REPORT OF THE
JOINT COMMISSION ON HEALTH CARE

STUDY OF ORGAN DONATION AND TRANSPLANTATION PURSUANT TO SJR 454 AND ITEM 335 OF THE 1999 APPROPRIATION ACT

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

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Preface

Senate Joint Resolution (SJR) 454 of the 1999 Session of the General Assembly directed the Joint Commission on Health Care to continue its review of organ donation issues in the Commonwealth. Specifically, SJR 454 directed JCHC to study the role of the Virginia Department of Motor Vehicles within the state's overall efforts to promote organ donation. Furthermore, SJR 454 directed JCHC to examine the appropriate level of state oversight of organ procurement organizations (OPOs) serving the Commonwealth, as well as the degree to which the number of OPOs in Virginia may affect organ recovery and allocation. In November 1998, JCHC staff presented an initial issue brief titled Review of Organ Donation Issues. The findings of that study are summarized on page one of this document.

Item 335 (HH) of the 1999 Appropriation Act directed the Department of Medical Assistance Services to assist JCHC in a review of Medicaid coverage and reimbursement policies for organ transplants. The review is required to include consideration of the appropriateness of (i) current Medicaid coverage for organ transplants; (ii) the reimbursement procedures and amounts applicable to organ transplants that are covered; (iii) fiscal impact of any changes in Medicaid policies related to coverage or reimbursement for organ transplants; and (iv) case management by the Department of Medical Assistance Services for transplant recipients.

Based on our research and analysis during this review, we concluded the following:

- A relatively small, but increasing, percentage of Virginians have chosen to indicate on their drivers licenses that they are willing to be organ donors.
- DMV's efforts to comply with its statutory responsibilities concerning organ donation appear to be reasonable and appropriate and recent changes to DMV policies and procedures have helped result in an increased number of people who have indicated a willingness to be organ donors.
- While the *Code of Virginia* states that an organ donor indicator on a driver's license is sufficient legal authority for the making of an anatomical gift without the consent of an individual's next-of-kin, a number of factors cause organ procurement organizations (OPOs) to nonetheless seek consent.
- Data maintained by DMV concerning organ donation preferences of licensed drivers can be accessed by OPOs via the Virginia State Police, but are used infrequently.

- The DMV database of organ donation preferences could serve as a basis for a Virginia organ donor registry.
- While the number of OPOs serving Virginia has implications for the allocation of organs, the state lacks the authority to limit their number but could establish some conditions concerning their operation.
- Organ transplant coverage provided by Virginia's Medicaid program is more restrictive than that offered by most other states, in that it only provides coverage for individuals under age 21.
- Medicaid programs in other states that provide transplant coverage for adults still pay for a relatively small percentage of the total organ transplants performed.
- Based on the experience of other states, JCHC staff estimate that the annual general fund cost of expanding Medicaid coverage for adult organ transplants would be approximately $1.5 million.

A number of policy options were offered for consideration by the Joint Commission on Health Care regarding the issues discussed in this report. These policy options are listed on pages 53-54.

Our review process on this topic included an initial staff briefing, which comprises the body of this report. This was followed by a public comment period during which time interested parties forwarded written comments to us regarding the report. The public comments (attached at Appendix B) provide additional insight into the various issues covered in this report. A second staff briefing (attached at Appendix C)was provided in order to provide supplemental information in response to the mandate of Item 335 (HH) of the 1999 Appropriation Act.

On behalf of the Joint Commission on Health Care and its staff, I would like to thank the Virginia Transplant Council, the Department of Motor Vehicles, and the Department of Medical Assistance Services for their cooperation and assistance during this study.

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Executive Director

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I.
Authority and Background for the Study

Senate Joint Resolution (SJR) 454, agreed to by the 1999 General Assembly, directed the Joint Commission on Health Care (JCHC) to continue its review of organ donation issues in the Commonwealth. Specifically, SJR 454 directed JCHC to study the role of the Virginia Department of Motor Vehicles within the state's overall efforts to promote organ donation. Furthermore, SJR 454 directed JCHC to examine the appropriate level of state oversight of organ procurement organizations (OPOs) serving the Commonwealth, as well as the degree to which the number of OPOs in Virginia may affect organ recovery and allocation (Appendix A).

In November 1998, JCHC staff presented an initial issue brief titled Review of Organ Donation Issues. The issue brief included the following findings:

- organ transplantation is a lifesaving medical procedure;
- the Virginia Transplant Council (VTC), a unit of the Virginia Department of Health, is statutorily-responsible for coordinating organ donation education and awareness activities within the state;
- as organ transplants have become more generally-accepted and successful, the demand for organs has far exceeded the available supply;
- the number of individuals who have died while awaiting a transplant has increased;
- five OPOs have been certified by the United States Health Care Financing Administration (HCFA) to recover human organs within designated geographic regions of Virginia;
- Virginia is served by five organ transplant centers, in addition to a transplant center at a United States Veteran's Administration medical center;
- organ procurement rates in Virginia were below the national average in 1997, based on the number of organs recovered per one million population standard used by HCFA for the certification of OPOs; and
- the organs recovered per one million population standard has been criticized by the General Accounting Office, and organ procurement organizations, for failing to account for differences in organ donation potential in different regions of the United States.

Item 335 (HH) of the 1999 Appropriation Act requires the Department of Medical Assistance Services to assist JCHC in a review of Medicaid coverage and reimbursement policies for organ transplants. The review is required to include consideration of the appropriateness of (i) current Medicaid coverage for organ transplants; (ii) the reimbursement procedures and amounts applicable to organ transplants that are covered; (iii) fiscal impact of any changes in Medicaid policies related to coverage or reimbursement for organ transplants; and (iv) case management by the Department of Medical Assistance Services for transplant recipients (Appendix B).

II.
Role of the Department of Motor Vehicles

The Virginia Department of Motor Vehicles Has Certain Statutory Responsibilities Pertaining to the Encouragement of Organ Donation

Section 46.2-342(D) of the *Code of Virginia* states that the Department of Motor Vehicles (DMV) "shall establish a method by which an applicant for a driver's license or an identification card may designate his willingness to be an organ donor...and shall cooperate with the Virginia Transplant Council to ensure that such method is designed to encourage organ donation with a minimum of effort on the part of the donor and the Department." Section 46.2-342(E) of the *Code of Virginia* provides that "If an applicant designates his willingness to be a donor...the Department may make a notation of this designation on his license or card and shall make a notation of this designation in his driver record." Section 46.2-342(I) of the *Code of Virginia* states that in the absence of gross negligence or willful misconduct, DMV and its employees shall be "immune from any civil or criminal liability in connection with the making of or failure to make a notation of donor designation on any license or card or in any person's driver record."

DMV is a non-voting member of the VTC, pursuant to §32.1-297.1(c) of the *Code of Virginia*. Effective July 1, 1999, DMV is also required to, in coordination with the VTC, "prepare an organ donor information brochure describing the organ donor program and providing instructions for completion of the uniform donor document and include a copy of such brochure with every driver's license renewal notice or application mailed to licensed drivers in Virginia."

The Role of DMV Is To Aid in the Promotion of Organ Donor Awareness and to Help Expand the Pool of Willing, Potential Organ Donors

DMV's main role is to assist, within the overall efforts of the VTC, make the number of individuals who express a willingness to be organ donors upon their death as large as possible. This is important because not all individuals who indicate a willingness to donate while alive will in fact be medically-suitable potential organ donors upon their death. It has been estimated that of the approximately 2 million people who die in the United States each year, only 15,000 or .0075 percent, will die in such a way so as to be medically-suitable for organ donation. For this reason, the VTC and DMV attempt to encourage as many additional Virginians as possible to indicate their willingness to be organ donors upon their death. This is done through provision of organ donor

awareness information, and providing individuals with the opportunity to indicate their organ donation preference on their driver's license.

DMV Has Established a Procedure for Allowing Individuals to Indicate a Preference for Organ Donation on their Driver's License

DMV has been involved with organ donation since 1977 when, as a result of new legislation, it began including a uniform donor card with every license issued. Completion of the uniform donor document was performed at the option of the licensed driver. The uniform donor document allowed an individual to specify certain organs or tissues for donation, or to allow donation of any and all organs and tissues. The document was required to be signed, dated, and witnessed. As a result of legislation enacted by the 1993 General Assembly, DMV eliminated use of the uniform donor document in 1994. In its place, DMV established a new procedure of including an organ donation question directly on the driver's license application, and of providing an organ donor indicator on the driver's license card and the license record.

Under the current DMV policy, individuals are asked on the driver's license application to "check box if you want to be an organ donor." If an individual checks the box, the DMV customer service representative enters a "Y" in the organ donor field of the driver's license record. If the box is not checked, the DMV computer system prompts the customer service representative to ask the customer, "Would you like to be an organ donor?" Based on the individual's response, the customer service representative enters one of the following codes into the DMV computer system:

- Y = Yes, I would like to be an organ donor;
- N = No, I would not like to be an organ donor;
- U = The customer is undecided about their choice; or
- R = The customer refuses to answer.

In order for DMV to issue a driver's license to an individual, the driver record database must contain either a "Y", "N", "U", or "R" in the organ donation field. However, only a "Y" appears on the driver's license card itself. Responses of "N", "U", or "R" do not appear on the license. However, they are recorded on the driver's license record in the DMV database. As of March 12, 1999, 23 percent of all individuals holding driver's licenses and identification cards issued by DMV contained a "Y" indicating a willingness to be an organ donor. This percentage comprises nearly 1.4 million individuals who have indicated an affirmative preference for organ donation through DMV (Figure 1).

It is hoped that, following an individual's decision to express an organ donation preference on his driver's license, that he will share his decision with his family members so that they are aware of his wishes. In practice, however,

this frequently may not be the case. According to a 1993 Gallup survey, 79 percent of Americans reported that they were willing to tell family members of their organ donation wishes, but only 47 percent actually had done so. If a family member had expressed a prior wish to be an organ donor, 93 percent of survey respondents reported that they would likely honor that wish. However, only 29 percent of respondents actually recalled another family member stating their organ donation preference.

Figure 1

Prevalence of "Yes" Organ Donor Indicators on Virginia Driver's licenses and Identification Cards Issued as of March 12, 1999

Type of DMV Document	Total Number Issued	Number Which Have A "Yes" Organ Donor Indicator	Percent Which Have a "Yes " Organ Donor Indicator
Driver's Licenses	5,564,201	1,363,195	24%
Identification Cards	344,201	36,794	10%
Grand Total	5,908,402	1,399,989	23%

Source: JCHC staff analysis of data provided by Department of Motor Vehicles.

DMV Policy Concerning The Organ Donor Indicator on Drivers Licenses Was Significantly Changed in January 1997

From 1994 through January 27, 1997, DMV customers had to respond to the "Do you want to be an organ donor?" question by choosing either Yes, No, or Undecided in order for a license to be issued. If the customer failed to make a selection, the DMV employee was required to ask the customer "Do you want to be an organ donor?" If the customer refused to provide a response, DMV assumed that the choice was No. The selection of either Yes, No, or Undecided appeared on both the driver's license card and the DMV driver's license database.

During the Fall of 1996, a customer visited the DMV Charlottesville Customer Service Center to renew his driver's license. Instead of indicating an organ donation preference from the choices of Yes, No, or Undecided, the customer wrote across the question: "This question is not appropriate for a driver's license application." The customer was subsequently denied a driver's license because the computer system was programmed to not issue a license without completion of the organ donation question. The customer wrote to the local newspaper and to the Governor explaining his feelings about this requirement and argued that DMV had no right to ask him about his organ donor preference.

DMV sought guidance on this matter from the Office of the Attorney General. The Attorney General's Office affirmed that DMV's process of soliciting organ donor preference information, and making it a requirement for issuance of a driver's license, was appropriate. According to the Attorney General's correspondence with DMV, organ donation is "a subject matter to which the General Assembly has attached a great deal of importance." The Attorney General's Office stated that "DMV's actions of soliciting the [organ donor] information and then noting it on the driver's license would appear to be an appropriate exercise of the Commissioner's authority as given to him by the General Assembly." The Attorney General's Office noted further that such action by DMV would be consistent with statutory mandates to cooperate with the Virginia Transplant Council, to establish a method for the designation of organ donation preferences, and to encourage organ donation.

Nevertheless, as a result of this customer's complaint and at the direction of a joint legislative study committee established by HJR 100 of the 1996 Session, and with the concurrence of the Virginia Transplant Council, DMV substantially changed its policy and procedure. Effective January 27, 1997, DMV customers were given the option of selecting "Yes" as an organ donation preference, or expressing no preference at all. If the customer failed to check the organ donor box on the application, they were no longer asked by DMV employees whether or not they wanted to be organ donors. Furthermore, a response to the organ donor box was no longer a requirement for issuance of a driver's license. Prior to the 1997 Session, the HJR 100 joint subcommittee had drafted legislation, which DMV opposed, prohibiting DMV from refusing to issue a driver's license when an applicant fails to respond to questions about their willingness to be an organ donor.

Number of DMV Customers Indicating Yes to Organ Donation Fell Sharply Following January 1997 Policy Change

According to DMV, it anticipated a decline in the number of its customers indicating a positive preference to become an organ donor as a result of the

January 1997 policy change. In fact, there was a significant decline in the percent of individuals choosing "Yes" for organ donation, as is summarized by Figure 2. Just as significantly, the vast majority of individuals who received licenses in 1997 and 1998 failed to respond at all to the organ donor question on the driver's license application.

In response to the substantial decline in number of people indicating yes, DMV changed its policy – to that previously described -effective February 4, 1999. According to DMV data, there was an immediate positive result to the policy change. During February 1999, 48,744 individuals placed a "Yes" organ donor indicator on their driver's license – compared to only 13,867 in February 1998. Likewise, during May 1999, 57,877 individuals placed a "Yes" organ donor indicator on their driver's license – compared to only 16,130 in May 1998.

Figure 2

Organ Donor Preference Rates for DMV Customers

	Percent of Driver's Licenses and Identification Cards Issued During the Year			
Calendar Year	**Yes**	**No**	**Undecided**	**No Response**
1995	32.3	44.3	23.3	N/A
1996	32.9	44.6	22.5	N/A
1997	20.4	2.4	1.2	76
1998	17.5	0.1	0.01	82.3

Note: A response had to be selected during 1995 and 1996 in order for a driver's license to be issued.
Source: Department of Motor Vehicles.

DMV Performs Other Types of Activities Intended to Promote Organ Donor Awareness and Help Increase the Number of Potential Organ Donors

DMV management discussed with JCHC staff a range of activities it has undertaken, and plans to undertake, to promote organ donor awareness in Virginia. The following activities were cited by DMV as examples of its overall effort to help encourage organ donation in its capacity as a member of the Virginia Transplant Council:

- displayed posters and provided brochures to the public at each of its customer service centers;

- informed its employees about organ donation through videos, fact sheets and articles in employee communications;

- implemented programming edits for driver's license renewals to ensure that the positive response of customers who previously indicated their intent to become donors remained on their driver's licenses, and not deleted in the absence of a positive organ donor response on a renewal application;

- worked with Virginia's print and broadcast media to promote organ donor awareness;

- revised its Internet Web site to provide extensive information about organ donation, such as reviewing the 25 different organs and tissues that can be donated, reassuring individuals that the level of medical care is not affected by a signed donor card, and providing links to other organ donor resources; and

- printed the slogan "Save a life. Be an organ donor" on its driver's license renewal notice as well as on the renewal notice envelope.

DMV Plans to Become More Proactive in Promoting Organ Donor Awareness

According to DMV, it would like to become more proactive in its method of promoting organ donor awareness in Virginia. In this regard, DMV plans to implement several additional activities and strategies in the near future:

- DMV plans to print the organ donation slogan, "Save a life – Be an organ donor" at the bottom of the clipboard that customers use when completing their applications. Some of the cost of this initiative will be absorbed by a private sector organization.

- DMV's new driver's license renewal service by touch-tone telephone and Internet, which is scheduled to be implemented in the third quarter of 1999, will provide individuals with the full range of organ donation choices currently available.

- DMV will publish information about special organ donor awareness license plates authorized by the General Assembly in 1996. For each twenty-five dollars collected by DMV in excess of 1000 registrations for the special plate, fifteen dollars will be paid to the Virginia Transplant Council to support its

programs and activities. However, unless 350 plates are pre-sold by June 30, 1999, the special plate will have to be re-authorized by the General Assembly. Only about 100 of the plates have been pre-sold as of March 1999.

- DMV plans to invite representatives of the Virginia Transplant Council to provide organ donor awareness training to new DMV employees as part of DMV's revamped new employee training module.

- During Organ Donor Awareness Week from April 18 – April 24 DMV plans to display "tent cards" in all customer service centers, while also conducting an aggressive media campaign about the agency's commitment to organ donor awareness and the agency's role as a universally recognized place for customers to record their intent to become donors.

DMV would also like to provide each customer with an organ donor brochure at the information desk where customers begin their visit to DMV. This initiative would help improve the ability of an individual to make an informed, thoughtful decision about his or her organ donation preference while at DMV. However, DMV stated that it currently lacks a sufficient number of organ donor brochures from VTC in order to distribute one to every customer who enters a DMV office. Given that there are approximately one million license renewals annually, DMV would need about one million brochures annually. The VTC, for its part, lacks sufficient financial resources to accommodate DMV's request for 1 million brochures on an annual basis.

However, DMV and VTC are now planning to jointly produce their own organ donor awareness brochure using DMV's internal printing resources and facilities. Currently, brochures are purchased by VTC from an external vendor and then provided to DMV. VTC and DMV believe that an adequate number of brochures, sufficient for delivery to each DMV customer, can be produced for less expense than would be required to purchase the brochures from an external vendor. DMV hopes to utilize some of its existing public/private partnerships to obtain some funding from private sector organizations for production of the brochures. DMV also plans to produce internally the required driver's license renewal notice insert, at an estimated unit production cost of one cent per insert.

DMV Is Similar to Motor Vehicle Agencies in Other States In Terms of Overall Efforts to Promote Organ Donor Awareness

All 50 states and the District of Columbia have programs by which an individual may express an organ donation preference while conducting transactions at the state motor vehicle agency. However, the specific details and mechanics of each state program vary considerably. For example, according to a 1996 survey by the American Association of Motor Vehicle Administrators:

- 32 jurisdictions place organ donor information on the driver's electronic record;

- 43 jurisdictions place the information directly on the driver's licenses;

- 25 jurisdictions, including Virginia, put the information on both the electronic record and the license; and

- 30 jurisdictions provide the individual with a donor card separate from the driver's license or require the individual to sign the back of the driver's license in order to indicate an organ donation preference.

Given the range of organ donor awareness activities currently undertaken or planned by DMV, and given the recent changes in its organ donor indicator policy, DMV's efforts to promote organ donor awareness appear to be reasonable and appropriate. Moreover, given the fact that all organ donor information is incorporated into the driver's license application, placed directly on the driver's license card, and also maintained electronically, Virginia's process is more straightforward than is the case in many other states.

One type of activity that is performed by motor vehicle agencies in some other states but not conducted in Virginia is to provide individuals with the opportunity to make a voluntary $1 contribution to a state organ and tissue donor awareness and education fund. Typically, these funds help support activities similar to those performed in Virginia by the Virginia Transplant Council. States that provide the opportunity for such voluntary contributions include: Colorado, Florida, Indiana, Iowa, Kentucky, Maryland , Missouri, Ohio, Pennsylvania, South Carolina, and Tennessee. In addition, motor vehicle agencies in some other states, including Alabama, Arkansas, Florida, and Maryland, permit OPO representatives to staff display tables within motor vehicle offices in order to provide information and answer questions about organ donation. In prior years, DMV has expressed opposition to these types of initiatives.

III.
The Utilization of DMV Organ Donor Preference Data and the Concept of a Virginia Organ Donor Registry

DMV Database Containing Individual Organ Donor Preferences is a Potentially Useful Tool for Promoting Organ Donation in Virginia

As previously discussed, DMV maintains an electronic record of the organ donation preferences of licensed drivers and identification card holders in Virginia. The organ donor preference data represents a single data field in a much larger driver's license database. This database is maintained by DMV personnel at DMV expense. As DMV policies and procedures related to organ donor preference indicators have changed over the past few years, DMV has had to re-program its computer system to reflect the new policies and accurately capture the specified data.

DMV data is generally considered to be privileged by the *Code of Virginia*. However, the organ donor preference indicator on the database is accessible by authorized representatives OPOs by calling the Virginia State Police. The State Police have direct access to the DMV driver's license database as part of the Virginia Criminal Information Network. If the OPO representative provides the name, social security number and/or date of birth, the State Police dispatcher will access the DMV database and inform the OPO of the individual's stated organ donor preference indicator.

The organ donor preference indicator data maintained by DMV could be used by OPOs as part of their organ donor awareness and procurement activities. In particular, it could be used as part of their process for approaching the families of deceased individuals in order to obtain consent for donation. The use of this data could be particularly helpful in cases where the deceased's organ donation preference is not known due to either (1) the absence of either a driver's license or some other type of organ donor card or advance directive or (2) the fact that the deceased had failed to inform his family of his organ donation preference prior to his death.

The DMV database could also be used to support analysis of organ donor preference rates by age and sex, and in various parts of the state. This information could also be used by VTC to improve the targeting and coordination of its educational and outreach activities, and by DMV management to help ensure consistency of implementation of its organ donor activities among its six districts, 72 customer service centers, two satellite offices, 25 license agents, and four dealer/training centers.

Figure 3 shows that during 1998, Virginia women were generally more likely than men to indicate a willingness to be an organ donor by placing a "Yes" on their driver's license. The table also illustrates that a willingness to be an organ donor tended to decrease, in percentage terms, among older DMV customers. Figure 4 shows that DMV's Fairfax district had the greatest percentage of customers indicating a willingness to be an organ donor during 1998. The Roanoke and Richmond districts, by comparison, had relatively low percentages of their customers indicate a willingness to be an organ donor.

Figure 3

Percentage of DMV Customers Indicating a Willingness To Be An Organ Donor During Calendar Year 1998, By Sex and Age

Age Bracket (Years)	Sex	
	Female	Male
<21	21.3	15.9
21-34	21.4	14.3
35-50	22.7	16.3
51-65	17.2	14.6
65+	9.0	9.1

Source: JCHC staff analysis of DMV Organ Donor Report for Calendar Year 1998.

Virginia Statute Provides that the Organ Donor Indicator Placed on Virginia Driver's License is Legally-Sufficient to Effectuate an Anatomical Gift

As discussed in JCHC's November 1998 issue brief titled Review of Organ Donation Issues, the *Code of Virginia* provides that the organ donor indicator placed on a Virginia driver's license is legally sufficient proof of an individual's willingness and intent to become an organ donor upon his or her death. Section 32.1-290 of the *Code of Virginia* , which is part of the state's Anatomical Gift Act, provides that "an anatomical gift may also be made by a donor in accordance with the procedures established by the Department of Motor Vehicles, pursuant to §46.2-342." Section 46.2-342(F) states that "the donor designation authorized

in subsection E shall be sufficient legal authority for the removal, following death, of the subject's organs or tissues without additional authority from the donor, or his family or estate." In other words, if an individual has placed a "Yes" on his or her driver's license indicating a willingness to be an organ donor, consent from the deceased's next-of-kin prior to organ recovery is not required as a matter of Virginia statutory law.

Figure 4

Percentage of DMV Customers Indicating a Willingness To Be An Organ Donor During Calendar Year 1998, By DMV District

District	Percent of District Customers Placing a Yes on License During 1998
Bristol	15.9
Fairfax	20.2
Portsmouth	17.6
Richmond	14.7
Roanoke	14.4
Staunton	17.7
DMV Image Retrieval Center	18.9
Other	15.2
STATE AVERAGE	17.6

Note: DMV Image Retrieval Center processes juvenile licenses and licenses for out-of-state customers. Other refers to individuals whose address does not indicate which DMV district the individual resides in.

Source: JCHC staff analysis of DMV Organ Donor Report for Calendar Year 1998.

The Virginia Anatomical Gift Act also indicates that legally-sufficient documentation indicating a willingness and preference to be an organ donor need not enumerate specific organs which may be recovered. Section 32.1-290(G) of the *Code of Virginia* states that "In the absence of contrary indications by the

donor, (i) an anatomical gift of a part is neither a refusal to give other parts nor a limitation on an anatomical gift under §32.1-290 or on a removal or release of other parts under §32.1-290,1..." The state Anatomical Gift Act also provides a measure of legal immunity for actions taken in conformance with the statute. Section 32.1-295 provides that a person who acts in good faith with the terms of this article, or under the anatomical gift laws of another state or a foreign country is not liable for damages in any civil action or subject to prosecution in any criminal proceeding for his act."

In 1986, in response to an inquiry from a member of the General Assembly, the Office of the Attorney General issued a formal opinion concerning the legal sufficiency of a signed organ donor card. The legislator asked three questions:

- Is an organ donor card, legally signed by the deceased, valid only when agreed to by the next-of-kin?
- Can another relative of the deceased force a "harvesting institution" to abide by the legally-valid request of the deceased to make an anatomical gift?
- Is the donee (such as on OPO or a transplant center), acting alone, on firm legal ground in recovering an organ if the donee is in possession of a legally signed organ donor card from the deceased?

The Office of the Attorney General's opinion contained the following conclusions:

- it is not necessary for next-of-kin to have agreed to the organ donor card for an anatomical gift to become effective;
- another relative can not force a donee, such as an OPO or a transplant center, to abide by the legally valid request of deceased if the donee chooses not to accept the gift; and
- an organ "harvesting institution" would be protected from civil or criminal liability if there was good faith reliance on a legally signed donor card.

At the time this opinion was drafted, the *Code of Virginia* required DMV to issue a uniform donor document to each individual who received a driver's license. At that time, the organ donor indicator was not yet incorporated directly onto the driver's license card itself. There have been no further formal Attorney General opinions on this issue since 1986.

DMV Database Appears to Be Infrequently Utilized for Organ Donation Purposes

Representatives of OPOs operating in Virginia indicate that they do not frequently use the DMV organ donor indicator data as part of their organ procurement activities -- even in cases where they do not have access to the deceased's driver's license card. Representatives of the OPOs provided a number of reasons for this:

- concern that employees of the Virginia State Police are too busy and do not want to be bothered with calls requesting organ donor information, particularly when the information is needed in the middle of the night;

- uncertainty as to whether a "Yes" organ donor indicator refers to a willingness to donate any and all organs, or only specific organs;

- concern that, if the organ donor indicator is "No", the OPO is obligated to share that information with the deceased's next-of-kin, which would be counterproductive to actually procuring the organ;

- concern that a "No" organ donor indicator may not accurately reflect an individual's true donation preference, since DMV is not an appropriate location in which to make a thoughtful, informed decision concerning organ donation; and

- consent of the next-of-kin is required regardless of what the deceased's organ donation preference is as documented by the DMV driver's license database.

Given the amount of State resources that are devoted to soliciting and collecting organ donor preferences, these concerns do not appear to rise to a level that warrants not utilizing the data. For example, as previously mentioned, the *Code of Virginia* specifically provides that absent contrary indications an anatomical gift is not limited to specific organs. Statute also provides that the driver's license organ donor indicator is sufficient legal authority to effectuate an anatomical gift. Strong consideration should be given to honoring the organ donor preference that the State has actively encouraged and enabled individuals to express in advance of their death.

Underutilization of organ donor preference data collected and maintained by DMV does not appear to be unique to Virginia. In 1997 the United Network for Organ Sharing (UNOS) Council on Organ Availability conducted a survey of OPOs concerning advance directives and donor card effectiveness. As shown in Figure 5, nearly 50 percent of the OPOs responding to the survey reported that they rarely checked for the existence of a signed donor card or driver's license that would authorize donation by the deceased.

The 1997 UNOS survey also asked OPOs about their practices of accessing organ donor preference data maintained electronically by state motor vehicle agency databases. According to the survey results:

- 42 percent of respondents (17 of 40 OPOS) reported that they could access state DMV or other database for donor name and intent;
- of those OPOs with DMV database access, 70 percent (12 of 17 OPOs) reported that they actually utilize the database; and
- 61 percent of all respondents reported that some other type of state or national donor registry would be useful.

Figure 5

Use of Organ Donor Preference Documentation by Organ Procurement Organizations

	Percent of Respondents		
Do you check for:	**Always**	**Usually**	**Rarely**
Signed donor cards	24	26	48
Driver's license signed authorizing donation	24	26	48
Other forms of advance directives	14	24	60
Appointed agent through durable power of attorney	7	14	68

Note: 41 of 63 OPOs (65%) responded to these questions on the survey.

Source: United Network for Organ Sharing Council for Organ Availability, Survey Report on Advance Directives and Donor Card Effectiveness.

The DMV database also appears to be underutilized at present by the VTC and DMV in terms of analyzing the organ donor preference trends across the state. This includes analyzing organ donor preference rates by DMV district, age bracket, and sex. This could be done utilizing data currently available, with the

results used to improve the targeting and coordination of organ donor awareness activities. To date, such analysis has not been performed. However, the VTC and DMV are currently negotiating a user agreement to facilitate greater use of DMV data by the VTC.

OPOs Operating in Virginia Will Not Honor the Organ Donation Preference of A Deceased Individual Without First Obtaining Consent from the Next-of-Kin

As discussed in JCHC's November 1998 organ donation issue brief, even in the presence of legally-sufficient documentation of the deceased's organ donation preference, OPOs operating in Virginia always seek the consent of the next-of-kin prior to recovering organs from a deceased individual. This is done in response to public relations/ethical, legal, and logistical concerns. From a public relations standpoint, the OPOs are apprehensive of possible damage to their reputations if they were not sensitive to the wishes of surviving family members in their time of grief. The OPOs have also expressed concerns about possible litigation by a deceased's survivors if their organ donation preferences were not adhered to.

From a logistical viewpoint, according to the OPOs, next-of-kin who are not willing to consent to donation will be unlikely to cooperate with OPO staff in providing the medical and social history of the deceased. According to the OPOs, while organs could still be recovered without obtaining this history, it is unlikely than any transplant surgeon would agree to use such an organ. However, since human organs are considered life saving (as opposed to life-enhancing in the case of human tissue), an organ from a donor whose medical and social history is unknown might be preferable to no organ at all, particularly in the case of a patient who faced a quick, certain death without a transplant.

The reluctance of OPOs to procure organs despite the presence of a legally-sufficient document of intent, without first obtaining consent from the next-of-kin is true nationally and is not limited to Virginia. The 1997 UNOS report on advance directives and donor card effectiveness was conducted to examine the feasibility and legal ramifications of enforcing the wishes of deceased individuals who possess validly signed and witnessed organ donor cards or other forms of advance directives. The UNOS report concluded that there was "an ambivalence among the OPO community concerning the use of advance directives." The UNOS report stated that "although federal law [the Uniform Anatomical Gift Act] immunizes OPOs and hospitals for good faith removal of organs and tissues, and public relations campaigns emphasize the signing of organ donor cards, donation is rarely performed without consent of next-of-kin."

There are some complicating factors surrounding the issue of legal sufficiency. One involves the provisions of the federal Omnibus Reconciliation

Act of 1986 (OBRA86). This federal law requires, in part, that all hospitals participating in Medicare or Medicaid assure that the families of potential organ donors are made aware of the option of organ and tissue donation, and of their option to decline to donate. Virginia's hospital licensure regulations (12VAC5-410-220) contain the identical requirement. The provisions of OBRA86 do not pertain directly to OPOs, who are ultimately responsible for procuring organs. However, it should be noted that one of the minimum procurement standards established by UNOS for OPOs is that "The host OPO must document consent by the donor's next-of-kin and medically/legally responsible person (e.g. medical examiner.) The 1997 UNOS Council on Organ Availability report on advance directives and donor card effectiveness recommended adoption of a policy of informing families of decedent wishes rather than asking for their consent to donation. According to the report, "repealing the provisions of the Omnibus Reconciliation Act of 1986 would clarify the legal framework supporting this policy."

As initially discussed in JCHC's November 1998 issue brief, Pittsburgh's Center for Organ Recovery (CORE) is the only OPO in the United States that has established and implemented a policy of strict enforcement of the donor card. In cases where CORE has evidence, as a result of legal documentation such as a signed donor card or a properly indicated driver's license, of what the deceased's organ donation preference was, consent from the next-of-kin is not sought. The deceased's family is still approached, but only for the purpose of making them aware of the deceased's wishes, clarifying CORE's intent to honor those wishes, and to obtain the medical and social history of the donor. In cases where CORE does not have evidence of the deceased's organ donation preference, consent from the next-of-kin is sought.

According to CORE's executive director, it has not suffered any adverse publicity or legal consequences in over 400 donor cases during the past three years. There has been only a single case where the deceased's family was adamantly opposed to donation despite the presence of evidence concerning the deceased's willingness to be an organ donor. In that case, CORE still proceeded with the organ recovery. According to CORE's executive director, litigation was threatened but never initiated. CORE's executive said that he is personally less concerned over the potential legal liability from the families of deceased individuals for the failure to honor their wishes, than he is from the families of potential transplant recipients for the failure to recover organs despite the presence of legally sufficient evidence of the deceased's willingness to be an organ donor. CORE's executive director said further that, "We push people to make end-of-life decisions prior to death...If someone has a donor card and we don't honor it, that is wrong."

It is important to note that the enforcement of a legally-sufficient donor card, driver's license or advance directive is not the same as presuming that an

individual has consented to donation in the absence of any writing indication. "Presumed consent" is the public policy of several European nations. Under this type of policy, all deceased individuals are as a matter of law considered to be potential organ donors, unless they have "opted-out" prior to death.

There Are Potential Organ Procurement Implications Associated with Not Utilizing Legally-Sufficient Evidence of a Deceased's Organ Donation Preference.

According to the results of a 1993 Gallup survey, 85 percent of Americans support organ donation. However, only about 50 percent of American's actually consent to donate the organs of a deceased family member when asked. During 1998, OPOs operating in Virginia had consent rates, as a percentage of medically-suitable potential donors, that approximated the national average of 50 percent:

- LifeNet – 60 percent,
- Washington Regional Transplant Consortium – 50 percent, and
- Virginia's Organ Procurement Agency – 42 percent.

The 1997 UNOS report on advance directives and donor card effectiveness found that 60 percent of the 41 OPOs responding had, within the prior year, experienced cases where the families of the deceased had overruled written wishes of potential donors. Nineteen OPOs responded when asked to identify the number of times that such instances had occurred. Among the 19 respondents, the median number of such instances where the family overruled the deceased's wishes was two, while the range was from one to 12. To the extent that this occurs in Virginia, it makes the state's policy of encouraging and allowing an individual to make an anatomical gift designation prior to death – through an indicator on a driver's license or some other legally-sufficient document – less meaningful. It also raises the likelihood that some valuable human organs will not be recovered, which does not help promote access to transplants for Virginia residents.

Donor Registries Can Provide a Number of Benefits for Organ Donor Awareness and Procurement, But Numerous Issues Must First Be Addressed

An organ donor registry can be thought of as a centralized collection of individuals' organ donation preferences which is accessible at the time that an individual dies and becomes eligible to donate. Studies indicate that families are far more likely to consent to donate when they know their loved ones wanted to donate. Registry programs are intended to provide this information at the time it is needed.

It certainly can be argued that the DMV database, containing organ donor preference data, constitutes an organ donor registry for Virginia. However, the

DMV database does not appear to be universally accepted as a true donor registry by OPOs operating in Virginia. This may be due to the combined effect of several different factors, including:

- concerns about the type of donor-preference information that is contained in the database;
- concerns about the legal-sufficiency of donation preference information; and
- the lack of a statutorily-defined purpose and objective for the registry.

At least four types of objectives, which are not necessarily mutually exclusive, have been cited for donor registries:

- to aid in organ procurement, either by helping persuade a deceased's next-of-kin to consent to donate, or to provide the necessary basis for the deceased's wishes to override any objections of the next-of-kin;
- to provide an additional means to promote organ donor awareness among the general public;
- to help empower individuals to make decisions about their own deaths; and
- to provide data necessary to help evaluate the effectiveness of organ donor education, outreach and awareness activities.

According to the 1997 UNOS study of Advance Directives and Donor Card Effectiveness, the keys to implementation of a successful registry are:

- the registry should be sufficiently comprehensive in terms of the type of individuals included in the registry, and the type of data that is recorded for each individual;
- the registry should allow for convenient, easy access by appropriate emergency, hospital, and OPO personnel;
- confidentiality of registry data should be adequately protected; and
- the registry should make it easy and convenient for citizens to change their organ donation preference.

Several other issues should be addressed when considering the development of a donor registry. These include:

- What are the specific goals of the registry?
- Is a registry the most cost effective approach for increasing donation?
- Are their sufficient resources and support for the registry?
- Will the registry be accepted by the public and the hospital and transplant communities?
- What data will be collected? (e.g. donation preferences, demographic data, family contacts?)
- Will the information be protected and accessible only to qualified personnel and researchers?
- What are the points of entry and procedures for collecting donor information? Will point-of-entry personnel be trained? Are they supportive of donation?
- How often will individuals come into contact with these points of entry (e.g. most state driver's license renewal cycles are four to five years)?
- How will the registry be publicized to prospective donors and professionals?
- How easy is it for individuals to change their donation preferences or other information?

The issue of how comprehensive the registry should be is significant. A donor registry can be "all-inclusive" in that it contains the organ donation preferences of all citizens wishing to communicate them, including the people whose preference is to not be an organ donor. On the other hand, a donor registry can be "donor-only" in that it contains data only for those persons whose stated preference is to be an organ donor. However, the issue of registry comprehensiveness can probably not be adequately addressed until the purpose and objective of the registry is determined.

The 1997 UNOS report on advance directives and donor card effectiveness concluded that creation of computerized donor registries, either national or state and available to appropriate law enforcement, OPO personnel, and coroners on a 24 hour basis, would greatly facilitate a policy of informing families of the deceased's organ donation wishes as opposed to seeking consent.

The Illinois Organ Donor Registry is the Largest in the Country, and Has Substantial Financial Support

The Illinois donor registry was established in 1992 to track individuals willing to be donors through an existing driver's license and identification card database. Illinois enacted an increase in motor vehicle title and transfer fees, which provides about $2 million annually to help fund organ donor awareness efforts and maintain the registry. The registry falls under the jurisdiction of the Secretary of State, as does the department of motor vehicles and the state police. Every applicant for a new or renewal driver's license or identification card at all motor vehicle facilities are asked: "Do you intend to sign the organ donor portion of your driver's license/identification card and participate in the registry as a potential donor?"

The Illinois registry is a "donor-only" registry that contains about 3.9 million enrollees, or about 40 percent of the state's 9.6 million licensed drivers and identification card holders. An additional 50,000 individuals enroll each month. The registry is accessible via a special 800 telephone hotline maintained by the state police, which receives about 55 calls each month from organ banks. The Secretary of State's office follows up with individuals who formally decline to participate in the registry, to ensure that they are as prepared as possible to answer the question when they visit the facility again. Those individuals joining the registry receive a follow-up letter from the Secretary of State reminding them to share their decision with family members. Individuals who change their mind about their donation preference can modify their record with a phone call to the secretary of state's office.

When an individual is seen as a likely candidate for donation, an OPO can access the registry to determine the individual's preference. Although state law provides that registry information is legally binding with respect to donation, hospitals and OPOs still insist on getting consent of the next-of-kin. However, knowledge of the deceased's wishes greatly increases the likelihood of family consent. The number of donors recovered by Illinois' largest OPO increased 50 percent from 1994-1997. It has been estimated that the registry played a significant role in that increase.

The Louisiana Donor Registry is All-Inclusive and Operated by the State's Organ Procurement Organization

Louisiana's registry was implemented in 1994 by the Louisiana Organ Procurement Agency (LAOPA) and is funded in part by a grant from the National Institutes of Health. Although individual donor preferences are still collected primarily through motor vehicle offices, the registry is controlled by LAOPA. A "living will" document, developed by LAOPA and approved by the state attorney general, is attached to each driver's license issued. Completed

documents are mailed to LAOPA each week, whereupon the entire document is scanned into the registry database. The document is bar coded, allowing LAOPA to evaluate the effectiveness of its donor education activities.

The registry contains 600,000 names and costs approximately $50,000 - $75,000 to manage annually. LAOPA seeks consent from the next-of-kin for individuals who have expressed a preference for donation. However, LAOPA has begun an intensive five-year public education campaign to promote the registry. Once the registry contains the names of more than 50 percent of Louisiana residents, LAOPA plans to accept the potential donor's wishes as a form of legal consent, regardless of the next-of-kin's attitude toward donation.

Some Other States Have Also Established Donor Registries

Other than Illinois and Louisiana, only a relatively small number of states are generally credited within the organ procurement profession as having donor registries from which information can be accessed at the time of death. Virginia is one such state. Other states include: Arkansas, Florida, New Jersey, Michigan, Missouri, Ohio, Georgia, and Maryland.

- The Arkansas donor registry is maintained by the Arkansas Regional Organ Recovery Agency. Organ preference data is collected at motor vehicle offices and downloaded to the OPO each month. The OPO uses the data to analyze the effectiveness of its organ donor awareness activities. Rather than having to return to DMV in order to change his organ donor preference, an individual can complete a donor designation change form – developed by the OPO – and mail it to the OPO at any time. Thirty-eight percent of the state's licensed drivers and identification card holders have expressed a preference for organ donation.

- The Georgia registry is a donor-only registry which contains the names of 2.5 million individuals, or 46 percent of the state's licensed drivers. A $7 discount off the motor vehicle license fee is provided to individuals who join the registry. The annual fiscal impact of this discount on the state motor vehicle department is about $4 million. The registry data is used to help achieve consent to donation from the next-of-kin. Eventually, the OPO would like to use the data to target and track donation preference rates across the state.

- The New Jersey Organ and Tissue Donor Registry was implemented in April 1998 by the New Jersey Organ and Tissue Sharing Network, which is one of the state's designated OPOs. Under the registry, the OPO shares with the registrant the responsibility of informing his or her family of his donation wishes. When someone declares his wish to donate and signs up with the registry, the OPO will automatically send a letter to the registrant's next-of-

kin. The registry will also serve as a quantitative tracking tool to aid in public outreach efforts.

The Commonwealth Needs to Make a Policy Decision Concerning Whether Organ Donor Preference Information in the DMV Database Should be Used for Organ Procurement; Other Policy Issues Should be Addressed as Well

Currently, the *Code of Virginia* contains no provision for an organ donor registry. Issues such as the purpose of the registry and what type of data it should contain are not addressed by state statute. What the state has is a simple organ donor preference variable in the DMV driver's license database that OPOs may access. The DMV database could easily serve as the basis for a formal, statutory organ donor registry in Virginia. It would enable Virginia to leverage the existing electronic database rather than create an entirely new database, as some other states have done. However, as previously mentioned, the DMV database does not appear to be universally-accepted as a true donor registry within the organ procurement community.

In order for the concept of a formal organ donor registry, based on the DMV database, to advance as a matter of public policy in Virginia, several policy issues should be addressed. These are set out below.

- What is the purpose and objective of maintaining a registry? The purpose of a registry could be viewed as a tool for aiding organ procurement efforts by enabling OPOs to determine whether a potential organ donor had previously indicated a willingness to be an organ donor. On the other hand, some OPOs interviewed by JCHC staff viewed the purpose of a Virginia organ donor registry in a more limited manner, primarily as an additional means of promoting organ donor awareness among the general public, and for evaluating the effectiveness of organ donor awareness activities.

- Should the registry contain information only for those individuals who have expressed a willingness to donate, or should it include information on all people who have expressed any type of organ donation preference? Currently in Virginia the DMV database includes all individuals who have expressed a preference, regardless of what that preference is. The one exception to this is for individuals who expressed a preference for donation from January 27, 1997 through February 3, 1999. For that time period, the database includes only the names of individuals who expressed a preference for donation.

- What type of ability do non-drivers have to join the registry? In Virginia non-drivers can indicate preference on photo identification card but have to go to DMV to get the identification card. However, to the extent that any non-

drivers have signed separate donor cards provided by an OPO, that information is not maintained in any database.

- How easy and convenient is it for an individual to change his donation preference? In Virginia an individual must return to DMV and pay a $5 fee for a new driver's license, or else wait for the license renewal to be mailed every fifth year. DMV does plan to begin its renewal by phone and Internet in the third quarter of 1999.

- To what extent should registry data be used as a management tool for analyzing the effectiveness of donor education and outreach efforts in various parts of the state? This could be done in Virginia, but has not been done to date.

In addressing each of these policy issues, the relative importance of organ transplantation within the framework of access to health care services should be a guiding consideration. To the extent that organ transplantation is viewed as being an important medical treatment for which individual access should be promoted, the state may wish to increase the scope of its efforts to increase the supply of organs. Given the persistent shortage of human organs available for transplant, use of the current DMV database as a formal donor registry could play a valuable role in aiding organ procurement within the state.

IV.
Certification, Accreditation, and Regulation of Organ Procurement Organizations

Issues Have Been Raised Concerning the Number of OPOs Operating in Virginia, and the Degree to Which OPOs are Accountable to the Commonwealth

SJR 454 states in part that:

- Virginia currently imposes no statutory or regulatory requirements on the structure or operation of OPOs;
- Some level of state accountability of OPOs operating in Virginia may help to promote more accurate assessment of OPO performance in procuring organs for transplantation; and
- It is unclear what impact, if any, the number of OPOs operating in Virginia may have on uniformity of service, efficient use of resources, and equal access for all Virginians to organs recovered within the boundaries of the Commonwealth.

This section of the report addresses these issues.

OPOs Must be Certified by the United States Health Care Financing Administration (HCFA)

Organ procurement organizations are provided with designated service areas by HCFA. Virginia is served by five OPOs: LifeNet (Eastern and Central Virginia), Washington Regional Transplant Consortium (WRTC -Northern Virginia), Virginia's Organ Procurement Agency (VOPA - Western Virginia), Tennessee Donor Services (TDS - Southwest Virginia) and the Carolina Organ Procurement Agency (COPA - Danville and Pittsylvania County). Of the five, only VOPA's service area does not extend outside the state of Virginia.

In order to be the designated OPO for a service area, an entity must meet several conditions. These are specified in federal regulations at 42 C.F.R.486 and include the following:

- participate in the Organ Procurement and Transplantation Network (OPTN);
- be a non-profit entity that is exempt from federal income taxation;

- have adequate accounting and fiscal procedures;
- have an agreement with the U.S. Secretary of Health and Human Resources to be reimbursed under Medicare for the procurement of covered organs;
- have a director and other such staff, including an organ donor coordinator and an organ procurement specialist, necessary to obtain organs effectively from donors in its service area;
- have a board of directors or an advisory board that has the authority to recommend policies relating to the donation, procurement and distribution of organs;
- have documented evidence that it has a working relationship with at least 75 percent of the hospitals that participate in the Medicare and Medicaid programs in its service area;
- arrange for the appropriate tissue typing of donated organs;
- have a system to equitably allocate donated organs among transplant patients that is consistent with the rules of the OPTN;
- provide or arrange for the transportation of donated organs to transplant centers;
- have arrangements to coordinate its activities with transplant centers in the area;
- have arrangements to cooperate with tissue banks;
- have a procedure for assuring the confidentiality of patient records;
- conduct and participate in professional education concerning organ procurement;
- ensure that appropriate donor screening and infection tests are performed;
- assist hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors; and
- ensure that donors are tested for human immunodeficiency viral markers consistent with OPTN rules and Centers for Disease Control guidelines.

HCFA has established performance standards for OPOs, which are contained in 42 CFR 486.310. These standards must be met for the OPO to be re-

certified by HCFA for a two year period. The standards, which first took effect on January 1, 1996, provide that each OPO must achieve at least 75 percent of the national mean – averaged over the two calendar years prior to the year of certification - for four of the following five performance categories:

- number of actual donors per one million population;
- number of kidneys recovered per one million population;
- number of extrarenal organs recovered per one million population;
- number of kidneys transplanted per one million population; and
- number of extrarenal organs transplanted per one million population.

HCFA last certified OPO's during calendar year 1998. The next scheduled re-certification process will take place during calendar year 2000. Figure 6 summarizes the actual performance of Virginia's OPOs, during the most recent HCFA certification period, in comparison to the HCFA standard.

HCFA may continue to designate an OPO that does not meet the performance standards if no OPO that meets the performance and qualification standards is willing to accept responsibility for the service area, and if the designated OPO submits an acceptable corrective action plan. A hospital may request, and HCFA may grant, a waiver permitting the hospital to have an agreement with an OPO other than the one designated for the service area in which the hospital is located.

Two OPOs have been decertified by HCFA since the current performance standards went into effect in 1996. One other OPO is currently contesting its decertification notice in court. As discussed in JCHC's November 1998 issue brief, the population –based performance standards used by HCFA have been criticized by the U.S. General Accounting Office and OPOs for their failure to take into account variations in donor potential in different parts of the United States.

OPOs Are Also Subject to UNOS Standards

UNOS has both membership and minimum procurement standards for OPOs. Most of the membership standards are essentially the same as the HCFA certification requirements. Some of the UNOS membership standards require an OPO to:

- have a medical director who is a licensed physician who is responsible for the medical and clinical activities of the OPO;

- have the technical ability to communicate the appropriate information in a timely fashion that is necessary to facilitate equitable distribution of organs; and

- report all key personnel changes (executive director, medical director) to UNOS within 30 days of the change; positions that are not filled within six months of vacancy must be reviewed by the UNOS Membership and Professional Standards Committee.

Figure 6

Actual Performance of OPOs Operating in Virginia in Comparison to HCFA Standards (Organs Procured and Transplanted Per One Million Population)

	Kidneys Procured	Extra-Renals Procured	Kidneys Transplanted	Extra-Renals Transplanted
COPA	33.58	42.22	30.79	38.46
LifeNet	41.34	42.02	35.58	39.14
TDS	44.73	52.95	39.48	46.89
VOPA	34.21	37.81	31.21	33.31
WRTC	35.59	36.35	31.81	32.57
U.S. Mean	37.72	36.88	36.88	33.1
75% of U.S. Mean	28.29	27.66	27.66	24.83

Note: Statistics are computed as a two-year average for the period 1996 and 1997. Extra-renal organs include liver, heart, lung, and pancreas.

Source: JCHC staff analysis of 1996/97 organ procurement organization performance data compiled by HCFA.

UNOS also has minimum procurement standards for OPOs. The OPO responding to an organ donor call is responsible for identifying, evaluating, and maintaining the donor consistent with specified medical and technical criteria, obtaining consent for the removal of organs, and verifying pronouncement of death. The OPO is also responsible for ensuring that tissue typing information about the donor is entered into the UNOS computer system, and that the

approved UNOS organ allocation computer program is executed for each donor organ. Every reasonable attempt shall be made to obtain a social history from, but not restricted to, the person granting permission for organ donation.

The OPO is also responsible for obtaining permission for visiting surgical teams to enter the operating room and surgically remove organs. When a non-renal organ is offered for transplantation, the recipient transplant center procurement team must be given the option of removing the non-renal organ unless extenuating circumstances dictate otherwise. The OPO is responsible for organ procurement quality including appropriate preservation and packaging of the organs, and assurance that adequate tissue typing material is procured, divided and packaged. The OPO is responsible for ensuring that written documentation of donor evaluation and maintenance, consent to donation, death pronouncement, and organ procurement quality accompanies the recovered organ to the transplant center. Finally, according to the UNOS standards, each OPO must develop and implement a plan to address multi-cultural issues related to organ donation.

OPOs May Seek Accreditation from the Association of Organ Procurement Organizations

The Association of Organ Procurement Organizations (AOPO) is the professional association to which all 62 OPOs currently belong. AOPO has developed a voluntary accreditation program for its members. In order to be accredited, an OPO must pay a $3,000 fee, and submit to a peer-review to determine compliance with AOPO's accreditation standards. These standards are fairly extensive, and comprise six areas: administration, clinical, safety, medical records, education, and ethics.

As of January 1999, 29 OPOs had been accredited by AOPO. However, it should be noted that 14 OPOs who did not previously belong to AOPO recently joined in the Fall of 1998. AOPO's executive director anticipates that these new members will have strong interest in accreditation. Among Virginia's OPOs, WRTC and LifeNet are accredited by AOPO. VOPA has not yet sought accreditation but plans to do so. COPA and TDS are among the 14 new members of AOPO, and are not yet accredited.

Many of the AOPO standards are similar in nature to the HCFA requirements and the UNOS standards. However, the AOPO standards are more extensive in number. For each standard there are more specific requirements and interpretations. Some of the administration standards include:

- the organ procurement organization shall be managed effectively and efficiently;

- the OPO shall have personnel policies and procedures in place to provide guidance for employees; and

- the OPO shall have policies and procedures established for the documentation of all direct and indirect costs, which shall be used as the basis for the establishment of organ and/or tissue acquisition charges.

Some of the AOPO clinical standards include:

- the OPO shall have policies and procedures to respond to referrals of potential donors in a prompt, professional and standardized manner;

- the OPO shall determine that death has been legally determined and documented in the donor's medical record; and

- evaluation and management of donors shall meet the OPTN standards and requirements in effect at the time of the donor recovery.

Florida is the Only State to Require State Regulation and Certification of OPOs

All OPOs, as well as tissue banks and eye banks, operating within Florida are required to be certified by the Florida Agency for Health Care Administration (AHCA). According to representatives of AHCA, Florida first began to regulate OPOs, tissue banks, and eye banks in 1992. At the time, according to AHCA, the state did not believe that there was sufficient accountability on the part of these procurement organizations to the state. Also, at that time, HCFA had not yet established performance standards for OPOs. In addition, tissue banks and eye banks were not yet regulated by the U.S. Food and Drug Administration, although they now are. According to AHCA, the OPOs, tissue banks, and eye banks operating in the state at the time did not oppose the concept of state regulation.

As part of its certification program, Florida assesses a $1,000 initial application fee from OPOs and tissue banks, and $500 from eye banks. In each subsequent year, state law requires OPOs to pay the greater of $1,000 or 0.25 percent of their total revenues produced from procurement activities within Florida. These fees, which by law cannot exceed $35,000 per OPO, are required to be used by the Agency for Health Care administration to support the certification program conducted by the Organ and Tissue Donor Advisory Board, maintain an organ and tissue donor registry, and support the organ and tissue donor education program. As part of its certification program, AHCA has developed through regulation administrative rules and standards which OPOs,

tissue banks, and eye banks must comply with. Compliance with these rules and standards are assessed through surveys conducted by AHCA staff.

Florida law requires an Organ and Tissue Procurement and Transplantation Advisory Board. The purpose of the advisory board is to assist the AHCA "in monitoring the appropriate and legitimate expenses associated with organ procurement, processing, and distribution for transplantation and developing methodologies to assure the uniform statewide reporting of data to facilitate the accurate and timely evaluation of the organ and tissue procurement and transplantation system." The Florida advisory board is also required by statute to:

- provide assistance to the Florida Medical Examiner's Commission in the development of appropriate procedures and protocols to assure continued improvement in the approval and release of potential organ and tissue donors by the district medical examiners and associate medical examiners;

- develop with and recommend to AHCA the necessary procedures and protocols required to assure that all residents of the state have reasonable access to available organ and tissue transplantation therapy; and

- develop with and recommend to AHCA any changes to laws, regulations or procedures required to assure that the statewide organ and tissue procurement and transplantation system will function smoothly, effectively, and efficiently.

The Florida Organ and Tissue Procurement and Transplantation Advisory Board consists of 14 members who are appointed by and report directly to the Florida Director of Health Care Administration. Membership requirements for the advisory board are specified by statute, and include representatives with expertise in various types of organ , tissue, eye, and bone marrow transplantation and procurement. The advisory board also contains representatives from the Florida Pediatric Society, Society of Pathologists, and Medical Examiners Commission.

In addition to the advisory board, Florida law also requires an organ and tissue donor education panel. The education panel consists of 12 members "to represent the interests of the public with regard to increasing the number of organ and tissue donors within the state." In terms of its membership and purpose, it is largely analogous to the Virginia Transplant Council. However, unlike in Virginia, all of the members of the Florida education panel are appointed by the Director of Health Care Administration. Florida law requires that the education panel and the state advisory board jointly develop education initiatives which, subject to approval by AHCA, the state shall implement.

Virginia Has More OPOs than Many Other States

There are only three other states in the country which have as many OPOs operating within their borders as does Virginia. These are California, Florida and New York. By contrast, ten states have all, or at least substantially all, of their jurisdictions served by a single OPO. These states are Alabama, Arizona, Colorado, Georgia, Hawaii, Illinois, Louisiana, Michigan, Nebraska, New Mexico, Oklahoma and Utah. Most of the New England states are served by a single OPO headquartered in Massachusetts. The number of OPOs in any state is a function of HCFA certification and voluntary consolidation agreements on the part of OPOs.

LifeNet and VOPA Discussed A Potential Merger, But Negotiations Were Unsuccessful

In 1997, LifeNet initiated negotiations with VOPA concerning a potential merger. The negotiations continued for 18 months. However, the negotiations ultimately proved to be unsuccessful, and were halted by LifeNet in 1998. By contrast, several years ago Louisiana was served by four OPOs. Through voluntary agreement, the four organizations were consolidated into one.

There Are Some Potential Implications Arising From the Fact That Virginia is Served by Five OPOs

There is disagreement among Virginia's OPOs concerning whether or not Virginia actually needs five OPOs operating within the state. Some stated that the number of OPOs serving Virginia is of no consequence – assuming that all of the OPOs are equally effective and efficient in procuring organs. However, it was suggested by one OPO that a single OPO operating in Virginia would result in several benefits. First, there would be increased administrative efficiencies for organ procurement through the need to support only a single organization dedicated to organ recovery. This would allow greater economies of scale through, for example, bulk purchasing of supplies and educational materials.

JCHC staff were also told that a single OPO in Virginia would help promote lower, or at least more stable, organ acquisition costs for transplant centers. Currently, there is some variation in organ acquisition charges among Virginia's OPOs (Figure 7). This variation may be due to some OPOs not including payment for surgeon fees. The OPO governing boards, which include transplant center representatives, must approve all of the OPO's organ acquisition charges. Kidney acquisition charges must also be approved by HCFA. However, in all likelihood, efficient administrative structures and costs are probably more a function of the effectiveness of the management of various OPOs, as opposed to the number of OPOs designated to operate in any given

state. An evaluation of the efficiency and effectiveness of the management structures of Virginia's OPOs was beyond the scope of this study.

Figure 7

Standard Organ Acquisition Charges of OPOs Operating in Virginia

	Heart	Kidney	Liver	Pancreas	Lung
LifeNet	16,500	16,000	17,500	15,500	18,000
VOPA	17,000	14,500	15,000	15,000	15,000
WRTC	13,900	18,200	12,200	13,000	13,350

Note: Tennessee Donor Services and the Carolina Organ Procurement Agency are not included because they do not have any transplant centers within the Virginia portion of their designated service areas.

Source: LifeNet, Virginia's Organ Procurement Agency, and the Washington Regional Transplant Consortium.

The Number of OPOs Operating in Virginia Poses Potential Effects on the Allocation of Organs Recovered Within the State

Representatives of one transplant center told JCHC staff that a single OPO would help promote equalized access to organs by all of the state's residents needing transplants – regardless of which part of the state they live in. Currently, an OPO service area is considered the "local" portion of the local, regional, and national organ allocation prioritization system operated by UNOS. Since there are five OPOs in Virginia, there are five different local areas. If a recovered organ can not be allocated within the local area, it then becomes available to the entire UNOS region XI, which also encompasses North Carolina, South Carolina, Tennessee, and Kentucky. If there is not a suitable candidate to receive the organ within the region, it is then made available nationally. However, the issue is further complicated in Virginia because the Virginia portion of WRTC's service area is actually in UNOS region II, along with Delaware, the District of Columbia, Maryland, New Jersey, Pennsylvania, and West Virginia. A single OPO for Virginia would result in the entire state being

considered the local area. Under such a scenario, a recovered organ would be made available throughout the entire state before being made available to other states in the UNOS region.

The issue of organ allocation was the subject of a 1999 study by the Institute of Medicine (IOM), which is part of the National Academy of Sciences. The IOM study was conducted pursuant to a congressional mandate, which was in response to federal proposals to modify the current organ allocation system. The proposed regulations required the Organ Procurement and Transplantation Network to develop criteria aimed at allocating organs first to those in the "highest medical urgency status," with reduced reliance on geographical factors, such as the location where an organ was recovered. According to the U.S. Department of Health and Human Services, the intent of the proposed changes was to reduce disparities in waiting times for patients at different transplant centers in different parts of the country. The proposed regulations also required development of criteria to be followed in deciding when to place patients on a transplant waiting list, and for determining the status of patients who are listed.

The IOM report made the following recommendations concerning organ procurement and transplantation:

- establish organ allocation areas for livers;
- discontinue use of waiting time as an allocation criteria for patients in statuses 2B and 3;
- exercise federal oversight; and
- establish independent scientific review.

In response to the proposed changes in the organ allocation system, a small but growing number of states have enacted or introduced legislation intended to help ensure that organs recovered within the state are allocated, to the greatest extent possible, to transplant recipients within their jurisdiction. States that have adopted such legislation include Florida, Louisiana, Oklahoma, South Carolina, and Wisconsin. Similar legislation is pending in Arizona and Texas. The South Carolina statute requires the OPO to use its best efforts to locate a suitable transplant recipient within the state for organs recovered in state. The OPO may enter into reciprocal agreements with qualified OPOs in other states, provided that the agreement is approved by UNOS.

As previously noted, Louisiana and Oklahoma are served by a single OPO. South Carolina, with the exception of two counties, is also served by a single OPO. Under the current organ allocation system, that fact may potentially make the task of actually keeping locally recovered organs within the state much easier than for a state served by multiple OPOs, such as Virginia is with five. The practical effect of such state statutes is yet to be determined, given the issues that are being debated at the national level concerning the proper method for

Current Transplant Coverage Policy Results from a 1992 Lawsuit

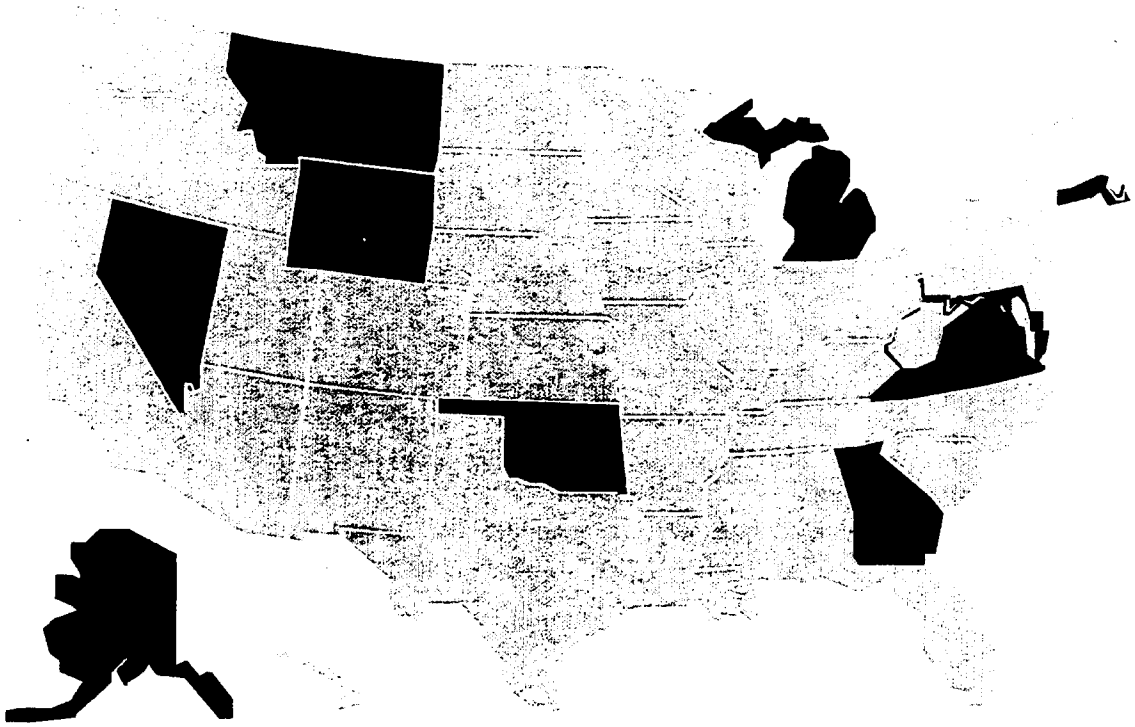
Prior to 1993, the Virginia Medicaid program did not provide any coverage for liver, heart, lung or heart&lung transplants. The program provided coverage for kidney and cornea transplants only. However, the federal 1989 COBRA expanded the scope of Medicaid's Early Periodic Screening, Diagnosis, and Treatment (EPSDT) program. Subsequently, HCFA began to interpret that statute to require that all necessary medical services, including transplants, be covered for EPSDT eligible children. HCFA held this interpretation even if a state Medicaid plan did not provide for organ transplant coverage. A 1992 federal lawsuit filed against DMAS, by the parents of a child in need of a heart transplant, resulted in a judicial ruling that upheld HCFA's interpretation of the statute. The case was appealed to the Fourth Circuit, which affirmed the lower court's ruling.

In the wake of the lawsuit, the Board of Medical Assistance Services studied the issue of Medicaid reimbursement policy for organ and tissue transplants. In July 1993, the study recommended adoption of the current coverage policy. The report stated that in its decision process the "Board considered the needs of the entire potential transplant population. While the needs of adults are compelling, the Board believes the needs of children must be given special consideration...In light of the potential benefits to the Commonwealth if children can be successfully transplanted and can go on to live healthy and productive lives, the Board in weighing these competing interests determined that coverage for children should be a priority." The study also recommended that "transplant centers that serve as providers will be expected to maintain their current efforts to provide uncompensated care to indigent Virginians requiring transplantation services." Finally, the study also recommended that efforts to improve the collection and analysis of data about organ and tissue transplantation in Virginia should be undertaken.

Virginia's Medicaid Organ Transplant Coverage Policy is More Restrictive than Most Other States

Virginia is one of only ten states that do not provide heart transplant coverage for adults through its Medicaid program (Figure 8), and one of only eight in the country that does not provide liver transplant coverage for adults (Figure 9). Virginia is one of 18 states that do not provide lung transplant coverage for adults. North Carolina, Tennessee and Kentucky are among the states that do provide lung transplant coverage for adults. Maryland does not in fact have an outright prohibition on heart, liver, and lung coverage. Rather, it provides coverage only on a case-by-case basis based on the recommendation of an external medical review contractor. Seventeen states provide pancreas coverage for adults, while 23 provide heart&lung transplant coverage.

Figure 8
State Medicaid Programs That Do Not Cover Heart Transplants for Individuals 21 Years of Age or Older
(States Shaded in Black Do Not Provide Coverage)



Source: United Network for Organ Sharing, and JCHC staff telephone survey.

Since 1990, the extent to which state Medicaid programs have covered organ transplants has stayed about the same, with some notable exceptions. For example, only one additional state added heart coverage since 1990, while five states repealed liver coverage and five added pancreas coverage. On the other hand, 17 states added lung transplant coverage. One of the states that expanded its Medicaid organ transplant coverage during that period of time was Arizona. This was the result of the fact that Arizona lost a state age discrimination lawsuit in 1994. The lawsuit had been filed by an individual over the age of 21 who had sought coverage for a liver transplant through Medicaid.

By virtue of its coverage policy, the Virginia Medicaid program does not provide coverage for that portion of the population that most frequently requires heart, lung, and liver transplants. Figure 10 illustrates that over 90 percent of the organ transplants performed in Virginia are for adult recipients.

Figure 9
State Medicaid Programs That Do Not Cover Liver Transplants for Individuals 21 Years of Age or Older
(States Shaded in Black Do Not Provide Coverage)

Source: United Network for Organ Sharing, and JCHC staff telephone survey.

Organ Transplant Coverage by Private Insurers Can Vary Widely

According to transplant center administrators interviewed by JCHC staff, large commercial insurers and large groups tend to provide better transplant coverage – in terms of types of organs covered and the amount of benefit ceilings/caps – than does the small group and individual health insurance market. For example within the Virginia state employee health benefits program, the Key Advantage program provides transplant coverage for kidney, heart, heart/lung, lung, liver, kidney/pancreas, small bowel, and small bowel/liver. There are no annual or lifetime benefit caps or ceilings under Key Advantage. The Cost Alliance program provides coverage for liver, kidney, and cornea transplants, and for bone marrow transplants in response to specific diagnoses. However, the Cost Alliance program contains a $1 million lifetime cap on benefit payments.

Figure 10
Heart, Lung, Liver, and Heart&Lung Transplants Performed in Virginia on Adult Recipients

Calendar Year	Total Transplants Performed In Virginia	Total Transplants Performed in Virginia for Individuals Over the Age of 21	Percent of Transplants Performed in Virginia for Individuals Over the Age of 21
1994	228	211	92%
1995	232	220	94%
1996	264	245	92%
1997	218	203	93%

Source: United Network for Organ Sharing and JCHC staff analysis.

Kaiser Permanente, one of the HMOs that contracts with the state employee health benefits program, provides full coverage for heart, liver, lung, heart/lung and pancreas/kidney transplants. Kaiser Permanente also provides coverage for kidney, cornea, and autologous bone marrow transplants. The Sentara Health Plan, another HMO in the state employee health benefits program provides heart, kidney, lung, corneal, and liver transplant coverage. Bone marrow transplant coverage is provided only in response to certain diagnoses. The Trigon Healthkeepers HMO provides transplant coverage for only liver, kidney, and cornea. Bone marrow transplant coverage is provided for the treatment of breast cancer. The Piedmont Community Health Plan, yet another HMO in the state employee health benefits program provides kidney, liver, heart, bone marrow, and cornea transplants. However, this HMO excludes coverage for lung, pancreas and intestinal transplants.

JCHC staff contacted the Virginia Association of Health Plans (VAHP) in order to obtain additional information concerning the extent of organ transplant

coverage by private health plans. VAHP was able to collect information from two of its member health plans. According to VAHP, the types of organs covered for transplant by these plans includes heart, lung, liver, heart/lung, and pancreas/kidney. Coverage for intestinal and bone marrow transplants varied. Artificial heart transplants were generally excluded from coverage. Both respondents require transplants to be medically necessary, and exclude coverage in the presence of active substance abuse on the part of the individual. One plan did not impose any annual or lifetime benefit caps for its enrollees. The second plan had a lifetime maximum benefit of $1 million. Neither plan reported coverage exclusions based on the age of the individual.

Organ Transplant Survival Rates Have Been Increasing, and Have Little Relationship to the Age of the Transplant Recipient

As post-transplant organ survival rates have increased, transplant has become a generally-accepted type of medical treatment for end-stage organ failure. Transplant survival rates are computed both in terms of graft (organ) survival rates and patient survival rates. Patient survival rates tend to be somewhat higher than graft survival rates. That is due, in part, to the fact that while a transplant recipient's body may reject a particular organ following a transplant, the patient could theoretically survive as the result of a second transplant. Patient survival rates also differ from graft survival rates because a transplant recipient's ultimate death may not be attributable to the transplanted organ.

Figure 11 illustrates that graft survival rates for one and three years following transplant increased significantly for livers and lungs from 1988 to 1995. The percentage increase was much less for hearts, but the overall survival rate for heart transplants continued to be substantially greater than for liver and lung transplants. Figure 12 illustrates the fact that the age of the recipient is not a clear indicator of post-transplant graft survival rates. It does not appear that children have better survival rates than older individuals. In fact, for heart and lung transplants, survival rates for 50 to 64 year olds are greater than for 11 to 17 year old recipients. While the 1993 DMAS organ transplant study did examine transplant survival rates, the report did not analyze those rates by the age of transplant recipients. According to transplant center surgeons and administrators interviewed by JCHC staff, a better indicator of post-transplant survival than recipient age is the health and medical status of an individual prior to the transplant.

Figure 11

United States Organ Transplant Graft Survival Rates, By Year of Transplant

	One-Year Survival Rate		Three-Year Survival Rate	
Organ	1988	1995	1988	1995
Heart	80.8%	84.6%	72.5%	77.8%
Liver	64.2%	77.7%	56.4%	70.7%
Lung	42.4%	76.1%	33.3%	58.6%

Source: United Network for Organ Sharing OPTN/Scientific Registry data as of March 1, 1999.

Figure 12

United States Organ Transplant Three-Year Graft Survival Rates, By Age of Recipient

Organ	**11-17**	**18-34**	**35-49**	**50-64**
Heart	69.8	75.1	77.5	75.5
Liver	69.6	65.4	68.5	65.5
Lung	43.9	52.8	57.3	55.1

Note: Survival rates calculated for transplants performed from October 1987 through December 1995.

Source: United Network for Organ Sharing OPTN/Scientific Registry data as of March 1, 1999.

Most Transplant Requests Received by DMAS Are Pre-Authorized, But Relatively Few of Those Transplants Actually Occur

During the time period FY 1994 through FY 1998, DMAS received 74 pre-authorization requests for solid organ transplant. This would include all transplants other than bone marrow. The majority of those requests, 57 requests or 77 percent, were pre-authorized. However, over that five-year period only 47 percent of the preauthorized requests, 27 in all, actually resulted in a transplant. In 11 cases where pre-authorization was approved, the individual died shortly thereafter and before a transplant could be performed. A probable explanation for the failure of the remaining pre-authorized cases to proceed to transplant is probably the inability of the individual to obtain a suitable organ. Therefore, in the large majority of cases that DMAS pre-authorized for transplant, the Virginia Medicaid program ultimately did not incur any transplant-related expenses. During the FY 1994 to FY 1998 time period, DMAS paid a total of $4,341,306 (total funds) in reimbursement for solid organ transplants. This comprised 56 percent of the $7,705,998 (total funds) that it paid for all types of transplants, including bone marrow, during that time period.

Prescription Drug Coverage and Case Management

Appropriate post-transplant medical management of transplant recipients is essential to their survival. Each transplant recipient must comply with a strict immuno-suppressive drug regimen, consisting of numerous medications, for the rest of his or her life in order to ensure that there bodies do not reject the transplanted organ. These prescription drugs are expensive, and can cost several thousand dollars per month. DMAS does provide a prescription drug benefit that is available to transplant recipients. Categorically-needy and medically-needy recipients pay a $1.00 per prescription co-payment directly to the dispensing pharmacy. However, the co-payment is waived for individuals under 21 years of age. DMAS currently pays for immuno-suppressive drugs for more than 500 transplant recipients, regardless of whether Medicaid paid for the transplant procedure itself.

Following an organ transplant, the recipient typically has to undergo an extensive period of rehabilitation before he or she can resume a fully normal and productive life. DMAS does not have a case management program designed specifically for transplant recipients. However, DMAS does provide coverage for outpatient hospital services. This includes therapeutic, rehabilitative and palliative services provided in an outpatient hospital setting and ordered and provided under the direction of a physician. Categorically-needy and medically-needy recipients pay a $3.00 per visit co-payment directly to the hospital. The co-payment is waived for individuals under 21 years of age. DMAS also provides coverage for general physical therapy, occupational therapy and other types of

rehabilitation services. Physical therapy and occupational therapy visits are limited to 24 per year unless approved by DMAS.

During the 1999 Session, DMAS Estimated The Cost of Expanded Transplant Coverage for Individuals 21 Years of Age and Over to be $23.5 Million

During the 1999 General Assembly Session, DMAS was requested to estimate the fiscal impact of expanding Medicaid organ transplant coverage, for heart, liver, lung, and heart lung, to Virginia residents 21 years of age and older. DMAS based its estimate on four major assumptions:

- That the current level of actual adult transplant activity will remain constant due to the fact that organ availability is a controlling factor.

- That 95 percent of all potential transplant recipients would become Medicaid eligible at some point prior to or on the day the actual transplant is performed. It was assumed that most recipients would meet spend down requirements for Medicaid eligibility at that time. This assumption takes into account costs associated with initial diagnosis and testing, early treatment, any initial hospitalization as well as the costs of laboratory work and drugs.

- That patients with private insurance would still become Medicaid eligible due to the fact that most insurance companies either do not cover transplants or have spending ceilings for policy holders.

- That patients 65 years of age and older will be covered by Medicare and therefore are not included in the cost estimate.

Figure 13 illustrates the components of the DMAS fiscal impact analysis.

According to DMAS, the estimated state general fund expenditures resulting from expanded coverage would be $11,388,842 annually. This was based on an estimated state average share during FY 2000 of 48.35 percent. That general fund estimate would correspond to the following estimated general fund expenditure for each type of transplant:

- Heart/Lung - $132,962
- Heart – $3,031,545
- Liver - $7,044,595
- Lung (single) - $265,925
- Lung (double) - $913,815

It may be noted that, at the time Virginia Medicaid policy was expanded to provide liver, heart, lung and bone marrow transplant coverage for children, the estimated total cost for FY95 and FY96 alone was more than $15 million.

However, the actual expenditures have proved to be much less - $7,705,998 from FY 1994 through FY 1998. This provides an indication that these expenditures can be difficult to estimate.

Figure 13

DMAS Analysis of Fiscal Impact of Expanding Medicaid Organ Transplant Coverage to Individuals 21 Years of Age and Older

Transplant Type	Actual Number Performed in Virginia During 1997	Estimated Transplants Performed on Individuals Age 21 – 64	Medicaid Eligible Transplant Estimate - 95%	Medicaid Global Fee	Estimated Total Cost for Coverage
Heart/Lung	2	2	2	$137,500	$275,000
Heart	73	57	54	$110,000	$6,270,000
Liver	120	94	89	$155,000	$14,570,000
Lung (single)	6	5	5	$110,000	$550,000
Lung (double)	17	14	13	$135,000	$1,890,000
TOTAL	218	172	163		23,550,000

Source: Department of Medical Assistance Services.

Figure 14 provides an illustration of the percentage of pediatric organ transplants performed in Virginia that DMAS paid for over a four year period. The table indicates that the percentage varied substantially from year to year, from 20 percent to 41 percent.

The percentage range of 20 to 41 percent of Virginia pediatric transplants reimbursed by DMAS stands in contrast to the assumption that DMAS would reimburse 95 percent of all adult transplants if Medicaid coverage were expanded. A key question is which percentage in the range of 20 to 40 percent would hold true for the adult population? DMAS staff have suggested that the percentage would be somewhat higher than that range. As explained by DMAS staff, in the event a child is sick and in need of a transplant, the parents would

presumably still be working and have insurance coverage for transplants. However, in the case of adults who are sick and in need of a transplant, they would presumably be unable to work, lose their insurance coverage, and be forced to spend-down their assets in order to qualify for Medicaid coverage. However, those types of assumptions stand in contrast to the fact that private insurance coverage is available, albeit to varying degrees, and transplants for individuals 21 years of age and older are being paid for by someone.

Figure 14

Pediatric Heart, Lung, Heart/Lung and Liver Transplants Performed in Virginia That Are Paid for by Medicaid

Calendar Year	Virginia Transplants for Recipients 21 Years of Age and Under	Number of Transplants Reimbursed by Medicaid	Percent of Transplants Reimbursed by Medicaid
1994	17	7	41%
1995	12	3	25%
1996	18	7	38%
1997	15	3	20%

Note: The number of transplants reimbursed by DMAS includes five transplants performed out-of-state during this time period.

Source: JCHC staff analysis of UNOS transplant and DMAS transplant reimbursement data.

The JCHC Staff Estimate of The Cost of Expanding Medicaid Organ Transplant Coverage For Adults is Substantially Less Than The Earlier Estimate Prepared by DMAS

JCHC staff estimate that the annual general fund cost of expanding Medicaid organ transplant coverage to adults between the ages of 21 and 64 is approximately $1.5 million. In order to prepare its estimate, JCHC staff collected data from (1) Medicaid agencies in other states which already cover organ transplants for adults, (2) organ transplant centers located in Virginia, and (3) the

United Network for Organ Sharing. Appendix C provides more detailed information concerning the methodology of the JCHC staff estimate.

In the course of preparing its cost estimate, JCHC staff determined the following:

- Virginia's five transplant centers performed 470 organ transplants for adults between the ages of 21 and 64 during 1998;
- 60 percent of the transplants performed in Virginia are kidney transplants; for which the Medicaid program already provides coverage for adults.
- Private insurance pays for almost 50 percent of all organ transplants performed on adults in Virginia, and for almost 66 percent of all non-kidney organ transplants performed on adults; and
- State Medicaid programs pay for only a small percentage of the total organ transplants performed on adults.

Organ transplantation is certainly an expensive medical procedure. However, its costs must be viewed in comparison to its benefits. The Commonwealth must achieve a balance between ensuring equitable access to potentially life-saving medical procedures, and using scarce resources to provide the most benefit to the greatest number of persons. Given that Virginia attempts to ensure access to medically necessary health care services through the Medicaid program, the relative importance of organ transplantation to health care access becomes an issue of public policy. The General Assembly could decide, as a matter of public policy, to expand Medicaid coverage for organ transplants. Such an expansion could be implemented gradually, perhaps by focusing on those types of transplants with the greatest survival rates.

VI.
Policy Options

The following policy options are offered for consideration by the Joint Commission on Health Care. However, these policy options do not represent the entire universe of options that the Joint Commission on Health Care may wish to pursue with regard to organ donation and transplantation. Options II through VII are not mutually exclusive; the Joint Commission on Health Care could choose to implement any or all of these policy options.

Option I: **Take No Action.**

Option II: **Introduce legislation which: (1) defines the Commonwealth's public policy as requiring that organ donor preference indicator data solicited, collected, and maintained by the Department of Motor Vehicles shall be used for the purpose of aiding in the procurement of human organs in Virginia in a manner that is consistent with the legally-sufficient expression of individual donor intent as indicated by the data; (2) directs the State Health Commissioner to appoint and convene a task force, consisting of representatives from the Virginia Transplant Council, including the Department of Motor Vehicles, to identify ways to better utilize organ donor preference data collected by the Department of Motor Vehicles in order to increase organ procurement in Virginia, and (3) requires the task force to report its findings and recommendations to the Governor, the Joint Commission on Health Care, and the 2001 General Assembly.**

Option III: **Introduce legislation authorizing a Virginia organ donor registry based on the currently available database maintained by the Department of Motor Vehicles, and requiring the Virginia Transplant Council, with assistance from the Department of Health, the Department of Motor Vehicles, and other appropriate state agencies and private entities, to develop a plan for utilization of the registry that is consistent with statutorily-defined objectives, access policy, confidentiality protections, and data requirements.**

Option IV: **Introduce legislation to broaden the type of information that the Virginia Transplant Council annually reports to the State Board of Health, to include information from organ procurement organizations such as organ donation consent rates, donor potential information, and organ acquisition charges.**

Option V: **Introduce legislation requiring organ procurement organizations operating in Virginia to be accredited by the Association of Organ Procurement Organizations.**

Option VI: **Introduce legislation which states that it is the policy of the Commonwealth that human organs recovered within Virginia shall first be made available, as a matter of priority, to Virginia residents who are in need of an organ transplant.**

Option VII: **Introduce legislation, and an accompanying budget amendment, expanding Medicaid coverage for certain types of organ transplants to individuals who are 21 years of age and older.**

APPENDIX A

SENATE JOINT RESOLUTION NO. 454

Directing the Joint Commission on Health Care to continue its review of organ donation issues in the Commonwealth by examining the appropriate level of state oversight of organ procurement organizations and the role of the Department of Motor Vehicles within the state's overall efforts to promote organ donation.

Agreed to by the Senate, February 9, 1999
Agreed to by the House of Delegates, February 18, 1999

WHEREAS, the Joint Commission on Health Care recently completed a review of organ donation issues in the Commonwealth; and

WHEREAS, organ transplantation is an increasingly common and successful medical procedure for improving and prolonging the lives of individuals suffering from kidney, liver, heart, lung, and pancreas failure; and

WHEREAS, the demand for human organs for transplantation far exceeds the available supply such that 1,451 individuals were on transplant waiting lists at Virginia transplant centers during 1997; and

WHEREAS, the number of deaths of individuals who are awaiting an organ transplant increased by 167 percent nationally from 1988 to 1996; and

WHEREAS, 111 individuals died in Virginia during 1997 while awaiting an organ transplant; and

WHEREAS, 63 organ procurement organizations (OPOs) have been designated and certified by the United States Health Care Financing Administration (HCFA) to retrieve, preserve, and transport organs, and to maintain a system of locating prospective recipients for available organs within specified geographic regions of the United States; and

WHEREAS, five OPOs have been designated and certified by HCFA to retrieve, preserve, and transport organs, and to maintain a system of locating prospective recipients for available organs within specified geographic regions of the Commonwealth; and

WHEREAS, service areas designated by HCFA for three of the five OPOs currently operating in Virginia include significant portions of other states and the District of Columbia; and

WHEREAS, there were 121 organ donors in Virginia during 1997, representing 22 percent of the potential donors referred to OPOs; and

WHEREAS, the number of organs procured in Virginia during 1997 was 66 per one million population, which was below the national average of 75 organs procured per one million population, and likewise, Virginia's 18 organ donors per one

million population was below the national average of 21 organ donors per one million population during 1997; and

WHEREAS, Virginia currently imposes no statutory or regulatory requirements on the structure or operations of OPOs; and

WHEREAS, some level of state accountability of OPOs may help to promote more accurate assessment of OPO performance in procuring organs for transplantation; and

WHEREAS, it is unclear what impact, if any, the number of OPOs operating in Virginia may have on uniformity of service, efficient use of resources, and equal access for all Virginians to organs recovered within the boundaries of the Commonwealth; and

WHEREAS, some OPOs operating in certain states have in recent years consolidated their activities with other OPOs within the state; and

WHEREAS, the Virginia Transplant Council (VTC) is located within the Virginia Department of Health and as such is accountable to the State Health Commissioner and to the State Board of Health; and

WHEREAS, the VTC has statutory responsibility for conducting educational and informational activities, and coordinating such activities as they relate to organ, tissue, and eye donation, procurement, and transplantation efforts within the Commonwealth; and

WHEREAS, the membership of the VTC is comprised of transplant centers, OPOs, eye banks, and tissue banks, as well as the Departments of Education, Health Professions, and Motor Vehicles; and

WHEREAS, the Department of Motor Vehicles (DMV) is required by law to establish a method by which an applicant for a driver's license or identification card may designate his or her willingness to be an organ donor, and the DMV is required to cooperate with the VTC to ensure that the method is designed to encourage organ donation with a minimum of effort; and

WHEREAS, as of November 1998, there were approximately 6.1 million individuals holding a Virginia driver's license or photo identification card issued by DMV, of which approximately 1.4 million displayed an indicator expressing a willingness to be an organ donor; and

WHEREAS, the number of individuals who have placed an organ donor indicator on their Virginia driver's licenses during transactions at DMV offices decreased from 775,561 during 1995 to 338,847 during 1997; and

WHEREAS, the VTC is not specifically authorized by the Code of Virginia to maintain a state organ donor registry; and

WHEREAS, the VTC would like to increase access to the Commonwealth's organ donor registry data maintained by DMV such that the data could be analyzed as a means of improving the coordination of VTC's educational and informational activities; and

WHEREAS, DMV performs activities to provide information intended to promote public awareness of the importance of organ donation; and

WHEREAS, it is useful to review the role of DMV, and the relationship between DMV and VTC, in order to ensure that organ donation information is being provided to Virginians in the most efficient and effective manner possible; and

WHEREAS, efficient and effective organ recovery and transplantation are vital components to the Commonwealth's overall health care delivery system; now, therefore, be it

RESOLVED by the Senate, the House of Delegates concurring, That the Joint Commission on Health Care be directed to continue its review of organ donation issues in the Commonwealth by examining the appropriate level of state oversight of organ procurement organizations and the role of the Department of Motor Vehicles within the state's overall efforts to promote organ donation. The Commission shall also consider the degree to which the number of organ procurement organizations serving the Commonwealth may affect organ recovery and allocation.

All agencies of the Commonwealth, including the Virginia Transplant Council and each of its member organizations, shall provide assistance to the Joint Commission on Health Care and its staff, upon request.

The Joint Commission on Health Care shall complete its work in time to submit its findings and recommendations to the Governor and the 2000 Session of the General Assembly as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents.

Health And Human Resources
Department of Medical Assistance Services

Language

Language:
Page 271, after line 40, insert:
"Z. As a condition of this appropriation, the Department of Medical Assistance Services shall assist the Joint Commission on Health Care in a review of Medicaid coverage and reimbursement policies for organ transplants. The review shall include, but not be limited to, consideration of the appropriateness of (i) current Medicaid coverage for organ transplants; (ii) the reimbursement procedures and amounts applicable to organ transplants that are covered; (iii) the fiscal impact of any changes in Medicaid policies related to coverage or reimbursement for organ transplants; and (iv) case management by the Department for transplant recipients."

APPENDIX B

SUMMARY OF PUBLIC COMMENTS: ORGAN DONATION/TRANSPLANTATION STUDY (SJR 454/APPROPRIATION ACT ITEM 335)

Individuals/Organizations Submitting Comments

A total of nine organizations and individuals submitted comments in response to the SJR 454/Appropriation Act Item 335 report on organ donation and transplantation.

- Virginia Transplant Council
- LifeNet
- Department of Motor Vehicles
- University of Virginia Health Sciences Center
- Virginia Hospital and HealthCare Association
- Medical College of Virginia Hospitals
- Old Dominion Eye Bank
- The Virginia Poverty Law Center
- One private citizen (Barbara, last name not provided)

Policy Options Included in the SJR 454/ Appropriation Act Item 335 Issue Brief

Option I: **Take No Action.**

Option II: **Introduce legislation which: (1) defines the Commonwealth's public policy as requiring that organ donor preference indicator data solicited, collected, and maintained by the Department of Motor Vehicles shall be used for the purpose of aiding in the procurement of human organs in Virginia in a manner that is consistent with the**

legally-sufficient expression of individual donor intent as indicated by the data; (2) directs the State Health Commissioner to appoint and convene a task force, consisting of representatives from the Virginia Transplant Council, including the Department of Motor Vehicles, to identify ways to better utilize organ donor preference data collected by the Department of Motor Vehicles in order to increase organ procurement in Virginia, and (3) requires the task force to report its findings and recommendations to the Governor, the Joint Commission on Health Care, and the 2001 General Assembly.

Option III: Introduce legislation authorizing a Virginia organ donor registry based on the currently available database maintained by the Department of Motor Vehicles, and requiring the Virginia Transplant Council, with assistance from the Department of Health, the Department of Motor Vehicles, and other appropriate state agencies and private entities, to develop a plan for utilization of the registry that is consistent with statutorily-defined objectives, access policy, confidentiality protections, and data requirements.

Option IV: Introduce legislation to broaden the type of information that the Virginia Transplant Council annually reports to the State Board of Health, to include information from organ procurement organizations such as organ donation consent rates, donor potential information, and organ acquisition charges.

Option V: Introduce legislation requiring organ procurement organizations operating in Virginia to be accredited by the Association of Organ Procurement Organizations.

Option VI: **Introduce legislation which states that it is the policy of the Commonwealth that human organs recovered within Virginia shall first be made available, as a matter of priority, to Virginia residents who are in need of an organ transplant.**

Option VII: **Introduce legislation, and an accompanying budget amendment, expanding Medicaid coverage for certain types of organ transplants to individuals who are 21 years of age and older.**

Overall Summary of Comments

None of the commenters expressed support for Option I. The greatest degree of widespread support was expressed for Options III and VII. None of the commenters expressed opposition to legislation that would create a Virginia organ donor registry. Likewise, none of the commenters expressed any opposition to expansion of the Virginia Medicaid program to provide organ transplant coverage for individuals who are 21 years of age or older.

The remaining policy options received varying degrees of support and opposition. Option II was supported by the Department of Motor Vehicles, LifeNet, the University of Virginia Health Sciences Center, and the Virginia Hospital and HealthCare Association. However, the Virginia Transplant Council opposed Option II as unnecessary and somewhat redundant given legislation enacted during the 1999 Session requiring the Virginia Transplant Council to develop a strategic plan. The Virginia Transplant Council, LifeNet, and the Old Dominion Eye Bank expressed opposition to Option IV, while the University of Virginia Health Sciences Center and the Virginia Hospital and HealthCare Association supported it. Option V was supported by the University of Virginia Health Sciences Center, the Virginia Hospital and HealthCare Association, and LifeNet but opposed by the Old Dominion Eye Bank. The Virginia Transplant Council expressed "no comment" with regard to Option V. Option VI was supported by the University of Virginia Health Sciences Center, the Virginia Hospital and HealthCare Association, and the Medical College of Virginia Hospitals. Option VI was opposed by LifeNet and the Virginia Transplant Council expressed "no comment."

Virginia Transplant Council (VTC)

The VTC strongly supports Option III to introduce legislation authorizing creation of a Virginia organ donor registry. VTC opposed Option IV, "as it is unclear how gathering organ consent rates, donor potential information, and organ acquisition charges would help the Council's mission of increasing donation." Further, "it would appear that the additional reporting of this information by VTC would be repetitious and an onus with unknown outcome." The VTC offered "no comment" on Option VI, noting that the issue of allocation is currently being debated and played out in the transplant community at the national level." The VTC also strongly supports Option VII.

LifeNet

LifeNet is one of the organ procurement organizations (OPOs) operating in Virginia, and is also a tissue bank. LifeNet expressed support for Option II, stating that "it is important to define the Commonwealth's public policy regarding the organ donor data that is obtained by the DMV and how that information is utilized." LifeNet defended the long-standing policy of the OPOs to require the donor's next-of-kin to consent to donation, noting that involves more than concerns over legal liability and public relations. However, LifeNet agreed that a "state-sponsored open forum discussion of the ethical issues surrounding the acknowledgment of the donor designation as consent for donation would provide the foundation for changing the current practice of consent to match the legal statutes." LifeNet also supported Option III, but requested that any registry not be limited to organs but also include tissues and eyes. LifeNet expressed support for Option V, but believes that any such accreditation requirement also should apply to both tissue banks and eye banks through the American Association of Tissue Banks and the Eye Bank Association of America. LifeNet opposes Option VI at the present time, believing that the issue of organ allocation is best addressed at the national level before any action is taken by the state. In addition, LifeNet believes "the best way to increase local sharing [of organs] in Virginia is through consolidation of OPOs that serve the state." Finally, LifeNet fully endorses Option VII.

Department of Motor Vehicles (DMV)

DMV commented that overall the issue brief did a good job of explaining its role in promoting organ donor awareness. DMV offered some clarifying information and expressed support for Options II and III. However, in considering the creation of an organ donor registry, "it should first be determined how the information will be used, what information will be needed, and the legality of making that information available." DMV suggested that the VTC serve as the "custodian" of the registry, if one is created.

University of Virginia Health Sciences Center (UVA)

UVA supported all of the policy options except for Option I. UVA did recommend caution with regard to Option VI. In terms of Option VI, UVA noted that "a preference in organ allocation to state residents which would circumvent the federal intent is tied up in the possibility of preemption." UVA's response indicated that while seven states have already enacted such statutes, and bills have been introduced in five other states, the ultimate affect of such laws may be for the judiciary to decide. As UVA stated, "no one can say with certainty what the ultimate outcome of litigation on this issue might be or whether all courts would reach the same conclusion."

UVA expressed support for Option VII and indicated that, among all of the Policy Options, this was its #1 priority. In its comments, UVA noted that the amount of "new" state money needed to expand the Medicaid program to cover organ transplants for adults "may prove to be somewhat less than expected." This is because "to the extent possible, state teaching hospitals have historically performed transplants on patients income eligible for Medicaid but not benefit eligible for transplantation." In addition, based on UVA's experience, "the insured population would be unlikely to become Medicaid eligible; private insurers provide transplant coverage with adequate benefit caps for heart, lung, liver, and in a few instances, pancreas."

UVA strongly supports Option III, and also supports Option II to encourage the use of donor preference data in its current availability as well (UVA #2 priority). Option IV was identified as UVA's #3 priority. UVA expressed support for Option V (priority #4), as accreditation of the OPOs that serve

Virginians awaiting transplant "would help the state's effort to reduce any disparity in the performance of OPOs."

Virginia Hospital and HealthCare Association (VHHA)

The VHHA supports reasonable efforts to increase the supply of organs for transplant. VHHA endorsed the comments provided by UVA, with one elaboration. With respect to Option II, VHHA believes that the use of DMV organ donor preference data as a legally-sufficient expression of donor intent "requires additional discussion given the potential public relations ramifications of eliminating the need for family consent." VHHA stated that "The need for family consent may frustrate potential donor's wishes to donate their organs. However, elimination of family consent does not eliminate the need to approach families with sensitivity. We suggest at a minimum that state law should be clarified so that provisions regarding legal sufficiency of the organ donor card are consistent with current practices and federal law that encourage or require consent of families prior to donation." Finally, VHHA supports Option V as an effective approach to ensure the "efficiency, effectiveness, and accountability" of OPOs operating in Virginia.

Medical College of Virginia Hospitals (MCVH)

MCVH strongly supports any and all efforts to increase organ donation. MCVH supports legislation that "would require strict enforcement of driver's license designation as legal and binding", and noted that the DMV database is a good resource. However, "we do encourage periodic reviews of this database to confirm the data is accurate, comprehensive, and easily accessible" to OPOs. MCVH expressed strong support for Option VI, and supported Option VII. In terms of Option VII, MCVH states that "all citizens of the Commonwealth deserve the opportunity to receive an organ transplant that may save their life."

Old Dominion Eye Bank (ODEB)

In terms of Option III, ODEB stated that the U.S. Food and Drug Administration mandates that a social/medical interview be conducted with the next-of-kin for every donor. "If we made our decision to remove and transplant tissue based on the distinction of a driver's license we would not be in compliance with FDA regulations." ODEB also commented

that "A designation on the driver's license, or a uniform donor document should be used as a mechanism to inform the next-of-kin of their loved one's wishes concerning organ donation and cannot be legislated. The DMV registry, however, can be a valuable tool to assist members of the VTC with community education." Finally, ODEB expressed opposition to Options IV and V.

The Virginia Poverty Law Center

The Virginia Poverty Law Center expressed support for Option VII. The comments noted that the current policy results in denial of medically necessary and life-sustaining services, and "unfairly discriminate solely on the basis of age." The Virginia Poverty Law Center questioned the assumptions used by the Department of Medical Assistance Services to estimate the cost of expanding transplant coverage to persons over age 21.

Private Citizen (Barbara, Last Name Not Provided)

This individual, who has a 30 year-old daughter who is waiting for a lung transplant, expressed support for Option VII. This individual's daughter is covered by the Medicaid program. However, "When we found out that after the age of 21 there was no help in paying for the transplant I was very upset." According to the individual, her daughter "doesn't want to be on the Medicaid Program, but there is a group of people out there that are riding the line in living and dying because of no insurance." Finally, the individual stated that "Patients facing transplants are already facing such critical issues. Putting a quart jar on a counter to hope for nickels and dimes to be tossed in to save lives is a lot like a death sentence and you are waiting for the public to decide who lives and who dies."

APPENDIX C

Medicaid Reimbursement of Organ Transplants: Follow-Up

Presentation to:
The Joint Commission on Health Care

Joseph Hilbert
Sr. Health Policy Analyst

July 27, 1999

Authority and Background for Study

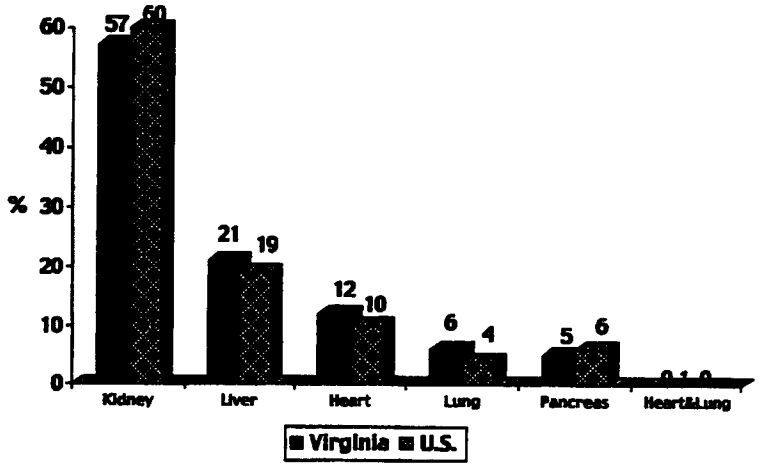
- Item 335 of 1999 Appropriation Act requires the Joint Commission on Health Care, with assistance from the Department of Medical Assistance Services, to review Medicaid coverage and reimbursement policies for organ transplants
- Initial results presented at the April 9, 1999 Commission meeting
  - Virginia's coverage for organs other than kidneys limited to individuals less than 21 years of age
  - Virginia's coverage more restrictive than most other states
  - DMAS' preliminary estimate (during 1999 Session) of annual general fund cost of expanding transplant coverage to adults: $11.3 million
- Joint Commission directed staff to continue to work with DMAS to evaluate the cost of expanding organ transplant coverage

Additional Data Collection Activities by JCHC Staff

- Survey of Medicaid agencies in other states
  - Number of heart, lung, heart & lung, and liver transplants reimbursed for individuals ages 21-64
  - Number of Medicaid-eligible individuals ages 21-64
  - Computed number of transplants reimbursed per 10,000 Medicaid-eligible individuals
- Survey of Virginia transplant centers
  - Payment mix of transplants currently performed
- Analysis of UNOS data for total number of transplants performed in Virginia for individuals ages 21 - 64
- JCHC staff survey instruments were reviewed by DMAS staff
  - DMAS staff did not have any comments on the instruments

Percent Distribution of Organ Transplants

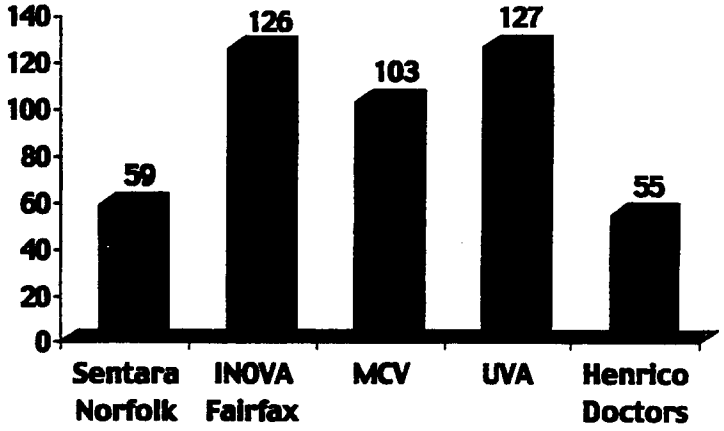
Transplants Received by Individuals 21 - 64 Years of Age During 1998



Source: JCHC staff analysis of 1998 data from United Network for Organ Sharing

Virginia's Five Transplant Centers Performed 470 Adult Transplants In 1998

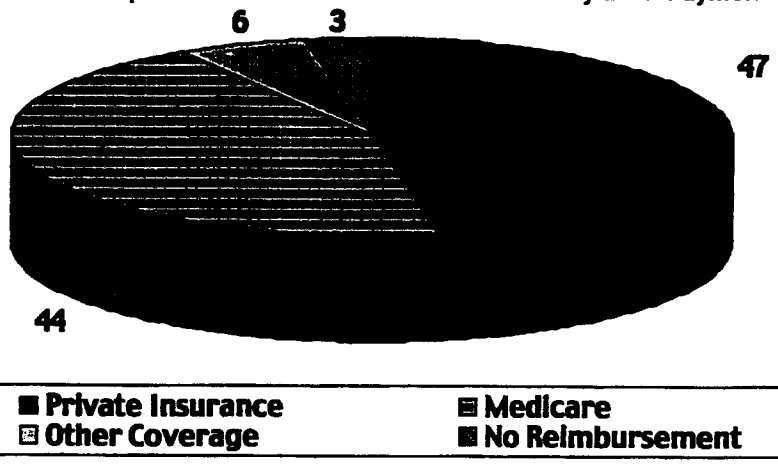
Number of Transplants Performed on Adults Between the Ages of 21 and 64 During 1998



Source: JCHC staff survey of Virginia transplant centers

Private Insurance Pays for Almost 50 Percent of All Adult Transplants in Virginia

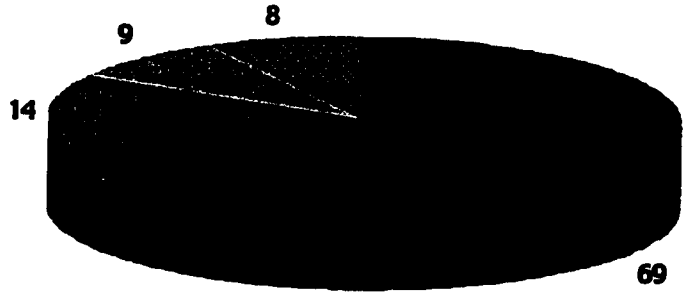
Percent of Transplants Performed In 1998 Reimbursed By Each Payment Source



Source: JCHC staff analysis of data from survey of Virginia transplant centers

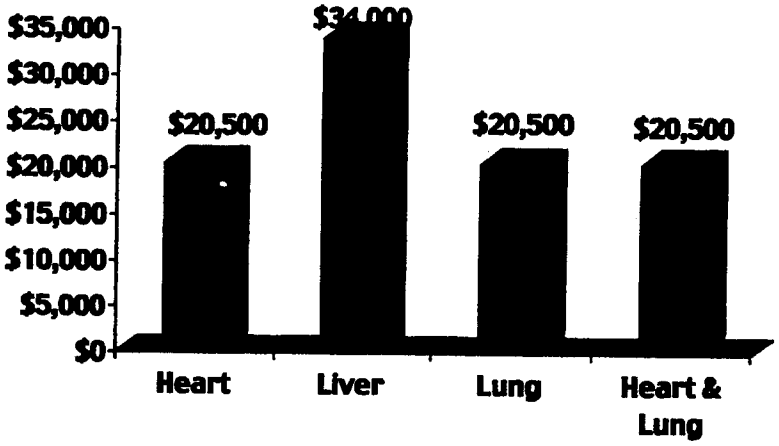
Private Insurance Pays For Two-Thirds of Adult Non-Renal Transplants in Virginia

Percent of Non-Renal Transplants Performed In 1998 Reimbursed by Each Payment Source



■ Private Insurance ■ Medicare ■ Other ■ No Reimbursement

Annual Post-Transplant Pharmaceutical Expenses



Source: Estimated by Medical College of Virginia Hospitals staff

Other State Medicaid Programs Pay for Relatively Few Adult Organ Transplants

- JCHC staff received survey responses from 38 states
  - 28 responses (57 percent of all states) contained useable data for analysis
    - 3 states did not cover adult transplants, 5 states were unable to provide requested data, and 2 states submitted incomplete data
- The reported number of adult organ transplants reimbursed per 10,000 Medicaid-eligible adults ranged from 4 (Missouri) to 0 (Vermont).
- The average number of adult organ transplants reimbursed per 10,000 Medicaid eligible adults was 1
- Two states reported transplant data only for the fee-for-service population, while the reported number of Medicaid-eligible individuals was for fee-for-service and managed care

JCHC Developed Cost Estimation Methodology In Consultation With DMAS Staff

- An estimate was computed based on the average number of organ transplants per 10,000 Medicaid-eligible adults between the ages of 21 and 64 in 28 other states
  - The average number (1.02) was applied to 183,705 Medicaid-eligible adults between the ages of 21 and 64 in Virginia to estimate total number of additional transplants that would be performed
  - Percent distribution of heart, lung, heart & lung, and liver transplants in Virginia applied to DMAS transplant reimbursement fee schedule, and to estimated pharmacy costs, to determine total transplant expenses
  - Total estimated costs multiplied by .4835 to estimate state general fund expenditure

Medicaid-Reimbursed Transplants Would Increase Following Expanded Coverage

- JCHC staff estimate that expanded Medicaid coverage would result in 19 additional annual adult organ transplants reimbursed by the Department of Medical Assistance Services
  - This would represent 4 percent of all adult organ transplants, and 9 percent of all adult non-renal organ transplants, performed in Virginia during 1998
  - Number of pediatric organ transplants actually reimbursed by DMAS from 1994 to 1997 ranged from 3 to 7 (fee-for-service population)
- There were 16 adult transplants performed by Virginia's transplant centers during 1998 for which no reimbursement was received
  - It is possible that at least some of these transplants involved Medicaid-eligible adults

JCHC Staff General Fund Annual Cost Estimate

Cost Component	Estimated General Fund Cost
Transplant Procedures	**$1,216,205**
Post-Transplant Pharmacy Costs	**$251,671**
Total General Fund Expenditures	**$1,467,876**

Source: JCHC staff analysis of data from other state Medicaid agencies, Virginia transplant centers, United Network for Organ Sharing, and Department of Medical Assistance Services.

Differences Between JCHC and DMAS Cost Estimates

- DMAS assumed 95 percent of adult organ transplants would be paid for by Medicaid
  - This key assumption is not supported by data from Virginia's five transplant centers, and from 28 other state Medicaid agencies that currently provide coverage for adult organ transplants
    - Medicaid paid for 8 percent of all adult transplants performed in the responding states during 1998
- Both estimates assume that transplant patients 65 years of age and older will be covered by Medicare
- Both estimates also assume that the level of actual adult transplant activity will remain constant due to the fact that organ availability is a controlling factor

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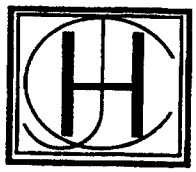

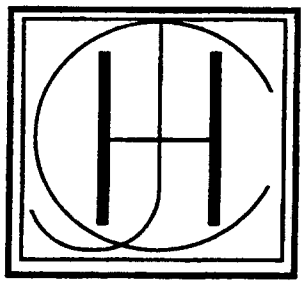

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