This is all the info
I used for my memo.
HHS contact:
Jackie White 690-5627
Deputy Executive Secretary

Jen--

An update on organ allocation....House Approps approved Labor/HHS bill on July 14 **with** the provision barring the agency from implementing the organ transplant regs. House is likely to take up the bill on the floor by the end of July. Senate might not mark up companion bill until September.

And an added note to the memo....the Wash Post ran a story on Thursday (7/16) about a change in national heart distribution policy that was approved by UNOS on June 25. This change is relevant and likely acceptable to Dr. Lowe because it does not remove regional considerations from the allocation policy for heart transplants, and it allows pediatric heart patients priority for hearts donated by adolescents.

UNOS' revised policy attempts to be a hybrid solution by maintaining regional concerns and categorizing patients by their medical condition. The problem, as the proponents of HHS' new regs see it, is that these revisions do not prioritize medical urgency over regional considerations.

The new policy dictates that hearts be allocated to the sickest patients **within the local area first**, then the less urgent **within the local area**, then patients within a 500-mile radius in order of medical urgency. While the policy does require that only the most sick patients are listed as "most urgent" and it grandfathers in patients currently waiting, it does not address the concerns raised by HHS that those who are in most need may wait longer based on where they live.

If you have a moment, we can discuss further.

Debra.

Return to Breaking News

UNOS News Release

For Immediate Release:
June 26, 1998

Contact: Bob Spieldenner
UNOS News Bureau (804) 327-1432

National Heart Distribution Policy to Change

Ft. Worth, TX – An improved method for ensuring equitable distribution of hearts to patients waiting for transplants was approved yesterday at the United Network for Organ Sharing (UNOS) Board Meeting. The system, which will go into effect in late 1998, establishes more objective medical urgency status levels and gives priority to pediatric patients for hearts retrieved from adolescent donors.

Since the present heart distribution policy was implemented nine years ago there have been many medical advances, especially with mechanical assist devices. The improved three-tiered system reflects those advances and includes the following status levels:

- **Status 1A** – Includes critically ill patients who require continuous inotropic drug therapy or mechanical assistance (e.g. artificial heart or ventricular assist device) and have a life expectancy of less than one month without transplantation.
- **Status 1B** – Includes medically stable patients who require continuous inotropic drug therapy or mechanical assistance and have a life expectancy greater than one month.
- **Status 2** – Includes patients with chronic heart failure who do not meet the higher urgency criteria for Status 1A or 1B listing.

"This improved system ensures that patients who have the most urgent medical need for a transplant and who have a high likelihood of survival following surgery will have the best chance of getting a heart," said UNOS President Larry Hunsicker, M.D.

"No patient who is currently listed at the highest medical urgency will see their status downgraded when the improved system takes effect. Patients who are listed as Status 1 will become Status 1A under the new system," Hunsicker added. The change will only affect patients not currently on the waiting list.

Also, the improved system creates 11 regional thoracic organ review boards, which will review Status 1A patient listings to make sure they are listed by the correct medical urgency status. The boards will periodically review Status 1B and Status 2 patient listings, as well.

Before the UNOS board voted yesterday, the proposed system received extensive medical and public review, including a public forum held in September 1997. Many of the comments received produced changes to the final system.

Pediatric heart policy changes

The improved system also set specific medical urgency status levels for patients less than 18 years of age that reflect the difference in heart disease progression between children and adults.

In addition to the pediatric status levels, the improved system specifies that pediatric patients (0–17 years of age) will be considered before adult patients of similar medical urgency for hearts from adolescent donors (ages 11-17). For example, a heart from a 15-year-old donor would be offered to a Status 1A pediatric patient before being offered to a Status 1A adult patient.

UNOS data show that with the change, graft survival for adolescent patients could improve without negatively impacting other patient groups. Potentially, the one-year mortality rate for adolescent heart recipients could be reduced by more than one-third and the three-year mortality rate by one-half.

"Generally, we think everyone does well with a younger donor," said Dr. Mark Boucek, Chief of Pediatric Cardiology at The Children's Hospital in Denver and Chairman of the UNOS Pediatric Transplantation Committee. "But the data indicate that while receiving an adolescent donor heart doesn't affect adults, age matching means a lot to pediatric patients."

####

Talk to Chris

July 14, 1998

MEMORANDUM

To: Jennifer

From: Debra

Re: Update on Organ Transplant Allocation

As requested, the following is an addendum to Susan's memo highlighting the fundamentals of the allocation policy debate, specific responses to the concerns of Dr. Betty Lowe, Medical Director of Arkansas Children's Hospital, and an update on the political outlook for the HHS regs concerning organ transplant policy.

Note: There are two recent federal regulations concerning organ transplantation. The first intends to increase organ donation by requiring hospitals participating in Medicare or Medicaid to report to organ procurement organizations all deaths so that medically suitable donors can be more readily identified. The goal is to increase organ donation by 20 percent. The second set of regulations involves the allocation process we have been researching.

Overview:

The debate over the proposed HHS regulations on transplant organ allocation is heating up on Capitol Hill. Secretary Shalala testified before a Joint Hearing of the Senate Labor and Human Resources Committee and House Commerce Committee on June 18 in vigorous support of the regulations and of allocating organs according to medical need as a top priority. Although the regulations remain in a "public comment period" until August 31, 1998, Jackie White, Deputy Executive Secretary at HRSA, indicated that the agency is likely to maintain the position Shalala has outlined.

The federal regs, however, are likely to face troubled waters ahead with strong opposition from leading members in both the House and the Senate. In fact, House Appropriations Chairman Bob Livingston (R-LA) has attached a rider to the **FY99 Labor/HHS Approps bill** which would delay implementation of the HHS regs (already delayed once until October 1998) until November, 1999. The Approps bill has passed through subcommittee in the House so far, and the debate is only expected to intensify from all sides.

Rationale from the Federal Regs:

I have a copy of the federal regs on transplant organ allocation policy. The following are highlights of the points supporting the policy.

- The current allocation system remains heavily weighted to the local use of organs instead of making organs available on a broader regional or national basis for patients with the greatest medical need **consistent with sound medical judgment.**
- Criteria used in listing those who need transplantation vary from one center to the next, as do the criteria used to determine the medical status of patients.
- Waiting times for organs are much longer in some geographic areas than in others. Therefore, less ill patients may receive transplants while more severely ill patients, maybe a few miles away, may die.
- A recent report from the HHS Inspector General found that inequities among patients and transplant centers still exist and may have worsened since the initial 1991 report.

Additionally, the Secretary, in her June 18 testimony, emphasized that the regulations do not prescribe any particular policy, but rather recommend that medical need, and not geography, becomes the top consideration for deciding who receives organs. The rules further recommend establishing standard criteria for placing patients on the waiting list and determining medical status.

Dr. Lowe's Concerns:

Dr. Lowe wrote to HRC at the beginning of June expressing concern about the HHS regs and the impact on Arkansas Children's Hospital, specifically the cardiology department. The following are some of Dr. Lowe's objections and potential responses:

- *Arkansas residents would be more willing to donate organs knowing that they would save the lives of Arkansas patients.* A 1994 organ network survey shows that the overwhelming majority of donor families state as their preference that organs go to the neediest patients, regardless of geography.
- *Only the major centers in large metropolitan areas will survive, resulting in heart transplants only for those able to afford the travel and hotel costs for long periods of time as they wait for an organ.* Small and medium-sized centers should receive organs as well because they also serve patients with the greatest medical need. Further, the regs specifically reject the imposition of volume standards that would cause smaller centers to close.
- *Ischemic time (time from excision of the organ to transplantation) is of concern if transplanted organs are traveling farther distances.* The fundamental principle of the regulations is that determinations be consistent with reasonable medical judgment. HHS is not recommending any policy that would jeopardize health or safety by overextending ischemic times.

The Political Landscape:

The HHS regulations are becoming increasingly controversial as politicos and advocates have taken public positions opposing the policies.

In addition to the Chairman of the House Appropriations Committee, HHS is facing considerable opposition from the Hill. House Commerce Health and Environment Subcommittee Chairman Mike Bilirakis (R-FL), who co-chaired the June 18 hearing, argues that the regs will weaken successful organ donation programs, such as the one in his state, because Americans will be less likely to donate if they believe their organs may be transported out of state. House Commerce Committee Chairman Thomas Bliley (R-VA) believes that the issue of organ allocation remains outside of the purview of Congress or the federal Government, and Senator Bill Frist (R-TN) has worried publicly that the regs will force some medical centers to close because organs would be redirected to larger centers with longer waiting lists.

UNOS, the United Network for Organ Sharing which operates the transplant program, has publicly opposed the regulations and is said to have hired a high powered lobbying firm to increase pressure on Members of Congress. The University of Pittsburgh Medical Center, regarded as the nation's premier transplant center, would benefit under the new HHS policy, has hired former House Minority Leader Robert Michel (R-IL).

Jen - fyi - this is what happens when you leave the desk! Total Pages: 13

LRM ID: RJP244

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

URGENT

Monday, April 6, 1998

LEGISLATIVE REFERRAL MEMORANDUM

TO: Legislative Liaison Officer - See Distribution below

FROM: Janet R. Forsgren (for) Assistant Director for Legislative Reference
OMB CONTACT: Robert J. Pellicci
PHONE: (202)395-4871 FAX: (202)395-6148

SUBJECT: **HHS Oversight Testimony on the national organ transplant allocation system**

DEADLINE: **10:00 a.m. Tuesday, April 7, 1998**

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President. **Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.**

COMMENTS: Field hearing in Milwaukee, Wisconsin, before the House Committee on Government Reform and Oversight on Wednesday, April 8th. HRSA Acting Administrator Dr. Fox is the witness.

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LRM ID: RJP244 **SUBJECT:** HHS Oversight Testimony on the national organ transplant allocation system

RESPONSE TO
LEGISLATIVE REFERRAL
MEMORANDUM

If your response to this request for views is short (e.g., concur/no comment), we prefer that you respond by e-mail or by faxing us this response sheet. If the response is short and you prefer to call, please call the branch-wide line shown below (NOT the analyst's line) to leave a message with a legislative assistant.

You may also respond by:
(1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); or
(2) sending us a memo or letter
Please include the LRM number shown above, and the subject shown below.

TO: **Robert J. Pellicci Phone: 395-4871 Fax: 395-6148**
Office of Management and Budget
Branch-Wide Line (to reach legislative assistant): 395-7362

FROM: _____ _____ **(Date)**

_____ _____ **(Name)**

_____ _____ **(Agency)**

_____ _____ **(Telephone)**

The following is the response of our agency to your request for views on the above-captioned subject:

_____ **Concur**

_____ **No Objection**

_____ **No Comment**

_____ **See proposed edits on pages** _____

_____ **Other:** _____

_____ **FAX RETURN of** _____ **pages, attached to this response sheet**

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

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

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

the system.

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

I am pleased to report that the system envisioned by Congress works very well. It is a much more efficient and equitable system than what existed prior to its creation. It has allowed dedicated surgeons and organ procurement professionals, and many others who work with them, to routinely save lives in cases where death would have been certain only twenty years ago. It has, to a very large extent, eliminated the kinds of abuses that occurred before passage of the 1984 law.

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

innovations make transplantation an option for more and more patients.

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

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

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

donations.

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

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

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

the OPTN, which were published last week.

Six principles underlie the regulation:

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

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

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

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

5. Thorough, timely, and easy to use information about transplant centers, including center-specific performance data, is essential for measuring quality of care and should be

readily available to help patients and physicians in choosing among transplant centers.

6. Potential conflicts of interest should be minimized for those who are responsible for operation of the OPTN.

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

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

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

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

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

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

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

> "...current organ distribution practices fall short of congressional and professional expectations," and that "there has been substantial progress in developing a national organ distribution system grounded in uniform policies and standards. However, organ

distribution remains...confined primarily within the individual service areas of the...Organ Procurement Organizations."

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

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

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

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

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

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

main criterion for allocating organs.

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

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

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

accommodate the changes. We encourage public debate on the regulation, whether it be at a hearing like this one or within the confines of the OPTN.

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

LIFE-AND-DEATH LOBBYING

BY W. JOHN MOORE

Bill Frist, R-Tenn., was a transplant surgeon for 14 years. He founded Vanderbilt University's transplant center. Before being elected to the Senate in 1994, he carried in his pocket a list of about 20 patients who desperately needed a replacement heart, kidney or liver. "We decide who lives and who dies," Frist says.

Now he and other lawmakers are grappling with a similar ethical dilemma created by a shortage of suitable organs. Nationwide, 56,000 people are waiting for organs, and each day 10 of them die. The Clinton Administration recently issued new organ-allocation rules designed to eliminate regional disparities in the time patients wait for transplants. But those rules have provoked a clash between major hospitals and regional transplant centers. It's a matter not only of life and death but also of dollars and cents. "Nobody wants to talk about this, but the dynamics of this include money," Frist says.

Organ transplantation is a big business. A liver transplant, including the first year of patient care, costs $315,000; a heart transplant, $253,000; a kidney, $116,000, according to Dr. Roger W. Evans, a senior Mayo Clinic health policy analyst. Successful transplant programs also generate research dollars and drug company money, he adds.

Prominent hospitals, such as the University of Pittsburgh Medical Center, once dominated the field. But as dozens of transplant centers have opened up, the big hospitals have seen a drop in transplants. The Pittsburgh facility performed 569 liver transplants in 1990, only 244 in 1996. "It's clear from looking at the statistics that as programs have been started around the country, they have significantly cut into [the major hospitals'] numbers and it's clear that there's a financial impact related to that," said Rep. Greg Ganske, R-Iowa, a former surgeon who opposes the Administration's rules.

Pittsburgh's Medical Center has long pressed for changes in the organ-sharing system. In 1996, the hospital turned to real estate developer David M. Matter for help. Matter is a low-key Friend of Bill, a former college chum who ran Bill Clinton's losing campaign for senior class president of Georgetown University. He has also contributed to Clinton's campaigns, slept in the White House, and even spent election night 1996 with the first family.

He wrote to the President, describing inequities in the transplant system. Matter's letter worked. Clinton spoke to Health and Human Services (HHS) Secretary Donna E. Shalala, who then held agency hearings on organ donations.

Matter is hardly the Pittsburgh hospital's only weapon in Washington. During the past two years, it has spent $260,000 on Capitol Hill lobbying. And it has hired Hogan & Hartson, a prominent Washington law firm, as well as longtime Clinton pal, Little Rock lawyer John R. Tisdale. "Pittsburgh has fought tooth and nail to sustain what is nothing more than its market share in transplantation," Evans says. "It has spent more money, time and effort than any institution in the country."

Of course, the Pittsburgh hospital's administrators see their fight differently. The allocation system for liver transplantation "is fundamentally unfair, and results in the needless loss of life of patients waiting for transplants," Dr. John J. Fung, the hospital's top transplant surgeon, recently testified on Capitol Hill. His evidence: If you live in Nashville, you waited 71 days for a liver. In New England, the wait was 648 days.

Shalala's regulations would replace the regional system with one that would put the sickest patients at the top of the waiting list. But the rules have created another lobbying extravaganza. The hundreds of regional transplant centers fear that the HHS rules could force some of them to close.

Along with the United Network for Organ Sharing (UNOS), they swung into action. Louisiana transplant centers lobbied a powerful ally, House Appropriations Committee chairman Bob Livingston, R-La., who added language to a supplemental appropriations bill that deferred implementation of the new rules until at least Oct. 1. (Louisiana law says organs must first be made available in the state.)

The transplant centers pressed their case with lobbyists from Patton Boggs and Van Scoyoc Associates Inc. They attacked the substance of HHS's sickest-first approach. "The Secretary's own regulation admits that the department's policy is likely to result in decreased survival, increased retransplantation, increased number of waiting-list patients and increased waiting times over all," said Martha M. Kendrick, a Patton Boggs partner who represents the Patient Access to Transplantation Coalition, a group of regional transplant centers.

The centers also mobilized home-state lawmakers. Of course, on Capitol Hill, this debate transcends ideology and party loyalty: Senators and House members from states with transplant centers trashed Shalala's rules.

K STREET'S SCALPELS ARE OUT OVER HHS'S TRANSPLANT REGS.

Almost sheepishly, Lawrence G. Hunsicker, UNOS's immediate past president, admitted that his group followed the tactics of the major hospitals "to get heard."

But in a letter to Congress, Shalala blasted UNOS's "cynical, political" lobbying efforts. "UNOS has launched a campaign that factually misrepresents the department's interests in issuing the rule and mischaracterizes its provisions," she wrote.

Still, a cease-fire may be in the offing. Moreover, everyone agrees that the transplant debate should focus on increasing the number of available organs. Nobody needs to lobby on *that* issue. ■

Labor-HHS Bill Is Loaded With Hot-Button Issues

Democrats rage against cuts in summer jobs, home energy assistance and education, but budget caps limit options

As congressional Republicans and the White House head toward another fall showdown over federal spending, the fiscal 1999 Labor, Health and Human Services, and Education appropriations bill is shaping up as a political flashpoint.

The House Appropriations Committee approved its version of the measure, 32-23, on July 14, after adding amendments that would overturn a Clinton administration directive requiring states to cover the impotence drug Viagra under Medicaid; give women in managed-care plans easier access to gynecologists; and require clinics receiving federal family planning funds to notify parents before providing contraceptives to minors.

Democrats spent much of the markup session railing against provisions in the Republican-drafted bill that would eliminate summer jobs for poor youths, end the Low-Income Home Energy Assistance Program (LIHEAP) and reduce spending for President Clinton's education priorities.

Clinton himself stepped up the rhetoric, announcing in a strongly worded statement on July 14 that he would veto the bill — which would provide $81.9 billion in discretionary spending and $214.5 billion in mandatory funds — because it would deny education and training opportunities to students across the country.

"By turning their backs on America's young in this bill, the House Republicans are taking a step backward," Clinton said in a statement.

The White House Office of Management and Budget sent the committee a nine-page letter outlining specific objections, ranging from the measure's two-year time limit on federal bilingual education aid to provisions that it said would weaken federal labor law.

Despite the tough talk, however, Democrats made few moves to restore education and social service spending cuts during the more than four-hour committee session.

The truth is that Democrats face the same constraints that, in part, forced Republicans to make the cuts: tight spending caps imposed under the 1997 balanced-budget law (PL 105-33). *(1997 CQ Weekly, p. 2992)*

To get around the caps and increase education and health programs, Clinton's fiscal 1999 budget relied on expected revenues from comprehensive tobacco legislation (S 1415) that would have raised $516 billion over 25 years. The bill was killed by Senate Republicans. *(CQ Weekly, p. 1669)*

Without additional tobacco revenues, Democrats must find offsetting spending cuts in order to increase aid for White House priorities.

"The Democrats' argument is not with us, their argument is with what their own leadership and the president of the United States agreed to last year," said Appropriations Committee Chairman Robert L. Livingston, R-La.

"What they really want is more money. If you're going to follow last year's balanced-budget act, there isn't any more," he said.

While some House Republican moderates have threatened to oppose the bill, Livingston said he believed it would pass. The legislation is tentatively scheduled for House floor debate before the end of the month.

A Senate Appropriations Committee aide said that chamber's panel might not mark up a companion bill until September.

Box Score

Bill:
Unnumbered House bill — Fiscal 1999 appropriations for the departments of Labor, Health and Human Services, and Education.

Latest action:
House Appropriations Committee approved June 14, 32-23.

Next likely action:
House floor consideration.

Reference:
Subcommittee approval, CQ Weekly, p. 1758.

Viagra for the Poor

Instead of focusing on provisions in the underlying bill, lawmakers spent most of the markup debating a series of policy riders.

Panel members, like the rest of American society, had sharp opinions about Viagra, the anti-impotence drug approved by the Food and Drug Administration earlier this year.

The administration on July 2 announced that state-run Medicaid programs, which provide health coverage for the poor, elderly and disabled, would cover Viagra when medically necessary. The directive was in keeping with overall policy requiring state Medicaid programs to cover FDA-approved medicines.

State governors, who jointly fund the Medicaid program, objected to the decision, citing lack of medical consensus on the need for the drug and the high cost, as much as $10 per dose.

David R. Obey, D-Wis., offered an amendment, approved by voice vote, that would bar use of federal funds to reimburse states for providing Viagra. The savings the amendment would generate — as much as $100 million — would instead be spent on mental health services to youth at risk of violent behavior.

"Given the mixed results so far with the drug in question, and given the fact that there are so many other health maladies that are not covered, there is no need at this time to use scarce Medicaid dollars for Viagra," Obey said.

The committee by voice vote later

By Sue Kirchhoff

Labor-HHS-Education Spending

Unnumbered bill as approved by the House Appropriations Committee on July 14
(in thousands of dollars of new budget authority)

	Fiscal 1998 Appropriation	Clinton Request	House Committee
Labor Department			
Training and employment services	$ 5,232,737	$ 5,323,373	$ 3,750,873
Trade adjustment, allowances	349,000	360,700	360,700
Unemployment insurance (advance)	392,000	357,000	357,000
Trust fund	*3,273,621*	*3,206,076*	*3,122,476*
Black lung disability	1,007,000	1,021,000	1,021,000
Occupational Safety & Health	336,678	355,045	336,678
Other	2,026,543	2,074,483	2,016,079
Total, Labor Department	**$ 9,343,958**	**$ 9,491,601**	**$ 7,842,330**
Health and Human Services			
Public Health			
Health resources and services	3,661,720	3,826,256	3,947,810
Ryan White AIDS program	*1,149,512*	*1,312,982*	*1,330,600*
Disease control	2,332,638	2,454,459	2,540,433
National Institutes of Health	13,622,386	14,763,313	14,862,023
Substance abuse/mental health	2,147,156	2,274,643	2,418,005
Health care financing			
Medicaid grants to states	100,959,559	107,916,644	107,916,644
Medicare and other Medicaid	60,904,000	62,953,000	62,953,000
Public Welfare			
Low-income home energy assistance	1,000,000	1,100,000	0
Refugee assistance	415,000	415,000	415,165
Community services block grants	489,685	489,100	500,000
Child care block grant	1,002,672	1,176,672	1,000,000
Social Services block grants	2,299,000	1,909,000	2,299,000
Head Start	4,347,433	4,660,000	4,500,000
Programs for the aging	871,020	871,050	861,020
Foster care, adoption assistance	4,311,000	5,141,500	4,921,500
Other, including recissions	-4,477,906	347,364	20,289
Total, HHS	**$ 193,885,363**	**$ 210,298,001**	**$ 209,154,889**
Education Department			
Elementary and Secondary Education			
Goals 2000	491,000	501,000	245,500
Compensatory education (Title 1)	8,021,827	8,495,882	8,056,152
Impact aid	808,000	696,000	848,000
School improvement	1,541,188	1,475,800	1,536,834
Bilingual, immigrant education	354,000	387,000	354,000
Special education	4,531,685	4,554,685	4,824,685
Higher Education			
Pell grants, student financial aid	7,344,934	7,594,000	8,218,429
Guaranteed student loans	46,482	48,482	48,482
Higher education grants	943,738	1,288,405	944,198
Vocational, adult education	1,147,147	1,150,147	1,153,247
Rehabilitation services	2,591,195	2,645,266	2,646,640
Education research	431,438	689,367	447,667
Other	3,897,082	4,064,534	3,638,998
Total, Education Department	**$ 32,149,716**	**$ 33,590,568**	**$ 32,962,832**
Domestic Volunteer Service Programs	256,604	278,422	251,369
Corporation for Public Broadcasting	300,000	340,000	340,000
Supplemental Security Income	16,370,000	21,797,000	21,747,000
Other related agencies	9,951,776	10,811,247	10,751,172
GRAND TOTAL	**$ 262,257,417**	**$ 286,606,839**	**$ 283,049,592**
Trust Funds	*$ 9,663,495*	*$ 9,678,172*	*$ 9,576,963*

SOURCE: *House Appropriations Committee*

adopted an amendment by Mark W. Neumann, R-Wis., drafted with the aid of the National Governors' Association, that would bar use of federal funds to punish states that chose not to offer Viagra. States could still use their own funds to provide the drug.

Finally, the panel approved a third amendment by Randy "Duke" Cunningham, R-Calif., that would allow federal funds for Viagra in post-surgical treatment, such as in cases of prostate cancer.

Managed Care

By a 29-25 vote, the committee approved an amendment by Nita M. Lowey, D-N.Y., that would allow women to designate obstetrician-gynecologists as their primary care physicians in both private and federal managed care plans. It would also ensure that women who did not choose their gynecologist as their main doctor would have direct access to routine obgyn services without first having to get authorization.

Approval of Lowey's amendment reflected the sensitivity of both parties to voter concerns about the quality of care in managed-care plans, which is emerging as a top political issue. Both Republicans and Democrats have introduced broader proposals to expand patients' rights that include provisions similar to Lowey's. *(Health plans, p. 1933)*

"If we can't deliver on a patients' bill of rights, let's simply deliver on this," Lowey said.

By voice vote, the committee adopted an amendment by Carrie P. Meek, D-Fla., to add a new label to cigarettes warning of the particular health risks of smoking for African-Americans. Two studies released this month found that African-Americans absorb more nicotine than other smokers, which may be one reason they are more likely to develop lung cancer.

The Meek amendment would add a fifth warning label to the four warning labels that now rotate on cigarette packages. It would read, "Surgeon General's Warning: African-Americans suffer the highest death rates from several diseases caused by smoking."

The committee approved, 32-24, an amendment by Ernest Istook, R-Okla., that would require clinics receiving Title X family planning funds to notify parents in writing at least five business days before dispensing contraceptives to minors. A second provision, adopted 56-0, would require clinics to comply with state laws requiring notification of sexual abuse, rape, incest or other crimes.

On a 26-26 vote, the committee defeated an effort by Todd Tiahrt, R-Kan., that would have required family planning groups receiving Title X funds to physically separate abortion and family planning activities.

The Istook and Tiahrt amendments were supported by Christian conservatives, who have criticized the House Republican leadership for paying too little attention to their core issues. House Majority Whip Tom DeLay, R-Texas, a member of the committee who was absent for most of the proceedings, showed up for the family planning votes.

Mine Safety

The committee defeated, 19-33, an amendment by Rosa DeLauro, D-Conn., that would have eliminated a rider that has been attached to the bill every year since 1979 barring the Labor Department's Office of Mine Safety and Health Administration from enforcing training requirements in sand and gravel pits.

The ban was originally based on concern that safety standards developed for coal mines were not applicable to open-pit quarries. But DeLauro said that 600 workers have died in quarries since the safety agency was first barred from enforcing training rules.

"It is time to take the preventive measure of eliminating this rider," DeLauro said.

Labor-HHS Subcommittee Chairman John Edward Porter, R-Ill., and Anne M. Northup, R-Ky., argued against removing the rider, saying the industry and administration were meeting to try to reach a compromise. They said that if the rider was removed, there would be no incentive for the two sides to reach an agreement.

"We all want the same thing, and that is to have safety in the workplace," Northup argued.

In one of the few efforts to alter the spending priorities in the underlying bill, Steny H. Hoyer, D-Md., offered an amendment to eliminate a provision that would allow states to roll Clinton's Goals 2000 education improvement program, as well as the Eisenhower grants program for teacher training, into an existing block grant and use the funding for other purposes. It failed, 24-29.

Spending Reductions

The bill would eliminate the $1.1 billion LIHEAP program and would not include any funds for summer jobs for low-income youths in fiscal 1999, a savings of $871 million. Those reductions would help pay for a $1.2 billion increase for the National Institutes of Health.

Republicans included no funding for Clinton's proposal to hire 100,000 new teachers and reduce average class size in early grades, which was to be funded partly through tobacco revenues.

The bill would bar the administration from implementing voluntary national math and reading tests, limit student participation in federally funded bilingual education programs to two years and deny federal funds to schools unless they install software on their computers to block students from accessing pornography on the Internet.

It would bar the Health and Human Services Department from implementing pending rules to transform the way organs are distributed for transplantation, from a system based regionally to one based on medical need. *(CQ Weekly, p. 1691)*

However, the bill would increase funding for some education programs, including aid to disabled students. It raises the maximum Pell Grant for disadvantaged college students by $150 to $3,150 per year, above the administration request.

The bill also would increase funding for the Centers for Disease Control and Prevention, the Head Start preschool program, and breast and cervical cancer screening, among other programs.

OMB said that, overall, the bill was $2 billion below Clinton's request for education spending. Acting OMB Director Jacob J. Lew said the administration was willing to work with Republicans to find either spending offsets or user fees to increase funding. Democrats have offered few proposals.

"Your side has had an opportunity for the last four hours to shape the bill in a different way. . . . The difficulty is that you can't bring yourselves to say 'no' to anything," said Porter.

He added that the Democrats' lack of spending restraint was a big reason that Republicans now control Congress. ◆

Return to Breaking News

UNOS News Release

For Immediate Release:
June 26, 1998

Contact: Bob Spieldenner
UNOS News Bureau (804) 327-1432

National Heart Distribution Policy to Change

Ft. Worth, TX – An improved method for ensuring equitable distribution of hearts to patients waiting for transplants was approved yesterday at the United Network for Organ Sharing (UNOS) Board Meeting. The system, which will go into effect in late 1998, establishes more objective medical urgency status levels and gives priority to pediatric patients for hearts retrieved from adolescent donors.

Since the present heart distribution policy was implemented nine years ago there have been many medical advances, especially with mechanical assist devices. The improved three-tiered system reflects those advances and includes the following status levels:

- **Status 1A** – Includes critically ill patients who require continuous inotropic drug therapy or mechanical assistance (e.g. artificial heart or ventricular assist device) and have a life expectancy of less than one month without transplantation.
- **Status 1B** – Includes medically stable patients who require continuous inotropic drug therapy or mechanical assistance and have a life expectancy greater than one month.
- **Status 2** – Includes patients with chronic heart failure who do not meet the higher urgency criteria for Status 1A or 1B listing.

"This improved system ensures that patients who have the most urgent medical need for a transplant and who have a high likelihood of survival following surgery will have the best chance of getting a heart," said UNOS President Larry Hunsicker, M.D.

"No patient who is currently listed at the highest medical urgency will see their status downgraded when the improved system takes effect. Patients who are listed as Status 1 will become Status 1A under the new system," Hunsicker added. The change will only affect patients not currently on the waiting list.

Also, the improved system creates 11 regional thoracic organ review boards, which will review Status 1A patient listings to make sure they are listed by the correct medical urgency status. The boards will periodically review Status 1B and Status 2 patient listings, as well.

Before the UNOS board voted yesterday, the proposed system received extensive medical and public review, including a public forum held in September 1997. Many of the comments received produced changes to the final system.

Pediatric heart policy changes

The improved system also set specific medical urgency status levels for patients less than 18 years of age that reflect the difference in heart disease progression between children and adults.

In addition to the pediatric status levels, the improved system specifies that pediatric patients (0–17 years of age) will be considered before adult patients of similar medical urgency for hearts from adolescent donors (ages 11-17). For example, a heart from a 15-year-old donor would be offered to a Status 1A pediatric patient before being offered to a Status 1A adult patient.

UNOS data show that with the change, graft survival for adolescent patients could improve without negatively impacting other patient groups. Potentially, the one-year mortality rate for adolescent heart recipients could be reduced by more than one-third and the three-year mortality rate by one-half.

"Generally, we think everyone does well with a younger donor," said Dr. Mark Boucek, Chief of Pediatric Cardiology at The Children's Hospital in Denver and Chairman of the UNOS Pediatric Transplantation Committee. "But the data indicate that while receiving an adolescent donor heart doesn't affect adults, age matching means a lot to pediatric patients."

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cc's Jan Klein

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

June 11, 1998

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

Dear Hillary:

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

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

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

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

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

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

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

Sincerely yours,

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

BAL/sam

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

Network for Heart Transplants to Give Sickest Patients Pr

By LAURA MECKLER
Associated Press

In a little-noticed move, the network that runs the nation's transplant system has changed its policy for allocating hearts to make sure the sickest patients get first crack at available organs.

But the new heart allocation policy still relies on geographic boundaries, which are at the center of a heated dispute between the network and the U.S. Department of Health and Human Services.

The change, in the works for more than a year, creates a new category for heart patients expected to die within 30 days without a transplant. It will take effect in late 1998.

Under old classifications, the most urgent category included all critically ill patients who depended on certain drugs or mechanical devices, no matter what their life expectancy. It was developed before such devices were widely and successfully used and allowed people who were not even in the hospital to qualify for the most urgent listing.

Under the new policy, hearts still will be allocated to the sickest patients within the local area first, then to the less urgent—but still local—patients. If there are no local matches, they will be offered to patients within a 500-mile radius, in order of medical urgency.

"We're not changing the philosophy, we're changing the way we're measuring and defining urgency," said Walter Graham, executive director of the United Network for Organ Sharing.

Under a regulation proposed early this year, HHS ordered the network to develop new policies that give priority to the sickest patients, no matter where they live. The network is lobbying Congress to overturn these rules before they become final.

Still, John Nelson, a top HHS official overseeing the network, notes that the new heart policy accomplishes some of what HHS wants: It makes certain that only the most critically ill patients are listed in the most urgent category, and it grandfathers patients currently waiting under the old rules.

"It should show everyone we're probably closer than they thought," Nelson said.

The new heart policy also gives pediatric heart patients first chance at hearts donated by adolescents.

Patients under age 18 will be considered for hearts from donors aged 11 to 18 before adults of the same medical urgency. Data show that receiving a younger heart significantly improves the survival chances for children but does not make much of a difference to a

In determining urgency, th policy creates three categories for patients awaiting transplants.

"Status 1A" patients, those expected to die within 30 days, will get first chance at a donated heart.

"Status 1B" patients will get the second chance. That includes people who depend on certain drugs or mechanical devices but who are medically stable and expected to live more than a month.

"Status 2" patients include all other transplant candidates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Health Resources and Services Administration
Rockville, MD 20857

HHS to Congress UNOS

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

Dear Dr. Hunsicker:

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

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

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

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

Our second challenge is addressed by HHS' organ network regulations which ask the transplant community to formulate new policies to eliminate the unfairness caused by the existing allocation systems. The regulations require the organ network, in devising the policies, to meet three broad performance goals: 1) standardization of listing criteria; 2) standardization of determining medical status of patients; and 3) that medical urgency, determined by the exercise of sound medical judgment, not geography, be the main criterion for allocating organs. All three elements are necessary in our effort to achieve the best results for patients.

The regulations, which we first proposed in 1994, reflect substantial written public comments as well as testimony received during three days of public hearings in December 1996. UNOS responded to the published rule in writing and testified about the issues addressed by the rule at the 1996 hearings.

You have a third opportunity for formal input, now on the newly-published final rule.

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

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

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

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

UNOS claim:

1. UNOS claim:

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

The facts:

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

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

policy whose disadvantages outweigh its advantages.

2. UNOS claim:

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

The facts:

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

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

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

3. UNOS claim:

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

The facts:

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

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

4. UNOS claim:

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

The facts:

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

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

5. UNOS claim:

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

The facts:

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

6. UNOS claim:

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

The facts:

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

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

7. UNOS claim:

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

The facts:

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

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

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

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

Throughout the development of our regulations, this Department has created many opportunities for UNOS, the transplant community and the public to participate in the process. At this Department's 1996 public hearings on donation and allocation, UNOS was the first organization to present its views. More recently, the Department's Science Advisor and I met on several occasions with Dr. Burdick, then President of UNOS' Board and other UNOS staff to keep them informed of the Department's preliminary thinking and to receive feedback. On the day the regulation was announced, HHS staff met at length with and briefed you and your staff on the particulars of the regulation and committed, yet again, to working with you and others in the transplant community to develop policies that treat patients fairly.

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

Sincerely,

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

Return to Secretary's letter

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

cc's Jean Klein

ARKANSAS CHILDREN'S HOSPITAL

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

June 11, 1998

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

Dear Hillary:

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

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

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

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

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

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

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

Sincerely yours,

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

BAL/sam

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

THE WHITE HOUSE

July 4, 1998

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

Dear Betty:

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

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

Sincerely yours,

Hillary

Hillary Rodham Clinton

July 13, 1998

MEMORANDUM

To: Jennifer

From: Debra

Re: Update on Organ Transplant Allocation

As requested, the following is an addendum to Susan's memo highlighting the fundamentals of the allocation policy debate, and an update on the political outlook for the HHS regs concerning organ transplant policy.

Note: There are two recent federal regulations concerning organ transplantation. The first intends to increase organ donation by requiring hospitals participating in Medicare or Medicaid to report to organ procurement organizations all deaths so that medically suitable donors can be more readily identified. The goal is to increase organ donation by 20 percent. The second set of regulations involves the allocation process we have been researching.

Overview:

The debate over the proposed HHS regulations on transplant organ allocation is heating up on Capitol Hill. Secretary Shalala testified before a Joint Hearing of the Senate Labor and Human Resources Committee and House Commerce Committee on June 18 in vigorous support of the regulations and of allocating organs according to medical need as the top priority. Although the regulations remain in an "public comment period" until August 31, 1998, Jackie White, Deputy Executive Secretary at HRSA, indicated that the agency is likely to maintain the position Shalala has outlined.

The federal rules are likely to face troubled waters ahead with strong opposition from leading members in both the House and the Senate. In fact, House Appropriations Chairman Bob Livingston (R-LA) has attached a rider to the FY99 Labor/HHS Approps bill which would delay implementation of the HHS regs (already delayed until October 1998) until November, 1999. The approps bill has only passed through subcommittee in the House so far, and the debate is only expected to intensify from all sides.

Rationale from the Federal Regs:

I have a copy of the federal regs on transplant organ allocation policy. The following are highlights of the points supporting the policy.

- The current allocation system remains heavily weighted to the local use of organs instead of making organs available on a broader regional or national basis for

patients with the greatest medical need **consistent with sound medical judgment.**

- Criteria used in listing those who need transplantation vary from one center to the next, as do the criteria used to determine the medical status of patients.
- Waiting times for organs are much longer in some geographic areas than in others. Less ill patients may receive transplants while more severely ill patients, maybe a few miles away, may die.
- A recent report from the HHS Inspector General found that inequities among patients and transplant centers still exist and may have worsened.

The Secretary, in her June 18 testimony, emphasized that the regulations do not prescribe any particular policy, but rather recommend that medical need, and not geography, becomes the top consideration for deciding who receives organs. In addition, the rules recommend establishing standard criteria for placing patients on the waiting list and determining medical status

The Political Landscape:

The HHS regulations are becoming increasingly controversial as more political players and advocates have taken public positions opposing the policies.

In addition to the Chairman of the House Appropriations Committee, HHS is facing considerable opposition from the Hill. House Commerce Health and Environment Subcommittee Chairman Mike Bilirakis (R-FL), who co-chaired the June 18 hearing, argues that the regs will weaken successful organ donation programs, such as the one in his state. He believes that Americans will be less likely to donate if they believe their organs may be transported out of state. House Commerce Committee Chairman Thomas Bliley (R-VA) believes that the issue of organ allocation remains outside of the purview of Congress or the federal Government, and Senator Bill Frist (R-TN) has been publicly worrying that the regs will force some medical centers to close, because organs would be redirected to larger centers with longer waiting lists.

UNOS, the United Network for Organ Sharing which operates the transplant program, has publicly opposed the regulations and is said to have hired a high powered lobbying firm to increase pressure on Members of Congress. The University of Pittsburgh Medical Center, regarded as the nation's premier transplant center, would benefit under the new HHS policy, has hired former House Minority Leader Robert Michel (R-IL)

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

Executive Secretariat

FACSIMILE

PLEASE NOTIFY OR HAND-CARRY THIS TRANSMISSION TO THE FOLLOWING PERSON AS SOON AS POSSIBLE:

Name: Debbie Waxman

Address: _____

Message: Per our discussion.

Telephone: Office: _____ FAX: _____

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FROM: Jackie White

FAX NUMBER: _____
OFFICE NUMBER: 202 690 6141

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

FOR RELEASE UPON DELIVERY

TESTIMONY OF

DONNA E. SHALALA

SECRETARY OF HEALTH AND HUMAN SERVICES

BEFORE THE

SENATE LABOR AND HUMAN RESOURCES

AND

HOUSE COMMERCE COMMITTEES

JOINT HEARING ON ORGAN DONATION ALLOCATION

JUNE 18, 1998

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

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

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

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

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

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

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

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

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

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

Approximately 10,000 to 15,000 deaths in the United States each year could result in viable organ donation. But only 5,500 cadaveric donors, about one half to one third of all potential donors, contribute organs for transplantation. While the number of cadaveric organ donors has increased by 30 percent, the number of deaths on the waiting lists has also grown, by nearly 177 percent during the same period.

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

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

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

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

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

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

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

In 1991, the HHS Inspector General found that the national Organ Procurement and Transplantation network was inequitable, particularly with respect to race and geography, and that it did not meet the intent of the 1984 Act. As you know, the Office of Inspector General is an

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

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

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

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

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

These waiting list disparities are the most visible shortcoming of the current system. Less visible are the resulting inequities among those who receive organs. Where waiting times are the shortest, organs may go to patients who are less ill; while at the same moment, in areas where patients wait longer, organs often are not offered to patients with greater medical need. In the worst cases, patients die in areas where waiting times are long, while, at the same time, organs are being made available to less ill patients in areas with shorter waiting times.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Lawmakers Undecided on Taking Lives Into Congress' Hands

Members debate whether to delay regulations that allocate organs for transplant on basis of medical need instead of locality

In his days as a surgeon, Sen. Bill Frist, R-Tenn., carried with him a list of 20 patients who were waiting for a heart or a lung for a transplant that would save their lives.

"I realized every time I looked at that card . . . one out of four would die," Frist testified at a contentious joint committee hearing June 18 on organ allocation. "That's the sort of issue we're dealing with: Who lives and who dies."

His fellow lawmakers are now having to confront the same questions as Congress considers whether to get involved in a thorny battle over the nation's organ allocation system.

At issue are new Health and Human Services (HHS) regulations that would transform the way organs are distributed for transplantation from a system based regionally to one in which medical necessity, not geography, is the primary factor in determining who receives the organs.

The proposed changes were supposed to take effect July 1, but that deadline was delayed until Oct. 1 as part of the 1998 supplemental spending measure (PL 105-174) signed into law May 1. *(Supplemental, CQ Weekly, p. 1132)*

Now, some lawmakers want to postpone by one year the effective date of the rules. It is unclear, however, if Congress will act on the issue.

"The question before us today is what the government can and should do" to fix the problem, said Michael Bilirakis, R-Fla., chairman of the House Commerce Health and Environment Subcommittee, which held the joint hearing with the Senate Labor and Human Resources Committee.

House Commerce Committee Chairman Thomas J. Bliley Jr., R-Va., said that Congress had no role whatsoever in the issue.

"No president, no legislature, no judge and certainly no bureaucracy has the competence to make the life-and-death decisions for allocating organs," he said.

Testifying at the hearing, HHS Secretary Donna E. Shalala defended the proposed regulations, saying medical need, not geography, should be the top criterion for deciding who receives organs for transplantation.

"Put simply: Organs should follow people. People shouldn't follow organs," Shalala said.

Shalala and other proponents of the new regulations said that advances in preservation technology mean that organs can be transported from region to region more easily.

Regional Disparities

Currently, most organs that become available are matched first to a list of patients in the local area, then in the region. If no match is made on the regional list, then the organ is made available to patients nationwide.

"Patients in some parts of the country can wait as much as five times longer than patients in other parts of the country who have the same severity of illness," Shalala said. "Less ill patients receive transplants while more severely ill patients, perhaps only a few miles away, die."

Shalala said that a recent report released by the HHS inspector general bolsters her case. The report found that inequities identified in 1991 in the nation's transplant system remain and in some cases have worsened. The need is acute because there is greater demand for organs than existing supply can meet, with currently more than 56,000 people on waiting lists for organ transplants. Every day, Shalala said, more than 10 die while waiting.

"We need a level playing field so that the same medical criteria are used for all patients — and so that organs are allocated according to medical need," Shalala told the panel.

Shalala stressed that the exact wording of the policy will be developed by the independent agency that contracts with HHS to run the nation's transplant system, the United Network for Organ Sharing. She said HHS has intentionally steered clear of mandating an allocation policy.

But Frist and other lawmakers said they feared that the proposed changes would cause some medical centers to close, because organs would be directed to larger centers with the longest list of patients. And members from states with smaller transplant centers said they feared the proposed policy would hurt local programs.

By Mary Agnes Carey

Quick Contents

Proposed new regulations that would move the system allocating organs for transplants toward a single national program have generated fierce debate on Capitol Hill. But it is unclear whether lawmakers will act to block the new rules.

Shalala said such fears were unfounded. "There is no suggestion here there would be a rigid, centralized system," she said. "The point here is to make sure that where you live doesn't result in discrimination."

Bilirakis said the proposed policy would weaken organ donation programs such as the one in Florida, a state that has successfully increased the number of donations in recent years. He said that if people thought the organs would be transported out of state, they might be less willing to become donors.

But others said the changes would benefit many patients, especially minorities in urban areas that may be punished by the current geographic focus that dominates who receives available organs.

"The new rule is humane and just," said Rep. Louis Stokes, D-Ohio.

Regional Interests

The network that operates the transplant program has been at odds with HHS over changes to the current regulations governing organ donation, and has said they could force smaller transplant centers out of business.

"Medium and small transplant programs alike are deeply concerned that a policy that focuses so heavily on waiting time will result in organs not being made available to them frequently enough to sustain a viable program," said Dr. Lawrence G. Hunsicker, president of the United Network for Organ Sharing.

Hunsicker said the new policy will result in "significantly lower survival rates, fewer people transplanted, longer waiting lists and patients waiting almost twice as long for a transplant. It will also result in poorer outcomes because patients will be much sicker at the time of transplantation."

Dr. Michael E. DeBakey, a world-renowned heart surgeon, said the new regulations could unintentionally cause some transplant centers to close.

"Organs are in desperately short supply, and reallocating them to a few large transplant centers could deprive patients of life-saving care close to home, forcing them to travel great distances to get a transplant," he wrote in a June 17 letter to members of Congress.

But Sen. Bob Kerrey, D-Neb., said the proposed changes would even out the regional disparity in waiting periods for potential recipients.

"I am particularly troubled by the geographic disparities in waiting times," he said. "This variation means that whether you live or die can be determined by where you live . . . not by your medical need or your prospects for a successful transplant."

Rep. Sherrod Brown, D-Ohio, said the proposed regulations would provide greater equality for patients awaiting an organ transplant.

"While the final judgment concerning who receives a lifesaving organ should always rest with the transplant surgeon, I believe a patient seeking an organ transplant in Ohio should have the same chance to receive this gift of life as a patient who lives in Oregon," Brown said.

Critics of the proposed rules, such as Sen. Robert G. Torricelli, D-N.J., argued that it would increase waiting periods rather than decrease them. Torricelli introduced legislation that would delay implementation of the rules for one year and require a study to gauge the impact of the rules on community-based programs and low-income patients.

"Removing the geographic criteria for organ allocation will shift donated organs away from community-based facilities, like those in New Jersey, to a handful of large transplant centers that have the longest waiting lists," he said.

Sen. Ernest F. Hollings, D-S.C., also urged Shalala to leave well enough alone. "Don't mess it up with a 'sickest first' kind of nonsense," he said.

Sen. Rick Santorum, R-Pa., said lawmakers were pursuing the issue "like a highway bill, bringing pork to their districts."

Instead of defending what was best for their home turf, Santorum argued that lawmakers should instead focus on what will benefit patients most. Pennsylvania is home to the University of Pittsburgh, one of the nation's largest liver transplant centers that stands to benefit under the new HHS policy.

Bruce Weir, president of a patient's group called Transplant Recipients International Organization, Inc., took aim at the idea that organ donations would drop if the current policy were changed.

"Donor families tell us that geography was the last thing they would have thought of. They only hoped their gift would save a life," he said.

The complexities surrounding the organ donation issue made it hard for some lawmakers, even an experienced transplant surgeon such as Frist, to determine what road Congress should take on the issue.

"When there are not enough organs to go around, and life and death hang in the balance, medical decision-making must be above reproach," Frist said. "There is something that seems inherently unfair in giving an organ to one person over another, yet we know that we must find some way to allocate scarce organs to the many who desperately need them." ◆

CQ PHOTO / DOUGLAS GRAHAM

Frist, a transplant surgeon, told the joint committee that the organ donation policy is a question of "who lives and who dies."

*States passing laws to clash w/ HHS regulation

USA TODAY · TUESDAY, JUNE 16, 1998

Organ-preference laws clash with federal rule

By Mark Glassman
USA TODAY

Wisconsin Gov. Tommy Thompson is expected to sign a bill at the end of this month that promises state residents preferential consideration for organ transplants over potentially more critical patients who live outside the state.

Wisconsin would become the fourth state to pass the controversial "organs-for-state-residents-first" law. Oklahoma, Louisiana and South Carolina have passed similar laws, and at least two states have bills pending.

The laws put the states at odds with a regulation issued April 2 by Department of Health and Human Services (HHS) Secretary Donna Shalala. That regulation advocates the distribution of organs to patients based on relative medical need and minimizing waiting times, rather than simple geography. The rule is scheduled to take effect Oct. 1.

"The regulation proposed by HHS would pre-empt any state statutes," says Claude Earl Fox III, who heads the Health Resources and Services Administration of HHS. "It's best for the patient and the transplant community."

By Richard Ellis, NBC

Shalala: Her regulation states organ donations should be based on need.

Today, 60,000 people await organ transplants; and every day, 10 people die while waiting.

"The unfortunate thing is that in a state like New York, the proportion of donors to the population is not as great as it is in a state like Oklahoma," says Oklahoma state Sen. Angela Monson, who helped draft a bill similar to the Wisconsin law. "We think this is a more fair way to do it."

Since large states like New York are more densely populated than Wisconsin, those states contain more patients in urgent need of transplants. So under the new system proposed by HHS, New York would get more organs.

But donation rates are higher in Wisconsin than they are in New York, according to the United Network for Organ Sharing. Twenty-seven organs were donated for every million people in 1996 in Wisconsin, and in New York only 17 organs were donated per million.

So, the federal rule "punishes those states who happen to be of a smaller population and happen to do well in organ donation," says Monson. "It sets up a real disincentive for those states to get the numbers."

The Oklahoma law also calls for a "reciprocal agreement" with states that request Oklahoma organs, demanding a kidney coming in for every kidney going out.

"I understand the value of a national network, but I also understand the value of a network that brings it a little closer to home," says Monson. "It would be nice to know that the kid down the street or around the corner had an opportunity to share the gift of life with an Oklahoman."

But the Department of Health and Human Resources considers donations a national resource first.

"I don't believe (the state law) is to the benefit of the transplant patients or the transplant community," Fox says.

And in the face of an organ shortage, other organizations frown on such state pride.

"Donors' families do not care where their donors' organs go," says Lisa Kory, executive director of the Transplant Recipients International Organization.

"If you truly believe that organs are a national resource, then (state residence) doesn't matter" Kory says.