

ORGAN DONATION

House Bill 4851 as introduced First Analysis (10-5-99)

Sponsor: Rep. Andrew Richner
Committee: Health Policy

THE APPARENT PROBLEM:

The National Organ Transplant Act, enacted in 1984, called for the establishment of a national organ procurement and transplantation network (OPTN). Membership in the OPTN includes hospitals with transplant programs and organ procurement organizations (OPOs). The OPTN maintains a national computerized list of patients waiting for organ transplantation and a 24-hour-a-day computerized organ placement center which matches donors and recipients. Under the oversight of the U.S. Department of Health and Human Services (HHS), the OPTN has established voluntary policies for member organizations in regard to procurement of organs, organ allocation, and donor-recipient matches. Since 1986, HHS has contracted with the United Network for Organ Sharing (UNOS) to administer the OPTN. A nonprofit, independent corporation, UNOS' function includes the compilation of statistics used to ascertain and to coordinate both the availability and the location of donors and those who await transplant of organs and tissues.

Because of the voluntary nature of the OPTN policies, individual states and the 62 organ procurement organizations, which act as organ recovery and distribution agencies, have had some flexibility in deciding how to allocate organs that were procured, or donated, in their regions. In addition, there are different allocation policies for each type of organ. When organs become available, it is typical to look for recipients first in the local service area. The service areas are federally designated and each area may be a multi-state area or be an area that covers part or all of an individual state. In the case of liver donations, Michigan is part of a reciprocal agreement with Indiana and Ohio. In Michigan, with eight organ transplantation centers, an organ from a Michigan donor is usually given to a Michigan transplant patient.

Though many feel that the current system is working well both for individual regions and nationally, others feel that the OPTN created under the 1984 federal legislation has fallen short of its goals, especially that of establishing an equitable system of organ allocation. In a report released earlier this year, the HHS noted that wide disparities exist from state to state and even from region to region within the same state. A 1991 Inspector General report found that organ allocation was inequitable under the OPTN, especially in regard to race and geography, and that the system did not meet the intent of the 1984 act. In June of 1999, the Inspector General reaffirmed his earlier findings, concluding that "the national organ allocation system should focus on equity among patients, not among transplant centers, and on common medical criteria, not the circumstances of a patient's residence or transplant center affiliation." In addition, the Institute of Medicine, which was commissioned by Congress to study organ transplantation, recommended that there be a broader sharing of organs. To that end, HHS has proposed rules to codify the operation of the Organ Procurement Transplantation Network. The proposed rules are scheduled to go into effect on October 21, 1999.

Though the proposed HHS rules do not specifically detail an allocation procedure, some involved with organ transplantation have concerns over possible interpretations of certain provisions. For instance, some believe the rules call for the establishment of a national list in which donated organs would go to the sickest person on the list, regardless of the distance the organ had to travel or if a person lower on the list would have a greater chance of survival with that particular organ. In addition, since transplant centers and OPOs have to perform a certain number of transplants yearly and maintain a specified level of

survival rates, it is feared that creation of a national list could inadvertently cause small to medium transplantation centers to fall below the required numbers, and be forced to close. For these and other reasons, legislation has been proposed to codify the current allocation practices used in the state.

THE CONTENT OF THE BILL:

The bill would amend the Public Health Code to require a federally designated organ procurement agency to try to match, under certain conditions, a donated organ with a patient in this state before offering it to transplant patients in another state. The bill would apply to the heart, lungs, kidneys, liver, pancreas, intestine, or any other organ that required a constant flow of blood to remain useful for transplantation purposes. It would not apply to the gift of human tissue, bones, or corneas. The bill's requirements would only apply if all of the following existed:

* An organ was donated under the Uniform Anatomical Gift Law without specifying a transplant recipient, or the specified recipient rejected a gift of an organ made under the act.

* The federally designated organ procurement agency had jurisdiction over the allocation of the donated organ.

* A specified transplant recipient in another state did not exist as a result of a reciprocal organ-sharing arrangement with a federally designated organ procurement agency.

"Federally designated organ procurement organization" would be defined as an organization that was designated by the U.S. Department of Health and Human Services, Health Care Financing Administration or its successor, to perform or coordinate the surgical recovery, preservation, and transportation of human organs, and that maintained a system for locating prospective recipients for available organs. A "reciprocal organ-sharing agreement" would be an agreement with a qualified federally designated organ procurement organization that operated in another state, with the purpose of the agreement being to serve the best interests of Michigan residents.

MCL 333.10103a

FISCAL IMPLICATIONS:

Fiscal information is not available.

ARGUMENTS:

For:

A little over a year ago, Michigan's organ donation rate stood at 16.9 per million population, a rate below the national average of 21.2 per million population. At that time, over 2,000 Michigan residents were awaiting organ transplants. Nationally, over 55,000 patients are on transplant lists. The state has already taken the initiative to boost dwindling donation rates. Last year, Public Acts 118, 120, and 226, which expanded the Michigan anatomical gift donation program and simplified enrollment, were enacted. Though it is too early to evaluate the impact of the recent legislation, the U.S. Department of Health and Human Services reported in April of this year that the region comprised of Michigan, Indiana, and Ohio had the largest increase (13 percent) of organ donations last year. With at least 2,000 patients in the state waiting for transplants, it is crucial that organs donated in Michigan be allowed to be given to Michigan citizens. However, adoption of proposed federal rules could put an end to the current practice.

According to opponents of the federal rule, the rule would require the establishment of a national pool that would send donated organs to the sickest of patients. This is problematic for several reasons. First, there is a very limited time frame for organs to be used in a transplant before they are no longer viable. Secondly, the sickest of patients may not be the best candidates for transplant surgery as the probability of success decreases as a patient's condition deteriorates. Distributing organs regionally makes sense, as less transportation time or dollars are needed. Also, decisions as to who is the best candidate for a transplant should rest with the medical community.

Additionally, a national list raises concerns about possible disadvantages to the poor, elderly, and minorities who may be too far away from large transplantation centers that may receive the lion's share of available organs. The competition for donated organs has already intensified in recent years. The federal rules could make the situation worse. If larger centers have a greater number of critical patients, it is reasonable to assume that they would draw a higher

percentage of donated organs. Since hospitals doing transplants must perform a specified number each year and meet survival criteria, shipping organs nationally instead of keeping them in their donated regions could cause small to medium-sized programs to fall below required levels and be forced to close, further threatening local access to transplantation centers.

The health and well-being of Michigan residents needs to be protected. Advocates of the bill maintain that House Bill 4851 would protect current allocation practices within the state from the proposed federal regulations.

Against:

The issue as to whether the bill would allow current state organ allocation practices to remain the same is probably moot. The proposed rules contain a provision that would preempt states from establishing or continuing in effect “any law, rule, regulation, or other requirement that would restrict . . . the ability of any transplant hospital, OPOs, or other party to comply with organ allocation policies of the OPTN that have been approved by the Secretary under this part.” Therefore, if the adoption of the federal rule led to the creation of a national list where organs were distributed nationally to the sickest of patients, the federal rule would supercede the bill.

However, it is important to note that the federal rules do not mandate such a policy. In fact, the federal rules place the authority to shape allocation procedures back into the hands of the OPTN. The rules provide a framework, such as stating that medical urgency be the primary determining factor for allocation of an organ, rather than the geographic location of patients or the transplantation center that they list with. Sufficient evidence exists to support the contention that the current system of allocation, both nationally and within Michigan, simply is not working, and so results in many inequities.

In her remarks before the Senate Labor and Human Resources Committee and the House Commerce Committee on June 18, 1999, HHS Secretary Donna Shalala reported that the median waiting times for livers at one Kentucky transplantation center was only 38 days, yet 226 days at another. In Louisiana, patients waited 18 days for livers at one state center and 262 days at another. Michigan was cited as having patients

results in patients waiting two and a half times longer at one state transplantation center than at another.

In short, many misperceptions about the proposed federal rules appear to be circulating. At the same time, there is compelling evidence that current state and national policies pertaining to organ allocations are creating huge disparities between geographic locations and socioeconomic groups, as well as resulting in a higher-than-necessary number of deaths among organ transplant candidates.

POSITIONS:

The Michigan Health & Hospital Association (MHA) supports the bill. (9-30-99)

wait for 161 days at one center, and 401 days at a major transplantation center in the state. The question must be asked as to why anyone would want to codify a policy that

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