organs is far greater than the supply.

Last year in the U.S., approximately 2,500 heart transplants were performed. As of last month, there were more than 4,200 people waiting for new hearts.

The Institute of Medicine, part of the National Academy of Sciences, has estimated that 250,000 people in the U.S. would benefit from a heart transplant. Even under the best of circumstances the U.S. could double or perhaps triple the number of transplants.

That still would leave 97 percent of patients without an effective therapy. And it has hastened the development of xenotransplantation, the practice of obtaining lifesaving organs from animals.

HHS

FACT SHEET

TO: DEVORAH
FROM: JEN

65557

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

June 18, 1998

Contact: HRSA Press Office
(301) 443-3376

ORGAN TRANSPLANTATION REGULATION

Countering Misinformation - Seeking Fairer Treatment for Patients

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

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

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

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

Specifically, the regulation:

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

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

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

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

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

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

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

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

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

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

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

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

###



U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

The Honorable Thomas J. Bliley, Jr.
Chairman
Committee on Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

This correspondence sets forth the views of the Department of Justice on H.R. 2418, the "Organ Procurement and Transplantation Network Amendments of 1999 ("Organ Procurement Amendments")". The scheme established by the Organ Procurement Amendments raises significant constitutional concerns involving the separation of powers. (An identical letter has been sent to Congressman Dingell.)

Section 3(b)(3) of the bill would authorize a private organization, the Organ Procurement and Transplantation Network ("the Network"), to establish criteria for being a network participant and medical criteria for allocating organs. Section 3(g)(2) provides that "functions that are scientific, clinical, or medical in nature are not administrative or procedural functions and are within the sole discretion of the Network." Section 3(h) authorizes the Secretary of Health and Human Services to conduct public hearings to solicit comments concerning the Network's handling of its responsibilities, it does not authorize the Secretary to do anything with the comments other than passing them on to the Network and "consider[ing]" them.

The Constitution establishes a system of separate powers, and it provides that "[t]he executive Power shall be vested in a President of the United States of America," U.S. Const. art. II, § 1, who "shall take Care that the Laws be faithfully executed," *id.* art. II, § 3. A statute violates the separation of powers if it "impermissibly undermine[s]" the powers of the Executive Branch, . . . or "disrupts the proper balance between the coordinate branches [by] prevent[ing] the Executive Branch from accomplishing its constitutionally assigned functions" *Morrison v. Olson*, 487 U.S. 654, 695 (1988) (citations omitted).

The Organ Procurement Amendments implicate these principles because they appear to delegate to a private entity outside the Executive Branch significant federal regulatory functions. They appear to give the Network the authority to establish what are in effect regulations governing the conduct of private persons and institutions without the effective involvement of the Secretary.

Congress may clearly assign to private entities the job of making detailed recommendations in their areas of expertise to government officials and direct those officials to use the recommendations as the basis for their own decision-making and regulatory proposals. Indeed, Congress may direct executive officials to adopt existing private standards through the rule making processes otherwise prescribed by law. The Organ Procurement Amendments, however, appear to go beyond these permissible forms of legislation by actually giving to a private organization regulatory authority unfettered by executive involvement.

Thank you for the opportunity to present the Department's views on this bill. The Office of Management and Budget has advised that there is no objection to the submission of this letter from the standpoint of the Administration's program.

Sincerely,

Jon P. Jennings
Acting Assistant Attorney General

CONGRESS OF THE UNITED STATES
HOUSE OF REPRESENTATIVES
WASHINGTON, D.C. 20515

October 20, 1999

Chris Jennings
White House Health Care
1600 Pennsylvania Ave., NW
Washington, D.C. 20500

RE: Labor-HHS Appropriations

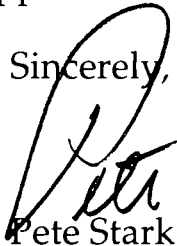
Dear Chris:

Attached is a letter I sent to the President requesting that if Congress sends Labor-HHS language including a moratorium on Secretary Shalala's organ allocation regulation, he make this one of the issues cited in his veto message.

The Institute of Medicine report strongly supports moving forward with the already delayed organ allocation regulations. Further delay will only cause needless deaths.

Thank you for your support on this very important matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Pete Stark", written over the printed name.

Pete Stark
Member of Congress



CONGRESS OF THE UNITED STATES
HOUSE OF REPRESENTATIVES
WASHINGTON, D.C. 20515

October 20, 1999

President William J. Clinton
1600 Pennsylvania Ave., NW
Washington, DC 20500

Dear President Clinton:

I'd like to congratulate you and the Secretary of HHS for standing firm on the side of patients by issuing a revised organ allocation regulation. This regulation incorporates the Institute of Medicine's recommendations, advice of the transplant community, and the needs of patients seeking organ transplants nationwide to ensure that the sickest patients receive organs first. However, we've still got a fight ahead of us.

House Labor-HHS language includes a moratorium on the Secretary's organ allocation regulation even though the Secretary's revised regulations include IoM recommendations such as requiring that allocation is based on "sound medical judgment," that organs are distributed "over as broad a geographic area as feasible," and that timely data about transplant center performance be provided. The Institute of Medicine (IoM) report strongly supports moving forward with the already delayed regulations.

Any additional delays in implementing this regulation will only cause needless deaths. If Congress sends you Labor-HHS language including a moratorium on the Secretary's regulation, I hope you will make it one of the issues you cite in your veto message.

On a similar matter, the House is planning to bring H.R. 2418, the "Organ Procurement and Transplantation Network Amendments of 1999," to the floor next week. This bill removes the Secretary's legitimate authority over the program, provides unreasonable protections for the current contractor, while simultaneously making data less available to the public. In fact, if enacted, transplant center performance data recently released by the Department would be unavailable to the public. This legislation would set different allocation policies than those under the Secretary's regulation and is probably unconstitutional in its delegation of power to private parties.

I am seeking your continued support of the Secretary's authority to oversee the program as well as your outspoken opposition to legislation which attempts to reshape the Department's policies on organ procurement and transplantation.

Sincerely,



Pete Stark
Member of Congress

CONGRESS OF THE UNITED STATES
HOUSE OF REPRESENTATIVES
WASHINGTON, D.C. 20515

October 20, 1999

Chris Jennings
White House Health Care
1600 Pennsylvania Ave., NW
Washington, D.C. 20500

RE: Labor-HHS Appropriations

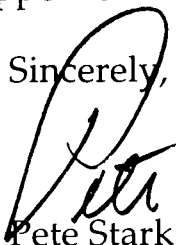
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Pete Stark
Member of Congress

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HOUSE OF REPRESENTATIVES
WASHINGTON, D.C. 20515

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Sincerely,



Pete Stark
Member of Congress





U.S. DEPARTMENT OF
HEALTH & HUMAN SERVICES
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OFFICE OF THE ASSISTANT SECRETARY FOR LEGISLATION
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TO:	<u>Chris Jennings / Devora</u>	☒ RICHARD J. TARPLIN
OFFICE:	_____	☐ KEVIN BURKE
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PHONE:	_____	☐ ROSE CLEMENT LUSI
FAX:	<u>456-5551</u>	☐ ALICE ARTIS
TOTAL PAGES (INCLUDING COVER):	<u>3</u>	☐ FRANKIE MELTON

REMARKS:

FYI



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

October 13, 1999

The Honorable Thomas Bliley
Chairman
Committee on Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Bliley:

I am writing to express the Administration's strong opposition to the Organ Procurement and Transplantation Network Amendments of 1999 (H.R. 2418) that would reauthorize the National Organ Transplantation Act (NOTA), as amended. We have serious concerns that the bill would preserve existing inequities in the organ transplantation system and could result in potential harm to patients. We are committed to working with you and your colleagues in the Congress to develop NOTA reauthorization legislation that better reflects the recent recommendations of the Institute of Medicine (IOM) and that results in a fairer transplantation system for all patients in this country and their families. If this bill were presented to the President in its current form, I would recommend that he veto the bill.

As you know, we believe the current organ allocation policies established by the Organ Procurement and Transplantation Network (OPTN) are inequitable because patients with similar severities of illness are treated differently, depending on where they may live or at which transplant center they may be listed. For this reason, on April 2, 1998, the Department of Health and Human Services issued a Final Rule for the OPTN that establishes a framework for organ allocation policies, to be developed by the network, that are based on sound medical judgment, and that are fairer and more equitable for all parties. The IOM's Committee on Organ Procurement and Transplantation Policy, in its report of July 22, 1999, validated this regulatory framework. In response to the IOM report, as well as written comments submitted concerning the April 2 rule, and lengthy discussions with representatives of the transplant community, we are in the process of making revisions to improve the rule.

We have several serious concerns with H.R. 2418:

One important shortcoming is that H.R. 2418 does not require the standardization of patient listing practices and the broader sharing of organs, two items that we and the IOM consider essential to ensuring fairness in the system and optimal outcomes for patients.

The Honorable Thomas Bliley - page 2

In addition, we believe that H.R. 2418 raises serious Constitutional issues. For example, the bill provides for a delegation of governmental authority to a private entity without appropriate standards of federal review. Yet the bill does not stipulate that binding and enforceable policies for the OPTN be reviewed by the federal government; instead, it provides authority to promulgate policies exclusively to the OPTN. Without regulatory guidelines approved by the Department, the ability of the OPTN to enforce any policies that it develops pursuant to NOTA will likely be the subject of legal challenge, and the current problem of having unenforceable voluntary guidelines will persist.

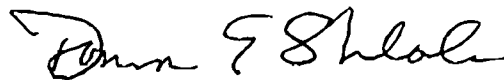
H.R. 2418 contains provisions that grant extraordinary powers to the private sector to select and approve the federal contractor that manages the OPTN. This is inconsistent with existing principles of the federal acquisition process which promote full and open competition in the awarding of federal contracts.

H.R. 2418 also would reduce the federal role in overseeing the OPTN, despite the recent recommendation from the IOM that, "The Department of Health and Human Services should exercise the legitimate oversight responsibilities assigned to it by the National Organ Transplant Act, and articulated in the Final Rule, to manage the system of organ procurement and transplantation in the public interest."

Finally, we are concerned that, although H.R. 2418 requires that the OPTN Board of Directors have physician representation of no less than 50 percent, it makes no such percentage requirements for transplant candidates, transplant recipients, and donor families, who we believe should have a significant representation on the Board.

In conclusion, Mr. Chairman, I regret that we must oppose H.R. 2418 because it provides extraordinary powers to a private entity and reduces the federal oversight role of our nation's organ procurement and transplantation system embodied in NOTA and affirmed by the IOM. I am hopeful that we can work together to develop reauthorization legislation that truly embodies the goals of NOTA and results in a fairer system for all patients in this country.

Sincerely,



Donna E. Shalala



**Executive Office of the President of the United States
Office of Management and Budget**

*Office of Information and Regulatory Affairs
Human Resources and Housing Branch
New Executive Office Building
Room 10235
Washington, DC 20503*

FAX TRANSMITTAL

FAX: 202-395-6974

DATE:

10/7/99

TO:

Deborah Allen

FROM:

Allison Eyd

Total number of pages (Including Transmittal Sheet):

18

Recipient's Fax Number:

205557

Recipient's Telephone Number:

Comments:

DRAFT

October 4, 1999, a.m.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Billing Code: _____

42 CFR Part 121

Organ Procurement and Transplantation Network; Final Rule

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final Rule

SUMMARY: This document sets forth improvements to the final rule governing the operation of the Organ Procurement and Transplantation Network (OPTN), published in 1998. It reflects the advice of a panel convened by the National Academy of Science's Institute of Medicine, as called for in the omnibus appropriations act of 1999. It also reflects comments on the 1998 rule and consultation with representatives of the organ transplantation community, as recommended in the same legislation; and it outlines new transplant data developed in the period since enactment of the appropriations act.

DATES: These amendments are effective (insert ?? days after publication in the Federal Register).

FOR FURTHER INFORMATION: D.W. Chen, M.D., M.P.H., Director, Division of Transplantation, Office of Special Programs, Health Resources and Services Administration, 5600 Fishers Lane, Room 7C-22, Rockville, MD 20857, telephone 301-443-7577.

SUPPLEMENTARY INFORMATION: On April 2, 1998, the Department of Health and Human Services (HHS) published in the Federal Register a final rule pertaining to the operation of the Organ Procurement and Transplantation Network (63 FR 16296). In concordance with the National Organ Transplant Act (NOTA) of 1984, as amended, the purpose of the final rule is to help achieve the most equitable and medically effective use of human organs which are donated in trust for transplantation. Toward this end, the final rule establishes performance goals intended to bring about 1) standardized criteria for placing patients on transplant waiting lists, 2) standardized criteria for defining a patient's medical status, and 3) allocation policies that make most effective use of organs, especially by making them available whenever feasible to the most medically urgent patients. The final rule also sets standards for availability of organ transplantation data, and it addresses the governing structure of the OPTN. No provision of the final rule is intended to interfere with the discretion of individual health professionals and patients in medical decision-making, and the rule looks to the OPTN to design organ allocation

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Page 2

policies. At the same time, the rule defines the policy oversight responsibilities of the Secretary of HHS. In concert with efforts to encourage organ donation, the final rule is intended to help make best use of the limited number of organs available for transplantation.

The final rule invited further comments, which have been received and reviewed. In addition, the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999 delayed implementation of the final rule until October 21, 1999. The Act called for independent review through the National Academy of Science's Institute of Medicine. It also suggested development of improved information on the effectiveness of the transplantation system, including center-specific information if possible. Finally, it suggested further discussions between HHS and representatives of the transplant community. Each of these areas has been addressed.

I. Background

A. Legislative and Regulatory History

Legislative and regulatory history are outlined in the preamble to the April 2, 1998 final rule. In addition to the underlying statute (the National Organ Transplant Act of 1984), of particular importance is Section 1138 of the Social Security Act, enacted in 1986. This legislation requires hospitals that perform organ transplants and organ procurement organizations (OPOs) that coordinate organ procurement, to be members of, and abide by the rules and requirements of, the OPTN as a condition for participation in the Medicare and Medicaid programs. This provision subjects a transplant hospital's entire Medicare and Medicaid participation, and thus in reality its economic survival, to OPTN policy and enforcement. But authority for establishing conditions of participation in Medicare and Medicaid resides with the Secretary and cannot be exercised by another party without either oversight authority or delegation. Thus, review and oversight authority of OPTN policies by the Secretary of HHS is made necessary by Section 1138. A Federal Register notice published on December 18, 1989 (54 FR 51802) addressed this need by stating that no OPTN policies are legally binding "rules or requirements" of the OPTN for purposes of Section 1138, unless they have been approved by the Secretary. The final rule published April 2, 1998, defines the structure for such review and approval, thus setting the stage for OPTN "rules or requirements" which would be enforceable on transplant centers under Section 1138.

In October 1998, the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999 delayed implementation of the final rule to Oct. 21, 1999. (Section 213 of the Departments of Labor, HHS, Education and Related Agencies Appropriation Act for Fiscal year 1999, enacted by section 101(f) of Division A of Public law 105.277). The Act directed that the Institute of Medicine conduct a review of the current policies of the OPTN and the final rule. The Act also suggested that the Secretary "may conduct a series of discussions

Page 3

with the OPTN in order to resolve issues raised by the final rule." In addition, the Act indicated a need for improved availability of data on transplantation and transplant center performance.

B. Institute of Medicine Report

The Institute of Medicine (IOM) issued its report, *Organ Procurement and Transplantation*, on July 22, 1999. The report included five major recommendations. The Department has relied heavily on the guidance in the IOM report in reviewing the provisions of its final rule. In general, the IOM report validates the concerns that gave rise to the final rule and the approaches taken in the rule:

"RECOMMENDATION 1: Establish Organ Allocation Areas for Livers. The committee recommends that the DHHS Final Rule be implemented by the establishment of Organ Allocation Areas (OAAs) for livers - each serving a population base of at least 9 million people (unless such an area would exceed the limits of acceptable cold ischemic time). OAAs should generally be established through sharing arrangements among organ procurement organizations to avoid disrupting effective current procurement activities."

"RECOMMENDATION 2: Discontinue Use of Waiting time as an Allocation Criterion for Patients in Statuses 2B and 3. The heterogeneity and wide range of severity of illness in statuses 2B and 3 make waiting time relatively misleading within these categories. For this reason, waiting time should be discontinued as an allocation criterion for status 2B and 3 patients. An appropriate medical triage system should be developed to ensure equitable allocation of organs to patients in these categories. Such a system may, for example, be based on a point system arising out of medical characteristics and disease prognoses rather than waiting times."

"RECOMMENDATION 3: Exercise Federal Oversight. The Department of Health and Human Services should exercise the legitimate oversight responsibilities assigned to it by the National Organ Transplant Act, and articulated in the final rule, to manage the system of organ procurement and transplantation in the public interest. This oversight should include greater use of patient-centered, outcome-oriented performance measures for OPOs, transplant centers, and the OPTN."

"RECOMMENDATION 4: Establish Independent Scientific Review. The Department of Health and Human Services should establish an external, independent, multidisciplinary scientific review board responsible for assisting the Secretary in ensuring that the system of organ procurement and transplantation is grounded on the best available medical science and is as effective and as equitable as possible."

waiting time in the status
↑
1, 2a, 2b, 3

overall time waiting time only

not clinically homogeneous categories

also UNOS

should not

use in allocation

get point for being well longer + can get transplanted sooner

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"RECOMMENDATION 5: *Improve Data Collection and Dissemination.* Within the bounds of donor and recipient confidentiality and sound medical judgment, the OPTN contractor should improve its collection of standardized and useful data regarding the system of organ procurement and transplantation and make it widely available to independent investigators and scientific reviewers in a timely manner. The Department of Health and Human Services should provide an independent, objective assessment of the quality and effectiveness of the data that are collected and how they are analyzed and disseminated by the OPTN."

In addition, the General Accounting Office (GAO) made findings in two other areas required by the omnibus appropriations act: the possibility of legal liability of OPTN members arising from their peer review activities, and the confidentiality of information. Regarding liability, the General Counsel of the GAO found no apparent conflict between the final rule and State laws governing peer review. Regarding confidentiality, the counsel found that the Secretary of HHS has authority under the final rule to decide that the public interest in disclosure of information about organ transplants outweighs the interest in confidentiality.

C. Discussions with OPTN

Representatives of HHS met with members of the transplant community on numerous occasions in the period immediately following publication of the final rule. Since enactment of the omnibus appropriations act of 1999, representatives of HHS have met on 12 separate occasions with representatives of 11 transplant organizations: the United Network for Organ Sharing (the current OPTN contractor), Transplant Recipients International Organization, American Liver Foundation, National Transplant Action Committee, National Minority Organ and Tissue Transplant Education Program, National Kidney Foundation, Patient Access to Transplantation Coalition, American Society of Transplantation, American Society of Transplant Surgeons, North American Transplant Coordinators Organization, and the American Nephrology Nurses Association. On September 15, 1999, an additional meeting with representation invited from all of these organizations took place to discuss together issues that had been surfaced:

Clarifications -- A number of issues raised concerning the final rule represented misunderstandings of the intent or content of the rule. HHS is further clarifying these issues with this publication:

- "National" lists: The final rule does not require single national lists for allocation of organs, beyond the national registry lists already utilized by the OPTN. As underscored by the IOM recommendations, it is the Department's goal to achieve sharing of organs broad enough to achieve the most medically effective results for patients, especially by providing organs for patients with greatest medical urgency, whenever medically feasible. The final rule directs

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the OPTN to overcome as much as possible arbitrary geographic barriers to allocation which restrict the allocation of organs to patients with greatest medical urgency and are not based on medical criteria.

- **Most Medically Urgent Patients:** The final rule follows, and intends to expand, existing policy in serving most medically urgent patients first, wherever medically feasible. It is not the Department's intention to require transplantation of patients too ill to benefit: the final rule specifically prohibits policies that might result in such futile transplantations and organ wastage. Providing available organs to patients with greatest medical urgency is already the policy of the OPTN within allocation areas. Transplant priority for patients with greatest medical urgency, wherever medically feasible, follows the tenets of medical practice generally and is already accepted throughout the transplant community and general public.
- **Medical Factors Limiting Organ Movement:** The final rule fully recognizes limitations on movement of organs resulting from medical factors, especially limits of ischemic time. As recommended by the IOM report, and as intended by the final rule, sharing of organs should be broad enough to enable medically effective use of organs, especially to enable organs to reach most medically urgent patients, but ischemic time limits and any other medical factors affecting the viability of the organ must be considered in designing allocation policies.
- **Small and Medium Sized Transplant Centers:** The Department does not expect the final rule to cause the closure of small or medium sized transplant centers or otherwise diminish access to transplantation for certain populations, including those living in rural areas. The IOM report did not find evidence that the rule would have such effects; and a report by the HHS Office of Inspector General ("Fostering Equity in Patient Access to Transplantation: Local Access to Liver Transplantation," dated August 1999) concluded that geographic distribution of liver transplant centers is unlikely to change as a result of national policies on organ allocation. The Department is concerned that patient access to transplant services not be adversely affected by closure of small and medium sized centers. Thus, the final rule includes provision for monitoring any effects of policy changes on patient access to transplantation.
- **Designated Transplant Program Requirements:** The final rule carries forward the policies in the proposed rule that provided separate OPTN designated transplant program requirements for non-Medicare and Medicaid participating transplant programs and those which are certified as Medicare and Medicaid participating programs. The Department has received comments, including those from UNOS, similar to those submitted in response to the proposed rule, suggesting that uniform standards be applied for designation status. The Department continues to have no objection to this suggestion in principle, but believes that the OPTN should submit such standards for the Secretary's consideration as possible changes to the Medicare Hospital Conditions of Participation.

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Secretarial Oversight of OPTN Policies -- All but one of the participants in the discussions agreed that HHS should exercise an oversight role over OPTN policies, although there were different views among the participants as to how such oversight should be carried out. Exercise of HHS oversight was also one of the five primary recommendations of the IOM report. Further, as explained in "Legislative and Regulatory History" above, Section 1138 of the Social Security Act elevates OPTN membership and policies to the status of conditions of participation in Medicare and Medicaid for transplant hospitals and OPOs, thus necessitating Secretarial review and oversight authority over those policies. The final rule provides the framework for such oversight. An additional recommendation by the IOM was establishment of an independent scientific review board "for assisting the Secretary in ensuring that the system of organ procurement and transplantation is grounded on the best available medical science and is as effective and as equitable as possible." In addition to implementing the final rule, the Department intends to create such an advisory board.

It is not the desire, nor is it the intention, of the Department to interfere in the practice of medicine. Decisions about who should receive a particular organ in a particular situation involve levels of detail, subtlety, and urgency which must be judged by transplant professionals. The proper role of the Department, as reflected in the final rule, is to assure that the policy framework within which those decisions are made is one that serves the ends of public interest as the law intended.

OPTN Board Composition -- Participants expressed a variety of views on proposed requirements concerning the composition of the OPTN Board of Directors. Some participants believed the Board should include at least 50 percent representation of transplant physicians and transplant surgeons, to ensure preponderance of medical expertise. Others suggested more even division of representation among transplant physicians and transplant surgeons, other non-physician transplant professionals, and representatives of patients and donor families. Concern was also raised that a combination of percentage representation requirements with specific categorical representation requirements would make the Board too large and therefore unwieldy. The Department has concluded that the final rule should provide additional flexibility to the OPTN in designing its Board of Directors, so as to achieve a balance among physician, patient, and other representatives. This notice includes amendments which identify categories of membership, but do not require a specific number of members from each category. The amended rule requires approximately 50 percent transplant physician or transplant surgeon membership, instead of no more than 50 percent.

Broader Geographic Sharing of Organs -- As indicated above, the final rule's emphasis on broader sharing of organs was misunderstood in several ways, and through this notice clarifying language is incorporated in the rule to make its intent clear. Establishment of liver allocation areas broad enough to provide for medically effective allocation of organs was the leading recommendation of the IOM report. Some participants in the September 15 discussion

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expressed concern about the need for the transplant system to use standard criteria for listing patients and assigning their urgency status, and likewise the need for enforcement mechanisms to ensure that medically urgent patients are not disadvantaged through misuse of listing or status categories. The final rule calls on the OPTN to develop such standard criteria. Further, by establishing a framework for Secretarial review and approval of OPTN policies, as well as review and evaluation procedures for the OPTN, the rule provides a foundation for enforcement of these standard criteria.

Frequency and Timeliness of Data -- Most participants expressed support for enhanced frequency and timeliness of data. Likewise, the IOM report strongly urged improvements in data collection and dissemination, both for physician and patient information and to provide outcome data that may improve understanding of best medical practices. As OPTN contractor, UNOS expressed concern about its ability to meet the frequency requirements in the April 2 final rule. The Department has decided to retain the 6 month data presentation requirement with the added provision that this period can be longer as the Secretary prescribes.

The Department recognizes the progress that UNOS has made in increasing the availability of program-specific information for use by patients, families, physicians, and payors. To respond to the contractor's concerns in its ability to meet the timeliness and frequency of reporting requirements in the final rule, HHS will delay the effective date of the data reporting requirement for the first program specific report submitted under section 121.11(b)(1)(iv) nine months to allow OPTN member organizations adequate time to become fully Y2K compliant and ensure that all data submitted to the OPTN is done so electronically. This will allow the contractor to meet the Department's and the IOM's expectations that information be more timely and accessible.

Use of Waiting Time -- The IOM report recommended that the OPTN discontinue use of waiting time as an allocation criterion for liver transplant patients in statuses 2B and 3. In general, the IOM found the emphasis on cumulative waiting times to be inappropriate as a criterion for allocation and as a measure of equity in the transplant system, pointing instead toward more medically relevant measures. HHS generally agrees with these findings, although the Department believes that waiting time in status (unlike cumulative waiting time) can be one among several useful criteria in assessing variability in results for patients at different transplant centers. To date, waiting times have been used in examining the performance of the transplant system in part because waiting times are used by the OPTN as an allocation criterion, and in part due to lack of better measures. It is for these reasons that waiting times were included as performance measures in the final rule published April 2. In addition, the IOM recommendation points again to the need for better data to provide alternatives to waiting time as a performance measure. Based on the IOM's recommendations and comments from the transplant community the Department has concluded that additional flexibility is warranted to allow the application of other measures of system equity as they become available.

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OPTN review of member compliance with final rule requirements and mandatory OPTN policies -- Many members of the transplant community expressed concerns about cheating and noncompliance with OPTN policies. The OPTN is required by §121.10 to conduct reviews and evaluations of each OPTN member's compliance with these rules and approved OPTN policies. Thus, the OPTN is required to implement a review process to ensure that individuals receiving transplants are accurately listed and in proper classification categories to receive organs. Currently, UNOS liver and thoracic Regional Review Boards (RRBs) provide retrospective review of designation of status 1 and 2A patients for livers and 1A patients for hearts. The Department will explore with the OPTN contractor issues related to the conduct of prospective and/or retrospective reviews of all listings and changes in status categories to assure that centers are making appropriate classification determinations. Reviews, prospective and/or retrospective, might be performed by existing OPTN RRBs composed of physicians from transplant centers. In addition, the Secretary may task an independent third party, such as the Joint Commission on the Accreditation of Health Organizations (JCAHO) or a Peer Review Organization (PRO), to monitor the OPTN enforcement system by independently conducting audits of the work of the RRBs.

Incentives for High Performing OPOs -- Concern has been expressed that by emphasizing broader sharing of organs, the final rule might bring about reduced organ donation. The Department disagrees, and the IOM report did not find evidence to support this fear. In the discussions, however, HHS presented the possibility that positive rewards might be offered for high performing OPOs, to add to incentives for organ donation. The Department believes that high performance by OPOs should be rewarded, in a way that does not disadvantage patients by compromising one of the fundamental objectives that the final rule is trying to achieve - namely broader sharing of organs. Therefore, the Department encourages the OPTN to develop and recommend to the Secretary policy incentives to reward high-performing OPOs. In addition, in response to longer-standing concerns, HHS' Health Care Financing Administration (HCFA) is reviewing the way it currently measures OPO performance.

Policies to Address Socioeconomic Barriers -- Some in the transplant community have expressed concern that the final rule would require transplant hospitals to make their own financial resources available to pay for transplant and follow-up care for patients unable to pay. However, this was not the intention of the April 2 final rule. The rule calls on the OPTN Board of Directors to recommend policies that would reduce inequities in access resulting from socioeconomic status and ensure that the registration fee itself does not represent a barrier to transplantation.

Registration Fees -- UNOS objects to Secretarial review of that portion of registration fees paid by OPTN members (and indirectly by patients and their insurers) which represents UNOS expenditures that are not directly related to the tasks performed under the contracts with HHS. The final rule specifies that the Secretary has oversight of that portion of the registration fee directly related to operation of the OPTN.

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Health Resources and Services Administration (HRSA)-HCFA Cooperation - Although not raised in discussions with the transplant community, a few written comments noted the need for increased coordination between HRSA and HCFA on transplantation issues within their respective areas of responsibility. HRSA and HCFA have pursued several cooperative efforts to achieve increased organ donation, a goal of the Administration's National Organ and Tissue Donation Initiative which was launched in December, 1997. On June 22, 1998, HCFA published a final rule (42 CFR Part 482) regarding Medicare and Medicaid Programs Hospital Conditions of Participation (HCOP) for Organ, Tissue, and Eye donation which requires hospitals to refer all deaths and imminent deaths to local OPOs and conduct donation request training programs with appropriate staff representatives. In 1999, HRSA and HCFA jointly sponsored projects to encourage collaboration between hospitals and OPOs in effectively implementing this regulation. HCFA's responsibility for OPO performance standard establishment, certification and re-certification of OPOs, and OPO waiver request review, involves close cooperation with HRSA to identify practices most likely to benefit donor families and transplant patients, and which impact current organ allocation policy. In addition, HCFA and HRSA are working to enhance and better coordinate collection, reporting, and analysis of organ procurement and transplant data in an effort to assure optimum performance of the OPTN.

F. Data

The appropriations act called for "timely and accurate program-specific information on the performance of transplant programs." The IOM report, in reviewing 68,000 medical records, made a significant contribution in the data area, although the report also cited the paucity of data available and recommended improved data collection and dissemination. In addition, UNOS recently has added Internet-based capability, both for providing information to physicians and the public and for collecting data from its members.

Finally, HHS has developed new center-specific analyses that show varying outcomes for patients among different transplant hospitals. Department staff analyzed OPTN patient outcome data for liver and heart transplants with respect to three critical issues: 1) the likelihood that, having been listed as a transplant candidate, a patient will receive an organ within one year; 2) the likelihood that a patient will die within one year of listing while awaiting transplantation; and, 3) the likelihood that a patient will still be alive one year after listing, irrespective of whether he or she underwent a transplant procedure. After risk adjustment (i.e., adjustment for differences in the mix of patients' health status from program to program), the analyses revealed substantial differences in outcomes from one transplant program to another. The principal findings for liver transplants illustrate that:

- 10 percent of the programs have a standardized risk-adjusted rate of transplantation within one year of listing of 71 percent or more; whereas, for another ten percent of the programs, the rate is 25 percent or less;

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- the likelihood of dying within one year of listing while awaiting a transplant ranges from less than 8 percent to more than 22 percent; and
- the likelihood of surviving one year after listing as a transplant candidate or a recipient ranges from approximately 65 percent to almost 86 percent.

The analogous values for heart transplants are 36-72 percent (transplantation within one year of listing), 9-23 percent (death within one year of listing while awaiting a transplant), and 67-84 percent (survival for one year after listing irrespective of whether transplanted or not).

In the course of performing these analyses, Department staff identified gaps in the data currently collected by the Scientific Registry - e.g., additional clinical details about patients' conditions at the time of listing (which could improve risk adjustment) and additional data on clinical complications (which could help in assessing quality of life following transplantation). The Department has provided these analyses to UNOS and has encouraged it, in its management of the OPTN and its operation of the Scientific Registry, to broaden the scope of data collection and make increased use of program-specific performance analyses. The analyses are included in the *U.S. Department of Health and Human Services 1999 Report to Congress on the Scientific and Clinical Status of Organ Transplantation*.

II. Public Comments

Between April 2 and September 16, 1998, a total of 2,590 comments on the final rule were received. (Letters with petitions or with form letters attached were counted as one comment. A total of 13,507 form letters were received.) The majority of the comments reflected the misunderstandings about the final rule addressed in "Clarifications" above. This notice includes changes intended to make these issues clear. Other issues raised by commenters were subsequently discussed in the meetings conducted this year pursuant to the appropriation act of 1999, and they are outlined above.

III. Changes in the Regulatory Text

As a result of the comments received, the Department has made several modifications to the final rule published on April 2, 1998. Some changes have been made to clarify the regulatory language, with no resulting change in policy. Other revisions to the regulatory text add provisions or modify requirements from the previously published final rule.

1. Definition of Organ

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The Department has deleted bone marrow from the definition of organ in § 121.2 because it falls within the scope of a different statutory authority. Although the NOTA refers to bone marrow for purposes of the Scientific Registry, subsequent legislation established a separate program to address unrelated bone marrow transplants. In its comments, UNOS recommended that the definition be expanded to include intestine, stomach, or a collection of human cells which perform a vital function of an organ, including any organ containing vasculature that carries blood after transplantation. In the Preamble to the rule published on April 2, 1998, the Department stated: "The inclusion of other organs, such as the stomach and intestines, not only would have an impact on other requirements in these regulations such as the development of allocation policies, certification of designated transplant programs, and establishment of training requirements but also would affect OPO requirements to procure these organs in accordance with rules of the Health Care Financing Administration (HCFA). Thus, the Department believes it would be premature for this rule to specify other organs in addition to those already named. Instead, the Department will direct the OPTN contractor to consider which organs or parts of organs, if any, should be subject to OPTN policies, and to submit recommendations to the Secretary." The Department's position on this issue remains unchanged.

2. National List

To avoid misunderstandings as discussed above, the term "national list" has been changed to "waiting list" in § 121.2, retaining the definition for "national list". The term "national list" has been replaced with "waiting list" throughout the final rule. The Department wishes to clarify that the term "national list" was incorporated into the regulation to reflect statutory language in Section 372 of the Public Health Service (PHS) Act, 42 U.S.C. 274, which requires the OPTN to "establish a national list of individuals who need organs," but not to influence allocation policy. The Department is fully aware that within the OPTN, current allocation convention is to maintain a single database from which subordinate lists are derived. The Department recognizes that current OPTN policy allocates zero mismatched kidneys nationally, because scientific evidence has shown this policy to result in better patient and graft survival. It is not the Department's intent or its desire to create a single national list for allocation other than the lists already utilized by the OPTN for allocation purposes.

3. Composition of OPTN Board of Directors

The Department wishes to ensure adequate public representation on the OPTN Board of Directors, while giving the OPTN sufficient flexibility to constitute a balanced and effective Board. Thus the Department has retained the requirement under § 121.3(a)(3)(iii) that the Board of Directors shall include at least 25 percent transplant candidates, transplant recipients, organ donors, and family members, while at the same time, revising § 121.3(a)(1) to enable the OPTN to govern itself with greater flexibility than was provided by the specificity of the language in the previously published final rule, in accordance with comments from UNOS and others. The revised language maintains the requirement that the Board of Directors include representatives of

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OPOs; transplant centers; voluntary health associations; transplant coordinators, histocompatibility experts, other non-physician transplant professionals; and the general public, but does not mandate a specific number of members from each category. The Secretary believes that the less prescriptive language in this final rule will better allow the OPTN itself to determine the appropriate size of, and representation on, its Board of Directors, while achieving a balance among physician, patient, and other representatives.

Former § 121.3(a)(2) has been deleted. That paragraph prohibited representation on the Board by transplant recipients, transplant candidates, organ donors, family members, or the members of the general public who are employees of, or have similar relationships with, the specified categories of members required to be on the Board. The Secretary agrees with comments received that the benefits to be derived from representation on the Board by organ transplant recipients, candidates, donors, and their families, who may have such employment or other financial ties, outweigh the potential problems that could arise from such relationships.

In keeping with the need for greater flexibility in the Board membership provisions, former § 121.3(a)(3), now § 121.3(a)(2), has been revised to require approximately 50 percent transplant surgeons or transplant physicians on the Board, rather than the more restrictive language of the earlier rule requiring no more than 50 percent. The comparable requirement in § 121.3(b)(1) for the Executive Committee of the Board has been similarly revised. It should be pointed out that transplant physicians or transplant surgeons elected to the Board or Executive Committee under other categories shall be counted toward the requirements of these paragraphs of the final rule.

The Department has also added to the requirements for the Executive Committee composition a parallel requirement to that for the Board: at least 25 percent of its members shall be transplant candidates, transplant recipients, organ donors, and family members.

Furthermore, the requirement for a two year term for Board members in former § 121.3(a)(4) has been deleted. The Department acknowledges that Board members have diverse backgrounds and will require different periods of time to become familiar with the complex issues coming before the Board. Thus, we believe that it is appropriate for the OPTN to determine for itself the length of the term for Board members, subject to Departmental review.

4. Socioeconomic Issues

As articulated in the April 2, 1998 rule, the Department is concerned that all patients in the country have access to transplantation, and encourages the OPTN to work toward this goal. Several members of the transplant community, however, expressed concern that § 121.4(a)(3) would require transplant hospitals to make their own financial resources available to pay for transplant and follow-up care for patients unable to pay. That section did not contain such a requirement. It merely required the OPTN Board of Directors to recommend policies that reduce inequities resulting from socioeconomic status, including policies that ensure that patients

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needing a transplant may be listed despite an inability to pay. The intent of this section was to help ensure that the registration fee is not a barrier to those needing an organ transplant. However, to allay the concerns expressed, the Department has amended the language of § 121.4(a)(3)(ii) to reflect the regulatory intent more clearly, and to specify that paragraph (3)(i) refers only to the registration fee.

5. Secretarial Review of OPTN Policies

As discussed above, the Department received a number of comments on this provision, although many were prompted by misunderstanding of the requirement. Nevertheless, the Department has decided to respond to concerns expressed by UNOS, the American Society of Transplantation, and the American Society of Transplant Surgeons by modifying the language of § 121.4(b)(2) to make clear that the Board of Directors is required to provide the Secretary with proposed policies that the OPTN recommends be enforceable under § 121.10 (including allocation policies), and others as specified by the Secretary. Thus, not all OPTN policies are subject to review.

The timing requirement has also been changed from 30 days to 60 days before implementation of the proposed policy to provide a more realistic estimate of the time required for review by the public, should public review be necessary. Section 121.4(c) has also been modified to require the publication in the Federal Register of lists of significant OPTN policies rather than all policies, many of which pertain to purely procedural or administrative matters of the OPTN.

6. Registration Fee

In response to comments from UNOS that it "does not understand the legal authority under which HHS now proposes to convert" its "private, voluntary fee into a mandatory, government-imposed fee," the Department has modified the language of § 121.5(c) to clarify that the portion of the registration fee subject to Secretarial oversight is that portion directly related to operation of the OPTN; any other fee may only be charged on a voluntary basis to OPTN members.

7. Human Immunodeficiency Virus (HIV)

UNOS commented that the language of §§ 371(b) and 372(b) of the PHS Act is broad enough to permit transplantation of organs from HIV positive donors to HIV positive recipients. The Department has considered this interpretation and has revised § 121.6(b) to reflect the language of the statute. We note however that regulations governing OPOs, at 42 CFR 486.306(q), require OPOs to screen donors "to ensure that appropriate donor screening and infection tests, consistent with the OPTN standards and the Centers for Disease Control and Prevention (CDC) guidelines that are appended to this subpart, are performed.....to prevent the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome." The OPO regulations require two thresholds for OPO donor screening: meeting the OPTN standards and

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the CDC guidelines. OPOs must comply with the CDC "Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs" as appended to the regulations for OPOs (see 42 CFR 486, Subpart G, Appendix A). As a result, the OPO regulations will still preclude transplantation of an organ from an HIV-positive donor into any transplant recipient. The OPTN may propose standards permitting such transplantation to the Secretary for consideration and potential change in existing CDC guidelines.

8. Criteria for Listing Patients

The previously published final rule required the OPTN to standardize objective and measurable medical criteria for including patients on the waiting list. In drafting the language of that section, the Department expected that the criteria developed for adding patients to the waiting list would inherently contain criteria for removing patients from the list. Commenters pointed out that the rule should be specific in this respect. The Department agrees with this suggested clarification and has amended § 121.8(a)(1).

9. Organ Allocation

The Department received many comments on issues related to § 121.8(a). It was pointed out that § 121.8(a)(2) needed more flexibility to recognize that medical urgency status is not an appropriate factor in all situations, such as kidney transplantation. The Department agrees and has revised that paragraph to require the grouping of medical urgency status categories "where appropriate."

In light of the IOM report and the many comments received from the public on the issue of equity in the allocation of organs, the Department has reconsidered the use of waiting time as *the* factor in determining allocation priorities. Just as medical urgency status may not be applicable in all situations, as discussed below, the Department is persuaded that waiting time by itself may not be the only measure of equity, although it may be appropriate in some situations. Thus, the Department has deleted former § 121.8(a)(3)(i), and replaced it with a new § 121.8(a)(3)(iii). Former § 121.8(a)(3)(ii) has been renumbered § 121.8(a)(3)(i).

Revised § 121.8(a)(3)(ii) preserves the requirement to minimize the importance of place of residence and place of listing in determining access. However, the new paragraph places the requirement in the unambiguous context of organ sharing, and modifies it to the extent that organ viability and other medical considerations may be taken into account in relation to place of residence and place of listing. These clarifications reinforce the view inherent in the April 2, 1998, regulation that geographic sharing has limits due to variances in ischemic time, and that greater flexibility is needed to develop policies that reflect special situations, such as those relating to pediatric patients.

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New § 121.8(a)(3)(iii) gives the OPTN more flexibility in proposing policies that are most equitable in differing situations. For example, the new paragraph includes the revised language of § 121.8(a)(2) discussed above, which provides that, "where appropriate", standardized, objective, and measurable medical criteria shall provide for allocation in order of decreasing medical urgency status. For each status category, the range of performance indicators used to measure inter-transplant program variance has been broadened to provide greater flexibility, allowing, in addition to waiting time in status, use of other performance indicators for the measurement of equity such as pretransplantation mortality rate and transplantation rate, as was suggested by the IOM. Ongoing research, including within the Department, is attempting to validate these and other measures.

10. Impact of OPTN Policies on Access

The Department has revised § 121.8(a)(4)(ii) to provide explicitly that in developing policies, the OPTN will be required to consider the impact of its policies on access to transplantation. As noted above, the Department is concerned that all patients in the country have access to transplantation, and to this end, is encouraging the OPTN to help needy patients overcome barriers to access, by making policy recommendations for improved private and public payer and service provider coverage of organ transplantation and necessary follow-up care, and transplant hospital efforts to obtain financial resources for such patients from all available sources.

11. Department of Veterans Affairs Hospitals

The term "Dean's Committee" has been deleted from § 121.9(a)(3) to reflect current terminology used by the Department of Veterans Affairs.

12. Department of Defense Hospitals

Transplants are carried out in Federal hospitals owned and operated by the Department of Defense (DoD). Therefore, transplant programs in DoD hospitals have been added to those eligible to receive organs for transplantation under § 121.9(a).

13. Enforcement

Section 121.10(c)(1) has been edited to clarify that appropriate enforcement action may include termination of a transplant program's reimbursement under Medicare and Medicaid. In addition, the Department wishes to clarify that the regulation permits the OPTN to develop policies that will contain lesser or intermediate level sanctions which may be taken by the OPTN, but these policies must first be approved by the Secretary in order for them to be enforceable.

14. Reporting Requirements

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Section 121.11(b)(2) has been amended to include transplant program costs among the items to be reported by transplant hospitals to the OPTN and the Secretary. Although the language in the previously published final rule was sufficiently broad to permit the Secretary to specify that cost information be submitted, it was felt that its specific inclusion in the rule would ensure that such information would be made available on a timely basis when requested, consistent with Section 213(d) of the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999.

15. State Preemption

The Department received input at meetings with UNOS expressing concern that §121.12, which prohibits any State or local governing entity from establishing or continuing in effect any law, rule, regulation, or other requirement preempting the provisions of this regulation, would, without any basis in statute, establish Federal authority over State authority. More than 10 States have passed legislation to date giving preference to State residents in the allocation of organs donated in those States. The NOTA envisioned a national system for organ sharing and allocation, to be established by the OPTN under Secretarial oversight. The Supremacy Clause of the U.S. Constitution prohibits States from restricting the effect of Federal laws. The State preference laws thwart organ sharing policies of the OPTN to the extent that those policies would allocate organs across State borders (as is already the case with OPTN policies, such as for the regional sharing of Status 1 livers). Further, a State enforcing such a law would render impossible the compliance of transplant hospitals and OPOs with OPTN rules, thus jeopardizing their Medicare and Medicaid participation. In this respect, too, the restrictive State laws thwart the Federal scheme created by Congress.

It is important to note that the inclusion of §121.12 in the regulation in 1998 did not establish Federal preemption. Rather, it reflected the Secretary's conclusions about the effects of Federal statutes in light of the Supremacy Clause. Nevertheless, because the Department views preemption as flowing from the statutory scheme, the section of the regulation articulating the Department's views on the matter is unnecessary as a legal matter. Accordingly, §121.12 has been deleted.

16. Advisory Committee on Organ Transplantation

The Department intends to implement the recommendation of the IOM, as discussed above, to create an independent, multidisciplinary scientific advisory board which will assist the Secretary in "ensuring that the system of organ procurement and transplantation is grounded on the best available medical science and is as effective and as equitable as possible." Constitution of such an advisory committee and its consultation by the Secretary, as appropriate, in the words of the IOM, "...would also enhance public confidence in the integrity and effectiveness of the system." To carry out this recommendation, the Department has added a new § 121.12 to provide for the establishment of an Advisory Committee on Organ Transplantation, replacing §121.12 on Preemption, which has been deleted. The Committee, to be established in accordance with the

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Federal Advisory Committee Act [5 U.S.C. APP], will be available to the Secretary to provide comments on proposed OPTN policies and other matters related to transplantation. As part of this process of establishing an Advisory Committee, the Secretary intends to solicit nominations from the transplant community and the general public. Consistent with this new section, § 121.4(b)(2) has been amended to include the Advisory Committee as a group from which the Secretary may seek comments on proposed OPTN policies.

Impact Analyses

The Department has determined that there are no changes in the regulation that require new analyses. Earlier analyses from the April 2, 1998, rule apply entirely to the current regulation.

List of Subjects in 42 CFR Part 121

Organs-human, Organ procurement and transplantation network, Organ transplantation, Hospitals.

Dated:

Administrator
Health Resources and Services Administration

Approved:

Secretary

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CONGRESS OF THE UNITED STATES
HOUSE OF REPRESENTATIVES
WASHINGTON, D.C. 20515

COMMITTEES:
WAYS AND MEANS
JOINT ECONOMIC

Extension of Remarks
Representative Pete Stark
Introductory Statement for the Health Care Worker Needlestick Prevention Act
May 20, 1999

Mr. Speaker, I am pleased to join with my colleagues Marge Roukema (R-NJ), George Miller (D-CA), and Rob Andrews (D-NJ) to introduce the Health Care Worker Needlestick Prevention Act, a bill to prevent dangerous, costly and preventable needlestick injuries to our nation's health care workers.

For far too long, we have stood by and watched as health care workers suffer needlestick and sharps injuries in our nation's hospitals our health care system. According to a 1997 report by the Occupational Safety & Health Administration (OSHA), approximately 800,000 hospital-based workers are injured annually from accidental needlesticks. Many of those injuries infections from bloodborne diseases, the worst of which include HIV/AIDS, and Hepatitis B & C.

OSHA estimates that approximately 16,000 needlesticks are contaminated by the HIV/AIDS. As of December 1998, the Center for Disease Control (CDC) had documented 54 cases of HIV seroconversions from needlesticks and more than 110 "possible" cases among U.S. healthcare workers. In addition, according to the International Health Care Worker Safety Center at the University of Virginia, there are an estimated 18 to 35 new occupational HIV infections of health care workers occurring from accidental needlesticks each year.

These injuries are largely preventable through use of newer technologies that use engineering devices to minimize accidental needlesticks. Hundreds of hospitals across the country have already converted to the use of these devices, but there are still thousands that haven't done so. Our legislation would make such safety devices the norm rather than the exception.

The Health Care Worker Needlestick Prevention Act is modeled after a California state law. Last year, California became the first state in the nation to require needlestick protections. The legislation was signed into law by then-Governor Pete Wilson and was endorsed by a wide coalition including the California Health Care Association (the state hospital trade association), Kaiser Permanente, health care workers, and labor unions alike.

The California Occupational Safety and Health Administration (Cal-OSHA) has estimated that each needlestick injury costs between \$2,234 and \$3,832 for treatment, testing, and prophylactic drugs. Cal-OSHA has also estimated that the California safe needles and sharps law, passed last year and effective this August, will save affected businesses and facilities over \$100 million per year in excess of the cost of the new devices. Similar bills are now pending in state legislatures across the country.

While states are stepping to the plate to address this pressing concern, this is a national crisis and it deserves a national solution. The Health Care Worker Needlestick Prevention Act would amend OSHA's bloodborne pathogens standard to require the use of safe needle technology as the means for preventing needlestick injuries. It is a real-life solution that recognizes that these technologies are still not available or appropriate for use in every situation. To that end, it includes an exception process if the device would interfere with patient or worker safety, interfere with the success of a medical procedure, or if no such device is available in the marketplace. It would also require stricter reporting of needlestick injuries and creates a new clearinghouse on safer needle technology within NIOSH (National Institute for Occupational Safety and Health) to collect the data and to assist employers with training curriculum and other advice on available technologies.

We stand here today with broad-based support similar to that which made the California law possible. Our legislation is endorsed by numerous organizations including: the Service Employees International Union; the American Nurses Association; the American Federation of State, County and Municipal Employees; Kaiser Permanente; The Consumer Federation of America; Becton Dickinson, a major medical device manufacturer; and the Emergency Nurses Association, the American Public Health Association, and AIDS Action.

It is time to take the appropriate step of protecting our health care workers. They simply should not be forced to risk their lives while trying to save ours.

Mr. Speaker, I want to especially thank Congresswoman Roukema for her leadership on this issue and urge my colleagues on both sides of the aisle to join us in support this crucial effort.

Attached is a more detailed summary of the bill.

JOHN W OLVER

PLEASE REPLY TO:

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Congress of the United States
House of Representatives
Washington, DC 20515-2101

IMPROVE HEALTH CARE FOR AMERICA'S UNDERSERVED

COSPONSOR THE MEDICAID NURSING INCENTIVE ACT

April 12, 1999

Dear Colleague:

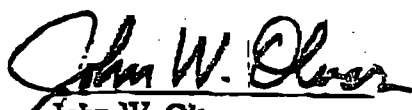
Each year, millions of Americans go without the health care services they need simply because physicians are not available to treat them. This problem plagues urban and rural areas alike. From the streets of Los Angeles, California to the hills of North Adams, Massachusetts, Americans are unable to find physicians who are willing to establish practices in their communities.

Medicaid beneficiaries are particularly vulnerable to problems with accessing health care, since an increasing number of health professionals have chosen not to care for them or have been unwilling to locate in the inner-city or rural communities in which many beneficiaries live. Fortunately, there is an exception to this trend: nurse practitioners and clinical nurse specialists frequently accept patients whom others will not treat and serve in areas where others refuse to work. This exception was highlighted in *The 1994 Physician Payment Review Commission's Report to Congress* which indicated that nurse practitioners play a disproportionately greater role in caring for underserved populations than do physicians.

Congress has already recognized the valuable services of nurse practitioners and clinical nurse specialists. For more than a decade, CHAMPUS has provided direct payment to nurse practitioners. In 1990, Congress mandated direct payment for nurse practitioner services under the Federal Employee Health Benefits Plan (FEHBP). In 1997, under the Balanced Budget Act, Congress provided direct Medicare reimbursement for nurse practitioners and clinical nurse specialists in all geographic areas. The bill I am introducing will establish the same payment policy under Medicaid.

I urge you to join me in making cost-effective high quality health care available and accessible to all Americans. Please contact Kelly Bovio of my staff, at 5-5335, to cosponsor the Medicaid Nursing Incentive Act.

Sincerely,


John W. Olver
Member of Congress

economic slowdown, a reduction in anticipated revenues, or an unexpected increase in mandatory spending could cause publicly held debt to exceed the new limits and create a debt crisis.

DEMOCRATIC LOCK BOX

The Democratic Lock Box creates a supermajority point of order against a budget resolution or any legislation that does not save at least 40 percent of the on-budget surplus for Medicare over the next 15 years and adds a new supermajority point of order against a budget resolution that violates the off-budget treatment of Social Security. (The budget act already contains supermajority points of order against a budget resolution or any legislation that reduces the Social Security surplus.)

The Democratic Lock Box has several advantages over the Republican approach.

(1) *It protects Social Security.* The language reserves all Social Security surpluses for Social Security, and does not allow these surpluses to be used for anything that does not increase the Solvency of the Social Security program.

(2) *It protects Medicare.* The Democratic bill reserves 40 percent of the on-budget surplus for Medicare; allows sufficient funding to extend the life of the Medicare HI Trust Fund through at least 2027.

(3) *It relies on responsible enforcement mechanisms.* The Democratic approach does not establish binding limits on publicly held debt and does not create a risk of default. Enforcement is through current budget procedures and across-the-board cuts. The Lock Box also restores the current pay-as-you-go point of order, which makes certain that no on-budget surplus can be used. Without a change in law, the Republican tax cuts will result in a pay-as-you-go sequester, which will come largely from Medicare.

(4) *It reduces more debt.* The Democratic Lock Box reduces more debt than the Republican proposal, which will lower future interest costs and free up government resources to meet its existing Social Security and Medicare obligations.

COMPARISON OF DEMOCRATIC AND REPUBLICAN LOCK BOX PROPOSALS

Democratic	Republican
Reserves 77 percent of unified surplus for Social Security and Medicare.	Chooses to reserve 62 percent of unified surplus for Social Security but includes "any and all" surpluses.
Preserves Social Security surplus from being used for other purposes.	Allows Social Security surplus to be used for anything labeled "Social Security reform" including tax cuts.
Reserves 40 percent of on-budget surplus for Medicare through 2027.	Reserves nothing for Medicare.
Enforcement through existing budget rules and across-the-board cuts; provisions that covered the first budget surplus since 1983.	Enforcement through debt ceiling, putting United States creditworthiness at risk and jeopardizing Social Security benefits.
Requires 60 votes to violate off-budget treatment of Social Security or the existing Medicare reserve.	Requires 60 votes to violate off-budget treatment of Social Security; reserves nothing for Medicare.
Reduces debt held by the public to \$1.6 trillion in 2009, \$300 billion below the Republicans.	Reduces debt held by the public to \$1.5 trillion in 2009.

SOCIAL SECURITY AND MEDICARE LOCK BOX ACT

The "Social Security and Medicare Lock Box Act" creates new budget points of order and budget enforcement mechanisms that would preclude any portion of the Social Security surplus or any portion of the surplus reserved for Medicare from being used for new spending or tax cuts. Over the next 15 years, the lockbox would save 77 percent of the total unified surplus. The Medicare reserve would save 15 percent of the unified surplus and 40 percent of the on-budget surplus over the next 15 years.

SECTION 1: SHORT TITLE

Titles the bill the "Social Security and Medicare Lock Box Act."

SECTION 2: DEFINITIONS

Amends section 3 of the Congressional Budget Act of 1974 by adding a definition of the term "Medicare surplus reserve." The Medicare surplus reserve refers to surplus amounts reserved to strengthen and extend the Medicare program.

SECTION 3: PROTECTION OF SOCIAL SECURITY TRUST FUNDS

Section 3 reaffirms Congress's support for the off-budget treatment of Social Security (section 13301 of the Omnibus Budget Reconciliation Act of 1990).

SECTION 4: SOCIAL SECURITY OFF-BUDGET POINT OF ORDER

Section 4 creates a supermajority point of order in the House and Senate against a budget resolution that violates the off-budget treatment of Social Security (section 13301 of the Omnibus Budget Reconciliation Act of 1990).

SECTION 5: MEDICARE SURPLUS RESERVE POINT OF ORDER

Section 5 creates a supermajority point of order in the House and Senate against a concurrent resolution on the budget (or amendment, motion, or conference report on the resolution) that would decrease the surplus in any of the fiscal years covered by the budget resolution below the level of the Medicare surplus reserve.

SECTION 6: ENFORCEMENT OF MEDICARE SURPLUS RESERVE

Section 6 creates a supermajority point of order in the House and Senate against any bill, joint resolution, amendment, motion, or conference report that would decrease the Medicare surplus reserve in any of the years covered by the budget resolution.

SECTION 7: SUPERMAJORITY POINTS OF ORDER

Section 7 makes all new points of order created in this amendment waivable only by a three-fifths supermajority vote.

SECTION 8: MEDICARE SURPLUS RESERVE

Section 8 lists the amounts reserved for Medicare in each year from 2000-2014. These amounts total \$55 billion over 2000-2004; \$316 billion over the period 2000-2009, and \$707 billion for the period 2000-2014. This section also creates a procedure that requires these amounts to be adjusted annually in the budget resolution to make certain that they are sufficient to extend the solvency of the Hospital Insurance Trust Fund through 2027. The Medicare surplus reserve, however, cannot exceed the total on-budget surplus in any year so as not to deplete the Social Security surplus.

SECTION 9: PAY-AS-YOU-GO AND DISCRETIONARY CAP EXTENSION

Section 9 extends current budgetary discipline embodied in the discretionary spending caps, the paygo rule in the Senate, and the paygo sequestration provisions of the Budget Enforcement Act until Congress enacts legislation certifying that it has ensured the long-term fiscal solvency of Social Security and extend the solvency of Medicare through fiscal year 2027.

SECTION 10: ADJUSTMENT OF BUDGET LEVELS AND REPEAL

Section 10 directs the Chairmen of the Budget Committees to revise the budget resolution to make it consistent with this Act and repeals the provision of the budget resolution that weakened the paygo rule in the Senate by allowing the on-budget surplus to be used for tax cuts.

By Mr. DASCHLE (for himself,
Mrs. BOXER, and Mr. DORGAN):

S. 863. A bill to amend title XIX of the Social Security Act to provide for Medicaid coverage of all certified nurse practitioners and clinical nurse specialists to the Committee on Finance.

MEDICAID NURSING INCENTIVE ACT

Mr. DASCHLE. Mr. President, today I am introducing the Medicaid Nursing Incentive Act, a bill to provide direct Medicaid reimbursement for nurse practitioners and clinical nurse specialists.

This legislation eliminates a counterproductive Medicaid payment policy. Under current law, State Medicaid programs may exclude certified nurse practitioners and clinical nurse specialists from Medicaid reimbursement, even though these practitioners are fully trained to provide many of the same services as those provided by primary care physicians. This policy is both discriminatory and shortsighted; it severs a critical access link for Medicaid beneficiaries.

The ultimate goal of this proposal is to enhance the availability of cost-effective primary care to our nation's most vulnerable citizens.

Studies have documented the fact that millions of Americans each year go without the health care services they need, because physicians simply are not available to care for them. This problem plagues rural and urban areas alike, in parts of the country as diverse as south central Los Angeles and Lemmon, South Dakota.

Medicaid beneficiaries are particularly vulnerable, since in recent years an increasing number of health professionals have chosen not to care for them or have been unwilling to locate in the inner-city and rural communities where many beneficiaries live. Fortunately, there is an exception to the trend: nurse practitioners and clinical nurse specialists frequently accept patients whom others will not treat and serve in areas where others refuse to work.

Studies have shown that nurse practitioners and clinical nurse specialists provide quality, cost-effective care. Their advanced clinical training enables them to assume responsibility for up to 80 percent of the primary care services usually performed by physicians, often at a lower cost and with a high level of patient satisfaction.

Congress has already recognized the expanding contributions of nurse practitioners and clinical nurse specialists. For more than a decade, CHAMPUS has provided direct payment to nurse practitioners. In 1990, Congress mandated direct payment for nurse practitioner services under the Federal Employee Health Benefits Plan. The Medicare program, which already covered nurse practitioners and clinical nurse specialist services in rural areas, was modified under the Balanced Budget Act of 1997 to provide coverage for these services in all geographic areas. The bill I am introducing today establishes the same payment policy under Medicaid.

Mr. President, the ramifications of this issue extend beyond the Medicaid program and its beneficiaries. There is a broader lesson here that applies to our effort to make cost-effective, high-quality health care services available and accessible to all Americans.

One of the cornerstones of this kind of care is the expansion of primary and preventive care, delivered to individuals in convenient, familiar places where they live, work, and go to school. More than 2 million of our nation's nurses currently provide care in these sites—in home health agencies, nursing homes, ambulatory care clinics, and schools. In places like South Dakota, nurses are often the only health care professionals available in the small towns and rural counties across the state.

These nurses and other nonphysician health professionals play an important role in the delivery of care. And this role will only increase as we move from a system that focuses on the costly treatment of illness to one that emphasizes primary preventive care and health promotion.

But, first, we must reevaluate outdated attitudes and break down barriers that prevent nurses from using the full range of their training and skills in caring for patients. In 1994, the Pew Health Professions Commission concluded that nurse practitioners are not being fully utilized to deliver primary care services. The commission recommended eliminating fiscal discrimination by paying nurse practitioners directly for the services they provide. This step will help nurse practitioners and clinical nurse specialists expand access to the primary care that so many communities currently lack.

As I have worked on access and reimbursement issues related to nurse practitioners and clinical nurse specialists, I have encountered two related issues I would also like to highlight.

Later this month, I plan to introduce legislation to increase the reimbursement rate for nurse practitioners and clinical nurse specialists who practice in rural and underserved areas. Currently, physicians who serve in a health professional shortage area receive a 10 percent boost in their Medicare payment as an incentive to provide services in the regions that need them the most. As we know, nurses are already providing critical primary and preventive care in these areas and deserve the bonus payments that physicians are already receiving.

I would also encourage my colleagues to closely monitor the impact of Medicaid managed care on access to care provided by nurse practitioners and clinical nurse specialists. In some areas of the country, implementation of managed care has prevented patients from continuing to receive health care services from nurse practitioners and clinical nurse specialists because they are not listed as primary care providers or preferred providers. Advanced practice nurses provide cost-effective,

local, quality care, and I am concerned about early reports that access to these professionals is being limited by new health delivery arrangements. We should certainly keep an eye on this issue as Medicaid managed care systems develop.

Mr. President, I hope my colleagues will carefully consider the issues I have raised and support the measure I am introducing today, recognizing the critical role nurse practitioners and other nonphysician health professionals play in our health care delivery system, as well as the increasingly significant contribution they can make in the future. I ask unanimous consent that the full text of the bill be printed in the RECORD.

There being no objection, the bill was ordered to be printed in the RECORD, as follows:

S. 553

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Medicaid Nursing Incentive Act of 1999".

SEC. 2. MEDICAID COVERAGE OF ALL CERTIFIED NURSE PRACTITIONER AND CLINICAL NURSE SPECIALIST SERVICES.

(a) IN GENERAL.—Section 1905(a)(21) of the Social Security Act (42 U.S.C. 1396a)(a)(21)) is amended to read as follows:

"(21) services furnished by a certified nurse practitioner (as defined by the Secretary) or clinical nurse specialist (as defined in subsection (v)) which the certified nurse practitioner or clinical nurse specialist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law), whether or not the certified nurse practitioner or clinical nurse specialist is under the supervision of, or associated with, a physician or other health care provider."

(b) CLINICAL NURSE SPECIALIST DEFINED.—Section 1905 of such Act (42 U.S.C. 1396d) is amended by adding at the end the following:

"(v) The term 'clinical nurse specialist' means an individual who—

"(1) is a registered nurse and is licensed to practice nursing in the State in which the clinical nurse specialist services are performed; and

"(2) holds a master's degree in a defined area of clinical nursing from an accredited educational institution."

(c) EFFECTIVE DATE.—The amendments made by this section shall become effective with respect to payments for calendar quarters beginning on or after January 1, 2000.

By Mr. BINGAMAN (for himself and Mr. CHAFES):

S. 554. A bill to designate April 22 as Earth Day, to the Committee on the Judiciary.

EARTH DAY ACT

Mr. BINGAMAN. Mr. President, this bill that I have sent to the desk is being introduced on behalf of myself and Senator CHAFES. It is entitled "The Earth Day Act." Its purpose is to designate April 22 as Earth Day.

Today, of course, is April 22. Let me provide a little history for my colleagues or anyone listening.

The first Earth Day was 29 years ago, in 1970, and I think we are all aware that Earth Day was first conceived by

our former colleague, Senator Gaylord Nelson, who is universally considered the founder of Earth Day.

He has written a short summary of what brought Earth Day about, how it came about. In it he points out that in a speech that he gave in Seattle in September of 1969, he announced that there would be a national environmental teach-in in the spring of 1970. And the wire services picked up that story. And the next thing he knew, there was a movement afoot to actually have that happen.

That first Earth Day involved some 20 million Americans. Since then, the concept and the idea of Earth Day has focused the attention of the country, focused the attention of the world, in fact, on the importance of our environment and the importance of preserving and maintaining our environment. We have a great debt of gratitude we owe to former Senator Nelson for his leadership on this.

We also owe a great debt of gratitude to the person that did the nuts and bolts work of organizing that first Earth Day, and that, of course is Denis Hayes. He is now president of the Seattle-based Bullitt Foundation, but he has been recognized recently by Time magazine as one of their heroes of the planet. I think his instrumental role, his essential role in bringing about that first Earth Day, making such a success of it, has been recognized by all.

He is now, of course, trying to get in place the organization to make Earth Day 2000, which will occur exactly a year from today, an even greater celebration than we have known before.

Mr. President, I firmly believe that it is appropriate that we officially designate April 22 as Earth Day and that we permanently designate it as Earth Day. It has come to be known as Earth Day—April 22—for all of us. There are celebrations and teach-ins, and recognitions going on throughout our country today. As we hear the news about Kosovo, which is bad, and the news about Littleton, Colorado, and the terrible tragedy there, which is bad, and many of the other news stories that bombard us, it is good to know that there is one news story that we can all celebrate and rally around, and that is that today, again, we will be able to celebrate Earth Day.

Mr. President, it is my sincere hope that Senator CHAFES and I can work in the next year to gain additional cosponsors and to obtain enactment of this, so that by the time Earth Day 2000 arrives, we will be able to have this in law, have it signed by the President. I am sure it will be supported by all of our colleagues. I think we all recognize the importance of this to many of the people we represent. I hope very much that this bill can be enacted.

By Mr. BIDEN:

S. 555. A bill to amend the Internal Revenue Code of 1986 to provide the same tax treatment for danger pay allowance as for combat pay, to the Committee on Finance.