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DEPARTMENT OF HEALTH AND HUMAN SERVICES — Health Care Financing Administration

Press Office
200 Independence Ave., S.W.
Room 303-D
Washington, D.C. 20201
(202) 690-6145 Phone
(202) 690-7159 Fax

FAX TRANSMISSION

To: CHRIS JENNINGS **Date:** 11/23/99

Fax: 456-5557 **Pages:** 3 **including this cover sheet.**

Phone:

From: **Chris Peacock**

Subject:

HERE'S THE RELEASE FROM TODAY'S CALL.

NYT'S DENISE GRADY IS DOING STORY TO RUN THURSDAY. IT'LL MENTION THIS, BUT ALSO ANOTHER STUDY IN THE NEJM ON MORTALITY RATES AT FOR-PROFIT DIALYSIS CENTERS DROPPING. WE COORDINATED A RESPONSE WITH ASPA.

[redacted]

I'M OUT WEDNESDAY. CAM GARDETT AND/OR CRAIG PALOSKY HAVE BACKGROUND.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Press Office
Washington, DC 20201

MEDICARE NEWS

EMBARGOED FOR 5:00 P.M. RELEASE
Wednesday, November 24, 1999

CONTACT: HCFA Press Office
(202) 690-6145

HCFA ANNOUNCES NEW STEPS FOR RACIAL EQUALITY IN KIDNEY TRANSPLANTATION

The Health Care Financing Administration announced today that the Medicare program is taking new steps to ensure that all patients with renal failure, regardless of race or ethnicity, are being evaluated for kidney transplantation.

The effort will include communication, enforcement and technical assistance to dialysis centers, which are required by regulation to assure that all patients in the facility are assessed for and fully informed about their suitability for transplantation as part of the patient's long-term care plan.

"Medicare rules require that all patients with kidney failure be evaluated and informed about transplantation," said HCFA Administrator Nancy-Ann DeParle. "We want to be sure this is happening and be sure there is equal opportunity for transplantation when needed, regardless of a patient's race."

The Medicare program provides insurance coverage for most Americans with permanent kidney failure, paying for dialysis treatment and transplantation through the End State Renal Disease (ESRD) program. Medicare covers a total of 310,000 ESRD patients, with estimated fiscal year 1999 spending of $11.8 billion.

HCFA's announcement was made as a study by John Ayanian, M.D., and colleagues at Harvard Medical School appeared in the New England Journal of Medicine. The investigators interviewed a sample of patients with kidney failure and found that black end stage renal disease (ESRD) patients were less likely than white ESRD patients to want a transplant (76.3 percent vs. 79.3 percent among women, and 80.7 percent vs. 85.5 percent among men).

Racial differences were substantially greater in rates of referral for a transplant evaluation (50.4 percent for black woman and 70.5 percent for white women, and 53.9 percent for black men vs. 76.2 percent for white men) and placement on a waiting list for transplantation within 18 months after starting dialysis (31.3 percent for black women vs. 56.5 percent for white women, and 35.3 percent for black men vs. 60.6 percent for white men). These racial differences remained significant after adjusting for patients' preferences and expectations about transplantations, sociodemographic characteristics, health status, perceptions of care and comorbid illnesses.

Medicare will take a three-pronged approach to addressing transplant assessment disparities:

First, the program will remind all certified dialysis facilities of its requirements that all ESRD patients are to be assessed for and fully informed about transplantation as part of the patient's long-term care plan.

Second, HCFA will work with the State Survey Agencies in evaluating the study findings and paying particular attention to dialysis facility compliance with regulations. State Survey Agencies inspect ESRD and other health care facilities to determine their compliance with Medicare certification requirements.

Finally, Medicare will work with the ESRD Network Organizations to identify ways that the Networks can work with the patients, the renal community, and the dialysis facilities in their area to increase transplant assessment rates. ESRD Network Organizations monitor the quality of care provided in dialysis facilities and assist facilities to improve patient care as opportunities present themselves.

"All three approaches will enforce and reinforce Medicare's commitment to its ESRD beneficiaries by assuring that they will receive the quality of care that they depend on, including the opportunity to be fully informed about and assessed for transplantation," DeParle said.

RICK SANTORUM
PENNSYLVANIA

COMMITTEES:
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United States Senate
WASHINGTON, DC 20510-3804
202-224-6324

November 15, 1999

The Honorable Trent Lott
Majority Leader
United States Senate
S-230, The Capitol
Washington, D.C. 20510

Dear Senator Lott:

I am pleased that Congressional leaders and the administration recently reached a consensus agreement concerning the implementation date for a new regulation (the revised Final Rule) aimed at modernizing our national organ transplantation and allocation system.

It is my understanding that the revised Final Rule, first proposed in February 1998 by the Secretary of Health and Human Services, will go into effect six weeks after the FY2000 Labor-HHS appropriations bill becomes law. This would presumably entail a 21-day period for public comment and then an additional 21 days for the Secretary to review those comments.

As you know, I have been active in the debate to maintain the most equitable and advanced transplantation system. I want to ensure that this good-faith, above-the-board agreement on implementing the revised Final Rule is not subverted by countervailing legislative language. Therefore, I ask that I be notified immediately should any amendment, resolution, or sense of the Senate be offered or otherwise come under consideration by the Senate that addresses this subject either directly or indirectly. I would also appreciate being notified prior to any unanimous consent being granted or the disposal of any motion with regard to any Senate action on this subject matter.

Thank you for your assistance with this important matter.

Sincerely,

Rick

Rick Santorum

RJS/ps

RICK SANTORUM
PENNSYLVANIA

COMMITTEES:
AGRICULTURE
ARMED SERVICES
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Sincerely,

Rick Santorum

RJS/ps

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

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

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

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

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

Extended Moratorium Part of Calculated Strategy to Delay HHS Rule Indefinitely:
The bipartisan agreement reached last week includes report language expressing the intent of Congress to impose no further delay in the rule beyond the six week consultation period.

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

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

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

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

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

UNITED STATES SENATE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS
WASHINGTON, DC 20510-6300

DATE: 11/17/99

TO: Chris, Rich, Dan

FAX: _____

FROM: cybele

(202) 224-7675 phone
(202) 224-3533 fax

NUMBER OF PAGES: 2

MESSAGE: Organ letter on work incentives.

The final rule entitled "Organ Procurement and Transplantation Network", promulgated by the Secretary of Health and Human Services on April 2, 1998, together with the amendments to such rules promulgated on October 20, 1999 shall not become effective before the expiration of the 90-day period beginning on the date of enactment of this Act.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET

OFFICE OF HEALTH AND PERSONNEL
OLD EXECUTIVE OFFICE BUILDING, ROOM 238
FAX NUMBER: (202) 395-5631

FAX SHEET

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ROOM 416G, HUMPHREY BUILDING
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WASHINGTON, D.C. 20201

PHONE: (202) 690-7627 *FAX: (202) 690-7380*

OFFICE OF THE ASSISTANT SECRETARY FOR LEGISLATION
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REMARKS:

COPY FOR YOUR INFORMATION

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

OCT 27 1999

MEMORANDUM FOR THE PRESIDENT

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

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

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

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

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

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

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

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

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

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

Donna E. Shalala

Attachments

Wash. Post; 10-23-99

An End to Organ Games?

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

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

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

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

Ensuring a healthy system

Monday, October 25, 1999

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

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

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

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

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

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

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

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

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

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

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

THE NATION'S NEWSPAPER 50 CENTS

USA TODAY

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THE HIT HOLLYWOOD OVERLOOKED 1D

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Tuesday, October 19, 1999

'fairer' transplant rules set

HHS policies would reduce inequities in organ cases

By Robert Davis
USA TODAY

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

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

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

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

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

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

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

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

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

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

The rules call for UNOS to establish policies that would:

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

▶ Expand organ-sharing regions to ensure that organs reach patients who need them most. A recent report found that the [illegible]

Editorial

The New York Times

July 26, 1999

Improving Access to Organs

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

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

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

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

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

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

THE LANCET

Volume 352, Number 9122

Changing the US transplant system

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

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

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

On the face of it, it is hard to see what is objectionable about Shalala's proposal, but the response of the United Network of Organ Sharing (UNOS), the DHHS contractor that operates OPTN, has been furious. In a letter sent to every US Senator last spring the outgoing president of UNOS, L G Hunsicker, described the regulations as a "federalisation of the current system which takes away control of the transplant system from doctors and patients in almost 300 transplant centers and hands it over to Federal regulators" and forces doctors to give livers "to the very sickest patients", who are likely to require second or third transplants and thus use organs that could have gone to save other patients. Hunsicker predicts that the regulations will make it more difficult for most patients to receive a transplant because organs will be shunted towards a few large transplant centres with the longest waiting lists and the sickest patients.

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

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

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

The Lancet

Withdrawal/Redaction Sheet
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. letter	Charles Fiske to President Clinton re: phone number and address (partial) (1 page)	10/27/1998	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20464

FOLDER TITLE:
Organ Allocation [Folder 2]

2012-0463-S
rc802

RESTRICTION CODES

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

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

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

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Charles Fiske
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(home)

C0013

October 27, 1998

President William Clinton
White House
1600 Pennsylvania Ave
Washington, DC 20500

Dear Mr. President,

Within the HHS Appropriations bill there is rider to delay the HHS final transplant regulations for an additional number of months. Last year former Congressman Livingston insert a one year delay on the regulations and required that the Institute of Medicine study their affects. The results of that study supported the Department's regulations and concluded that patients would be better served with the broader sharing of donated organs and more HHS oversight would insure that the national transplant system run in the public's best interest. Some transplant center, dissatisfied with the IOM results have pressured their elected members to again protect their programs by seeking an additional delay. Secretary Shalala got it right last year and again is correct in her support of regulations that will benefit transplant patient no matter who they are or where they live. Any further delay in the implementation of those regulations will be harmful to the most vulnerable of patients. I would strongly urge you to request that Congress remove the additional moratorium for the HHS transplant regulations. The national transplant system must care for patients first before the financial concerns of transplant centers. Your careful consideration of this request is appreciated by thousands of patients currently awaiting life saving transplant surgery.

Enclosed is a copy of a recent Washington Post editorial that clearly states the urgency and necessity of removing the delay in the implementation of the HHS transplant regulations.

Sincerely,

Charles Fiske

Enc. 1

Washington Post

An End to Organ Games?

Saturday, October 23, 1999; Page A22

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

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

Behind these concerns -- for which a congressionally mandated report from the National Academy of Sciences' Institute of Medicine found no evidence -- is the fear that local centers would close, eliminating the substantial income source they represent for the hospitals that house them. That may explain the otherwise remarkable fact that 10 states responded to the proposed rule by passing laws making it more difficult to

send organs out of state. The Institute of Medicine report even cites cases where grieving families willing to donate were urged to sign contracts requiring that organs go only to in-state recipients.

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

5TH DISTRICT, MARYLAND

CO-CHAIR
DEMOCRATIC STEERING COMMITTEE

COMMISSION ON SECURITY AND
COOPERATION IN EUROPE

Congress of the United States
House of Representatives
Washington, DC 20515–2005

TREASURY, POSTAL SERVICE,
AND GENERAL GOVERNMENT

LABOR,
HEALTH AND HUMAN SERVICES,
AND EDUCATION

LEGISLATIVE

COMMITTEE ON
HOUSE ADMINISTRATION

A FAX REPORT FROM THE OFFICE
OF
CONGRESSMAN STENY H. HOYER

FAX....FAX....FAX....FAX....FAX....FAX....FAX....FAX....FAX....FAX....FAX...FAX...FAX.

TO: Chris Jennings

FAX NUMBER 456-5557

FROM: Sonya Clay of Congressman Hoyer & Stephanie Simon of Cong. Stark

SUBJECT: HHS regulation Concerning organ procurement & H.R. 2418

DATE: 11-3-99 PAGES TO FOLLOW: 3

WE CAN BE REACHED AT :
OFFICE.....202-225-4131
FAX.....202-225-4300

NOTES:

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

November 2, 1999

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

Dear President Clinton:

We commend the Secretary of Health and Human Services (HHS) for supporting patients nationwide by issuing a revised regulation concerning organ procurement and transplantation policies. The HHS regulation attempts to ensure that the sickest patients receive organs first rather than relying on geographic boundaries to determine whether a patient in need will receive a transplant.

The Secretary's revised organ allocation regulation incorporates the Institute of Medicine's (IoM) recommendations, as well as advice of the transplant community, patients and other members of the general public to ensure policies are more fair for Americans nationwide. As the IoM recommended, the Secretary's regulations ensure HHS exercises "legitimate oversight responsibilities," that allocation is based on "sound medical judgment," that organs are distributed "over as broad a geographic area as feasible," and that timely "data collection and dissemination" be improved. We believe the experts should dictate the details of organ allocation and the IoM strongly supports moving forward with the Secretary's regulations.

Despite the Secretary's positive steps, the DC/Labor-HHS Appropriations bill includes a 90-day moratorium on the Secretary's revised organ allocation regulation. This Labor-HHS rider will only cause needless deaths. We urge you to make the DC/Labor-HHS moratorium on the Secretary's organ allocation regulation one of the issues you cite in your veto message.

In addition to harming and killing patients awaiting organs during the moratorium, the delay may provide an opportunity to pass H.R. 2418, the "Organ Procurement and Transplantation Network Amendments of 1999." This bill removes the Secretary's legitimate authority over the organ allocation program, provides unreasonable protections for the current contractor, and simultaneously makes data less available to the public. If enacted, the transplant center performance data recently released by the Department would be unavailable to the public and the Secretary's revised regulations would be rendered moot. This harmful legislation would set different allocation policies than recommended by the IoM and is probably unconstitutional in its delegation of power to a private contractor.

We are seeking your continued support of the Secretary's authority to oversee the organ allocation program as well as your outspoken opposition to legislation which attempts to reshape the Department's policies on organ procurement and transplantation. We also respectfully request that you to make the DC/Labor-HHS moratorium on the

Secretary's organ allocation regulation one of the issues you cite in your veto message.

Sincerely,

Pete Stark, MC

Steny H. Hoyer, MC

John P. Murtha, MC

Maurice D. Hinchey, MC

Constance A. Morella, MC

John Joseph Moakley, MC

Edolphus Towns, MC

Henry A. Waxman, MC

Alan B. Mollohan, MC

Barney Frank, MC

Zoe Lofgren, MC

David E. Price, MC

Maxine Waters, MC

Frank Mascara, MC

John W. Olver, MC

Nancy Pelosi, MC

Elijah E. Cummings, MC

Sherrod Brown, MC

Danny K. Davis, MC

Donna Christian-Christensen, MC

Albert Russell Wynn, MC

William J. Coyne, MC

Ron Klink, MC

Benjamin Cardin, MC

FACSIMILE SHEET

U.S.Department of Health & Human Services
HRSA
Health Resources & Services Administration

D.W. Chen, M.D., M.P.H., Director

Division of Transplantation
Office of Special Programs
Room 7C-22
5600 Fishers Lane
Rockville, MD 20857
Main Phone:(301) 443-7577
Fax Number:(301) 594-6095

Date: 10/19/99

To: Deborah Adler
Title:
Organization:

Fax #: (202) 456-5557 Voice#: (202) 456-5707
email:

From: D.W. Chen
Fax #: Voice #: 443-8036
email:

Pages, including this cover sheet: 21

Deborah — These are the top 21 Qs+As for the OPTN Amended Rule Roll Out. I can email you the entire set if you wish.
Take Care!

D.W.

AMENDMENTS TO THE FINAL RULE

QUESTION:

Does this amendment to the Final Rule represent significant change? If so, how?

ANSWER:

- Amendments were made to the April 2nd Final Rule in order to clarify a number of issues and to address areas of concern identified by the transplant community. Language was included to clarify "single national list," "sickest patient first," addressing socioeconomic barriers to transplantation, and the closure of small and medium sized centers. Revisions were made to the Rule in response to comments on Secretarial oversight and enforceability of OPTN policies, OPTN Board composition, broader sharing of organs and the use of waiting times in organ allocation, the applicability of medical urgency status to kidney allocation, HHS oversight of the patient registration fee, and timely and accurate reporting of center specific data (see next question on "What were the major areas of disagreement in the discussions with the transplant community and has the Department ignored or rejected these complaints and comments?").

MAJOR AREAS OF DISAGREEMENT

QUESTION:

What were the major areas of disagreement in the discussions with the transplant community and has the Department ignored or rejected these complaints and comments?

ANSWER:

- Many comments received during discussions with the transplant community centered on misunderstandings and the need for clarification. These included such things as: "single national list", "sickest patients first", addressing socioeconomic barriers to transplantation, and the closure of small and medium sized centers.

  - The Final Rule does not require a single national list for allocation of organs, beyond the national registry lists already utilized by the OPTN and we have replaced the words "national list" with "waiting list".
  - The Rule does not require that the sickest patients receive transplants; rather, it requires that patients with the greatest medical urgency who are appropriate transplant candidates, on the basis of sound medical judgement and avoiding futile transplantation, receive priority in allocation decisions.
  - The Final Rule make it clear that HHS does not require transplant hospitals to make their own financial resources available to pay for transplant and follow up care for patients unable to pay; the Rule calls on the OPTN to recommend policies that would reduce inequities in access resulting from socioeconomic status and ensure that the registration fee itself does not represent a barrier to transplantation.
  - The Department does not expect the Final Rule to cause the closure of small and medium sized transplant centers, or otherwise diminish access to transplantation for certain underserved populations. The IOM Report and a recent HHS OIG report supported this assertion. However, amendments to the Rule include provisions for monitoring the effect of policy changes on small and medium sized centers and on patient access to services.

During discussions with the transplant community a number of other issues of concern were discussed including: Secretarial oversight and enforceability of OPTN policies, OPTN Board composition, broader sharing of organs, the use of waiting times in organ allocation, applicability of medical urgency status in kidney allocation, incentives for high performing OPOs, HHS oversight of the patient registration fee, and timely and accurate reporting of center specific data.

- Under the Final Rule, HHS does not interfere with case-by-case medical

decision making or medical policies of the OPTN. These are to be made by transplant professionals, in consultation with patients, donors, and families. The Final Rule reinforces the Secretary's role in assuring that the OPTN operates in the public's interest, that the system is fair and operating effectively on behalf of all patients and donors who provide organs in trust. In order to assure that the system of organ procurement and transplantation is grounded on the best available medical science and is as effective and equitable as possible, the Department has incorporated the IOM's recommendation to establish an external, independent, scientific review board to assist the Secretary.

- The Final Rule strengthens the ability of the OPTN to review compliance with and enforce its policies to prevent "gaming" of the system.
- To assure adequate medical expertise on the OPTN Board of Directors, the Final Rule requires membership to be approximately 50 percent physicians and surgeons. At least 25 percent of the Board must be patients, recipients, donors, and families.
- Consistent with the IOM recommendation to ensure that life-saving organs can reach the medically urgent patients who need them the most, the Final Rule emphasizes the broader sharing of organs. Such sharing shall not compromise organ viability or other medical considerations.
- Consistent with the IOM recommendation that cumulative waiting time represents an inappropriate measure of equity and a criterion for allocation for less medically urgent patients, the Final Rule does not require reducing variations in waiting time in status; instead, waiting time in status can be among several performance indicators the OPTN may consider.
- The Final Rule recognizes that the term "status categories" as currently used for liver and heart patients is not used for kidney patients. The Department believes that there may well be different approaches to kidney allocation policies than for other types of organs.
- The Department believes that high performance by OPOs should be rewarded, but not in a way that compromises the broader sharing of organs. The preamble of the Final Rule encourages the OPTN to develop and recommend to the Secretary policy incentives to reward high performing OPOs.
- The Final Rule specifies that the Secretary has oversight of only that portion of the registration fee directly related to the OPTN.
- The Final Rule requires that timely and accurate program-specific data on transplant programs be made available to the public. These data shall be updated no less frequently than every six months and the OPTN will have until June 30, 2000 to be fully compliant with this provision.

IGNORED OR REJECTED COMPLAINTS

QUESTION:

Haven't you really ignored or rejected the complaints and comments by the transplant community?

ANSWER:

- No. The Department carefully analyzed the written comments submitted in response to the April 2nd rule, studied the IOM report recommendations very closely, and listened very carefully to the comments and feedback during the discussions with the transplant community. Clarifications and amendments to the Rule were made in response to this input. (See previous question on "What were the major areas of disagreement in the discussions with the transplant community and has the Department ignored or rejected these complaints and comments?")

COMMENTS OPPOSED TO RULE

QUESTION:

What about the written comments submitted in response to the April 2nd, 1998 Rule? Weren't they overwhelmingly opposed to the rule?

ANSWER:

- The Department received some 2,500 comments on the Final Rule. The majority of the comments reflected misunderstandings surrounding the April 2nd Rule and unrelated issues. The amended rule provides clarifications and changes intended to make these issues clear.

RESPONSE TO IOM RECOMMENDATIONS

QUESTION:

How have you responded to the IOM recommendations on waiting times? And how does that compare with the provisions of the April 2nd Rule?

ANSWER:

- In response to the IOM recommendations concerning the use of waiting time in organ allocation, the Department has amended the Final Rule to permit rather than require the use of "waiting time in status" as an allocation factor among other allocation factors. If "waiting time in status" is used as an allocation factor, the performance goal should be to minimize its inter-transplant program variation.

- In contrast to the April 2, 1998 Final Rule where waiting time in status was used to break ties within medical urgency status groups, the amended Final Rule does not require the use of waiting time as an allocation factor. However, if waiting time is used, the amended Rule requires the OPTN to seek to reduce the inter-transplant program variation in waiting time, as well as other selected performance indicators, to as small as can reasonably be achieved, unless to do so would result in transplanting less medically urgent patients or less medically urgent patients within a category of patients.

- In general, the IOM found the emphasis on cumulative waiting times to be inappropriate as a measure of equity in the transplant system and as a criterion for allocation for less medically urgent patients, pointing instead toward "more meaningful indicators of equitable access" such as "status-specific rates of pretransplantation mortality and transplantation." The IOM report indicated, however, that the use of "waiting times in status" for the most medically urgent liver transplant patients (those in status 1 and 2A) was "an appropriate criterion, along with necessary medical criteria." For less medically urgent patients (statuses 2B and 3), the IOM recommended that the OPTN discontinue use of waiting time as an allocation criterion and instead develop "an appropriate medical triage system . . . to ensure equitable allocation of organs to patients in these categories."

SECRETARIAL AUTHORITY

QUESTION:

Have you changed provisions regarding the Secretary's authority?

ANSWER:

- Yes. The Department has incorporated the IOM's recommendation to establish an external, independent, scientific review board responsible for assisting the Secretary in ensuring that the system of organ procurement and transplantation is grounded on the best available medical science and is as effective and equitable as possible. This advisory committee will be established consistent with the Federal Advisory Committee Act (FACA). The Advisory Committee will be available to the Secretary to provide comments on proposed OPTN policies and other matters relating to transplantation, including those where the OPTN and Secretary disagree. As part of the process of establishing the Committee, the Secretary intends to solicit nominations for Committee members from the transplant community and the general public. The Secretary's oversight authority is bound by NOTA and will be guided by the advice of the Advisory Committee. Under the Final Rule, HHS does not interfere with case-by-case medical decision making. These are to be made by transplant professionals, in consultation with patients, donors, and families.

GOVERNMENTAL INVOLVEMENT

QUESTION:

Why does the government need to insert itself in this system?

ANSWER:

- NOTA required the Secretary to contract for the operation of the OPTN to assist in the nationwide distribution of organs equitably among transplant patients. The Secretary is obligated to assure that this system is accountable to and operating in the public interest and that organs donated in trust are allocated fairly and effectively. Further, Section 1138 of the SSA requires that transplant hospitals and OPOs be members of, and abide by the rules and requirements of, the OPTN in order to participate in the Medicare and Medicaid programs. Only the Secretary of HHS can approve such binding and enforceable policies.

BENEFITS TO PATIENTS

QUESTION:

How will patients benefit from these changes?

ANSWER:

- Patients will benefit in a number of ways:
  - Access to timely and accurate program specific performance data to allow them to make informed decisions about choice of transplant center
  - Patients will have confidence that life saving organs can reach the medically urgent patients who need them most and that "gaming" of the system is minimized.
  - Patients will benefit from policy making by an OPTN board which is balanced in terms of medical expertise, non-physician transplant professionals, and patients, donors and families.
  - The OPTN will be tasked to examine policy recommendations which address access to transplantation regardless of ability to pay.

OPTN IMPROVEMENTS

QUESTION:

Hasn't UNOS already addressed problems related to data improvement and regional sharing of livers?

ANSWER:

- Yes. The OPTN has already taken positive steps to improve data quality by initiating an internet-based data submission process allowing each institution to maintain accurate and current data. These changes should result in substantial improvements in the timeliness of data collection and verification.

- Under recently revised UNOS liver allocation policy (*3.6 Allocation of Livers*, effective 8-16-99) there is now regional sharing sharing of livers for medically urgent patients. This is certainly a step in the right direction but should be applied to all status categories.

OBSTACLES TO IMPLEMENTATION

QUESTION:

Do you expect Congress to block the amended rule once again?

ANSWER:

- We hope not for the sake of patients. Everything that Congress asked for when they delayed the rule last year has been completed. The Institute of Medicine has reported back to Congress on the potential impact of the Rule and has strongly supported the Rule's basic principles of Federal oversight balanced by policymaking in the hands of the transplant experts and broader sharing to save more lives. The amended rule includes IOM recommendations and clarifies issues raised during the public comment period and extensive meetings with transplant and patient groups. We believe it is a good Rule and should be put in place so that patients can start to benefit from an improved system.

RESPONSE TO H.R. 2418

QUESTION:

HR 2418, the Bilirakis bill to reauthorize NOTA, is gaining steam. What is your response to this effort to derail the Secretary's authority.

ANSWER:

- Our concern is that the bill is a reversal on the progress made on behalf of patients by the transplant community and the Department and reinforced as important by the IOM. Instead of ensuring a more fair, balanced, and accountable system with oversight in the hands of the Federal government and policymaking in the hands of the transplant experts, H.R. 2418 grants authority to a private entity lacking the Constitutional authority to create and administer binding policies. It fails to address the inequities of arbitrary geographic boundaries and the need for accurate, timely, and user-friendly data for patients and physicians to use in making knowledgeable transplant decisions.

POLICY GOVERNANCE

QUESTION:

Hasn't UNOS already started making the changes called for in the Rule? Why can't you just let the experts set policy and govern the system?

ANSWER:

- We applaud UNOS and others in the transplant community for the progress they've made to date. Survival rates are better than ever before, and new organ sharing policies are moving in the right direction, although we think more could be done. But when you have some 66,000 people waiting for a scarce donated organ, only 21,000 transplants a year and some 13 people dying each day while waiting for a transplant, the American public must have confidence that the system is operating fairly and effectively. The rule provides the necessary oversight and public accountability, but it still leaves policy making and medical decision making in the hands of the experts. We believe this is the appropriate balance of responsibility and accountability to ensure that the public's health is protected. The rule also maintains the flexibility needed for policies to keep in step with scientific advancements.

RULE IMPACT ON UNOS CONTRACT

QUESTION:

How will this Rule impact the existing contracts with UNOS for the operations of the OPTN and the Scientific Registry? When do the project periods for both contracts expire?

ANSWER:

- There are significant differences between the Rule and the Department's contracts with UNOS to operate the OPTN and Scientific Registry. However, these contracts anticipated the issuance of a Final Rule, and it is the Department's expectation that the contracts be administered consistent with the new regulations. Where the Rule and the contracts differ, the Rule prevails.
- Requests for proposal (RFPs) are being prepared for both the OPTN and the Scientific Registry contracts. A Sources Sought for each contract was posted in the Commerce Business Daily in February 24, 1999 to survey the market for potential bidders when the contracts are resolicited early in the next year.
- The previous project period for both contracts expired September 30, 1999. To allow potential bidders adequate time to develop technical proposals and to facilitate transition to (a) new contractor(s), if (a) new contractor(s) are selected, one of two one-year option periods has been exercised.

USE OF WAITING TIME IN CURRENT OPTN LIVER ALLOCATION POLICIES

QUESTION:

How is waiting time being used to allocate livers under the current OPTN allocation policies?

ANSWER:

- Simple Answer: Length of waiting time and degree of blood type match weigh equally in the prioritization of transplant candidates within medical urgency status. In general, patients who wait the longest and have the most compatible blood type with the donor organ will receive the first offer of an organ.

- Under the current UNOS liver allocation policy (*3.6 Allocation of Livers*, effective 8-16-99) patients are first stratified in order of medical urgency from the most urgent, status 1, to least urgent, status 3. Status 1 candidates in the local area receive first offer of livers. If no local match can be made, then the liver is offered to status 1 candidates in the OPTN region. If a liver cannot be placed with a status 1 candidate either locally or regionally, it is then offered to candidates in order of descending medical urgency status -- categories 2A, 2B and 3 – first locally, then regionally, and finally nationally.

- A donor liver must first be of compatible in size to a transplant candidate before it will be offered. If the size criterion is satisfied, waiting time and the degree of blood type match are used to prioritize patients within medical urgency status categories. Candidates with blood types compatible to the donor's blood type receive more points (max 10 points). Similarly, patients that have been waiting longer receive more points (max 10 points). Patients are ranked in order of descending points within medical urgency status categories. Within a given medical urgency category, the patient with the most points receives first the offer. The waiting time for status 1 and 2A patients begins when the patient is placed in that status category and does not include the time from when the patient was first placed on the waiting list, if the patient was placed on the waiting list in another status category (e.g., status 3). Waiting time for status 2B and 3 medical urgency status candidates includes all time from time of listing.

USE OF WAITING TIME FOR ORGAN ALLOCATION IN THE AMENDED FINAL RULE

QUESTION:

How is waiting time being used to allocate organs in the amended Final Rule?

ANSWER:

- Under the amended Rule, if the performance indicator "waiting time in status" is used for allocation purposes, the OPTN shall seek to reduce the inter-transplant program variance in this indicator, as well as other selected performance indicators, to as small as can reasonably be achieved, unless to do so would result in transplanting less medically urgent patients or less medically urgent patients within a category of patients.

- In general, the IOM found the emphasis on cumulative waiting times to be inappropriate as a measure of equity in the transplant system and as a criterion for allocation for less medically urgent patients, pointing instead toward "more meaningful indicators of equitable access" such as "status-specific rates of pretransplantation mortality and transplantation." The IOM report indicated, however, that the use of "waiting times in status" for the most medically urgent liver transplant patients (those in status 1 and 2A) was "an appropriate criterion, along with necessary medical criteria." For less medically urgent patients (statuses 2B and 3), the IOM recommended that the OPTN discontinue use of waiting time as an allocation criterion and instead develop "an appropriate medical triage system . . . to ensure equitable allocation of organs to patients in these categories."

- To date, waiting times have been used in examining the performance of the transplant system in part because waiting times are used by the OPTN as an allocation criterion, and in part due to lack of better measures. It is for these reasons that reducing any variations in "waiting time in status," especially for the most medically urgent patients, was included as a performance measure in the final rule published April 2. In addition, the IOM recommendation points again to the need for better data to provide alternatives to waiting time as a performance measure. Based on the IOM's recommendations and comments from the transplant community, the Department has made additional refinements to the rule's discussion of waiting times.

Chris Jennings 6-5557

From the office of:

Congressman Pete Stark

13th District, California

239 Cannon House Office Building
Washington, D.C. 20515
Phone: (202) 225-5065 Fax: (202) 226-3805

To: Chuck Brain, White House Leg Affairs

From: Broderick Johnson
Office of Pete Stark (attn: Stephanie Simons)

Number of pages following this cover: 3

If you have any problems or questions, please call the sender at the number above.

Comments: FYI + see what you can do at your end to nudge this along. Thanks!

FORTNEY PETE STARK
THIRTEENTH DISTRICT, CALIFORNIA

COMMITTEES:
WAYS AND MEANS
JOINT ECONOMIC

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

October 20, 1999

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

RE: Labor-HHS Appropriations

Dear Chris:

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

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

Thank you for your support on this very important matter.

Sincerely,

Pete Stark
Member of Congress

FORTNEY PETE STARK
THIRTEENTH DISTRICT, CALIFORNIA

COMMITTEES:
WAYS AND MEANS
JOINT ECONOMIC

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

October 20, 1999

Jacob J. Lew
Director
Office of Management and Budget
Executive Office Building
Washington, D.C. 20503

RE: Labor-HHS Appropriations

Dear Jack:

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

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

Thank you for your support on this very important matter.

Sincerely,

Pete Stark
Member of Congress

FORTNEY PETE STARK
THIRTEENTH DISTRICT, CALIFORNIA

COMMITTEES:
WAYS AND MEANS
JOINT ECONOMIC

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

October 20, 1999

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

Dear President Clinton:

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

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

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

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

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

Sincerely,

Pete Stark
Member of Congress

THE WHITE HOUSE

WASHINGTON

COUNSEL'S OFFICE

FACSIMILE TRANSMISSION COVER SHEET

DATE: 10/28/99

TOTAL PAGES (INCLUDING COVER PAGE): 3

TO: Chris Jennings/Devaran Adler

ATTN:

FACSIMILE NUMBER: 65557

TELEPHONE NUMBER:

FROM: Bruce R. Lindsey at 202-456-2668

COMMENTS:

PLEASE DELIVER AS SOON AS POSSIBLE

THE WHITE HOUSE

WASHINGTON

Chris

October 27, 1999

MEMORANDUM FOR JOHN PODESTA AND JACOB J. LEW

FROM: BRUCE R. LINDSEY

RE: LABOR-HHS APPROPRIATIONS BILL

As you know, the Labor-HHS Appropriations Bill pending in Congress currently contains a provision placing another moratorium on the Regulations issued by HHS dealing with organ allocation. A brief history of the Congressional attempts to delay these regulations follows:

- Final Rule published April 2, 1998 to be effective 90 days later;
- June, 1998 moratorium delaying the effective date of the Final Rule until October 1, 1998 attached to a supplemental HHS appropriations bill;
- October 21, 1998 a one year moratorium on implementation of the Final Rule included in the Omnibus Budget Bill for 1999 with the Institute of Medicine mandated to complete a study of the Final Rule and report to Congress;
- July, 1999, delivery of the report of the IOM study supporting and endorsing the general concepts of increased organ donation, wider geographic sharing of donated organs to the sickest patients, more emphasis on patient equity and HHS oversight, and specifically supporting the Final Rule;
- October, 1999 HHS republication of a modified Final Rule to make clarifications suggested by the IOM report to be effective 30 days after publication.

The United Network for Organ Sharing, the federal contractor which operates the current program, and many of the physician members of UNOS have attempted to discredit the IOM and its report and have urged their Congressmen to disregard the findings of the IOM. Those Congressmen are now pushing for inclusion of another moratorium in the current Labor-HHS appropriations bill. The same Senators and Congressmen (principally from Florida, Virginia, Wisconsin, Oklahoma and Texas) who argued so strenuously for the IOM study during the last moratorium, now want to dismiss the IOM report because it does not validate their position.

HHS believes in the Final Rule and the policies incorporated in it; the IOM supports the Final Rule and the policies in it, especially as revised to respond to some of its suggestions; and the patient groups (the ones with the most at stake in this debate) are unanimous in their support of

the Final Rule. The Administration should demand that Congress remove this moratorium language from the current draft of the Labor-HHS appropriation bill along with the other offensive provisions in this bill which the Administration has already identified. The inclusion of this moratorium provision and the other offensive provisions should be included as reasons that the Administration will veto the current version of this appropriation bill.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET

OFFICE OF HEALTH AND PERSONNEL
OLD EXECUTIVE OFFICE BUILDING, ROOM 238
FAX NUMBER: (202) 395-5631

FAX SHEET

DATE: 10/27

PLEASE DELIVER THE FOLLOWING PAGES TO:

NAME: Chris Jennings

FAX NUMBER: 67431

NUMBER OF PAGES (Including cover page): 3

FROM:

DANIEL N. MENDELSON	**395-5178**	X
MOLLY O'MALLEY	**395-9132**	
JENNIFER FERGUSON	**395-3816**	

COMMENTS:

COPY FOR YOUR INFORMATION

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

OCT 27 1999

MEMORANDUM FOR THE PRESIDENT

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

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

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

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

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

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

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

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

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

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

Donna E. Shalala

Attachments