House Legislative Analysis Section

House Office Building, 9 South
Lansing, Michigan 48909
Phone: 517/373-6466

ORGAN DONATIONS

House Bill 4403 as passed by the House
Sponsor: Rep. Mark Jansen

House Bills 4430 and 4431 as passed by the House
Sponsor: Rep. Michael Murphy

Second Analysis (7-24-01)
Committee: Health Policy

THE APPARENT PROBLEM:

As a result of abuses in an unregulated organ transplantation market, in 1984 Congress passed the National Organ Transplant Act, which (among other things) established the organ procurement and transplantation network (OPTN). The act reportedly had as its goals both increasing organ donations and ensuring an equitable nationwide system for distributing donated organs for transplantation. The OPTN began operating in 1986 under a contract between the federal Department of Health and Human Services and a private, nonprofit organization, the United Network for Organ Sharing (UNOS). The OPTN was allowed to operate under voluntary policies developed by UNOS that, among other things, allocated organs for transplantation under a point system that prioritized patients who lived closest to the donor or who were listed with a transplant center closest to the donor. (The voluntary allocation policy also incorporated into its point system the patient's medical status, blood group, and waiting time.)

In 1991, the HHS Inspector General found that the national Organ Procurement and Transplantation Network's allocation policies were inequitable, particularly with respect to race and geography, and that the network did not meet the intent of the 1984 federal act. Patients with virtually identical medical needs were treated differently solely because of where they lived, and less ill patients were receiving transplants while more seriously ill patients, perhaps only a few miles away, died while waiting for a transplant.

As a result of the Inspector General's finding, the HHS proposed a rule on April 2, 1998 that called on its contractor, the United Network for Organ Sharing, to develop an allocation policy that would reduce the inequities in the allocation of organs in the network. More particularly, in Congressional testimony about two weeks after the proposed rule was published in the Federal Register, the Secretary of the Department of Health and Human Services said, in part, that the rule contained three goals that were consistent with the equity requirements of the National Organ Transplant Act. The first two goals required that criteria for placing patients on waiting lists for organ transplants, and for determining the medical status of patients, be standardized and based as much as possible on objective medical criteria. Reportedly, the United Network for Organ Sharing (UNOS) agreed with both of these goals. However, the third goal was met with a storm of opposition, not only from UNOS but from the organ procurement organizations (OPOs), many organ transplant centers, transplant physicians and surgeons, patients, and others.

The third goal would have required that medical urgency, not geography, be the main criterion for allocating organs. Smaller transplant centers worried that they would be swallowed up by larger centers, while OPOs (which generally are based on state service areas) that had worked hard to obtain transplantable organs worried that donated organs would be taken from their states, leaving them with shortages of an already extremely scarce resource. Some people also believed that the proposed rule would have required the creation of a single national waiting list for patients that would result in more patients' deaths and longer waits for all patients across the country, though the secretary of the HHS explicitly denied that the rule required such a national list. Some people feared that the rule would have forced doctors to transplant donated organs into the very sickest patients, contrary to sound medical judgment (though the federal definition of "medical urgency" included viability and chances of survival). In any event, the HHS eventually was forced to back down on its proposed rule. Reportedly, however, a number of states are proposing or passing legislation to indicate their intent that any of their residents who are candidates for organ donations receive priority for organs donated within those states, should the federal government ever again consider issuing a rule like the proposed 1998 rule.

In another organ donation-related issue, despite ongoing attempts to increase the number of organ donations, the growing need for organs for transplantation continues to exceed the number of organs donated. (See BACKGROUND INFORMATION.)

Legislation has been proposed that would statutorily give priority to Michigan residents for organs donated within the state, as well as expand the avenues for organ donation.

THE CONTENT OF THE BILLS:

The bills would amend the Public Health Code and the Estates and Protected Individuals Code to require Michigan residents to be given priority in "vascularized" organ donation programs (House Bill 4403) and to add patient advocates to the list of those authorized to make organ donations on the behalf of deceased individuals (House Bills 4430 and 4431). House Bill 4430 also would add drivers' licenses and state identification cards to the list of allowable "documents of gift."

<u>House Bill 4403</u> would amend the Public Health Code (MCL 333.10101) to define "vascularized organ" to mean a heart, lung, liver, pancreas, kidney, intestine, or other "physical part" (already defined in the code to mean organs, tissues, eyes, bones, arteries, blood, other fluids, and any other portions of a human body) – not including tissue, bone, or a cornea – that required a continuous flow of blood to remain useful for transplantation purposes.

The bill also would add a new section to the Public Health Code (MCL 333.101002b) to require that a vascularized organ that was obtained by an organ procurement organization (OPO) whose designated service area primarily included an area in Michigan (see BACKGROUND INFORMATION) be used within that designated service area with two exceptions:

- The organ donor had given the organ to a specified individual (the "donee") who had accepted the gift; or

- No suitable potential donee were specified on a hospital waiting list within the designated service area, in which case the organ procurement organization would be required to offer the organ for use by an entity that distributed vascularized organs on a regional or national basis under a contract with the federal Department of Health and Human Services (HSS), or a under a subcontract with a contractor with the HSS.

<u>House Bill 4430</u> would amend the Public Health Code (MCL 333.10102 and 333.10104) to add patient advocates to the prioritized list of people allowed to donate by proxy the cadavers or parts of cadavers of people who during their lifetime had not indicated in their wills or by means of donor cards their intent to donate their bodies after death for medical or scientific purposes. The bill also would add driver's or chauffeur's licenses and state personal identification cards – in addition, as currently, to wills and donor cards – to serve as "documents of gift" of an individual's body or body parts.

<u>Proxy donations: prioritized list</u>. The Public Health Code currently allows individuals "of sound mind and 18 years of age or more" to give all or any part of their bodies for a variety of purposes specified in the code – including medical or dental education, research, or therapy – with the gift to take effect upon death. The health code also lists, in descending priority, other people who can donate (in order of priority and when people in prior classes are not available at the time of death) a dead person's body or parts (after or immediately before death), if that person had not indicated an objection to such a donation while he or she was still alive or if none of the people in the same or earlier category on the list object. Currently, the list names the following people in the following order who can act as proxy donors, including the dead person's:

- spouse,
- adult son or daughter,
- either parent,
- adult brother or sister,
- guardian at the time of the person's death, or
- any other person authorized or under obligation to dispose of the body.

The bill would amend this section of the code to give a patient advocate priority over all family members in making a gift of a dead person's body or parts. The bill would do this by adding to the prioritized list, before "spouse," a patient advocate designated under the Estates and Protected Individuals Code who was authorized to make such a gift.

The bill also would amend this section of the health code to specify that individuals authorized to make a gift of a dead person's body or parts could do so only if each of three conditions were met: (1) an individual with higher priority on the list were not available or were not capable of making the decision at the time of the decedent's death; (2) the individual making the gift had not received actual notice that the dead person had expressed an unwillingness to make the gift; and (3) the individual making the gift had not received actual notice that someone having equal or higher priority on the list opposed the making of the gift. Finally, the bill would explicitly say that a gift made by someone on the list of authorized individuals would not be revocable by someone having a lower priority on the list.

Direct donation: "document of gift." Currently, the Public Health Code allows people during their lifetime to donate all or a part of their bodies when they die, either through their wills or by means of a "uniform donor card" that has been signed by the donor (or, if he or she can't sign, then at his or her direction) in the presence of two witnesses, who also must sign the card in the donor's presence. The health code specifies a form for a uniform donor card, and does not require that a donor card be delivered during the donor's lifetime to make the gift valid.

The bill would amend this section of the health code to add to the allowable "documents of gift" both a personal identification card or a motor vehicle operator's (or chauffeur's) license issued to the donor by the secretary of state that contained a statement that the card or license holder was an organ and tissue donor, along with the holder's signature and that of at least one witness. A donor who was unable to sign a "document of gift" could direct someone else to sign on his or her behalf if the signature of the other individual and at least one witness were made in the donor's presence. If a donor did not specify a gift of his or her entire body on his or her state personal identification card or state driver's or chauffeur's license, then the "gift" would be limited to parts of the donor's body and would not include the donor's entire body. Finally, the bill would not allow a donation by means of a "document of gift" to be revoked once the donor died.

House Bill 4431 would amend the Estates and Protected Individuals Code to do all of the following:

- amend the act's definition of "patient advocate" to include an individual authorized to make an anatomical gift on behalf of another individual" (in addition to a patient advocate's current authority "to exercise powers concerning another individual's care, custody, and medical treatment");

- allow someone making a patient advocate designation to include in the designation (a) the authority for the designated patient advocate to make an anatomical gift of all or part of the designating individual's body and (b) a statement of the patient's desires on the making of an anatomical gift;

- require patient advocate designations authorizing the making of an anatomical gift to include a statement that this authority would be exercisable only when the patient were dead or when the patient's death were ("within reasonable medical judgment") "imminent and inevitable" (and require acknowledgement of this condition in the acceptance of a designation as a patient advocate); and

- exclude the patient's death as revoking the part of a patient advocate designation that authorized the patient advocate to make an anatomical gift of all or part of the deceased patient's body.

Tie-bar. House Bills 4430 and 4431 are tie-barred. That is, if enacted, neither bill could take effect unless both bills took effect.

BACKGROUND INFORMATION:

Recent Michigan legislation. Public Acts 118, 120, and 226 of 1998 expanded the Michigan anatomical gift donation program. (See the House Legislative Analysis Section analysis of enrolled House Bills 4031 and 4620, and enrolled Senate Bill 458 dated 7-24-98.) Last session, a set of bills (House Bills 4383 and 4384) that were similar to the bills in this package passed the House but died in the Senate.

Michigan's OPO. The federally designated organ procurement organization (OPO) that covers about 90 percent of Michigan (and includes parts of Indiana and Ohio) is the Ann Arbor-based Gift of Life Transplantation Society of Michigan. According to the Gift of Life, as of April 1, 2001, in Michigan 1,734 people are on a waiting list for a liver transplant, 407 are waiting for a liver transplant, 141 people are waiting for a pancreas transplant, 114 are waiting for a lung transplant, and 82 are waiting for a heart transplant. According to the society, moreover, 110 people have received an organ transplant and 50 people have died waiting for a transplant "year-to-date." (As a comparison to the national figures, a November 1999 article in the *New York Times* said that an estimated 62,000 Americans were waiting for an organ transplant, and 4,000 people died in 1998 while waiting for a transplant.)

According to a September 1999 *Detroit Free Press* article, Michigan has nine transplant centers that cooperated to establish the Transplantation Society of Michigan and programs to promote organ donation.

FISCAL IMPLICATIONS:

Fiscal information is not available.

ARGUMENTS:

For:

In response to a federal attempt to change the way donated organs are allocated to potential transplant recipients, reportedly a number of states have enacted or are considering legislation that would statutorily implement their intent that residents within the state be given priority access to organs donated within the state. While many of the arguments against the proposed rule, which would have required donated organs to be shared across bigger regions with the sickest patients, have been political and economic, some people also believe that the existing so-called "geographic" allocation policy encourages people to consider organ donations, since the potential donors would know that their donation would go to a local, or at least state, resident. Given the dire shortage of organs donated for transplantation, policies that encourage potential donors should be promoted, while policies that would hinder donations should be discouraged. Concerns also have been expressed by transplant centers in Michigan, which have worried that, should geographic allocation be changed in favor of medical urgency, Michigan would lose much of its transplant business to other states with larger centers, such as the transplant center at the University of Pittsburgh in Pennsylvania, which pioneered liver transplants and still is one of the nation's major transplant centers.

Although federal law preempts state laws, according to a May 1999 Michigan Legislative Service Bureau (LSB) memorandum, there appears to be no explicit preemption provision in the federal organ transplant statutes. There is an explicit preemption provision in the federal regulations of organ transplantation, but it is a qualified provision. It only prohibits state laws that "would restrict in any way the ability of any transplant hospital, OPO [organ procurement organization], or other party to comply with organ allocation policies of the OPTN [organ procurement and transplantation network]." The LSB memo concludes, "Therefore, it appears that state law may supplement federal law so long as it does not restrict the ability of any transplant hospital, OPO, or other party's ability to comply with the policies of the OPTN."

House Bill 4403 would serve as a statement of intent by the state of Michigan that Michigan residents be given first access to organs donated in Michigan, should the federal government ever again try to change the geographic allocation of donated organs to a national allocation to the sickest patients first.

Response:

While some people argue that Michigan patients should be able to receive Michigan-donated organs (see, for example, the September 1999 article in the *Detroit Free Press* by the former director of Heart and Lung Transplantation at Henry Ford Hospital and the founder and former director of the Michigan Transplant Center and a University of Michigan transplant surgeon), it is questionable whether a potential transplant recipient cares whether a life-saving donated organ comes from Michigan or California.

For:

Demand for organ transplants far exceeds the supply of donated organs, both nationally and in Michigan. According to the United Network for Organ Sharing (UNOS), the number of people waiting for donated organs at the end of 1988 was 16,026, and the number of total donors was 4,083. By 1999, according to a *New York Times* article, an estimated 62,000 patients were waiting for organ transplants, and 4,000 people died in 1998 while waiting for a transplant. And while the number of people waiting for transplants has grown enormously, the number of donors continues to lag far behind the demand.

The rapid increase in the number of people waiting for organ transplants is partly a result of medical advances that have increased the number of organs that can be transplanted. During the 1970s, kidneys were the organs most often transplanted (and in fact the greatest number of people waiting for organ transplants continues to be people hoping for kidney transplants). During the 1980s, however, liver and heart transplantation became feasible, and during the 1990s, transplantation of lungs, intestines, and pancreases became possible. The package of Michigan legislation enacted in 1998 (see BACKGROUND INFORMATION) was designed to increase the visibility of the existing voluntary organ donation program and to improve its accessibility to potential organ donors, thereby increasing the numbers of donors and donated organs.

House Bills 4430 and 4431 would continue this effort to increase the number of organ donors by increasing the kinds of documents that could serve as "documents of gift" and by allowing a person's patient advocate to donate the person's organs by proxy after death (or when death were imminent). The bills also would prevent surviving family members from overriding the deceased individual's stated intent (through his or her patient advocate) to donate his or her body or organs after death.

Against:

As the federal Department of Health and Human Services (HHS) has argued when it proposed its controversial 1998 rule (which it has since modified in the face of much opposition), organs donated for transplantation should go to patients on the basis of medical need, not geographic location. Organs should go to patients with the greatest medical need, rather than to those who happen to live closest to the donors, and organs surely should not be denied to patients who need them simply because of arbitrary boundaries (such as the designated service areas for organ procurement organizations) that have no medical significance.

The 1997 report of the Organ Procurement and Transplant Network (OPTN), the first publication by the network that included data on local waiting times, showed that for the largest category of patients, waiting times ranged from 46 days in Iowa to 721 days in western Pennsylvania. With allocation based on geographic proximity rather than medical need, a patient in dire need of a transplant may die waiting for an organ to become available in his or her geographic area when organs in an adjacent area are being given to patients whose medical need is much less urgent. Particularly troubling for many people is the evidence that disparities in waiting times for organ transplants include inequities in allocation of organs not only based on geography, but on race as well. In 1991 the HHS Inspector General found that the OPTN was inequitable, particularly with respect to race and geography, a finding that the Inspector General reaffirmed in its updated report issued in 1998. The 1998 report found that the inequities identified in 1991 not only remained, but in some cases worsened, particularly for African Americans.

Finally, some people also argue that the debate over whether or not to change from a geographic allocation system to a medical urgency allocation system isn't even so much about saving patients' lives as it is about which transplant centers will get the scarce organs, and the profits and prestige that go with such centers. As medical transplantation has matured as a field, the academic medical centers that once dominated the field are now facing competition from a proliferation of programs in community-based hospitals. Nationwide, for example, the number of liver transplant programs has gone from 70 in 1988 to 125 in 1998. This proliferation of transplant programs has resulted in a kind of politics of local interest, which are partially economic (at an estimated $244,600 for a liver transplant, the economics can be significant) but also are a question of prestige and status and competitiveness among surgeons and institutions (which are important for attracting both doctors and patients).

Fairness and saving people's lives should be the main consideration in allocation scarce organs for transplantation, not artificial political boundaries.

POSITIONS:

The Department of Community Health indicated support for the bills. (4-24-01)

The Gift of Life Transplant Society of Michigan supports House Bills 4430 and 4431. (4-24-01)

The Michigan Health and Hospital Association supports the bills. (4-24-01)

The Henry Ford Health System indicated support for the bills. (4-24-01)

Analyst: S. Ekstrom

■This analysis was prepared by nonpartisan House staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.