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National Organ Allocation Policy: The Final Rule

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More than 5 years after its controversial introduction, the Final Rule continues to guide the nation's policy on cadaveric organ allocation. The Department of Health and Human Services (DHHS) issued the Final Rule in March 2000 to replace local and regional organ allocation systems with 1 national distribution protocol. This caused much debate among states, especially those that had been successful in their endeavors to increase organ donations. One of the primary concerns of the regulation's opponents was the fear that it would require local and regional centers to offer organs to patients nationwide without giving preference to local potential recipients. Over the years, however, this fear subsided as it became apparent that regional and local transplant organizations retained enough autonomy to continue giving priority to local patients. Another objection was that the Final Rule gave DHHS—and not the medical community—control of the organ allocation policy, with the DHHS Secretary having the ultimate authority. Objections to DHHS control waned because physicians and transplant specialists both continue to play important roles in organ allocation oversight.

Background

The United States Congress passed the Uniform Anatomical Gift Act in 1968 in an effort to have a national organ transplantation policy. By 1980, every state and the District of Columbia had adopted some form of the act, and in 1984 Congress passed the National Organ Transplant Act (NOTA) to streamline the organ distribution process. One of the primary purposes of NOTA was to establish the Organ Procurement and Transplantation Network (OPTN), a system that both maintains the names of individuals who need transplants and, when organs become available, matches organs with appropriate patients.

In 1986, the Health Resources and Services Administration, a division of DHHS, contracted with the United Network for Organ Sharing (UNOS) to maintain the OPTN. Today, UNOS continues to administer the OPTN to ensure the "effectiveness, efficiency and equity of organ sharing in the national system of organ allocation," as well as to increase "the supply of donated organs available for transplantation" [1]. UNOS has set about achieving these goals by organizing the country into 11 geographic regions, which are further divided into local organ procurement organization service areas.

The Organ Donation Process after Donor Death

The organ donation process begins for the potential donor when a hospital physician caring for a patient concludes the patient will not survive. When determining death,

states abide by the Uniform Determination of Death Act of 1980, which is endorsed by the American Medical Association and provides that a patient who has “sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead" [2]. Many states have provisions that amend this general definition.

Once the physician declares the patient’s impending death, the hospital informs a local organ procurement organization (OPO) of the possible organ donation. Upon death of the patient, usually because of irreversible functions of the brain, an OPO representative secures permission from the patient’s family and performs a medical evaluation of the potential organ. The OPO then accesses the UNOS computer to match the donor’s characteristics to those of a patient awaiting an organ [3]. For each organ recovered from the donor, the computer generates a separate list that ranks potential recipients using factors such as tissue match, blood type, length of time on the waiting list, immune status, and the distance between the potential recipient and the donor [3]. Donation procedures for all solid organs except for kidneys take the potential recipient's degree of medical urgency into consideration. Once a match becomes apparent, the OPO representative contacts the transplant team of the first patient on each list.

The Organ Allocation System

Organs and tissue eligible for donation include the heart, kidneys, lungs, pancreas, liver, intestines, corneas, skin, tendons, bone, and heart valves. While the specific donation procedure for each organ differs slightly, the current organ allocation system favors placing organs with local patients. If the organ cannot be matched to a patient in the local area, it is next offered to patients within the UNOS multi-state region in which the organ donor resides. If the organ fails to be matched regionally, it will then be offered to patients nationwide.

The Final Rule

Before 2000 organs donated in the United States were distributed locally or regionally, meaning that an organ might have gone to a patient inside a region who needed it less urgently than a patient outside the region. This resulted in a discrepancy between the availability of organs in states with larger donor banks and those with smaller donor banks. Because of the inconsistency of organ availability among states, as well as the increasingly limited supply of organs nationwide, there was growing support for a change in the organ allocation system.

In 1998, DHHS Secretary Donna Shalala issued the original Final Rule designed to distribute organs more equitably by replacing the local allocation system with a national one. A number of states, however, worried that if organs donated by their residents were given to out-of-state recipients, willingness to donate would decrease [4]. In an effort to curb this effect, some states passed laws that limited the transfer of organs out of state, to, for example, situations in which a suitable match could not be found in state.

Although scheduled for October 1999, implementation of the original Final Rule was delayed by the Omnibus Act and, later, by the Ticket to Work and Work Incentives Improvement Act of 1999 that postponed the original rule's effective date to March 2000. During this time, DHHS invited the public to submit comments about the rule. On March 16, 2000, DHHS announced an amended Final Rule that reflected public input by including clarifications of many of the criticized provisions of the original regulation. Nevertheless, the State of Wisconsin, University of Wisconsin Hospitals and Clinics Authority, Froedtert Memorial Lutheran Hospital, Oregon Health Sciences University, and the State of New Jersey brought a suit in federal court seeking injunctive relief from the Final Rule. The court dismissed the case in November 2000, holding that a state may not bring an action against the federal government. The plaintiffs chose not to appeal the case because of their low probability of succeeding.

Current Policy

The amended Final Rule, still in effect today, directs the OPTN to create policies based on sound medical judgment and to avoid futile transplantations [5]. Specifically, the amended Final Rule provides that "organs should be distributed over as broad a geographic area as feasible" and considers the urgency of a recipient patient's need for an organ transplantation [6]. In effect, states may still give preference to local and regional organ recipients; however, if a match is not made, the amended rule directs states to offer the organ to patients nationwide.

Under the amended rule, the DHHS Secretary may approve or veto any allocation policies developed by the OPTN, although to date this has not happened. As the administrator of the OPTN, UNOS develops policies by a consensus of organ transplant and procurement professionals, patients, and donor families. UNOS is also responsible for ensuring these policies are followed by, for example, auditing and monitoring all transplant centers and organ procurement organizations in the United States.

Ethics Perspective

In general, the AMA *Code of Medical Ethics* (*Code*) accords with the Final Rule. The *Code* states that organs should be considered a national, rather than a local or regional, resource. That is, geographical priorities in the allocation of organs should be prohibited except when the transportation of organs would threaten their suitability for transplantation. Moreover, the *Code* emphasizes 5 ethically appropriate criteria for the allocation of any limited medical resource. These criteria include likelihood of benefit, urgency of need, change in quality of life, duration of benefit, and the amount of resources required for successful treatment [7]. Finally, the *Code* states that patients should not be placed on the waiting lists of multiple local transplant centers but rather on a single waiting list for each type of organ. For more about the "spirit" of the *Code* regarding organ donation and transplantation, see "The Living Code."

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