

New HHS Rule Calls for Organ Allocation Based on Medical Criteria, Not Geography

By Jennifer Brooks

Closing the Gap, Organ and Tissue Donation • May 1998

The demand for organs for transplantation in the U.S. far exceeds the supply. Despite technological advances in preserving organs, the current system for allocating scarce organs—especially livers—is based largely on local organ allocation, rather than broader regional or national allocation according to medical need. This means a patient who is less ill in one geographic area with a short waiting list may get a matching organ before a patient whose condition is more medically urgent in another area with a longer waiting time.

In March 1998, Secretary of Health and Human Services, Donna E. Shalala, announced a new regulation to improve the nation's organ transplantation system. The new rule will assure that the allocation of scarce organs will be based on uniform medical criteria with less reliance on geographic location.

"Patients who need an organ transplant should not have to gamble that an organ will become available in their local area, nor should they have to travel to transplant centers far from home simply to improve their chances of getting an organ," Secretary Shalala said in a press statement. "Instead, patients everywhere in the country should have an equal chance to receive an organ based on their medical condition and the judgement of their physicians."

The new regulation builds on medical technology advancements; it looks to the medical community for leadership in policy development with participation by patients, donors and their families; and it sets performance goals for fair and effective use of donated organs.

Transplant Recipients International Organization, Inc. (TRIO), an organization representing more than 4,000 organ and tissue donors, recipients and transplant candidates, released a statement that hailed the new regulation as "a tremendous step towards an equitable distribution of this life-saving resource." Bruce Weir, national president of TRIO, said based on his initial review and a briefing he attended, he believes TRIO's major areas of concern affecting patients have been addressed.

"TRIO's preeminent concern is the fair sharing of organs among the nation's 58,000 transplant candidates. We believe these new regulations can ensure more equitable sharing of organs while leaving delicate medical decisions with physicians because the guidelines place medical urgency over geography," said Weir, who received a heart transplant in 1988.

But not everyone is happy about the new rule. Larry Hunsicker, MD, president of United Network for Organ Sharing (UNOS), feels "in the long run, fewer people will get liver transplants and fewer lives will be saved. The regulations would require doctors to put a greater emphasis on providing liver transplants to the very sickest patients, a sentiment with which we sympathize," Hunsicker said. "But there is a dire shortage of organs, and many of the very sickest patients would not be able to survive without a second or even a third transplant. This means that fewer livers will be available and over time thousands fewer lives will be saved."



Did you know?

Every 16 minutes, a new name is added to the national organ transplant waiting list.

Hunsicker also added that many liver transplant programs would have to shut down because "the regulations would divert livers from many smaller transplant programs to a few large centers."

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

The new rule calls on the Organ Procurement and Transplantation Network (OPTN) to develop revised organ allocation policies that will reduce the current geographic disparities in the amount of time patients wait for an organ. Specifically, the OPTN is to develop uniform criteria for determining a patient's medical status and eligibility for placement on a waiting list. The criteria will be aimed at assuring that patients with greatest medical need will receive scarce organs based on medical judgement and common medical criteria, no matter where they live or in what transplant center they are awaiting treatment.

Current medical criteria for listing patients and assessing their status vary from one transplant center to another, making it difficult to objectively compare the medical need of patients awaiting organ transplantation in different centers and different areas of the country.

Under the new regulation, performance goals would be established to guide the OPTN as it modifies existing organ allocation policies. Under the current policies, matching organs are usually made available to all listed patients in a local organ procurement area before they are made available to other patients outside the area. This, according to HHS officials, means less ill patients in the local procurement may receive a transplant while patients with more urgent medical need in another area continue to wait.

Three new sets of criteria for organ allocation would be developed by the OPTN under the new regulations. Development of the criteria would include public input and comment and final HHS approval. Secretary Shalala emphasized that the regulation looks to transplant professionals in the OPTN to develop the revised policies.

"We are not substituting our judgement for the judgement of medical professionals," she said. "We are asking them to make the system fairer, and we are setting clear performance goals to guide their work."

The OPTN is responsible for developing:

- Criteria aimed at allocating organs first to those in the highest medical urgency status, with reduced reliance on geographical factors. HHS officials said this should reduce disparities in waiting times for patients at different transplant centers in

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different areas of the country. Today, there is a wide variation in waiting times, with patients in some areas waiting five times longer or more for an organ than in other areas. The new criteria is expected to provide for wider sharing to assure organs were made available to patients with greatest medical need.

- Criteria to be followed in deciding when to place patients on the waiting list for an organ. Currently, each transplant center establishes its own criteria, with the result that patients listed at one center may not be as ill as patients not yet listed at another center with more stringent medical listing criteria. Under the regulation, the OPTN would develop medically objective criteria to be used by all transplant centers.
- Criteria for determining the status of patients who are listed. Medically objective, uniform criteria would help ensure a “level playing field” in selecting among patients and determining which have the greatest medical need. The OPTN is already developing uniform criteria of this kind.

“Together, these new uniform criteria will add up to a fairer and more understandable system which will serve both patients and the transplant system better,” Secretary Shalala said.

OPTN is the non-profit private sector system created by the National Organ Transplant Act of 1984. Originally, OPTN member-

ship and policies were voluntary. But with the enactment of the Omnibus Budget Reconciliation Act of 1986—adding Section 1138 of the Social Security Act—all hospitals that perform transplants and all organ procurement organizations were required to abide by the rules and requirements of the OPTN in order to receive Medicare and Medicaid reimbursement.

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

After two extensive comment periods, including three days of special hearings in December 1996, HHS announced a final rule providing a framework for the operation of the OPTN, and aimed at assuring that the Nation’s organ procurement and transplantation system operates for the greatest benefit of transplant patients.

The final rule includes a new 60-day comment period and becomes effective 90 days after publication in the *Federal Register*. The OPTN would have another 60 days to propose new criteria for livers, and a year for development of criteria for other organs.

For more information, contact HHS’s Health Resources and Services Administration at 301-443-3376. Or browse their Web site at <http://www.hrsa.dhhs.gov>. ❖

