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IN THE

# SUPREME COURT OF VIRGINIA

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RECORD NO. 992018

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STATE HEALTH COMMISSIONER,

*Appellant*

v.

SENTARA NORFOLK GENERAL HOSPITAL

*Appellee*

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JOINT APPENDIX

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a certificate of public need to establish liver transplantation services at it existing tertiary care facility in Norfolk, Virginia. In support of its Petition for Appeal, Sentara Norfolk General Hospital states as follows:

## PARTIES

1. Sentara Norfolk General Hospital ("SNGH" or the "Appellant") is a licensed inpatient acute care hospital serving the tertiary and trauma care needs of the greater Tidewater region. SNGH currently provides organ transplantation services including kidney, heart, lung and heart-lung transplantation and seeks to provide liver transplant services as well. SNGH is the only transplant provider in its health planning region, HPR V. which includes the Greater Tidewater, the Peninsula, The Northern Neck and the Eastern Shore.

2. Randolph L. Gordon, M.D., M.P.H. is the State Health Commissioner for the Commonwealth of Virginia. The Commissioner is the executive officer of the Board of Health and is charged with the responsibility of supervising and managing the Department of Health (the "Department") in accordance with the policies, rules and regulations of the Board of Health.

3. The Eastern Virginia Health Systems Agency ("EVHSA") is a regional health planning agency as set forth in § 32.1-102.1. The Commissioner is required to consider the recommendation and the reasons therefor of the regional health planning agency on applications for certificates of public need ("COPN"). The

EVHSA staff recommended that SNGH's project be denied. The EVHSA Board voted to recommend approval of the project. The Adjudication Officer considered both the report of the EVHSA staff and the recommendation of the EVHSA Board in making his findings conclusions and recommendations on the project.

## CASE DECISION APPEALED FROM

4. SNGH appeals from the November 3, 1997 decision of the Commissioner denying its application for a COPN to establish liver transplantation services as part of the successful organ transplantation program that currently exists at the hospital. The Commissioner, in the case decision, "decline[d] to adopt Adjudication Officer Perry's recommendation" that SNGH's COPN request be approved, but left intact the Adjudication Officer's findings of fact and conclusions of law.

## JURISDICTION AND VENUE

5. SNGH timely filed a Notice of Appeal from the Case Decision. A copy of the Notice of Appeal is attached as Exhibit A.
6. Jurisdiction for this action exists under Virginia Code §§ 9-6.14:16.
7. Venue for this action lies in the Circuit Court for the City of Norfolk in accordance with Virginia Code §§ 9-6.14:5.

8. Pursuant to Virginia Code § 32.1-102.9, the judge designated to preside over the appeal of an administrative case arising under the COPN laws shall be designated by the Chief Justice of the Supreme Court of Virginia from a circuit other than the circuit where the project will be located. A copy of the Request for Designation of Judge pursuant to § 32.1.102.9 is attached as Exhibit B.

9. Virginia Code § 9-6.14:21 provides a basis for an award of attorneys' fees if SNGH substantially prevails on the merits of this case and the agency's position is not substantially justified.

## STATEMENT OF FACTS

10. On July 31, 1996, SNGH submitted a certificate of public need ("COPN") application to add to its complement of transplant services the ability to perform liver transplants.

11. The application was reviewed for completeness and accepted into the COPN review cycle commencing on September 10, 1996.

12. The Eastern Virginia Health Systems Agency ("EVHSA") held a public hearing on SNGH's application on September 16, 1996.

13. The EVHSA Board met on November 12, 1996 to consider SNGH's application for establishment of liver transplantation services. Although the EVHSA staff recommended that the project be denied, the EVHSA Board voted to recommend approval of the COPN, finding that the project would improve the availability and

geographical accessibility to liver transplant services for local residents and that having a liver transplant service would round out the complement of transplant services that are presently provided at SNGH.

14. By letter dated February 28, 1997, the state staff of the Department of Health, Division of Certificate of Public Need ( DCOPN or "State Staff") transmitted its recommendation on the project. The State Staff recommended the project be denied because:

(i) No substantial need for the proposed new service has been demonstrated.

(ii) A single facility waiting list, as now exists with only one liver transplant program in the organ procurement organization's area, permits better management of patients on the waiting list and decreases waiting list mortality.

(iii) Establishment of a liver transplant program at SNGH has a considerable probability of reducing volume at the Medical College of Virginia Hospital ("MCV") to a level that would harm training programs now in operation at MCV.

15. An informal fact finding conference ("IFFC") was held before Raymond Perry, Adjudication Officer, on May 20, 1997. At the IFFC, SNGH presented evidence including compelling medical testimony of the need of the population in SNGH's service area for improved access to liver transplant services, as well as evidence

that the project fully complied with the provisions of the State Medical Facilities Plan and all twenty statutory criteria for issuances of COPNs.

16. University Health Services and the Medical College of Virginia Hospitals (collectively referred to as "MCV") sought to establish good cause standing. The Commissioner found that MCV did not have standing; thus, MCV is not a party to this matter.

17. The Adjudication Officer reviewed the evidence, testimony, the reports of the EVHSA staff and the DCOPN staff, and exhibits submitted for the record. The Adjudication Officer made a written report including findings of fact, conclusions of law and a recommendation for approval of SNGH's COPN request. A copy of the Adjudication Officer's report is attached as Exhibit C.

18. Specifically, the Adjudication Officer found that "the main population of PD 20 is approximately two hours driving time from Richmond, the location of MCVH that provides the closest liver transplant program.... The population is estimated to be 1.7 million by the year 2000. A significant proportion of this population two hours drive or more from a liver transplant service. The proposed project would assure liver transplant services within two hours of this population."

19. The Adjudication Officer also found that "there are currently no liver transplant programs in HPR V. SNGH is the singular transplant service provider in HPR V.... SNGH has been providing some transplant services for twenty-five years. It has met the volume and survival standards for the other transplant services it provides.

SNGH can be expected to be able to meet the volume and survival standards for liver transplant services."

20. The Adjudication Officer also found that the costs and charges associated with providing liver transplant services at SNGH would be low. Specifically, he noted that "when compared to other transplant service providers in the state, SNGH was determined by the DCOPN staff to have typically low costs and charges. SNGH's costs were determined to be approximately 77% of the combined average of Fairfax, UVAH and MCVH. Additionally, SNGH's case mix [measuring the seventy of illness] was determined to be 118% [higher] of the average for the group."

21. Based on the evidentiary record, the Adjudication Officer determined that existing providers of services would not be harmed by a program at SNGH because "in 1996, all three liver transplant programs in Virginia substantially exceeded the volume requirements of the SMFP."

22. The Adjudication Officer found the improvement in geographic access compelling noting that "there is no liver transplantation service in HPR V at the present time. Residents in need of liver transplantation must travel outside of the area for liver transplant services. The proposed project will make liver transplantation geographically available to a significant population that now must travel more than two hours diving time to get to the nearest provider."

23. The Adjudication Officer also recognized improved financial access, an important aspect of the project; noting that "SNGH has a long tradition of providing health

services to persons who cannot afford to pay. This is true of its general hospital services as well as its transplant services. It is reasonable to expect that approval of the proposed project will increase financial accessibility to liver transplant services for a significant population."

24. The Adjudication Officer concluded that "in view of the fact that no other transplant program is within HPR V, one can conclude that the availability of a liver transplant program at SNGH would reduce the travel time and therefore the cost of services for residents of its services area who now must travel out of the area for services. There is an ample number of potential liver transplantation patients to allow the development of a liver transplantation program at SNGH."

25. The Adjudication Officer concluded that SNGH's project should be approved because:

    (i) the proposed project is consistent with *all* of the pertinent standards for reviewing transplant services in the SMFP;

    (ii) the applicant is physically located so that it is accessible to a substantial population in eastern Virginia and northeastern North Carolina that does not reside within two-hours' driving time of the transplant center at the Medical College of Virginia;

    (iii) the proposed project was recommended for approval by the Eastern Virginia Health Systems Agency for the reason of improving area residents' access to liver transplant services;

(iv) the number of liver transplant patients from Eastern Virginia appears to be increasing and, coupled with the projected short start-up of the SNGH liver transplant service, no significant impact on liver transplant volume at the MCVH transplant center should occur in the first three years; and

(v) the SNGH liver transplant program and the MCVH liver transplant program will both be served by the LifeNet Organ Procurement Organization, permitting collaborative participation in developing mutually acceptable rules and guidelines to assure proper organ allocation policies and procedures among patients and between institutions.

26. The Commissioner, upon review of the report filed by Adjudication Officer Perry, declined to adopt Mr. Perry's recommendation that the project be approved, but left standing the findings and conclusions supporting approval of the project. The Commissioner also found that the SMFP standards duly adopted by the Board of Health and pursuant to which the SNGH project had been reviewed, were inaccurate, outdated, inadequate or otherwise inapplicable and advised the Division of Certificate of Public Need to initiate the process to propose changes to those standards. The Commissioner also concluded that the project would adversely impact MCV based upon an erroneous finding of fact based on evidence that does not appear in the record. A copy of the Commissioner's Decision is attached as Exhibit D.

A. The Commissioner lacks the legal authority to set aside the State Medical Facilities Plan in order to deny a COPN application which is fully consistent with the COPN statute and relevant regulations.

25. Under Virginia COPN law, a COPN application must be consistent with the most recent applicable provisions of the State Medical Facilities Plan ("SMFP") for a project to be approved. Va. Code § 32.1-102.3(A).

26. The SMFP is a duly promulgated regulation, adopted by the Board of Health which includes: i) methodologies for projecting need for medical care facility beds and services; ii) statistical information on the availability of medical care facilities and services; and iii) procedures, criteria and standards for review of applications for projects of medical care facilities and services. Va. Code § 32.1-102.1.

27. The COPN statute gives the Commissioner the limited authority to disregard the provisions of the SMFP to <u>issue</u> <u>or</u> <u>approve</u> a COPN that is not consistent with the current SMFP if the Commissioner determines, "*upon presentation of appropriate evidence*, that it is inaccurate, outdated, inadequate, or otherwise inapplicable." Va. Code § 32.1-102.3(A).

28. The statute does not give the Commissioner the authority to *deny* a certificate to an applicant who meets all of the relevant standards of the SMFP.

29. None of the parties to this matter, and not even the provider who sought to establish good cause, argued or *presented evidence* to show that the SMFP standards applicable to liver transplantation services were inaccurate, outdated, inadequate or otherwise inapplicable."

30. The Commissioner's decision unlawfully seeks to change the standard by which COPN applications for liver transplantation services are judged and to apply that proposed change in standard retroactively to SNGH.

31. Even if there had been a basis articulated in the record for setting aside the SMFP, the Commissioner can not lawfully amend the regulation himself nor can he lawfully apply such amendment retroactively.

32. By statute and regulation, "The most recent applicable provision of the State Medical Facilities Plan shall remain in force until any such chapter is amended, modified or repealed *by the Board of Health*." 12 VAC 5-220-10 (emphasis added); See also Va. Code § 32.1-122.08.

33. The Case Decision unlawfully seeks to apply to SNGH a proposed standard which has not yet been articulated, instead of the standard that has been duly adopted by the Board of Health pursuant to statute and regulation, remains in full force and effect until it is changed by the Board of Health.

B. The Commissioner's finding that "the numbers of available organs may be reaching a plateau" is unsupported by any evidence in the administrative record.

34. The Commissioner relies heavily upon alleged "evidence" that the number of liver transplants and organs are "leveling out."

35. In his case decision the Commissioner cites "[i]ndications in the health care system" to support his conclusion that the supply of organs and the numbers of procedures are "stabilizing" or "leveling out."

36. Contrary to the Commissioner's conclusion, the record contains uncontroverted evidence that the number of liver transplantation procedures performed in the Commonwealth and originating from the Tidewater area has been growing continually.

37. There is no evidence in the record that the volume of procedures or availability of organs for transplant "may be reaching a plateau" or "stabilizing" as the Commissioner stated in his decision.

38. The 'indications" cited by the Commissioner are not part of the record and may not be relied on by the agency to support its decision.

39. Under Virginia administrative law, the Commissioner may rely on public data, documents or information, only if he has first provided all parties with advance notice of his intent to rely on such information. Va. Code § 9-6.14:11.B. No such notice was provided in this case.

40. There is no evidence in the record to support the Commissioner's finding that the number of transplants or organs available for transplant may be stabilizing or reaching a plateau.

41. The only evidence regarding the volume of liver transplant activity in the Commonwealth shows an average annual increase in number of transplants for the last few years.

C. The Commissioner's determination that "an additional liver transplant center at SNGH may seriously impact the established liver transplant fellowship program at MCVH" is based on an incorrect finding of fact, which is unsupported by and contrary to the unrebutted evidence in the record.

42. The Commissioner's decision recites the Adjudication Officer's incorrect finding that a liver transplant training program must perform an annual volume of 45 liver transplants to maintain accreditation.

43. The uncontroverted evidence in the record is that the current standard of the American College of Transplant Surgeons provides that a fellow must perform at least 45 procedures over the course of a fellowship, usually a two year period, for a program to be certified as a training program. This translates to 22 to 23 procedures per year for a typical fellowship. Smaller volume programs can still maintain accreditation by extending the length of the fellowship.

44. As the uncontroverted evidence in the record establishes, the current standard for training certification, which was adopted just days before the IFFC, permits a program with substantially lower volumes to obtain or maintain accreditation than that previously required (an annual volume of at least 50 liver transplants) would have been required in the past.

45. The Commissioner's conclusion that MCV's training program may be harmed - a conclusion which is based on an erroneous finding, is without support in the evidentiary record.

## ERRORS ASSIGNED

46. SNGH hereby restates and reallege all assertions contained in paragraphs 1-45.

47. The Commissioner abused his discretion and exceeded the scope of his authority under the COPN law by denying to SNGH a COPN application which is fully consistent with applicable health planning standards set out in the statutes and duly promulgated regulations governing the review of COPN projects in the Commonwealth of Virginia/and which was recognized by the Department's Adjudication Officer as meeting all of those standards.

48. The Case Decision does not comply with the basic law which gives the Commissioner authority to set aside the SMFP as outdated and obsolete only for purposes of approving a project, not for purposes of denying a project which meets all relevant standards.

49. The Case Decision represents an unlawful and arbitrary and capricious attempt to apply retroactively to SNGH a proposed regulatory change that has not been made yet (and indeed, may not ever be made).

50. The Commissioner abused his discretion and exceeded the scope of his authority by attempting to usurp from the Board of Health, the authority to amend the provisions of the SMFP.

51. The Commissioner did not comply with or observe the procedural requirements of the Administrative Process Act and the basic COPN law in issuing the Case Decision, a noncompliance which has materially and detrimentally affected SNGH.

52. The findings of fact made by the Commissioner are not supported by the evidentiary record, or are based on evidence which is not part of the record.

53. The case decision is not supported by substantial evidence in the record.

## Statement of Relief Requested

For the foregoing reasons, Sentara Norfolk General Hospital prays:

1. That the Case Decision of the State Health Commissioner dated November 3, 1997 denying Sentara Norfolk General Hospitals request for a certificate of public need to establish liver transplantation be REVERSED and VACATED;

2. That the Court ORDER the issuance of a case decision consistent with the findings, conclusions and recommendation made by the Adjudication Officer;

3. That the Court ORDER the Commissioner to pay the reasonable costs and attorneys' fees incurred by Sentara Norfolk General Hospital in pursuing this appeal; and

4. That the Court ORDER such other relief as it may deem appropriate in this case.

Respectfully submitted,

SENTARA NORFOLK GENERAL HOSPITAL

By: _____
Counsel

Thomas W. McCandlish
Laura G. Aaron
Mezzullo & McCandlish
1111 East Main Street
Suite 1500
Richmond, Virginia 23219
(804) 775-3100

J:\HCT\SENTARA\NORFOLK\ORGAN.22\PETITION-APPEAL

A

COMMONWEALTH OF VIRGINIA
BEFORE THE STATE HEALTH COMMISSIONER

In re: Certificate of Public Need No, VA-03365
Sentara Norfolk General Hospital
Norfolk, Virginia
Establish Liver Transplant Services

## NOTICE OF APPEAL

Pursuant to Rule 2A:2 of the Rules of the Supreme Court of Virginia, Sentara Norfolk General Hospital ("SNGH") hereby gives notice of its intent to appeal the November 3, 1997 case decision of the State Health Commissioner denying the request of SNGH to establish liver transplant services at its existing hospital facility in Norfolk, Virginia. The case decision was received by SNGH on Tuesday, November 4, 1997.

The identity and address of the appellant is:

Sentara Norfolk General Hospital
600 Gresham Road
Norfolk, Virginia 23501

Counsel: Thomas W. McCandlish
Mezzullo & McCandlish
1111 East Main Street
Suite 1500
Richmond, Virginia 23219

The identity and address of the appellees are:

Randolph L. Gordon, M.D., M.P.H.
State Health Commissioner
Department of Health
1500 East Main Street
Suite 105
Richmond, Virginia 23219

Counsel: Carol S. Nance
Assistant Attorney General
Office of the Attorney General
900 East Main Street
Richmond, Virginia 23219

Eastern Virginia Health Systems Agency, Inc.
18 The Koger Center
Suite 232
Norfolk, Virginia 23502

Registered Agent:

Norma R. Spencer
18 The Koger Center
Suite 232
Norfolk, Virginia 23502

The appeal shall be taken to the Circuit Court for the City of Norfolk.

Respectfully submitted,

Sentara Norfolk General Hospital

By: _____
Counsel

Thomas W. McCandlish
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Mezzullo & McCandlish
1111 East Main Street
Suite 1500
Richmond, Virginia 23219
(804) 775-3100

## CERTIFICATE OF SERVICE

This is to certify that a true copy of this Notice of Appeal was delivered on this 12th day of November, 1997 by hand to:

Randolph L. Gordon, M.D., M.P.H.
State Health Commissioner
Department of Health
1500 East Main Street
Suite 105
Richmond, Virginia 23219

and mailed, postage prepaid, to the following this 12th day of November, 1997

Carol S. Nance
Assistant Attorney General
Office of the Attorney General
900 East Main Street
Richmond, Virginia 23219

Paul M. Boynton
Eastern Virginia Health Systems Agency, Inc.
18 The Koger Center
Suite 232
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Norfolk, Virginia 23502

Counsel

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VIRGINIA:

IN THE CIRCUIT COURT FOR THE CITY OF NORFOLK

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|---|---|---|
| SENTARA NORFOLK GENERAL HOSPITAL | ) | |
| | ) | |
| Appellant, | ) | |
| | ) | |
| v. | ) | |
| | ) | |
| STATE HEALTH COMMISSIONER | ) | Chancery No. C97-2071 |
| | ) | |
| and | ) | |
| | ) | |
| EASTERN VIRGINIA HEALTH SYSTEMS AGENCY, INC. | ) | |
| | ) | |
| Appellees. | ) | |
| | ) | |

**REQUEST FOR DESIGNATION OF JUDGE**
**PURSUANT TO § 32.1-102.9 OF THE CODE OF VIRGINIA**

Appellant, Sentara Norfolk General Hospital ('SNGH"), by counsel, hereby submits this Request for Designation pursuant to § 32.1-102.9 of the Code of Virginia, and in support thereof states as follows:

1. The above-referenced case is an appeal from an administrative case decision by the State Health Commissioner under the Certificate of Public Need laws of the Commonwealth of Virginia.

2. Jurisdiction and venue for this action properly lie in the Circuit Court for the City of Norfolk pursuant to Virginia Codes §§ 9-6.14:5, 9-6.14:16 and 8.01-261 of the Code of Virginia.

3. Pursuant to Virginia Code § 32.1-102.9 the judge designated to preside over the appeal of an administrative case arising under the Certificate of Public Need laws shall be designated by the Chief Justice of the Supreme Court of Virginia from a circuit other than the circuit where the project is or will be under construction, located or undertaken.

WHEREFORE, SNGH respectfully requests the Chief Judge of the Circuit Court for the City of Norfolk to request the Chief Justice of the Supreme Court of Virginia to designate a judge to preside over this litigation consistent with the requirements of Virginia Code § 32.1-102.9.

Respectfully submitted,

SENTARA NORFOLK GENERAL HOSPITAL

By: _____
Counsel

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Laura G. Aaron, VSB No. 28848
Mezzullo & McCandlish, P.C.
1111 East Main Street
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(804) 775-3100

## CERTIFICATE OF SERVICE

I hereby certify that on this 5th day of December, 1997, I caused a copy of the foregoing Request for Designation to be delivered by first class mail to the following at the addresses listed:

Paul M. Boynton
Eastern Virginia Health Systems Agency, Inc.
18 The Koger Center
Suite 232
Norfolk, Virginia 23502

Carol Nance
Assistant Attorney General
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900 East Main Street
Richmond, Virginia 23219

Norma R. Spencer
Eastern Virginia Health Systems Agency, Inc.
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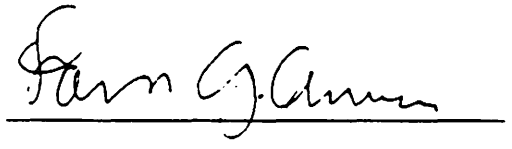
Norfolk, Virginia 23502



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**COPN Request No. VA-5969**
**Sentara Norfolk General Hospital**
**Norfolk, Virginia**
**Establish Liver Transplant Services**

**Findings**

1. Sentara Norfolk General Hospital (SNGH) is part of Sentara Health System.

2. SNGH is licensed for 644 beds and is located in Norfolk, Virginia, Planning District (PD) 20 in Health Planning Region (HPR) V.

3. HPR V is served by the Eastern Virginia Health Systems Agency (EVHSA).

4. SNGH is one of the Commonwealth's major tertiary-care hospitals and the primary trauma-care center for the Hampton Roads area and adjacent areas of northeastern North Carolina.

5. SNGH is the principal teaching hospital for undergraduate and graduate medical students at the Eastern Virginia Medical School (EVMS), which shares the Eastern Virginia Medical Center campus with SNGH.

6. SNGH currently provides extensive organ transplant services through its "transplant center." The SNGH Transplant Center currently performs kidney, heart, lung, and heart/lung transplants. SNGH proposes to expand its transplant services to include liver transplantation.

7. Liver transplant services are currently provided at three other locations in Virginia: in the Central Virginia Health Planning Region (HPR IV) in Richmond, at the Medical College of Virginia Hospitals of Virginia Commonwealth University (MCVH); in the Northwest Virginia Health Planning Region (HPR I) in Charlottesville, at the University of Virginia Hospital (UVAH); and in The Northern Virginia Health Planning Region (HPR II) in Fairfax at the Fairfax Hospital (FH).

8. There are 102 liver transplant programs nationally, which performed 3,652 liver transplants in 1994. The average volume of liver transplant procedures per program was 36 in 1994. In Virginia, according to statistics from the United Network of Organ Services (UNOS), in 1994, eighteen residents of the SNGH primary service area received liver transplants, in 1995, twenty-one SNGH primary service area residents received liver transplants, and in 1996, twenty-eight SNGH primary service area residents received liver transplants.

9. Reportedly approximately 25-30 adult patients are referred out of the SNGH region and or state for liver transplants each year by Sentara physicians. Additionally, based on information furnished by MCVH's liver transplant program, there are also a significant number of patients referred to their center by other Hampton Roads (PDs 20 and 21) physicians,who do not practice in the Sentara Health System.

10. The Division of Certificate of Public Need staff estimates that 40%-50% of the liver transplant patients at MCVH and 10%-20% of the liver transplant patients at UVAH originate from the potential SNGH service area, PDs 20 (Southampton Roads), 21 (Newport News-Hampton area), and PD 22 (Virginia's Eastern Shore), and northeastern North Carolina. This area has a population estimated to exceed 1.7 million people by the year 2000.

11. SNGH assumes the accessibility of a liver transplant program in Hampton Roads will attract patient referrals from both Sentara and non-Sentara physicians. SNGH bases its assumption other solid organ transplantation services it provides and the fact that other solid organ transplant patients are currently referred by both Sentara and Non-Sentara physicians to SNGH's existing transplantation services. SNGH projects that its liver transplant program will perform six transplants the first year of operation, twelve in year two, and fifteen in year three.

12. SNGH proposes to recruit a surgeon with liver transplant experience (Dr. Colonna) into one of the private, Sentara-affiliated surgical practice groups within the region to implement the liver transplant program. Dr. Colonna was trained at MCV-VCU and at the University of California in Los Angeles, allegedly one of the busiest liver transplant centers in the nation. Recently, Dr. Colonna has served as director of the transplant program at Fairfax Hospital.

13. SNGH expects the liver transplant surgeon, Dr. Colonna, will immediately meet the minimum UNOS transplant surgeon criteria for implementation of a liver transplant program.

14. Three SNGH gastroenterologists (GI physicians), who respectively trained at the University of Wisconsin, Yale, and the Medical College of Virginia, have committed medically to manage liver transplant patients and also to obtain any additional training necessary to provide optimal post-surgical medical care for these patients.

15. Other physicians available within the community to support the liver program include Dr. Scott Stanley, a surgical pathologist, who completed his medical training at the University of Minnesota in its liver transplantation program. Dr. Martha Mooney, an infectious disease specialist who supports the kidney, heart, and lung transplant programs, will also provide support for the liver transplant program. SNGH has several intensive care specialists on its medical staff who will provide support to the transplant physicians as well. Also, several members of the anesthesia practice which provides expert services to support Sentara Norfolk General Hospital's surgery program have had experience with liver transplants in their medical training and fellowships, as well as with the existing transplant programs at SNGH.

16. Costs of implementing the liver transplant program will be moderate because the Center performs kidney, heart, lung, and heart/lung transplants. SNGH has sufficient capacity in its intensive care units to accommodate the post-transplant follow-up care; therefore only incremental operating costs will be associated with establishing the liver transplant service. The administrative and clerical staff that support the current organ transplant programs will also support the proposed liver transplant program. Additional program and hospital staff needed to assure operation of the

program include a full-time RN Transplant Coordinator, a part-time Licensed Clinical Social Worker, and a qualified full time technician to operate the intraoperative cell-saver. These additional salary dollars have been detailed in the Financial Data section of SNGH's application.

17. Allegedly, establishment of the liver transplant program requires no additional inpatient beds or facility construction, as liver transplant patients would be incorporated into the existing vascular step-down and intensive care units within SNGH. The actual transplantation surgical procedure would be performed within the surgical suites at SNGH. Some of the more costly equipment used to support this complicated procedure (such as the bypass pump and the intraoperative cell saver) is already available at SNGH, due to other tertiary-care transplant programs provided at the hospital.

18. Upon discharge, liver transplant patients are proposed to be followed initially in the Transplant Outpatient Clinic located on the fifth floor of SNGH. SNGH plans that patients will be followed in the Clinic for three months post-discharge, and follow-up care required after the initial period will be coordinated with the patient's primary care and/or referring physician. The Transplant Outpatient Clinic presently supports the outpatient needs for the kidney, heart, and heart/lung programs. Thus, the liver transplant outpatients will utilize the existing Transplant Center examination rooms, waiting rooms, etc. SNGH proposes that long-term follow-up on these patients will comply with standard protocols and procedures in place within existing transplant programs and the proposed liver transplant program and will include at least an annual examination.

19. Reimbursement for liver transplantation is expected to be from sources similar to the existing organ transplant programs. SNGH's current contracts with insurers such as Aetna, Cigna, Blue Cross, Met Life, and MetraHealth Travelers, include the ability for patients to have transplant services provided at SNGH. Patients covered by the Sentara insurance products that provide coverage for transplant services will also have the ability to have liver transplant services provided at SNGH.

20. The liver transplant program expects to perform transplants on patients without the ability to pay, as part of Sentara's charitable mission of improving the health of citizens in the Hampton Roads community. Historically, SNGH has provided a larger percentage of charity care than other Tidewater area hospitals.

21. The application's projected capital costs for this project are:

| **SNGH Liver Transplant Program** | |
|---|---|
| Direct Construction Costs | $ 0 |
| Equipment | $ 54,400 |
| Legal Fees | $ 7,500 |
| Total Projected Capital Costs | $ 61,900 |

22. SNGH is located at least two hours away from Richmond, the nearest liver transplant program to residents of PD 20.

23. The survival rate of liver transplant patients apparently is not strongly related to the volume of procedures performed at the facility in which the transplant was provided.

24. MCVH has a fully accredited liver transplant training program. Accreditation of liver transplant training programs by the American College of Surgeons is related to the volume of procedures performed in a facility. Full accreditation, as a liver transplant training program, is dependent upon at least 45 liver transplant procedures being performed annually by each fellow in the training program.

**DISCUSSION**

Applications for certificate of public need are required to be considered in relation to the twenty general criteria that are specified in the COPN law. Following is a discussion of the relationship of the proposed project to the COPN criteria.

1. **The recommendation and the reasons therefor of the appropriate health systems agency.**

The EVHSA Board of Directors recommended approval of the proposed liver transplant program at SNGH based upon the following stated rationale:

> *"The project will improve the availability and geographic accessibility to liver transplant services for PD 20 residents, and having a liver transplant service will round out the complement of services that are presently provided at Sentara Norfolk General Hospital."*

2. **The relationship of the project to the applicable health plans of the regional health planning agency, the Virginia Health Planning Board, and the State Board of Health.**

The State Medical Facility Plan (SMFP) contains criteria and standards for determining the need for proposed new organ transplant services.

***Acceptability***

> ***"Consumer Participation - Providers of organ transplantation services should provide a program of patient and family education regarding the nature of the patient's organ disease and the treatment of the patient and family in the management of the organ pre- and post-transplantation."***

SNGH is an existing major provider of organ transplant services in Virginia. The application states that "as an existing provider of organ transplantation services, SNGH already has appropriate

education programs in place." The application includes examples of patient education material and copies of policy and procedure statements regarding patient education for kidney transplant patients. SNGH subsequently furnished DCOPN a draft "Liver Transplant Protocol," which prescribes staff activities for patient and family education. The application meets this standard.

*Accessibility*

***Travel Time - "Organ transplantation services, of any type, should be accessible within two hours driving time, under normal conditions, of 95% of Virginia's population."***

The main population of PD 20 is approximately two hours driving time from Richmond, the location of MCVH that provides the closest liver transplant program. Norfolk, location of SNGH, is generally about two hours drive from MCVH. SNGH serves a patient population from a wide geographic area that includes PD 20, PD 21, PD 22 and eastern North Carolina. The population is estimated to be 1.7 million by the year 2000. A significant proportion of this population two hours drive or more from a liver transplant service. The proposed project would assure liver transplant services within two hours of this population.

*Availability*

***"Regionalization of Services - There should be no more than one transplant program for each organ system in a health planning region."***

There are currently no liver transplant programs in HPR V. SNGH is the singular transplant service provider in HPR V. The addition of liver transplantation service at SNGH would be consistent with this standard.

***"Conditional Approval - approval of organ transplantation programs shall be conditioned upon a facility's meeting both minimum volume and survival standards. Failure to meet these standards within two years of initiation of the service may be cause for revocation of the certificate of public need."***

SNGH has been providing some transplant services for twenty-five years. It has met the volume and survival standards for the other transplant services it provides. SNGH can be expected to be able to meet the volume and survival standards for liver transplant services.

***"HCFA/Medicare Requirements - 1. Proposals to establish new transplantation programs should demonstrate compliance with all Medicare program coverage criteria within two years of the initiation of the program. 2. Proposals to expand existing transplantation programs should demonstrate that existing organ transplantation services comply with all applicable federal Health Care Financing Administration (HCFA) criteria for Medicare program coverage."***

SNGH is certified by HCFA as a provider of transplant services. Its heart and kidney transplant services fully comply with Medicare requirements and the only facet of the lung transplant program that fails to meet Medicare criteria is the low volume due to constraints on organ availability. SNGH is anticipated to meet the HCFA/Medicare requirements.

*Continuity*

> ***"Discharge planning and follow-up care - A. Providers of transplantation services should have written policies and procedures for discharge planning and follow-up care for the patient and family which are part of the institution's overall discharge planning program. B. Providers of organ transplantation services should have established protocols for referring physicians and the organ transplantation service to assure adequate post-operative diagnostic evaluation for transplant patients."***

SNGH has the requisite policies and procedures in place to meet the standards for continuity of care.

*Cost*

> ***"Cost and charges - The total cost (direct and indirect) for providing all organ transplantation services should be comparable to other similar providers in the health planning region and the state."***

SNGH is the only provider of transplantation services in its HPR. SNGH's case-mix indices, net patient revenue, and costs were compared with those the other major tertiary-care hospitals in Virginia, all of which offer transplant services for one or more solid-organ systems by DCOPN staff. When compared to other transplant service providers in the state, SNGH was determined by the DCOPN staff to have typically low costs and charges. SNGH's costs were compared to were determined to be approximately 77% of the combined average of Fairfax, UVAH and MCVH. Additionally, SNGH's case mix was determined to be 118% of the average for the group. It is reasonable to believe that the costs and charges for the proposed liver transplant service at SNGH will be comparable to the costs and charges for liver transplant services at the other Virginia liver transplant provider institutions.

**Quality**

> ***"Minimal utilization - 1. Proposals to establish...transplantation services should demonstrate that a minimum number of transplants will be performed annually. The minimum number of required liver transplants is twelve (12)."***

SNGH projects that it will be able to exceed the minimal number of requisite liver transplants following its start-up year. It is reasonable to believe that a liver transplant program at SNGH will be able to meet the minimal volume standard.

***"2. Successful transplantation programs are expected to perform substantially larger numbers of transplants annually. Performance of minimum transplantation volumes does not necessarily indicate a need for additional transplantation capacity or programs."***

In 1996, all three liver transplant programs in Virginia substantially exceeded the volume requirements of the SMFP. Sixty-six liver transplants were performed at MCVH, 37 liver transplants were performed at UVAH, and 53 liver transplants were performed at Fairfax Hospital. It may be anticipated that an additional liver transplant program at SNGH will also meet this standard.

***"3. Preference will be given to expansion of successful existing services, either by enabling necessary increases in the number of organ systems being transplanted or by adding transplantation capability for additional organ systems, rather than developing other programs that could reduce average program volume."***

SNGH currently provides successful transplantation services for kidney, heart, and heart/lung patients. In 1988, SNGH was one of only five hospitals in Virginia providing transplant services and was second (after MCVH) in the volume of transplants. In 1988, the kidney was the only organ transplanted at SNGH. Heart, lung, and heart-lung transplant services were added at SNGH from 1989 through 1993. In 1995, SNGH was fourth in total volume among the eight Virginia hospitals offering transplant services for one or more organs. From 1988 to 1995, SNGH's annual transplant volume first increased and then declined back to the 1988 level. During the period, total statewide transplant volume more than doubled, reflecting the addition of a number of new transplant programs at other Virginia hospitals. From May 1, 1995 through April 30, 1996, SNGH transplant center totals were 39 kidney transplants, 17 heart transplants and six heart-lung transplants. SNGH has a very active transplant center. The provision of liver transplant services would add a new transplant program to an already successful SNGH transplant center. The proposed project is consistent with this standard.

***"Minimum survival rates - 1. Facilities should demonstrate that they will achieve and maintain minimum transplant survival rates. The minimum one-year survival rate for liver transplant recipients is 50%-60%."***

SNGH meets or exceeds the minimal survival rates for each of its existing organ transplant programs and there is every reason to believe, if liver transplant services are initiated by SNGH, liver transplant patients will meet or exceed the minimal survival rates.

***"2. Survival rates beyond one year should be consistent with the HCFA Medicare program requirements, or with applicable professional-society-recommended standards acceptable to the department where there are no HCFA criteria."***

The HCFA two-year standard for liver transplant programs is 60%. SNGH has a history of compliance with the survival rates in its other transplant services and can be expected to meet the

HCFA standard for the liver transplant service. (Note: The HCFA standard for heart recipients is 65%, SNGH achieves 94.5%; the HCFA standard for lung recipients is 62%; SNGH achieves 66%; there is no HCFA standard for kidney recipients, but SNGH achieves 90%.)

> ***"Service proficiency - Proposals to add organ transplantation services should demonstrate at least two years successful experience with all existing organ transplantation systems."***

SNGH meets this standard.

> ***"Staffing - 1. All physicians that perform transplants should be board certified by the appropriate professional examining board, and should have a minimum of one year of formal training and two years experience in transplant surgery and post-operative care."***

The applicant asserts that, upon receipt of a certificate of public need, the physician group which serves the transplant center at SNGH will recruit and hire a liver transplant surgeon who meets all relevant criteria. SNGH can meet this criterion.

> ***"2. Organ transplantation services should have a complete team of surgical, medical and other specialists, with at least two years experience in the proposed organ transplantation system."***

The applicant will be able to comply with this standard. SNGH has in place already surgical, medical and other specialty physicians on staff with liver experience.

> ***"Systems Operations - 1. Providers of organ transplantation services should document that they participate in a regional and national organ donor network. The facility should have written policies and procedures governing organ and tissue procurement."***

SNGH has policies and procedures which meet this standard; and SNGH also is a member of the regional and national organ donor networks. SNGH meets this standard.

> ***"2. Providers of organ transplantation services should have an ongoing approved medical education program."***

SNGH has an approved medical education program in place and all of its physicians associated with the transplant program participate in continuing medical education programs.

> ***"3. Providers of organ transplant services should demonstrate that they have direct and immediate access to a histocompatibility testing laboratory that meets the American Society for Histocompatibility and Immunogenetics (ASHI) standards."***

SNGH operates an ASHI accredited laboratory. The proposed project meets this standard.

3. **The relationship of the project to the long-range development plan, if any, of the person applying for a certificate.**

SNGH currently provides transplant services for kidneys, hearts, lungs, and heart-lungs. SNGH serves a large population of persons who are not within two hours driving time of the nearest liver transplantation services at MCVH. The COPN staff has estimated the population outside of the two-hour driving time radius of MCVH to be in excess of 400,000 persons. The addition of liver transplant services will round-out the transplantation services provided by SNGH to its service area population. The proposed project is consistent with SNGH's long-range development plan for its transplant center.

4. **The need that the population served or to be served by the project has for the project.**

The population that uses SNGH for its tertiary services is relatively concentrated in eastern Virginia. Patient origin statistics show that the hospital serves PDs 20, 21 and 22 and northeastern North Carolina. The population of this hospital service area is estimated to be 1.7 million people. The number of liver transplantations from this population group has increased each year for the past three years from 18 (1994) to 28 (1996), and there is no reason to believe that this trend will not continue assuming that organs continue to come available.

The applicant asserts that residents of its service area in need of liver transplantation must now leave the area to go to providers in Richmond, Charlottesville, Fairfax and out-of-state. The applicant asserts that travel for persons with end stage liver disease is burdensome due to the numerous evaluations that persons awaiting livers are subjected to while awaiting the availability of organs, and that most patients have to rely upon family members to assist them, which creates additional burdens on the patient's families. SNGH asserts that the process is burdensome, expensive and time-consuming for its service area residents, but that much of the inconvenience, anxiety and expense can be eliminated with the initiation of liver transplantation services at SNGH.

The applicant asserts that referrals of patients to out-of-area providers often results in repetitions of the diagnostic tests that were performed on the patients prior to referral to the transplantation facility and that coordination of patient care between the transplant facility and the referral physician is often poor. SNGH believes that approval of its proposed project will eliminate these problems for its service area.

5. **The extent to which the project will be accessible to all residents of the area proposed to be served.**

There is no liver transplantation service in HPR V at the present time. Residents in need of liver transplantation must travel outside of the area for liver transplant services. The proposed project will make liver transplantation geographically available to a significant population that now must travel more than two hours' driving time to get to the nearest provider.

SNGH has a long tradition of providing health services to persons who cannot afford to pay. This is true of its general hospital services as well as its transplant services. It is reasonable to expect that approval of the proposed project will increase financial accessibility to liver transplant services for a significant population.

6. **The area, population, topography, highway facilities and availability of the services to be provided by the project in the particular part of the health service area in which the project is proposed.**

The location of SNGH in downtown Norfolk is convenient to the area population by automobile. The area is served by a network of interstate highways and major thoroughfares. The area has many waterways with bridges and tunnels that often become crowded and sometimes inhibit traffic. There is no other liver transplant service provider in the region, which includes PD 17, 18, 20, 21, and 22. Residents who require liver transplantation services must travel outside of the region to receive the service. A substantial number of people in the area, 400,000 plus, are not within two-hours drive of a liver transplantation program.

7. **Less costly or more effective alternate methods of reasonably meeting identified health service needs.**

SNGH provides organ transplantation services at its "Transplant Center." When the costs and charges of all Virginia transplant programs are compared, the SNGH costs and charges are comparable to that of the other Virginia programs. In view of the fact that no other transplant program is within HPR V, one can conclude that the availability of a liver transplant program at SNGH would reduce the travel time and therefore the cost of services for residents of its services area who now must travel out of the area for services. The addition of liver transplants to the SNGH array of solid organ transplant services can be accomplished at minimal addition expense. No capital expenses for new construction are involved. Much of the equipment and support services expenses can be avoided due to their current availability at SNGH for existing transplant services.

8. **The immediate and long-term financial feasibility of the project.**

The proposed project is financially feasible in both the short term and the long term. There is an ample number of potential liver transplantation patients to allow the development of a liver transplantation program at SNGH. The development of the SNGH liver transplant program should have minimal impact upon existing providers of liver transplant services. SNGH expects to serve six patients during year one, 12 in year two, and 15 in year three. This timetable for development should provide minimal disruption to the volume of patients who currently seek liver transplant services from other in-state providers.

9. **The relationship of the project to the existing health care system of the area in which the project is proposed.**

SNGH is a major tertiary care referral facility that serves the eastern portion of Virginia and northeastern North Carolina. It provides most medical and surgical services that are required by its service area population. It is the only facility in HPR V that provides transplant services. It is a major trauma center. If liver transplant services are to be provided in HPR V, SNGH is the only location where all of the support services are already in place to do so. Additionally, SNGH provides the referral relationships that a transplant center requires to maintain continuity of patient care services.

10. **The availability of resources for the project.**

SNGH has the necessary resources to initiate the liver transplant service and to sustain the service until the time that it becomes self-sustaining through reimbursement income. SNGH has the ability and the contacts to recruit the necessary experienced personnel that it will require to initiate a successful liver transplant program.

11. **The organizational relationship of the project to necessary ancillary and support services.**

SNGH, through it existing transplant programs, has in place and on staff the necessary personnel, equipment, policies and procedures to support a liver transplant program.

12. **The relationship of the project to the clinical needs of health professional training programs in the area in which the project is proposed.**

SNGH has long been associated with the Eastern Virginia Medical School (EVMS). The initiation of liver transplant services at SNGH will provide opportunities for medical students of EVMS and residents in the SNGH postgraduate training programs to observe and study liver transplantation as a part of their training; however, there is no plan to train transplant surgeons as a part of the proposed project.

The SNGH liver transplant program may temporarily reduce the volume of patients being referred to other in-state providers, especially MCVH, where most area patients are referred; however, the proposed slow startup of the SNGH program should provide minimal impact upon volumes of patients at MCVH. The number of liver transplant patients from the SNGH service area increased by three, from 1994 (18 recipients) to 1995 (21 recipients), and by seven, from 1995 (21 recipients) to 1996 (28 recipients). This annual increase in liver transplant recipients should mitigate the impact that the addition of a liver transplant program at SNGH will have upon other in-state providers.

13. **The special needs and circumstances of an applicant for a certificate, such as a medical school, hospital, multidisciplinary clinic, specialty center or regional health service provider, if a substantial portion of the applicant's services or resources or both is provided to individuals not residing in the health service area in which the project is to be located.**

SNGH is a regional health service provider that is the main tertiary hospital facility that serves eastern Virginia and northeastern North Carolina. The initiation of liver transplant services will increase accessibility for the population that historically has relied upon SNGH for tertiary care services.

14. **The special needs and circumstances of health maintenance organizations. When considering the special needs and circumstances of health maintenance organizations, the Commissioner may grant a certificate for a project if the Commissioner finds that the project is needed by the enrolled or reasonably anticipated new members of the health maintenance organization or the beds or services to be provided are not available from providers which are not health maintenance organizations or from other health maintenance organizations in a reasonable and cost effective manner.**

Although "Sentara" owns and provides health maintenance organization services, this criterion is not applicable to this project.

15. **The special needs and circumstances for biomedical and behavioral research projects which are designed to meet a national need and for which local conditions offer special advantages.**

This criterion is not applicable to the proposed project.

16. **In the case of the construction project, the costs and benefits of the proposed construction.**

This criterion is not applicable to the proposed project.

17. **The probable impact of the project on the costs of and charges for providing health services by the applicant for a certificate and on the costs and charges to the public for providing health services by other persons in the area.**

SNGH asserts that most costs associated with the delivery of transplant services are variable and that any reduction in volume that may be experienced by other providers of liver transplant services as a result of the establishment of services at SNGH should be minimized. The addition of the service at SNGH will not increase the cost of delivery of liver transplant services because many of the necessary fixed costs are already in place at the SNGH transplant center. SNGH was determined by the staff of the DCOPN to have lower charges than other transplant programs in Virginia while having a patient case mix with an 18% higher acuity. The location of a liver transplant program at SNGH should serve to reduce travel expenses for those residents in the SNGH service area who require liver transplants.

18. **Improvements or innovations in the financing and delivery of health services which foster competition and serve to promote quality assurance and cost effectiveness.**

The proposed project offers no specific improvements or innovations in the financing and delivery of liver transplantation service which will foster competition or promote competition and cost effectiveness.

SNGH asserts that its liver transplant program will improve the continuity of care provided to residents of its service area who require transplants and also reduce their travel costs by keeping them closer to home. SNGH alleges that by improving continuity and coordination of patient care, the transplant patient outcomes should ultimately be affected positively.

19. **In the case of health services or facilities proposed to be provided, the efficiency and appropriateness of the use of existing services and facilities in the area similar to those proposed.**

There are no other liver transplantation services available in HPR V. The residents in need of liver transplants from this area are currently traveling to other liver transplant providers in Virginia and out of state. The predominant number of referred liver transplant patients are currently served at MCVH. Based upon the analysis performed by the staff of DCOPN, the SNGH service area residents make up about 30% of the utilization of the MCVH liver transplant program. The MCVH liver transplant program had 66 liver transplants in 1996.

20. **The need and the availability in the health service area for osteopathic and allopathic services and facilities and the impact on existing and proposed institutional training programs for doctors of osteopathy and medicine at the student, internship, and residency training levels.**

SNGH provides one of the primary hospital sites for training EVMS physicians. There is no other allopathic or osteopathic training program in eastern Virginia. The proposed initiation of liver transplant services at SNGH will provide an additional learning opportunity for medical students at EVMS.

The development of a liver transplant service at SNGH should only marginally alter the volume of liver transplants at MCVH, which is located in HPR IV, where a fully accredited fellowship training program for liver transplant surgeons exists. The MCVH certification is dependent upon maintaining a certain volume of liver transplant patients. The American College of Surgeons certification requires 45 liver transplants to be performed annually. In 1996, sixty-six liver transplants were performed at MCVH.

The transplantation program at MCVH draws patients from all of Virginia and out-of -state as well. MCVH is a nationally known transplantation center.

**Recommendation**

I have reviewed and evaluated all aspects of the proposed project. I have listened to the testimony of experts from the hospital, and reviewed the position of the Eastern Virginia Health Systems Agency, and its staff, and the staff of the Division of Certificate of Public Need. Additionally, I have carefully studied the SMFP and the guidance that it offers as it applies to this proposed project. I recommend approval of the proposal to establish liver transplant services at Sentara Norfolk General Hospital. The rationale in support of the recommendation is:

1) the proposed project is consistent with all of the pertinent standards for reviewing transplant services in the SMFP;

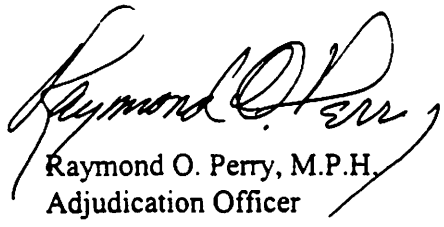
2) the applicant is physically located so that it is accessible to a substantial population in eastern Virginia and northeastern North Carolina that does not reside within two-hours' driving time of the transplant center at the Medical College of Virginia;

3) the proposed project was recommended for approval by the Eastern Virginia Health Systems Agency for the reason of improving area residents' access to liver transplant services; and,

4) the number of liver transplant patients from eastern Virginia appears to be increasing and, coupled with the projected slow start-up of the SNGH liver transplant service, no significant impact on liver transplant volume at the MCVH transplant center should occur in the first three years.

5) the SNGH liver transplant program and the MCVH liver transplant program will both be served by the LifeNet Organ Procurement Organization, permitting collaborative participation in developing mutually acceptable rules and guidelines to assure proper organ allocation policies and procedures among patients and between institutions.

Respectfully submitted,



Raymond O. Perry, M.P.H.
Adjudication Officer

# COMMONWEALTH of VIRGINIA

*Department of Health*
P O BOX 2448
RICHMOND, VA 23218

RANDOLPH L. GORDON, M.D., M.P.H.
COMMISSIONER

TDD 1-800-828-1120


October 31, 1997

Mark S. Hedberg, Esquire
Hunton and Williams
Riverfront Plaza, East Tower
951 East Byrd Street
Richmond, Virginia 23219-4074

Dear Mr. Hedberg:

Re: **University Health Services (UHS) and Medical College of Virginia Hospitals (MCVH)**

**Petition to Show "Good Cause" for Standing in the Review of:**

**COPN Request No. VA-5969**
**Sentara Norfolk General Hospital**
**Norfolk, Virginia**
**Addition of Liver Transplant Services**

In accordance with Chapter 4, Article 1:1 of Title 32.1 of the Code of Virginia 1950, as amended, I reviewed the University Health Services and Medical College of Virginia Hospital's petition asserting "good cause standing" in the review of the certificate of public need for the proposed Sentara Norfolk General Hospital liver transplant services program. Additionally, I have received and reviewed the report and the recommendation made by Raymond O. Perry, Adjudication Officer for the informal fact-finding conference. Based upon Mr. Perry's report and recommendation, I am denying the petition. In making my decision, I have adopted the enclosed Findings and Recommendation of Mr. Perry regarding the petition.

In order to establish "good cause standing" under § 32.1-102.6, it is incumbent upon the petitioners to show that "(i) there is significant relevant information not previously presented at and not available at the time of the public hearing, (ii) there have been significant changes in factors or circumstances relating to the application subsequent to the public hearing, or (iii) there is a substantial material mistake of fact or law in the Department staff's report on the application or in

the report submitted by the health systems agency." The petition proffered in behalf of University Health Services and the Medical College of Virginia Hospital fails to show "good cause" with respect to any of these foregoing requirements.

As required by § 32.1-102 of the Code of Virginia, all factors which must be taken into account in making this determination have been considered and I have concluded that standing for University Health Services and the Medical College of Virginia Hospital is not warranted.

Sincerely,

Randolph L. Gordon, M.D., M.P.H.
State Health Commissioner

Enclosure

pc: Raymond O. Perry, M..P.H., Adjudication Officer
Carol S. Nance, Esquire, Assistant Attorney General
Paul E. Parker, Director, Office of Resources Development
Nancy R. Hofheimer, Director, Office of Health Facilities Regulation
Joseph M. Teefey, Director, Department of Medical Assistance Services
Paul M. Boynton, Executive Director, Eastern Virginia Health Systems Agency
Trigon Blue Cross/Blue Shield of Virginia
The Honorable Robert C. Metcalf, Secretary of Health and Human Resources
Members of the State Board of Health
Thomas W. McCandlish, Esquire, Counsel to Sentara Norfolk General Hospital

**University Health Services (UHS) and**
**Medical College of Virginia Hospitals (MCVH)**
**Petition to Show "Good Cause"**
**for Standing in the Review of:**

**COPN Request No. VA-5969**
**Sentara Norfolk General Hospital**
**Norfolk, Virginia**
**Addition of Liver Transplant Services**

University Health Services, Inc. ("UHS") and the Medical College of Virginia Hospitals ("MCVH"). collectively, "the Petitioner") seek to demonstrate "good cause" standing to participate as a party at the informal fact-finding conference ("IFFC") scheduled with respect to the certificate of public need application by Sentara Norfolk General Hospital to establish liver transplant services at the Sentara Norfolk General Hospital.

In order to show "good cause" and participate as a party with standing in the review of COPN Request Nos. VA-5969, the Petitioner must show that: "*(i) there is significant relevant information not previously presented at and not available at the time of the public hearing, (ii) there have been significant changes in factors or circumstances relating to the application subsequent to the public hearing, or (iii) there is a substantial material mistake of fact or law in the Department staff's report on the application or in the report submitted by the health systems agency.*"

The Petitioner first asserts that "*there is significant, relevant information not previously presented at and not available at the time of the public hearing*" which entitles the Petitioner to standing in the review of the proposal by SNGH to establish a liver transplant program.

In support of its assertion the Petitioner states that since the public hearing on the proposed project was conducted by the Eastern Virginia Health Systems Agency (EVHSA), it has reached a lease agreement with Bon Secours DePaul Hospital in the City of Norfolk for space in which its liver transplant physicians will provide pre- and post-operative care for liver transplant patients who are served in the MCVH liver transplant program. The MCVH liver transplant physicians expect to begin seeing patients in the near future. The Petitioner asserts that it does not believe that the infrequent pre- and post-operative visits to MCVH are burdensome for liver transplant patients, and they clearly do not constitute public need for another liver transplant program. However, the Petitioner asserts that it is interested in making services as convenient as possible to MCVH liver transplant patients and that this new clinic will serve as an alternative to the proposed project, which information was not available at the time of the public hearing. The Petitioner argues that this clinic alternative to the proposed Project provides virtually all of the proposed Project's purported benefits with none of its risks or adverse consequences.

While the development of an outpatient clinic in another local area hospital (e.g., DePaul) does allow for some of the travel time and expense of patients who now travel to Richmond for post-operative liver transplant services to be reduced, it does not provide the liver transplant service itself within a two-hour driving time of a significantly large population as would the proposed project. The placement of the liver transplant service at the SNGH facility would provide liver transplant services in a health planning region of

the state which currently has none. This proposed clinic does not effect a significant change in the manner in which actual transplant services are currently delivered by the MCVH transplant center. The primary transplant services will still require travel by residents of the SNGH tertiary service area to Richmond to receive the liver transplants, and a number of follow-up trips to Richmond for post-operative services. The petitioner's assertion that its potential opening of a clinic for liver patients in Norfolk constitutes "significant relevant information not previously presented at and not available at the time of the public hearing" should be rejected.

The Petitioner next asserts *(2) there have been significant changes in factors or circumstances relating to the application subsequent to the public hearing.* In support of this claim the Petitioner also relies upon its stated intention to establish a clinic at the Bon Secours DePaul Hospital in Norfolk for liver transplant patients. Aside from the fact that the alleged development of the clinic by MCVH liver transplant physicians has no relationship to the application of SNGH, for the same reasons and rationale stated above, this assertion of the Petitioner should be rejected.

Thirdly, the petitioner asserts that *(3) there is a substantial material mistake of fact or law in the department staffs report on the application or in the report submitted by the regional health planning agency* which entitles the Petitioner to standing in the review of the proposal by SNGH to establish a liver transplant program.

In support of this assertion the Petitioner claims that the staff reports of the Eastern Virginia Healths Systems Agency (EVHSA) and the Division of Certificate of Public Need contain certain statements and omissions which constitute substantial, material mistakes of fact or law, notwithstanding the fact that they reached the right result, and that these errors entitle the Petitioner to standing in the review of the proposal by SNGH to establish a liver transplant program. The Petitioner offers five arguments in support of this assertion.

1. The Petitioner argues that the EVHSA Staff Report failed to recognize and appropriately consider the substantial adverse effect the proposed project will have on liver transplant research activities and training programs at MCVH.

The EVHSA staff report devoted significant attention to the potential impact that creation of the new liver transplant service may have upon the service provided by MCVH. Whether the report captured the full impact that MCVH alleges that the new program will have upon MCVH's liver transplant program seems to be the subject for the Petitioner's concern;; however, the actual degree of impact remains to be seen and cannot be determined to be a mistake of fact or law in the EVHSA staff report. This argument does not identify a substantial material mistake of fact or law the report submitted by the regional health planning agency. This argument is rejected.

2. The Petitioner argues that the EVHSA Staff Report failed to recognize and appropriately consider the substantial adverse effect on patients that will result from the loss of flexibility in waiting list management due to the creation of a second liver transplant program that would be served by LifeNet, the organ procurement organization (OPO) that currently serves only one liver transplant program - the program at MCVH.

The Petitioner's argument regarding increased patient mortality because a second liver transplant program would be established in the same area that is served by LifeNet, the single Organ Procurement Organization (OPO), thereby creating a dual waiting list which would not be able to be "managed" by MCVH, and thus cause increased waiting list mortality, is not convincing. MCVH allegedly experiences a wait list mortality rate of slightly over 5% compared to the national average wait list mortality of approximately 14%. MCVH attributes its lower waitlist mortality rate to the fact that, as the single liver transplant center in the LifeNet OPO, it has total control over which of its patients on the wait list will receive the next available liver transplant service. If a second liver transplant program is established in the area, then both programs would necessarily have to work from an agreed-upon protocol to determine who would receive the next liver transplant. MCVH believes that its current policy of transplanting the patient most in need may be in jeopardy and lead to increased mortality among its waitlist patients. This argument does not identify a substantial material mistake of fact or law in the report submitted by the regional health planning agency. This argument is rejected, especially since the OPO, not the institution, makes the objective organ-assignment determinations.

LifeNet presently serves both institutions for the purpose of procuring and distributing hearts, kidneys, lungs and pancreases. The distribution of livers to persons in need of transplants is no more important than the distribution of the other important life-prolonging organs. The protocol for the distribution of these other vital organs has been satisfactorily agreed upon by both institutions, each of which participates on the LifeNet governing board, and the same can be expected for the procurement and distribution of livers. If waitlist mortality should increase, the policy for which patient gets the liver transplant will need to be refined. There is no reason that one can automatically conclude that waitlist mortality will increase with two programs. The OPO is the organization that will, by law, govern the liver transplantation, just as it does the transplantation of other vital organs.

This argument does not identify a substantial material mistake of fact or law in the report submitted by the regional health planning agency. This argument is rejected.

3. The Petitioner argues that the DCOPN Staff Report significantly overestimates the number of pre- and post operative physician visits required to be made by liver transplant patients, and thereby significantly overestimates the benefits of the Project.

The decision to approve or deny the application is not concerned with over or under estimates of numbers of pre and post operative visits for liver transplant patients, although it has been expressed as a concern among those who traveled more than two hours to services. Clearly, such visits are determined by the condition of the patients; wide variances from the average would not be surprising. Whether the DCOPN staff overestimated the average number of visits is not a significant error. The simple truth of the matter is that whoever lives more than two hours from the location of their liver transplant will have to travel to get to the transplant center multiple times. The SMFP rule is that liver transplant services should be available to 95% of the population within two hours' driving time. The MCVH transplant program is not available within the two-hour driving time for more than 400,000 persons in the SNGH service area (PDs 20 and 22). Therefore, in eastern Virginia, the location of SNGH, more than 6% of the state's population resides in excess of two hours' driving time of the nearest liver transplant facility, MCVH, and it is not located within the same Health Planning Region as the population at risk.

This argument does not identify a substantial material mistake of fact or law in the report submitted by the Division of Certificate of Public Need staff. This argument is rejected.

4. The petitioner argues that the DCOPN Staff Report fails to recognize and appropriately consider the substantial adverse affect the Project will have on liver transplantation research activities at MCVH.

It is not uncommon for institutions to collaborate in research projects and protocols and certainly, if a large volume of patients is required for the research concerning liver transplants, one could expect such collaboration between MCVH and SNGH, both of which would be served by the same OPO. There is no reason to expect research at MCVH to be affected by the initiation of liver transplant services at SNGH. Furthermore, any impact of the proposed project upon the research programs of MCVH should not be significant, especially in view of the slow projected start-up of the SNGH program of six, twelve and fifteen patients, respectively, in the first three years of operation.

This argument does not identify a substantial material mistake of fact or law the report submitted by the Division of Certificate of Public Need staff. This argument is rejected.

5. The Petitioner argues that the DCOPN Staff Report erroneously asserts that it is reasonable to conclude that MCVH's liver transplant charges have been and will be increasing at a rate (5% per year) similar to that projected by the applicant.

The DCOPN staff did erroneously conclude that MCVH's liver transplant charges would increase at a rate of 5% per year, which is similar to the charges proposed by the applicant; however, the assumption was not a significant error. It was a mere harmless error. There are several comparable solid organ transplant programs to compare between the two institutions and it is reasonable to believe that the SNGH charge structure will be comparable to the MCVH charge structure. SNGH has lower charges than MCVH in its other solid organ transplant programs, and it is reasonable to expect the liver transplant program charges will not be substantially different from those of the existing transplant services.

This argument does not identify a substantial material mistake of fact or law in the report submitted by the Division of Certificate of Public Need staff. This argument is rejected.

**Recommendation**

The Petitioner has not provided the necessary "good cause" threshold proofs that would entitle the Petitioner with "standing" to participate in the review of the proposed project. The Petitioner should be advised that its petition is rejected.

Respectfully submitted,

Raymond. O. Perry, M.P.H.
Adjudication Officer

D

# COMMONWEALTH of VIRGINIA

*Department of Health*
P O BOX 2448
RICHMOND, VA 23218

RANDOLPH L. GORDON, M.D., M.P.H.
COMMISSIONER

TDD 1-800-828-1120

November 3, 1997

Thomas W. McCandlish, Esquire
Mezzullo and McCandlish
1111 East Main Street, Suite 1500
Richmond, Virginia 23206

Dear Mr. McCandlish:

Re: Certificate of Public Need No. VA-03365
Sentara Norfolk General Hospital
Norfolk, Virginia
Establish Liver Transplant Services

In accordance with Chapter 4, Article 1:1 of Title 32.1 of the Code of Virginia 1950, as amended, I reviewed the application and supporting documents requesting a certificate of public need for the above referenced project. Additionally, I have received and reviewed the findings, conclusions, and recommendation of Raymond O. Perry, who presided over the informal fact-finding conference, conducted during the course of review of the application. Based upon my review of all these materials in view of the specialized knowledge of Virginia's healthcare system required of the position of Commissioner, I decline to adopt Adjudication Officer Perry's recommendation and have determined that the application to establish a liver transplantation service at Sentara Norfolk General Hospital (SNGH) should be denied at this time.

The reasons for my decision are as follows:

1. The State Medical Facilities Plan, 12 VAC § 5-280-70, requires an annual volume of twelve liver transplants per year per center to meet minimal utilization standards. It also states that "successful transplantation programs are expected to perform substantially larger numbers of transplants annually. Performance of minimum transplantation volumes does not necessarily indicate a need for additional transplantation capacity or programs." The average number of liver

transplants performed per transplant center nationally in 1994 was 36. In 1996 the average number of liver transplants performed per transplant center in Virginia was 52. The American College of Surgeons requires transplant centers to perform at least 45 liver transplants in order to be certified as training centers.

The State Medical Facilities Plan governing organ transplantation services was promulgated in 1992 and has not been amended. It is apparent from the more current statistics cited above that statistics used in 1992 to identify the minimum standard have been superseded. Accordingly, pursuant to Va. Code § 32.1-102.3(A), I find that the provisions of the State Medical Facilities Plan as they relate to liver transplantation services are inaccurate, outdated, inadequate or otherwise inapplicable. Because they fail to reflect current standards, they should not be applied here, and I will direct that procedures be initiated to make appropriate amendments to such plan.

2. The number of organ transplantations that may be performed is dependent upon the supply of organs. Indications in the healthcare system are that the numbers of available organs may be reaching a plateau; consequently, the actual numbers of transplantations performed appear to be stabilizing. Therefore, if established, an additional liver transplant center at SNGH may erode the quality of other transplant centers by reducing the volume of liver transplants at the other centers. In 1996, Medical College of Virginia Hospitals (MCVH) performed 66 liver transplants, the University of Virginia Hospitals (UVAH) performed 37, and Fairfax hospital performed 53. In the same year SNGH referred 28 patients from its service area (PDs 20, 21, and 22) for liver transplants. Over time, it is reasonable to assume that SNGH would perform the majority of liver transplants from its service area and possibly some from the surrounding PDs, thus reducing the volume of liver transplants at MCVH and UVAH by 40%-50% and 10%-20%, respectively, by the elimination of referrals. Such spreading of patients over four programs would place the Commonwealth's programs below the national average of 36 transplants per center. It is not reasonable to assume that an increase in liver transplantation capability in the state will be met with an increase in available livers for transplantation, nor would more sites provide the increased volume necessary to maintain four transplant centers of quality, especially since the increase in organ donations appears to be leveling out.

SNGH assures that it will perform only six liver transplants in year one, twelve in year two, and 15 in year three of operation. If true, this may mitigate the concerns of reducing volume at other centers on the one hand, but on the other it will not be meeting the needs of its service area and is only marginally at or above the

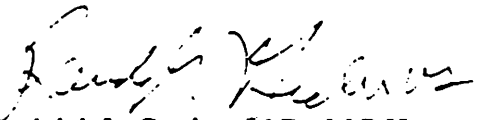
minimum number of twelve liver transplants deemed appropriate to maintain quality even in 1992. Further, although outdated and inapplicable, as stated above, the State Medical Facilities Plan, 12 VAC § 5-280-70, contemplates that "successful transplantation programs are expected to perform substantially larger numbers of transplants annually. Performance of minimum transplantation volumes does not necessarily indicate a need for additional transplantation capacity or programs." Thus, even the unamended State Medical Facilities Plan governing liver transplantation services is not binding as to minimum acceptable volumes.

3. In considering general criterion number 20 specified in Va. Code § 32.1-102.3(B) ("the impact on existing...institutional training programs for doctors of...medicine at the student, internship, and residency training levels"), I determine that an additional liver transplant center at SNGH may seriously impact the established liver transplant fellowship training program at MCVH. Certification as a training program for liver transplantation by the American College of Surgeons requires the training institution to perform 45 liver transplants annually. For the reasons discussed above, an additional transplant service at SNGH may reduce the volume of liver transplants performed at MCVH below that required for certification and could jeopardize its program.

In conclusion, I find that the State Medical Facilities Plan is outdated and inapplicable to a determination of need for liver transplantation services and does not support the award of a COPN to SNGH for liver transplantation services at this time. Additionally, because the system presently (i) reflects no need for additional liver transplantation sites in light of organ supply; (ii) appears to have no excess of transplantation procedures requiring accommodation whereas approval of another site could result in an excess of facilities lacking volume to meet the national average or to assure essential technical experience; and (iii) should maintain and sustain necessary training programs in the Commonwealth, the application for a COPN for liver transplantation services at SNGH is premature. If the volume of liver transplants performed by the other transplant centers in the Commonwealth resumes its former increase, then the addition of another liver transplant center may not pose a threat to quality or established medical training programs and may provide a more convenient site for residents of PDs 20, 21, and 22. At this point in time, however, I determine that any possible convenience gained by these residents is outweighed by the risk of adversely affecting quality and having a possibly serious negative impact on an established medical training program, and I direct the Division of Certificate of Public Need to initiate a process to update the State Medical Facilities Plan regarding liver transplantation services.

As provided by Rule 2A:2 of the Rules of the Supreme Court of Virginia, you have 30 days from the date of service (the date you actually received this decision or the date it was mailed to you, whichever occurred first) within which to appeal this decision by filing notice with the State Health Commissioner. In the event that this decision is served on you by mail, three days are added to that period.

Sincerely,



Randolph L. Gordon, M.D., M.P.H.
Commissioner

Enclosures

pc: Raymond O. Perry, M.P.H., Adjudication Officer
Carol S. Nance, Assistant Attorney General
Paul E. Parker, Director, Division of Certificate of Public Need
Nancy R. Hofheimer, Director, Center for Quality Health Care Services and Consumer Protection
Paul M. Boynton, Executive Director, Eastern Virginia Health Systems Agency
Joseph M. Teefey, Director, Department of Medical Assistance Services
Trigon Blue Cross/Blue Shield of Virginia
The Honorable Robert C. Metcalf, Secretary of Health and Human Resources
Members of the State Board of Health

COURT OF APPEALS OF VIRGINIA

Present: Judges Benton, Bray and Senior Judge Overton
Argued at Norfolk, Virginia

SENTARA NORFOLK GENERAL HOSPITAL

v. Record No. 1798-98-1

OPINION BY
JUDGE NELSON T. OVERTON
JULY 27, 1999

STATE HEALTH COMMISSIONER
and
EASTERN VIRGINIA HEALTH SYSTEMS AGENCY, INC.

FROM THE CIRCUIT COURT OF THE CITY OF NORFOLK
Theodore J. Markow, Judge Designate

Thomas W. McCandlish (Laura G. Aaron; Mary Jane Hall; Mezzullo & McCandlish, on briefs), for appellant.

Carol S. Nance, Assistant Attorney General (Mark L. Earley, Attorney General; Ashley L. Taylor, Jr., Deputy Attorney General; Jane D. Hickey, Senior Assistant Attorney General, on brief), for appellee State Health Commissioner.

No brief or argument for appellee Eastern Virginia Health Systems Agency, Inc.

Sentara Norfolk General Hospital (Sentara) appeals from a decision of the Circuit Court of the City of Norfolk that affirmed a ruling of the State Health Commissioner (Commissioner). The Commissioner denied Sentara a Certificate of Public Need (COPN) to initiate a liver transplant service at its hospital in Norfolk, Virginia. Sentara contends the Commissioner committed reversible error when he denied Sentara's application, despite the fact that the application satisfied all

the existing criteria for issuing a COPN. Sentara also argues that the Commissioner's decision was based upon evidence not contained in the record and upon a material mistake of fact. We agree and reverse the trial court.

I.

On July 31, 1996, Sentara filed an application for a COPN seeking authorization to perform liver transplants. Following a public hearing, the Eastern Virginia Health Systems Agency Board voted to recommend approval of the COPN. On February 28, 1997, however, the Department of Health's Division of Certificate of Public Need (DCOPN) recommended that the application be denied. The matter was then referred to an adjudication officer.

Following an informal hearing, the adjudication officer issued a report recommending that the COPN be approved. The adjudication officer concluded that Sentara's plan satisfied all the applicable statutory factors, including all applicable factors listed in the State Medical Facilities Plan (SMFP).[1] With regard to the SMFP's minimum requirement that a facility perform twelve transplants per year, he found that Sentara would perform six transplants in the first year of its program, twelve in the second year, and fifteen in the third year. The adjudication officer further found that "it may be anticipated"

[1]The version of the SMFP in effect at the time this petition was filed was adopted in 1992.

that Sentara eventually would be able to substantially exceed the regulatory minimum.

The evidence before the adjudication officer proved that in 1996, facilities able to perform liver transplants nationwide averaged thirty-six such procedures for the year. Medical College of Virginia Hospital (MCVH) performed sixty-six liver transplants in 1996, the University of Virginia Hospital (UVAH) performed thirty-seven, and Fairfax Hospital performed fifty-three. From 1992 through 1995, MCVH performed, respectively, thirty-one, thirty-seven, thirty-three, and thirty-nine liver transplants.

In 1994, eighteen residents of Sentara's primary service area received liver transplants. This figure rose to twenty-one in 1995, and twenty-eight in 1996.[2] The adjudication officer noted that forty to fifty percent of liver transplant patients at MCVH, and ten to twenty percent of liver transplant patients at UVAH originated from Sentara's potential service area.[3]

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[2]Dr. Michael Ryan testified that, of the twenty-eight persons from Sentara's potential service area who received liver transplants in 1996, MCVH performed twenty-four of those procedures.

[3]In another section of his report, the adjudication officer indicated that "[b]ased upon the analysis performed by the staff of DCOPN, [Sentara] service area residents make up about 30% of the utilization of the MCVH liver transplant program." It is not clear from the record how these apparently inconsistent figures were calculated. Based on Dr. Ryan's testimony, 36% of MCVH's transplant patients in 1996 came from Sentara's potential service area.

Nevertheless, he found that "the development of a liver transplant service at [Sentara] should only marginally alter the volume of liver transplants at MCVH, which is located in Health Planning Region (HPR) IV,[4] where a fully accredited fellowship training program for liver transplant surgeons exists." The adjudication officer explained that "the number of liver transplant patients from eastern Virginia appears to be increasing and, coupled with the projected slow start-up of the [Sentara] liver transplant service, no significant impact on liver transplant volume at the MCVH transplant center should occur in the first three years."

The Commissioner rejected the adjudication officer's recommendation and denied the COPN. Citing the average numbers of transplants performed in Virginia and nationwide in 1996, the Commissioner found that the SMFP minimum transplant requirement was too low and out of date. The Commissioner stated:

> I find that the provisions of the State Medical Facilities Plan as they relate to liver transplantation services are inaccurate, outdated, inadequate or otherwise inapplicable. Because they fail to reflect current standards, they should not be applied here, and I will direct that procedures be initiated to make appropriate amendments to such plan.

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[4]The Commonwealth is divided into five Health Planning Regions (HPRs). MCVH is in region IV, while Sentara is in region V.

The Commissioner further found that "[i]ndications in the healthcare system are that the numbers of available organs may be reaching a plateau." This fact would limit the number of procedures that could be performed each year, regardless of whether the demand for liver transplants continued to grow. The Commissioner expressed concern that adding a liver transplant program at Sentara could adversely affect other Virginia facilities, especially MCVH and UVAH. He cited the adjudication officer's finding that forty to fifty percent of MCVH's liver transplant volume, and ten to twenty percent of UVAH's volume came from Sentara's potential service area. The Commissioner also expressed concern that spreading patients over four programs would significantly reduce the average number of liver transplants performed at each facility and that this overall per-facility decrease in volume could adversely affect the quality of care each facility provided.

The Commissioner continued that, even if Sentara's transplant numbers remained around fifteen per year, the SMFP

> contemplates that "successful transplantation programs are expected to perform substantially larger numbers of transplants annually. Performance of minimum transplantation volumes does not necessarily indicate a need for additional transplantation capacity or programs." Thus, even the unamended State Medical Facilities Plan governing liver transplantation services is not binding as to minimum acceptable volumes.

The Commissioner suggested that, by performing twelve to fifteen transplants per year, Sentara might not be able to develop and maintain "essential technical expertise."

Finally, the Commissioner found that granting the COPN to Sentara could, by lowering the number of transplants performed at MCVH, adversely impact MCVH's liver transplant fellowship program. In what he now concedes was a mistake of fact, the Commissioner noted that the American College of Surgeons requires training facilities to perform forty-five transplants per year. The standard had been recently amended, however, by requiring transplant fellows to perform forty-five liver transplants during the course of their two-year fellowships.

Sentara appealed the Commissioner's ruling to the trial court, which affirmed the Commissioner. The trial court found that the Commissioner did not abuse his discretion in rejecting the COPN, even though Sentara met all the minimum SMFP requirements. The court held that the Commissioner's reliance on extra-record evidence and "institutional knowledge" regarding organ donation rates did not result in substantial prejudice to Sentara. Similarly, the trial court also ruled that the Commissioner's mistake of fact regarding fellowship requirements constituted harmless error.

II.

"Under Code § 32.1-24, the provisions of the Virginia Administrative Process Act . . . govern the procedures for

rendering case decisions and issuing orders and regulations by the Commissioner." Johnston-Willis, Ltd. v. Kenley, 6 Va. App. 231, 241, 369 S.E.2d 1, 6 (1988). "[T]he party complaining of an agency action has the burden of demonstrating an error of law subject to review." Hilliards v. Jackson, 28 Va. App. 475, 479, 506 S.E.2d 547, 549 (1998).

> Errors of law fall into two categories: first, whether the agency decisionmaker acted within the scope of his authority, and second, whether the decision itself was supported by the evidence. Where the agency has the statutory authorization to make the kind of decision it did and it did so within the statutory limits of its discretion and with the intent of the statute in mind, it has not committed an error of law in the first category.

Johnston-Willis, 6 Va. App. at 242, 369 S.E.2d at 7.

The level of deference accorded to an agency decision depends upon the nature of the legal question involved. "[W]here the question involves an interpretation which is within the specialized competence of the agency and the agency has been entrusted with wide discretion by the General Assembly, the agency's decision is entitled to special weight in the courts." Id. at 244, 369 S.E.2d at 8. Such deference is not in order, however, where the issue is one in which the courts have a special competence. See id. at 243-44, 369 S.E.2d at 7-8. "Thus, where the legal issues require a determination by the reviewing court whether an agency has, for example, accorded constitutional rights, failed to comply with statutory

authority, or failed to observe required procedures, less deference is required . . . ." Id. at 243, 369 S.E.2d at 7-8.

III.

Code § 32.1-102.3 provides that no hospital can commence any project without first obtaining a COPN from the Commissioner.

> Any decision to issue or approve the issuance of a certificate shall be consistent with the most recent applicable provisions of the State Medical Facilities Plan; however, if the Commissioner finds, upon presentation of appropriate evidence, that the provisions of such plan are inaccurate, outdated, inadequate or otherwise inapplicable, the Commissioner, consistent with such finding, may issue or approve the issuance of a certificate and shall initiate procedures to make appropriate amendments to such plan.

Code § 32.1-102.3(A) (emphasis added).

Sentara contends that while Code § 32.1-102.3(A) allows the Commissioner to grant a COPN if there is a need therefor and the Commissioner finds that the SMFP is outdated, the Commissioner cannot deny a COPN based on a finding that the existing SMFP is outdated. The Commissioner asserts that the statutory language "may issue or approve the issuance" of a COPN means that he may grant or deny a certificate on the ground that the SMFP is inaccurate or outdated. We agree with Sentara.

"[A]dministrative agencies, in the exercise of their powers, may validly act only within the authority conferred upon them by statutes vesting power in them." Sydnor Pump & Well Co.

v. Taylor, 201 Va. 311, 316, 110 S.E.2d 525, 529 (1959). And appellate courts "'must construe the law as it is written. An erroneous construction by those charged with its administration cannot be permitted to overrule the clear mandates of a statute.'" Richmond v. County of Henrico, 185 Va. 176, 189, 37 S.E.2d 873, 879 (1946) (citation omitted), modified on other grounds, 185 Va. 859, 41 S.E.2d 35 (1947).

"A primary rule of statutory construction is that courts must look first to the language of the statute. If a statute is clear and unambiguous, a court will give the statute its plain meaning." Loudoun County Dep't of Social Servs. v. Etzold, 245 Va. 80, 85, 425 S.E.2d 800, 802 (1993). "Generally, the words and phrases used in a statute should be given their ordinary and usually accepted meaning unless a different intention is fairly manifest." Woolfolk v. Commonwealth, 18 Va. App. 840, 847, 447 S.E.2d 530, 534 (1994). "[W]e must assume that 'the legislature chose, with care, the words it used when it enacted the relevant statute, and we are bound by those words as we interpret the statute.'" City of Virginia Beach v. ESG Enters., Inc., 243 Va. 149, 153, 413 S.E.2d 642, 644 (1992) (citation omitted).

Because this is an issue of statutory construction, we owe less deference to the Commissioner's interpretation. We interpret Code § 32.1-102.3(A) as providing that the Commissioner may, but is not required to, issue a COPN where a public need has been demonstrated for a project, but where the

petition does not satisfy an outdated or inaccurate SMFP. We reject the Commissioner's assertion, however, that the General Assembly intended to grant the Commissioner the authority to deny a COPN on the ground that the SMFP is outdated or inaccurate. The plain language of the statute provides that the Commissioner "may issue or approve" a petition that does not comply with an outdated or inaccurate SMFP. (Emphasis added.) It does not provide that he may deny or disapprove a petition on this basis. Accordingly, to the extent the Commissioner denied this application on the ground that the SMFP standards were outdated, inaccurate, inadequate or otherwise inapplicable, he exceeded his statutory authority.

IV.

Sentara further contends the circuit court erred in holding that the Commissioner's reliance on extra-record evidence of liver donation rates did not result in substantial prejudice to Sentara and that the court erred when it found that the Commissioner's mistake of fact regarding fellowship requirements was not material.

The adjudication officer did not make a finding regarding organ donation rates, although the record contains evidence concerning those rates. In a September 17, 1996 letter to the executive director of the Eastern Virginia Health Systems Agency, MCVH's Dr. Marc Posner wrote that in the three years through 1995, the number of liver transplants performed in

Virginia had reached a plateau, "indicating the driving force is now only the numbers of available donor organs." At the May 20, 1997 hearing conducted by the adjudication officer, Dr. John Colonna testified that "[w]e have all seen, at least in D.C., a great slowing on our organ donation since the recent 60 minute thing on non heartbeat donors." (Emphasis added.) There was also evidence that MCVH has to "import" livers from out of state and that liver transplants generally have always been limited by the supply of donated organs.

Also contained in the record is a chart titled "MCV Liver Transplant Program--Liver Donations in Virginia." The chart reflects that liver donations in Virginia increased every year from 1991 through 1994, but declined in 1995. Despite this decline, however, the number of liver transplants performed in Virginia in 1995 was fourteen percent higher than the number performed in 1994. And the 156 liver transplants performed in Virginia in 1996 was twenty-one percent higher than the 1994 figure. Statistics in the record reflect that the number of liver transplants in Virginia grew from twenty-two in 1988 to 156 in 1996.

We addressed the issue of extra-record evidence in Johnston-Willis: "Members of an administrative body cannot decide issues on personal knowledge, but must rely upon the evidence produced before them." Id. at 258, 369 S.E.2d at 16. Accordingly, as a preliminary matter, we must determine whether

evidence in the record proved that organ donation rates had reached a plateau, or whether the Commissioner relied on extra-record evidence in reaching this conclusion.

"The standard of review of an agency's factual findings on appeal to a circuit court is limited to determining whether substantial evidence in the agency record supports its decision." Avante at Lynchburg, Inc. v. Teefey, 28 Va. App. 156, 160, 502 S.E.2d 708, 710 (1998) (emphasis added). Under the "substantial evidence" standard, an agency's factual findings should be rejected "'only if, considering the record as a whole, a reasonable mind would necessarily come to a different conclusion.'" Tidewater Psychiatric Inst. v. Buttery, 8 Va. App. 380, 386, 382 S.E.2d 288, 291 (1989) (quoting Virginia Real Estate Comm'n v. Bias, 226 Va. 264, 269, 308 S.E.2d 123, 125 (1983)). "The phrase 'substantial evidence' refers to 'such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'" Bias, 226 Va. at 269, 308 S.E.2d at 125 (citation omitted). Additionally, "the court must review the facts in the light most favorable to sustaining the [Commissioner's] action and 'take due account of the presumption of official regularity, the experience and specialized competence of the [Commissioner], and the purposes of the basic law under which the [Commissioner] has acted.'" Bio-Medical Applications of Arlington, Inc. v. Kenley, 4 Va. App. 414, 427, 358 S.E.2d 722, 729 (1987) (quoting Code § 9-6.14:17).

Having reviewed the record, including those specific portions cited by the Commissioner, we find as a matter of law that the evidence contained in the record is insufficient to support the Commissioner's finding that organ donation rates have reached a plateau.[5] At best, the evidence in the record on trends in organ donation rates is inconclusive. We cannot conclude, for example, that a one year decline in organ donation rates reflects a trend. This faulty logic is demonstrated by the evidence on liver transplant rates. The number of liver transplants performed in Virginia declined in 1992 and 1994, but increased in 1993 and in 1995 and 1996. We conclude, therefore, that the Commissioner relied on extra-record evidence in making his factual finding on organ donation rates.

The Commissioner asserts that information on organ donation rates constituted part of his "institutional knowledge," upon which he could rely in making such a determination. While we do not reach the issue of whether the Commissioner can ever rely on institutional knowledge in making a decision on a COPN application, we hold that statistical evidence such as trends in organ donation rates does not constitute institutional knowledge. Similarly, the Commissioner has failed to establish

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[5]The Joint Appendix contains a photocopy of a 1998 newspaper article reporting that "the number of cadaver donors has remained at 5,400 a year for three years." In addition to the fact that this figure does not specifically address the level of liver donations, the article was published <u>after</u> the Commissioner rendered his decision.

that this empirical evidence could be classified as a "public statistic." Cf. Johnston-Willis, 6 Va. App. at 259, 369 S.E.2d at 16 (finding that data regarding birth and fertility rates received from the Virginia Center for Health Statistics constituted "public statistics" upon which the Commissioner could rely even though the statistics were not part of the record).

Having concluded that the Commissioner improperly relied upon extra-record evidence, we must determine whether this reliance constituted reversible error.

> [T]he rules of evidence are relaxed in an administrative proceeding and the findings will not be reversed solely because the Commissioner considered evidence not in the record. "[T]he mere fact that the [agency] has looked beyond the record does not invalidate its action unless substantial prejudice is shown to result." "No reversible error will be found . . . unless there is a clear showing of prejudice arising from the admission of such evidence, or unless it is plain that the agency's conclusions were determined by the improper evidence, and that a contrary result would have been reached in its absence."

Johnston-Willis, 6 Va. App. at 258, 369 S.E.2d at 16 (citations omitted).

If the record contains sufficient evidence to sustain the Commissioner's ruling, then Sentara's claim that it was prejudiced by the Commissioner's consideration of extra-record evidence regarding organ donation rates must fail. In reviewing the record, we owe "deference to [the agency's] findings of

fact, [and] where substantial evidence in the record exists to support the agency's conclusions, we may not substitute our own judgment for that of the agency." Smith v. Dept. of Mines, Minerals & Energy, 28 Va. App. 677, 687, 508 S.E.2d 342, 347 (1998). Nevertheless, "the reviewing courts should not abdicate their judicial function and merely rubber-stamp an agency determination." Johnston-Willis, 6 Va. App. at 243, 369 S.E.2d at 7-8. We will overturn the Commissioner's decision if it is arbitrary and capricious. See Tidewater Psychiatric Inst., 8 Va. App. at 386, 382 S.E.2d at 291.

The evidence proved, and the Commissioner did not dispute, that Sentara's petition satisfied all the pertinent statutory factors and the minimum requirements in the SMFP. See Code § 32.1-102.3(B). The Commissioner expressed two concerns: 1) the negative effect Sentara's program might have on the liver transplant programs at MCVH and UVAH, and 2) whether Sentara would be performing a sufficient number of transplants each year to maintain the requisite level of surgical expertise.

The Commissioner's concern that Sentara's program would adversely affect MCVH was speculative at best. By its third year, Sentara would be performing only fifteen transplants per year. Even if we assumed that all these patients would have been treated by MCVH, the number of transplants performed at

transplants a facility must perform each year to maintain its expertise in the field. The Commissioner's finding that Sentara would not be performing a sufficient number of transplants to maintain technical expertise is also not supported by the evidence.

When Sentara's petition is viewed in conjunction with the current SMFP and the other evidence in the record, it is apparent that the Commissioner's decision denying the COPN was arbitrary and capricious. Since the evidence contained in the record was insufficient to support the Commissioner's denial of the petition, we must find that Sentara was substantially prejudiced by the Commissioner's consideration of extra-record evidence regarding organ donation rates. Accordingly, the Commissioner's reliance on this evidence constituted reversible error.

Likewise, we cannot say the Commissioner's mistake of fact regarding fellowship requirements was harmless error. In the absence of substantial credible evidence supporting the Commissioner's decision to deny the COPN, we must assume that Sentara was also prejudiced by this mistake of fact.

For the reasons stated above, we hold that the Commissioner exceeded his statutory authority when he denied Sentara's petition for a COPN on the ground that the SMFP was out of date. Based on our review of the record, we hold that the Commissioner's denial of the petition was arbitrary and

capricious. And, in the absence of substantial evidence otherwise supporting the Commissioner's decision, his reliance on extra-record evidence and his mistake of fact regarding fellowship program certification requirements constituted reversible error. Accordingly, the judgment of the trial court is reversed and the case is remanded to the trial court for remand to the Commissioner, who is instructed to issue the COPN to Sentara and to conduct any further proceedings consistent with this decision. Sentara's request for costs and fees is denied.

Reversed and remanded.

Circuit Court
OF THE
City of Richmond
John Marshall Courts Building

T. J. MARKOW
JUDGE

400 NORTH NINTH STREET
RICHMOND, VIRGINIA 23219-1999



July 8, 1998

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Re: Sentara Norfolk General Hospital v. State Health Commissioner, et al.
Case No. 97-2071

Dear Counsel:

This case is before the court on a Petition for Appeal from a decision of the State Health Commissioner which declined to award a Certificate of Public Need ("COPN") to Sentara Norfolk General Hospital ("Sentara") to operate a liver transplant service.

**I. Factual Summary and Statutory Framework**

On July 31, 1996, Sentara submitted a COPN application to perform liver transplants. The Eastern Virginia Health Systems Agency ("EVHSA") held a public hearing on September 16, 1996. The EVHSA Board met on November 12, 1996 to consider Sentara's application and recommended that the project be approved, despite the fact that the EVHSA staff recommended a denial of Sentara's COPN. The Board found that the project would improve the availability and geographic accessability of liver transplant services for local residents and held that a liver transplant service would complement the other transplant services already provided by Sentara. On February 28, 1997, the staff of the Department of Health, Division of Certificate of Public Need, recommended that the project be denied. An informal, non-adversarial fact finding conference was conducted by Raymond Perry, Adjudication Officer, on May 20, 1997. Sentara presented evidence regarding its compliance with the State Medical Facilities Plan ("SMFP"), VR 355-30-105, and the twenty statutory criteria for issuance of a COPN, Va. Code § 32.1-102.3.

Part II, §§ 2.1 through 2.6, of the State Facilities Medical Plan includes provisions on Acceptability, Accessibility (within a two hour drive of 95% of Virginia's population), Availability (no more than one liver transplant program per health planning region), Continuity of Care, Cost (comparable to other similar service providers in the health planning region and the Commonwealth), and Quality (minimum of twelve liver transplants annually; substantially more for successful programs; minimum survival rates of 50-60%; staffing, operations, and support services in place).

After evaluating Sentara's application for consistence with the SMFP criteria, the Commissioner was bound to consider the following criteria pursuant to Code § 32.1-102.3: (1) the recommendation of the EVHSA; (2) the relationship of the project to the SMFP; (3) the relationship of the project to Sentara's long-range development plan; (4) the need that the population to be served has for the liver transplant service; (5) the extent to which the project will be accessible to all residents of the proposed service area; (6) the area, population, topography, highway facilities and availability of liver transplant services in the proposed health service area; (7) less costly or more effective methods of reasonably meeting identified health service needs; (8) the immediate and long-term financial feasibility of the project; (9) the relationship of the project to the existing health care system of the proposed project area; (10) the availability of resources for the project; (11) the organizational relationship of the project to necessary ancillary and support services; (12) the relationship of the project to the clinical needs of medical training programs in the proposed project area; (13) the special needs of Sentara for a COPN if a substantial portion of its services and/or resources are provided to individuals not residing in the health service area in which the project will operate; (14) the special needs and circumstances of health maintenance organizations; (15) the special needs and circumstances for biomedical and behavioral research projects; (16) the costs and benefits of any proposed construction; (17) the probable impact of the projects on Sentara's costs of, and charges for, providing health care and on the costs and charges to the public for providing health care by other area providers; (18) likelihood for increased competition which serves to promote quality assurance and cost effectiveness; (19) efficiency and appropriateness of using existing services and facilities in the area similar to Sentara's proposed center; and (20) the impact on existing and proposed institutional training programs for students, interns, and residents. Va. Code § 32.1-102.3(B)(1)-(20).

The Adjudication Officer found that Sentara's application was consistent with all SMFP criteria. The Adjudication Officer's recommendation for approval of Sentara's application was forwarded to the State Health Commissioner. This recommendation was reviewed

in the context of the entire Agency Record, as well as in the context of the Commissioner's professional knowledge of the health care system. The Commissioner rejected the Adjudication Officer's decision for the following reasons:

1. The 1992 SMFP standards regarding minimum transplant volume (twelve) were inaccurate, outdated, inadequate, or otherwise inapplicable in light of current average volumes in the Commonwealth's transplant centers (fifty-two) and among training centers certified by the American College of Surgeons (forty-five).[1]

2. If established, Sentara's liver transplant center may erode the quality of other transplant centers outside its service area by eliminating referrals to the Medical College of Virginia and the University of Virginia. This redistribution of patients would reduce the Commonwealth's liver transplant program below the national average of thirty-six transplants per center. The increased volume of transplant capability might also face a shortage of available transplant organs. Even assuming that Sentara performs its mandatory minimum volume of transplants, this does not indicate a need for additional transplantation programs.

3. If established, the Sentara liver transplant center may seriously impact the continued certification of the established liver transplant fellowship training program at MCV Hospital. See Va. Code § 32.1-102.3(B)(20).

**II. Legal Standard**

Judicial review of agency action may include (as here) a determination of whether there was substantial evidence in the agency record to support its findings of fact. Bio-Medical Applications of Arlington, Inc. v. Kenley, 4 Va. App. 414, 427 (1987) (citing State Board of Health v. Godfrey, 223 Va. 423, 433

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[1] The State Health Commissioner concedes that he misinterpreted the training center requirements. Each training fellow must perform forty-five liver transplants as primary surgeon during the *two-year* fellowship program (R-954, 1086). Assuming there is one new fellow each year, as well as an expert surgeon directing the program and performing the majority of procedures during the first year of each fellow's training, the training facilities will exceed forty-five transplants per year. In light of the other figures cited in support of the Commissioner's position, the court finds any error relating to relying on this incorrect training figure to be harmless. See Johnston-Willis, Ltd. v. Kenley, 6 Va. App. 231, 258-59 (1988).

(1982)). "'The phrase 'substantial evidence' refers to 'such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'" Id. (citing Virginia Real Estate Comm'n v. Bias, 226 Va. 264, 269 (1983)). The burden of proving a lack of substantial evidence in the record to support the Commissioner's decision is on Sentara. Va. Code § 9-6.14:17. "The Commissioner's decision must show that due consideration was given to the evidence bearing upon those factors which were relevant to the application under consideration" rather than all twenty Code factors. Bio-Medical Applications of Arlington, Inc., 4 Va. App. at 429. The Court must "take due account of the presumption of official regularity, the experience and specialized competence of the agency, and the purpose of the basic law under which the agency has acted." Id.

"A decision to issue or approve the issuance of a [COPN] shall be consistent with the most recent provisions of the [SMFP]; however, if the Commissioner finds, upon presentation of appropriate evidence, that the provisions of such plan are *inaccurate, outdated, inadequate or otherwise inapplicable*, the Commissioner, consistent with such finding, *may* issue or approve the issuance of a [COPN] or shall initiate procedures to make appropriate amendments to such plan." Va. Code § 32.1-102.3(A) (emphasis added). The Commissioner's decision on whether the SMFP is inaccurate, outdated, inadequate or otherwise inapplicable is a discretionary matter within his specialized competence and is entitled to great deference. See generally Dalton v. United States, 816 F.2d 971 (4th Cir. 1987) ("may" confers a discretionary power in an agency setting). The court may only interfere where such action is arbitrary and capricious, constituting a clear abuse of the Commissioner's delegated discretion. Johnston-Willis, Ltd. v. Kenley, 6 Va. App. 231, 244 (1988) (citation omitted).

**III. Discussion**

Sentara alleges that the Commissioner's decision is legally deficient in three major respects: it exceeds the scope of his authority under law; it relies on evidence that does not appear in the record; and it relies on a mistake of fact regarding an alleged adverse impact the project might have on the liver transplant program at MCV.

First, Sentara argues that since Sentara's application is fully "consistent" with the most recent SMFP provisions it must be approved by the Commissioner. See Va. Code § 32.1-102.3(A) ("Any decision to issue or approve the issuance of a [COPN] shall be consistent with the most recent applicable provisions of the [SMFP].") This assertion is patently incorrect. If an applicant complies with all criteria in the current SMFP then the Commissioner "may" issue the COPN. If the SMFP is not complied with

then he may not issue the COPN. Compliance does not mandate issuance. If it did then there would be no need for a Commissioner's judgment and expertise. The court cannot discern that legislative intent from the design of the statute.

The Commissioner found that the SMFP provisions regarding transplant volume were "outdated" and "inadequate" for current conditions circa 1997, even though Sentara's application was admittedly consistent with the current regulations promulgated in 1992. Sentara proposed to perform six liver transplants in year one, twelve transplants in year two, and fifteen in year three (R-134, 119, 278 & 418). The SMFP minimum utilization is twelve transplants annually. SMFP § 2.6(A)(1). "Successful transplantation programs are expected to perform substantially larger numbers of transplants annually. Performance of minimum transplantation volumes does not necessarily indicate a need for additional transplantation capacity or programs." SMFP § 2.6(A)(2). The national average volume of transplants per center was thirty-six in 1994 (R-677) and forty-three in 1995 (R-654). Virginia transplant centers performed an average of fifty-two procedures in 1996 (R-660, 834).

The Commissioner did not abuse his discretion in denying the issuance of the COPN. Code § 32.1-102.3(A) is written in the alternative: either the Commissioner "may" (but not must) issue or approve the COPN, <u>or</u> he shall (must) initiate amendment proceedings. Here, the Commissioner rejected Sentara's COPN and expressly directed the Division of Certificate of Public Need to initiate a process to update the SMFP regarding liver transplantation services. The Commissioner was acting within the discretionary authority conferred upon him by statute.

Sentara next argues that the Commissioner may not unilaterally amend the SMFP standards and retroactively apply these provisions to the petitioner. "The most recent applicable provision of the [SMFP] shall remain in force until any such chapter is amended, modified or repealed by the Board of Health." 12 VAC 5-220-10. The court finds that the Commissioner neither amended nor retroactively applied the SMFP regarding liver transplants. He merely determined that the SMFP minimum volume requirement was "outdated" and "inadequate" for current conditions, recommended that the Division of Certificate of Public Need initiate the amendment process, and then exercised his discretion to deny Sentara's COPN application.

The petitioner alleges that the Commissioner's finding that "the number of available organs may be reaching a plateau" is unsupported by any evidence in the administrative record. Sentara argues that the number of liver transplants performed in the Commonwealth and originating from the Tidewater area (Sentara's

location) has been growing at an average annual rate of 30%. R-834, 836. The petitioner maintains that the Commissioner's use of extra-record evidence has resulted in substantial prejudice. United States v. Pierce Auto Freight Lines, Inc., 327 U.S. 515, 530 (1946) (administrative agency's consideration of information outside the record does not invalidate its action unless substantial prejudice is shown). In response, the Commissioner argues that his institutional knowledge of the Commonwealth's health care system contributed to his declaration on the maturity of the liver transplant market in Virginia. He found that the number of available organs may be reaching a plateau, which will result in a stabilization of the actual number of transplants performed. Establishing a liver transplant center at Sentara will reduce its referrals to other liver transplant centers (twenty-eight patients[2] were referred outside its service area in 1996 (R-836)), thus reducing their transplant volume and quality of services. The overall result would be to reduce the annual number of liver transplants performed in each Virginia facility below the national average of thirty-six.

The test for substantial evidence is whether "considering the record as a whole, a reasonable mind would necessarily come to a different conclusion." Virginia Real Estate Commission v. Bias, 226 Va. 264, 269 (1983) (citation omitted). The record as a whole contains information on referrals and the transplant volume of competing facilities (both existing programs and training facilities). Combining these documented facts with the Commissioner's institutional knowledge of the availability of transplant organs, a reasonable mind could not necessarily conclude that Sentara's COPN should be approved.

Substantial prejudice has not resulted from the Commissioner's reliance on institutional knowledge and extra-record evidence. As detailed above, the SMFP criteria are a "threshold" that must be overcome before considering the § 32.1-102.3 provisions. The Commissioner found the 1992 SMFP standards on transplant volume to be outdated and inadequate in light of current data. This finding, coupled with a recommendation to amend the requisite number of procedures, was sufficient to deny the COPN. Further discussion of the project's impact on competing facilities, available organs and training programs was unnecessary, but hardly prejudicial.

Finally, the petitioner argues that the Commissioner's

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[2] This number was projected to grow to as many as thirty-seven patients in 1998 (R-838). Each liver transplant performed at Sentara would be one transplant not performed at one of the other facilities in the Commonwealth, thus decreasing the annual volume of competing centers.

decision relies on a mistake of fact regarding an alleged adverse impact the project might have on MCV's liver transplant program. As discussed in note 1, the court finds this misinterpretation to be harmless error.

In conclusion, the court denies the Petition for Appeal. An Order implementing this decision is enclosed.

Sincerely,

T.J. Markow

*VIRGINIA:*

*In the Circuit Court of the City of Norfolk*

SENTARA NORFOLK GENERAL HOSPITAL — Petitioner

v. — 97-2071

STATE HEALTH COMMISSIONER, ET AL. — Respondents

**O R D E R**

The parties appeared, by counsel, for hearing on the Petition for Appeal. Memoranda was received and argument was heard. For the reasons stated in the court's letter opinion to counsel, it is hereby **ORDERED** that the Petition for Appeal is denied. Petitioner's objections are noted.

A copy of this order was this day mailed to counsel of record. In accordance with Rule 1:13 of the Rules of Virginia Supreme Court, the court dispenses with the requirement of endorsement.

ENTER 7-8-98

T. J. Markow

# COMMONWEALTH of VIRGINIA

*Department of Health*
P O BOX 2448
RICHMOND, VA 23218

RANDOLPH L. GORDON, M.D., M.P.H.
COMMISSIONER

TDD 1-800-828-1120

November 3, 1997



Thomas W. McCandlish, Esquire
Mezzullo and McCandlish
1111 East Main Street, Suite 1500
Richmond, Virginia 23206

Dear Mr. McCandlish:

Re: Certificate of Public Need No. VA-03365
Sentara Norfolk General Hospital
Norfolk, Virginia
Establish Liver Transplant Services

In accordance with Chapter 4, Article 1:1 of Title 32.1 of the Code of Virginia 1950, as amended, I reviewed the application and supporting documents requesting a certificate of public need for the above referenced project. Additionally, I have received and reviewed the findings, conclusions, and recommendation of Raymond O. Perry, who presided over the informal fact-finding conference, conducted during the course of review of the application. Based upon my review of all these materials in view of the specialized knowledge of Virginia's healthcare system required of the position of Commissioner, I decline to adopt Adjudication Officer Perry's recommendation and have determined that the application to establish a liver transplantation service at Sentara Norfolk General Hospital (SNGH) should be denied at this time.

The reasons for my decision are as follows:

1. The State Medical Facilities Plan, 12 VAC § 5-280-70, requires an annual volume of twelve liver transplants per year per center to meet minimal utilization standards. It also states that "successful transplantation programs are expected to perform substantially larger numbers of transplants annually. Performance of minimum transplantation volumes does not necessarily indicate a need for additional transplantation capacity or programs." The average number of liver

transplants performed per transplant center nationally in 1994 was 36. In 1996 the average number of liver transplants performed per transplant center in Virginia was 52. The American College of Surgeons requires transplant centers to perform at least 45 liver transplants in order to be certified as training centers.

The State Medical Facilities Plan governing organ transplantation services was promulgated in 1992 and has not been amended. It is apparent from the more current statistics cited above that statistics used in 1992 to identify the minimum standard have been superseded. Accordingly, pursuant to Va. Code § 32.1-102.3(A), I find that the provisions of the State Medical Facilities Plan as they relate to liver transplantation services are inaccurate, outdated, inadequate or otherwise inapplicable. Because they fail to reflect current standards, they should not be applied here, and I will direct that procedures be initiated to make appropriate amendments to such plan.

2. The number of organ transplantations that may be performed is dependent upon the supply of organs. Indications in the healthcare system are that the numbers of available organs may be reaching a plateau; consequently, the actual numbers of transplantations performed appear to be stabilizing. Therefore, if established, an additional liver transplant center at SNGH may erode the quality of other transplant centers by reducing the volume of liver transplants at the other centers. In 1996, Medical College of Virginia Hospitals (MCVH) performed 66 liver transplants, the University of Virginia Hospitals (UVAH) performed 37, and Fairfax hospital performed 53. In the same year SNGH referred 28 patients from its service area (PDs 20, 21, and 22) for liver transplants. Over time, it is reasonable to assume that SNGH would perform the majority of liver transplants from its service area and possibly some from the surrounding PDs, thus reducing the volume of liver transplants at MCVH and UVAH by 40%-50% and 10%-20%, respectively, by the elimination of referrals. Such spreading of patients over four programs would place the Commonwealth's programs below the national average of 36 transplants per center. It is not reasonable to assume that an increase in liver transplantation capability in the state will be met with an increase in available livers for transplantation, nor would more sites provide the increased volume necessary to maintain four transplant centers of quality, especially since the increase in organ donations appears to be leveling out.

SNGH assures that it will perform only six liver transplants in year one, twelve in year two, and 15 in year three of operation. If true, this may mitigate the concerns of reducing volume at other centers on the one hand, but on the other it will not be meeting the needs of its service area and is only marginally at or above the

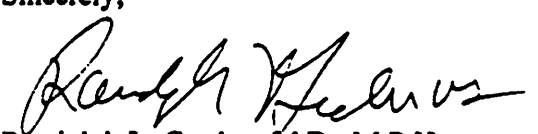
minimum number of twelve liver transplants deemed appropriate to maintain quality even in 1992. Further, although outdated and inapplicable, as stated above, the State Medical Facilities Plan, 12 VAC § 5-280-70, contemplates that "successful transplantation programs are expected to perform substantially larger numbers of transplants annually. Performance of minimum transplantation volumes does not necessarily indicate a need for additional transplantation capacity or programs." Thus, even the unamended State Medical Facilities Plan governing liver transplantation services is not binding as to minimum acceptable volumes.

3. In considering general criterion number 20 specified in Va. Code § 32.1-102.3(B) ("the impact on existing...institutional training programs for doctors of...medicine at the student, internship, and residency training levels"), I determine that an additional liver transplant center at SNGH may seriously impact the established liver transplant fellowship training program at MCVH. Certification as a training program for liver transplantation by the American College of Surgeons requires the training institution to perform 45 liver transplants annually. For the reasons discussed above, an additional transplant service at SNGH may reduce the volume of liver transplants performed at MCVH below that required for certification and could jeopardize its program.

In conclusion, I find that the State Medical Facilities Plan is outdated and inapplicable to a determination of need for liver transplantation services and does not support the award of a COPN to SNGH for liver transplantation services at this time. Additionally, because the system presently (i) reflects no need for additional liver transplantation sites in light of organ supply; (ii) appears to have no excess of transplantation procedures requiring accommodation whereas approval of another site could result in an excess of facilities lacking volume to meet the national average or to assure essential technical experience; and (iii) should maintain and sustain necessary training programs in the Commonwealth, the application for a COPN for liver transplantation services at SNGH is premature. If the volume of liver transplants performed by the other transplant centers in the Commonwealth resumes its former increase, then the addition of another liver transplant center may not pose a threat to quality or established medical training programs and may provide a more convenient site for residents of PDs 20, 21, and 22. At this point in time, however, I determine that any possible convenience gained by these residents is outweighed by the risk of adversely affecting quality and having a possibly serious negative impact on an established medical training program, and I direct the Division of Certificate of Public Need to initiate a process to update the State Medical Facilities Plan regarding liver transplantation services.

As provided by Rule 2A:2 of the Rules of the Supreme Court of Virginia, you have 30 days from the date of service (the date you actually received this decision or the date it was mailed to you, whichever occurred first) within which to appeal this decision by filing notice with the State Health Commissioner. In the event that this decision is served on you by mail, three days are added to that period.

Sincerely,



Randolph L. Gordon, M.D., M.P.H.
Commissioner

Enclosures

pc: Raymond O. Perry, M.P.H., Adjudication Officer
Carol S. Nance, Assistant Attorney General
Paul E. Parker, Director, Division of Certificate of Public Need
Nancy R. Hofheimer, Director, Center for Quality Health Care Services and Consumer Protection
Paul M. Boynton, Executive Director, Eastern Virginia Health Systems Agency
Joseph M. Teefey, Director, Department of Medical Assistance Services
Trigon Blue Cross/Blue Shield of Virginia
The Honorable Robert C. Metcalf, Secretary of Health and Human Resources
Members of the State Board of Health

**COPN Request No. VA-5969**
**Sentara Norfolk General Hospital**
**Norfolk, Virginia**
**Establish Liver Transplant Services**

**Findings**

1. Sentara Norfolk General Hospital (SNGH) is part of Sentara Health System.

2. SNGH is licensed for 644 beds and is located in Norfolk, Virginia, Planning District (PD) 20 in Health Planning Region (HPR) V.

3. HPR V is served by the Eastern Virginia Health Systems Agency (EVHSA).

4. SNGH is one of the Commonwealth's major tertiary-care hospitals and the primary trauma-care center for the Hampton Roads area and adjacent areas of northeastern North Carolina.

5. SNGH is the principal teaching hospital for undergraduate and graduate medical students at the Eastern Virginia Medical School (EVMS), which shares the Eastern Virginia Medical Center campus with SNGH.

6. SNGH currently provides extensive organ transplant services through its "transplant center." The SNGH Transplant Center currently performs kidney, heart, lung, and heart/lung transplants. SNGH proposes to expand its transplant services to include liver transplantation.

7. Liver transplant services are currently provided at three other locations in Virginia: in the Central Virginia Health Planning Region (HPR IV) in Richmond, at the Medical College of Virginia Hospitals of Virginia Commonwealth University (MCVH); in the Northwest Virginia Health Planning Region (HPR I) in Charlottesville, at the University of Virginia Hospital (UVAH); and in The Northern Virginia Health Planning Region (HPR II) in Fairfax at the Fairfax Hospital (FH).

8. There are 102 liver transplant programs nationally, which performed 3,652 liver transplants in 1994. The average volume of liver transplant procedures per program was 36 in 1994. In Virginia, according to statistics from the United Network of Organ Services (UNOS), in 1994, eighteen residents of the SNGH primary service area received liver transplants, in 1995, twenty-one SNGH primary service area residents received liver transplants, and in 1996, twenty-eight SNGH primary service area residents received liver transplants.

9. Reportedly approximately 25-30 adult patients are referred out of the SNGH region and/or state for liver transplants each year by Sentara physicians. Additionally, based on information furnished by MCVH's liver transplant program, there are also a significant number of patients referred to their center by other Hampton Roads (PDs 20 and 21) physicians,who do not practice in the Sentara Health System.

10. The Division of Certificate of Public Need staff estimates that 40%-50% of the liver transplant patients at MCVH and 10%-20% of the liver transplant patients at UVAH originate from the potential SNGH service area, PDs 20 (Southampton Roads), 21 (Newport News-Hampton area), and PD 22 (Virginia's Eastern Shore), and northeastern North Carolina. This area has a population estimated to exceed 1.7 million people by the year 2000.

11. SNGH assumes the accessibility of a liver transplant program in Hampton Roads will attract patient referrals from both Sentara and non-Sentara physicians. SNGH bases its assumption other solid organ transplantation services it provides and the fact that other solid organ transplant patients are currently referred by both Sentara and Non-Sentara physicians to SNGH's existing transplantation services. SNGH projects that its liver transplant program will perform six transplants the first year of operation, twelve in year two, and fifteen in year three.

12. SNGH proposes to recruit a surgeon with liver transplant experience (Dr. Colonna) into one of the private, Sentara-affiliated surgical practice groups within the region to implement the liver transplant program. Dr. Colonna was trained at MCV-VCU and at the University of California in Los Angeles, allegedly one of the busiest liver transplant centers in the nation. Recently, Dr. Colonna has served as director of the transplant program at Fairfax Hospital.

13. SNGH expects the liver transplant surgeon, Dr. Colonna, will immediately meet the minimum UNOS transplant surgeon criteria for implementation of a liver transplant program.

14. Three SNGH gastroenterologists (GI physicians), who respectively trained at the University of Wisconsin, Yale, and the Medical College of Virginia, have committed medically to manage liver transplant patients and also to obtain any additional training necessary to provide optimal post-surgical medical care for these patients.

15. Other physicians available within the community to support the liver program include Dr. Scott Stanley, a surgical pathologist, who completed his medical training at the University of Minnesota in its liver transplantation program. Dr. Martha Mooney, an infectious disease specialist who supports the kidney, heart, and lung transplant programs, will also provide support for the liver transplant program. SNGH has several intensive care specialists on its medical staff who will provide support to the transplant physicians as well. Also, several members of the anesthesia practice which provides expert services to support Sentara Norfolk General Hospital's surgery program have had experience with liver transplants in their medical training and fellowships, as well as with the existing transplant programs at SNGH.

16. Costs of implementing the liver transplant program will be moderate because the Center performs kidney, heart, lung, and heart/lung transplants. SNGH has sufficient capacity in its intensive care units to accommodate the post-transplant follow-up care; therefore only incremental operating costs will be associated with establishing the liver transplant service. The administrative and clerical staff that support the current organ transplant programs will also support the proposed liver transplant program. Additional program and hospital staff needed to assure operation of the

program include a full-time RN Transplant Coordinator, a part-time Licensed Clinical Social Worker, and a qualified full time technician to operate the intraoperative cell-saver. These additional salary dollars have been detailed in the Financial Data section of SNGH's application.

17. Allegedly, establishment of the liver transplant program requires no additional inpatient beds or facility construction, as liver transplant patients would be incorporated into the existing vascular step-down and intensive care units within SNGH. The actual transplantation surgical procedure would be performed within the surgical suites at SNGH. Some of the more costly equipment used to support this complicated procedure (such as the bypass pump and the intraoperative cell saver) is already available at SNGH, due to other tertiary-care transplant programs provided at the hospital.

18. Upon discharge, liver transplant patients are proposed to be followed initially in the Transplant Outpatient Clinic located on the fifth floor of SNGH. SNGH plans that patients will be followed in the Clinic for three months post-discharge, and follow-up care required after the initial period will be coordinated with the patient's primary care and/or referring physician. The Transplant Outpatient Clinic presently supports the outpatient needs for the kidney, heart, and heart lung programs. Thus, the liver transplant outpatients will utilize the existing Transplant Center examination rooms, waiting rooms, etc. SNGH proposes that long-term follow-up on these patients will comply with standard protocols and procedures in place within existing transplant programs and the proposed liver transplant program and will include at least an annual examination.

19. Reimbursement for liver transplantation is expected to be from sources similar to the existing organ transplant programs. SNGH's current contracts with insurers such as Aetna, Cigna, Blue Cross, Met Life, and MetraHealth Travelers, include the ability for patients to have transplant services provided at SNGH. Patients covered by the Sentara insurance products that provide coverage for transplant services will also have the ability to have liver transplant services provided at SNGH.

20. The liver transplant program expects to perform transplants on patients without the ability to pay, as part of Sentara's charitable mission of improving the health of citizens in the Hampton Roads community. Historically, SNGH has provided a larger percentage of charity care than other Tidewater area hospitals.

21. The application's projected capital costs for this project are:

| SNGH Liver Transplant Program | |
|---|---|
| Direct Construction Costs | $ 0 |
| Equipment | $ 54,400 |
| Legal Fees | $ 7,500 |
| Total Projected Capital Costs | $ 61,900 |

22. SNGH is located at least two hours away from Richmond, the nearest liver transplant program to residents of PD 20.

23. The survival rate of liver transplant patients apparently is not strongly related to the volume of procedures performed at the facility in which the transplant was provided.

24. MCVH has a fully accredited liver transplant training program. Accreditation of liver transplant training programs by the American College of Surgeons is related to the volume of procedures performed in a facility. Full accreditation, as a liver transplant training program, is dependent upon at least 45 liver transplant procedures being performed annually by each fellow in the training program.

**DISCUSSION**

Applications for certificate of public need are required to be considered in relation to the twenty general criteria that are specified in the COPN law. Following is a discussion of the relationship of the proposed project to the COPN criteria.

1. **The recommendation and the reasons therefor of the appropriate health systems agency.**

The EVHSA Board of Directors recommended approval of the proposed liver transplant program at SNGH based upon the following stated rationale:

> *"The project will improve the availability and geographic accessibility to liver transplant services for PD 20 residents, and having a liver transplant service will round out the complement of services that are presently provided at Sentara Norfolk General Hospital."*

2. **The relationship of the project to the applicable health plans of the regional health planning agency, the Virginia Health Planning Board, and the State Board of Health.**

The State Medical Facility Plan (SMFP) contains criteria and standards for determining the need for proposed new organ transplant services.

***Acceptability***

> ***"Consumer Participation - Providers of organ transplantation services should provide a program of patient and family education regarding the nature of the patient's organ disease and the treatment of the patient and family in the management of the organ pre- and post-transplantation."***

SNGH is an existing major provider of organ transplant services in Virginia. The application states that "as an existing provider of organ transplantation services, SNGH already has appropriate

education programs in place." The application includes examples of patient education material and copies of policy and procedure statements regarding patient education for kidney transplant patients. SNGH subsequently furnished DCOPN a draft "Liver Transplant Protocol," which prescribes staff activities for patient and family education. The application meets this standard.

*Accessibility*

***Travel Time - "Organ transplantation services, of any type, should be accessible within two hours driving time, under normal conditions, of 95% of Virginia's population."***

The main population of PD 20 is approximately two hours driving time from Richmond, the location of MCVH that provides the closest liver transplant program. Norfolk, location of SNGH, is generally about two hours drive from MCVH. SNGH serves a patient population from a wide geographic area that includes PD 20, PD 21, PD 22 and eastern North Carolina. The population is estimated to be 1.7 million by the year 2000. A significant proportion of this population two hours drive or more from a liver transplant service. The proposed project would assure liver transplant services within two hours of this population.

*Availability*

***"Regionalization of Services - There should be no more than one transplant program for each organ system in a health planning region."***

There are currently no liver transplant programs in HPR V. SNGH is the singular transplant service provider in HPR V. The addition of liver transplantation service at SNGH would be consistent with this standard.

***"Conditional Approval - approval of organ transplantation programs shall be conditioned upon a facility's meeting both minimum volume and survival standards. Failure to meet these standards within two years of initiation of the service may be cause for revocation of the certificate of public need."***

SNGH has been providing some transplant services for twenty-five years. It has met the volume and survival standards for the other transplant services it provides. SNGH can be expected to be able to meet the volume and survival standards for liver transplant services.

***"HCFA/Medicare Requirements - 1. Proposals to establish new transplantation programs should demonstrate compliance with all Medicare program coverage criteria within two years of the initiation of the program. 2. Proposals to expand existing transplantation programs should demonstrate that existing organ transplantation services comply with all applicable federal Health Care Financing Administration (HCFA) criteria for Medicare program coverage."***

SNGH is certified by HCFA as a provider of transplant services. Its heart and kidney transplant services fully comply with Medicare requirements and the only facet of the lung transplant program that fails to meet Medicare criteria is the low volume due to constraints on organ availability. SNGH is anticipated to meet the HCFA/Medicare requirements.

*Continuity*

> ***"Discharge planning and follow-up care - A. Providers of transplantation services should have written policies and procedures for discharge planning and follow-up care for the patient and family which are part of the institution's overall discharge planning program. B. Providers of organ transplantation services should have established protocols for referring physicians and the organ transplantation service to assure adequate post-operative diagnostic evaluation for transplant patients."***

SNGH has the requisite policies and procedures in place to meet the standards for continuity of care.

*Cost*

> ***"Cost and charges - The total cost (direct and indirect) for providing all organ transplantation services should be comparable to other similar providers in the health planning region and the state."***

SNGH is the only provider of transplantation services in its HPR. SNGH's case-mix indices, net patient revenue, and costs were compared with those the other major tertiary-care hospitals in Virginia, all of which offer transplant services for one or more solid-organ systems by DCOPN staff. When compared to other transplant service providers in the state, SNGH was determined by the DCOPN staff to have typically low costs and charges. SNGH's costs were compared to were determined to be approximately 77% of the combined average of Fairfax, UVAH and MCVH. Additionally, SNGH's case mix was determined to be 118% of the average for the group. It is reasonable to believe that the costs and charges for the proposed liver transplant service at SNGH will be comparable to the costs and charges for liver transplant services at the other Virginia liver transplant provider institutions.

**Quality**

> ***"Minimal utilization - 1. Proposals to establish...transplantation services should demonstrate that a minimum number of transplants will be performed annually. The minimum number of required liver transplants is twelve (12)."***

SNGH projects that it will be able to exceed the minimal number of requisite liver transplants following its start-up year. It is reasonable to believe that a liver transplant program at SNGH will be able to meet the minimal volume standard.

*"2. Successful transplantation programs are expected to perform substantially larger numbers of transplants annually. Performance of minimum transplantation volumes does not necessarily indicate a need for additional transplantation capacity or programs."*

In 1996, all three liver transplant programs in Virginia substantially exceeded the volume requirements of the SMFP. Sixty-six liver transplants were performed at MCVH. 37 liver transplants were performed at UVAH, and 53 liver transplants were performed at Fairfax Hospital. It may be anticipated that an additional liver transplant program at SNGH will also meet this standard.

*"3. Preference will be given to expansion of successful existing services, either by enabling necessary increases in the number of organ systems being transplanted or by adding transplantation capability for additional organ systems, rather than developing other programs that could reduce average program volume."*

SNGH currently provides successful transplantation services for kidney, heart, and heart lung patients. In 1988, SNGH was one of only five hospitals in Virginia providing transplant services and was second (after MCVH) in the volume of transplants. In 1988, the kidney was the only organ transplanted at SNGH. Heart, lung, and heart-lung transplant services were added at SNGH from 1989 through 1993. In 1995, SNGH was fourth in total volume among the eight Virginia hospitals offering transplant services for one or more organs. From 1988 to 1995, SNGH's annual transplant volume first increased and then declined back to the 1988 level. During the period, total statewide transplant volume more than doubled, reflecting the addition of a number of new transplant programs at other Virginia hospitals. From May 1, 1995 through April 30, 1996, SNGH transplant center totals were 39 kidney transplants, 17 heart transplants and six heart-lung transplants. SNGH has a very active transplant center. The provision of liver transplant services would add a new transplant program to an already successful SNGH transplant center. The proposed project is consistent with this standard.

*"Minimum survival rates - 1. Facilities should demonstrate that they will achieve and maintain minimum transplant survival rates. The minimum one-year survival rate for liver transplant recipients is 50%-60%."*

SNGH meets or exceeds the minimal survival rates for each of its existing organ transplant programs and there is every reason to believe, if liver transplant services are initiated by SNGH, liver transplant patients will meet or exceed the minimal survival rates.

*"2. Survival rates beyond one year should be consistent with the HCFA Medicare program requirements, or with applicable professional-society-recommended standards acceptable to the department where there are no HCFA criteria."*

The HCFA two-year standard for liver transplant programs is 60%. SNGH has a history of compliance with the survival rates in its other transplant services and can be expected to meet the

HCFA standard for the liver transplant service. (Note: The HCFA standard for heart recipients is 65%, SNGH achieves 94.5%; the HCFA standard for lung recipients is 62%; SNGH achieves 66%; there is no HCFA standard for kidney recipients, but SNGH achieves 90%.)

> ***"Service proficiency - Proposals to add organ transplantation services should demonstrate at least two years successful experience with all existing organ transplantation systems."***

SNGH meets this standard.

> ***"Staffing - 1. All physicians that perform transplants should be board certified by the appropriate professional examining board, and should have a minimum of one year of formal training and two years experience in transplant surgery and post-operative care."***

The applicant asserts that, upon receipt of a certificate of public need, the physician group which serves the transplant center at SNGH will recruit and hire a liver transplant surgeon who meets all relevant criteria. SNGH can meet this criterion.

> ***"2. Organ transplantation services should have a complete team of surgical, medical and other specialists, with at least two years experience in the proposed organ transplantation system."***

The applicant will be able to comply with this standard. SNGH has in place already surgical, medical and other specialty physicians on staff with liver experience.

> ***"Systems Operations - 1. Providers of organ transplantation services should document that they participate in a regional and national organ donor network. The facility should have written policies and procedures governing organ and tissue procurement."***

SNGH has policies and procedures which meet this standard; and SNGH also is a member of the regional and national organ donor networks. SNGH meets this standard.

> ***"2. Providers of organ transplantation services should have an ongoing approved medical education program."***

SNGH has an approved medical education program in place and all of its physicians associated with the transplant program participate in continuing medical education programs.

> ***"3. Providers of organ transplant services should demonstrate that they have direct and immediate access to a histocompatibility testing laboratory that meets the American Society for Histocompatibility and Immunogenetics (ASHI) standards."***

SNGH operates an ASHI accredited laboratory. The proposed project meets this standard.

3. **The relationship of the project to the long-range development plan, if any, of the person applying for a certificate.**

SNGH currently provides transplant services for kidneys, hearts, lungs, and heart-lungs. SNGH serves a large population of persons who are not within two hours driving time of the nearest liver transplantation services at MCVH. The COPN staff has estimated the population outside of the two-hour driving time radius of MCVH to be in excess of 400,000 persons. The addition of liver transplant services will round-out the transplantation services provided by SNGH to its service area population. The proposed project is consistent with SNGH's long-range development plan for its transplant center.

4. **The need that the population served or to be served by the project has for the project.**

The population that uses SNGH for its tertiary services is relatively concentrated in eastern Virginia. Patient origin statistics show that the hospital serves PDs 20, 21 and 22 and northeastern North Carolina. The population of this hospital service area is estimated to be 1.7 million people. The number of liver transplantations from this population group has increased each year for the past three years from 18 (1994) to 28 (1996), and there is no reason to believe that this trend will not continue assuming that organs continue to come available.

The applicant asserts that residents of its service area in need of liver transplantation must now leave the area to go to providers in Richmond, Charlottesville, Fairfax and out-of-state. The applicant asserts that travel for persons with end stage liver disease is burdensome due to the numerous evaluations that persons awaiting livers are subjected to while awaiting the availability of organs, and that most patients have to rely upon family members to assist them, which creates additional burdens on the patient's families. SNGH asserts that the process is burdensome, expensive and time-consuming for its service area residents, but that much of the inconvenience, anxiety and expense can be eliminated with the initiation of liver transplantation services at SNGH.

The applicant asserts that referrals of patients to out-of-area providers often results in repetitions of the diagnostic tests that were performed on the patients prior to referral to the transplantation facility and that coordination of patient care between the transplant facility and the referral physician is often poor. SNGH believes that approval of its proposed project will eliminate these problems for its service area.

5. **The extent to which the project will be accessible to all residents of the area proposed to be served.**

There is no liver transplantation service in HPR V at the present time. Residents in need of liver transplantation must travel outside of the area for liver transplant services. The proposed project will make liver transplantation geographically available to a significant population that now must travel more than two hours' driving time to get to the nearest provider.

SNGH has a long tradition of providing health services to persons who cannot afford to pay. This is true of its general hospital services as well as its transplant services. It is reasonable to expect that approval of the proposed project will increase financial accessibility to liver transplant services for a significant population.

6. **The area, population, topography, highway facilities and availability of the services to be provided by the project in the particular part of the health service area in which the project is proposed.**

The location of SNGH in downtown Norfolk is convenient to the area population by automobile. The area is served by a network of interstate highways and major thoroughfares. The area has many waterways with bridges and tunnels that often become crowded and sometimes inhibit traffic. There is no other liver transplant service provider in the region, which includes PD 17, 18, 20, 21, and 22. Residents who require liver transplantation services must travel outside of the region to receive the service. A substantial number of people in the area, 400,000 plus, are not within two-hours drive of a liver transplantation program.

7. **Less costly or more effective alternate methods of reasonably meeting identified health service needs.**

SNGH provides organ transplantation services at its "Transplant Center." When the costs and charges of all Virginia transplant programs are compared, the SNGH costs and charges are comparable to that of the other Virginia programs. In view of the fact that no other transplant program is within HPR V, one can conclude that the availability of a liver transplant program at SNGH would reduce the travel time and therefore the cost of services for residents of its services area who now must travel out of the area for services. The addition of liver transplants to the SNGH array of solid organ transplant services can be accomplished at minimal addition expense. No capital expenses for new construction are involved. Much of the equipment and support services expenses can be avoided due to their current availability at SNGH for existing transplant services.

8. **The immediate and long-term financial feasibility of the project.**

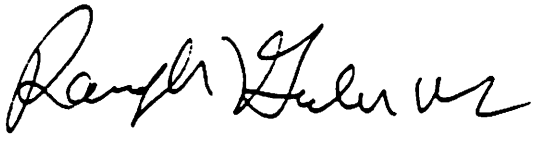
The proposed project is financially feasible in both the short term and the long term. There is an ample number of potential liver transplantation patients to allow the development of a liver transplantation program at SNGH. The development of the SNGH liver transplant program should have minimal impact upon existing providers of liver transplant services. SNGH expects to serve six patients during year one, 12 in year two, and 15 in year three. This timetable for development should provide minimal disruption to the volume of patients who currently seek liver transplant services from other in-state providers.

9. **The relationship of the project to the existing health care system of the area in which the project is proposed.**

the report submitted by the health systems agency." The petition proffered in behalf of University Health Services and the Medical College of Virginia Hospital fails to show "good cause" with respect to any of these foregoing requirements.

As required by § 32.1-102 of the Code of Virginia, all factors which must be taken into account in making this determination have been considered and I have concluded that standing for University Health Services and the Medical College of Virginia Hospital is not warranted.

Sincerely,



Randolph L. Gordon, M.D., M.P.H.
State Health Commissioner

Enclosure

pc: Raymond O. Perry, M..P.H., Adjudication Officer
Carol S. Nance, Esquire, Assistant Attorney General
Paul E. Parker, Director, Office of Resources Development
Nancy R. Hofheimer, Director, Office of Health Facilities Regulation
Joseph M. Teefey, Director, Department of Medical Assistance Services
Paul M. Boynton, Executive Director, Eastern Virginia Health Systems Agency
Trigon Blue Cross/Blue Shield of Virginia
The Honorable Robert C. Metcalf, Secretary of Health and Human Resources
Members of the State Board of Health
Thomas W. McCandlish, Esquire, Counsel to Sentara Norfolk General Hospital

# COMMONWEALTH of VIRGINIA

*Department of Health*
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RANDOLPH L. GORDON, M.D., M.P.H.
COMMISSIONER

TDD 1-800-828-1120

October 31, 1997



Mark S. Hedberg, Esquire
Hunton and Williams
Riverfront Plaza, East Tower
951 East Byrd Street
Richmond, Virginia 23219-4074

Dear Mr. Hedberg:

Re: **University Health Services (UHS) and Medical College of Virginia Hospitals (MCVH)**

**Petition to Show "Good Cause" for Standing in the Review of:**

**COPN Request No. VA-5969**
**Sentara Norfolk General Hospital**
**Norfolk, Virginia**
**Addition of Liver Transplant Services**

In accordance with Chapter 4, Article 1:1 of Title 32.1 of the Code of Virginia 1950, as amended, I reviewed the University Health Services and Medical College of Virginia Hospital's petition asserting "good cause standing" in the review of the certificate of public need for the proposed Sentara Norfolk General Hospital liver transplant services program. Additionally, I have received and reviewed the report and the recommendation made by Raymond O. Perry, Adjudication Officer for the informal fact-finding conference. Based upon Mr. Perry's report and recommendation, I am denying the petition. In making my decision, I have adopted the enclosed Findings and Recommendation of Mr. Perry regarding the petition.

In order to establish "good cause standing" under § 32.1-102.6, it is incumbent upon the petitioners to show that "(i) there is significant relevant information not previously presented at and not available at the time of the public hearing, (ii) there have been significant changes in factors or circumstances relating to the application subsequent to the public hearing, or (iii) there is a substantial material mistake of fact or law in the Department staff's report on the application or in

I have reviewed and evaluated all aspects of the proposed project. I have listened to the testimony of experts from the hospital, and reviewed the position of the Eastern Virginia Health Systems Agency, and its staff, and the staff of the Division of Certificate of Public Need. Additionally, I have carefully studied the SMFP and the guidance that it offers as it applies to this proposed project. I recommend approval of the proposal to establish liver transplant services at Sentara Norfolk General Hospital. The rationale in support of the recommendation is:

1) the proposed project is consistent with all of the pertinent standards for reviewing transplant services in the SMFP;

2) the applicant is physically located so that it is accessible to a substantial population in eastern Virginia and northeastern North Carolina that does not reside within two-hours' driving time of the transplant center at the Medical College of Virginia;

3) the proposed project was recommended for approval by the Eastern Virginia Health Systems Agency for the reason of improving area residents' access to liver transplant services; and,

4) the number of liver transplant patients from eastern Virginia appears to be increasing and, coupled with the projected slow start-up of the SNGH liver transplant service, no significant impact on liver transplant volume at the MCVH transplant center should occur in the first three years.

5) the SNGH liver transplant program and the MCVH liver transplant program will both be served by the LifeNet Organ Procurement Organization, permitting collaborative participation in developing mutually acceptable rules and guidelines to assure proper organ allocation policies and procedures among patients and between institutions.

Respectfully submitted,

Raymond O. Perry, M.P.H.
Adjudication Officer

The proposed project offers no specific improvements or innovations in the financing and delivery of liver transplantation service which will foster competition or promote competition and cost effectiveness.

SNGH asserts that its liver transplant program will improve the continuity of care provided to residents of its service area who require transplants and also reduce their travel costs by keeping them closer to home. SNGH alleges that by improving continuity and coordination of patient care, the transplant patient outcomes should ultimately be affected positively.

19. **In the case of health services or facilities proposed to be provided, the efficiency and appropriateness of the use of existing services and facilities in the area similar to those proposed.**

There are no other liver transplantation services available in HPR V. The residents in need of liver transplants from this area are currently traveling to other liver transplant providers in Virginia and out of state. The predominant number of referred liver transplant patients are currently served at MCVH. Based upon the analysis performed by the staff of DCOPN, the SNGH service area residents make up about 30% of the utilization of the MCVH liver transplant program. The MCVH liver transplant program had 66 liver transplants in 1996.

20. **The need and the availability in the health service area for osteopathic and allopathic services and facilities and the impact on existing and proposed institutional training programs for doctors of osteopathy and medicine at the student, internship, and residency training levels.**

SNGH provides one of the primary hospital sites for training EVMS physicians. There is no other allopathic or osteopathic training program in eastern Virginia. The proposed initiation of liver transplant services at SNGH will provide an additional learning opportunity for medical students at EVMS.

The development of a liver transplant service at SNGH should only marginally alter the volume of liver transplants at MCVH, which is located in HPR IV, where a fully accredited fellowship training program for liver transplant surgeons exists. The MCVH certification is dependent upon maintaining a certain volume of liver transplant patients. The American College of Surgeons certification requires 45 liver transplants to be performed annually. In 1996, sixty-six liver transplants were performed at MCVH.

The transplantation program at MCVH draws patients from all of Virginia and out-of-state as well. MCVH is a nationally known transplantation center.

**Recommendation**

SNGH is a regional health service provider that is the main tertiary hospital facility that serves eastern Virginia and northeastern North Carolina. The initiation of liver transplant services will increase accessibility for the population that historically has relied upon SNGH for tertiary care services.

14. **The special needs and circumstances of health maintenance organizations. When considering the special needs and circumstances of health maintenance organizations, the Commissioner may grant a certificate for a project if the Commissioner finds that the project is needed by the enrolled or reasonably anticipated new members of the health maintenance organization or the beds or services to be provided are not available from providers which are not health maintenance organizations or from other health maintenance organizations in a reasonable and cost effective manner.**

Although "Sentara" owns and provides health maintenance organization services, this criterion is not applicable to this project.

15. **The special needs and circumstances for biomedical and behavioral research projects which are designed to meet a national need and for which local conditions offer special advantages.**

This criterion is not applicable to the proposed project.

16. **In the case of the construction project, the costs and benefits of the proposed construction.**

This criterion is not applicable to the proposed project.

17. **The probable impact of the project on the costs of and charges for providing health services by the applicant for a certificate and on the costs and charges to the public for providing health services by other persons in the area.**

SNGH asserts that most costs associated with the delivery of transplant services are variable and that any reduction in volume that may be experienced by other providers of liver transplant services as a result of the establishment of services at SNGH should be minimized. The addition of the service at SNGH will not increase the cost of delivery of liver transplant services because many of the necessary fixed costs are already in place at the SNGH transplant center. SNGH was determined by the staff of the DCOPN to have lower charges than other transplant programs in Virginia while having a patient case mix with an 18% higher acuity. The location of a liver transplant program at SNGH should serve to reduce travel expenses for those residents in the SNGH service area who require liver transplants.

18. **Improvements or innovations in the financing and delivery of health services which foster competition and serve to promote quality assurance and cost effectiveness.**

SNGH is a major tertiary care referral facility that serves the eastern portion of Virginia and northeastern North Carolina. It provides most medical and surgical services that are required by its service area population. It is the only facility in HPR V that provides transplant services. It is a major trauma center. If liver transplant services are to be provided in HPR V, SNGH is the only location where all of the support services are already in place to do so. Additionally, SNGH provides the referral relationships that a transplant center requires to maintain continuity of patient care services.

10. **The availability of resources for the project.**

SNGH has the necessary resources to initiate the liver transplant service and to sustain the service until the time that it becomes self-sustaining through reimbursement income. SNGH has the ability and the contacts to recruit the necessary experienced personnel that it will require to initiate a successful liver transplant program.

11. **The organizational relationship of the project to necessary ancillary and support services.**

SNGH, through it existing transplant programs, has in place and on staff the necessary personnel, equipment, policies and procedures to support a liver transplant program.

12. **The relationship of the project to the clinical needs of health professional training programs in the area in which the project is proposed.**

SNGH has long been associated with the Eastern Virginia Medical School (EVMS). The initiation of liver transplant services at SNGH will provide opportunities for medical students of EVMS and residents in the SNGH postgraduate training programs to observe and study liver transplantation as a part of their training; however, there is no plan to train transplant surgeons as a part of the proposed project.

The SNGH liver transplant program may temporarily reduce the volume of patients being referred to other in-state providers, especially MCVH, where most area patients are referred; however, the proposed slow startup of the SNGH program should provide minimal impact upon volumes of patients at MCVH. The number of liver transplant patients from the SNGH service area increased by three, from 1994 (18 recipients) to 1995 (21 recipients), and by seven, from 1995 (21 recipients) to 1996 (28 recipients). This annual increase in liver transplant recipients should mitigate the impact that the addition of a liver transplant program at SNGH will have upon other in-state providers.

13. **The special needs and circumstances of an applicant for a certificate, such as a medical school, hospital, multidisciplinary clinic, specialty center or regional health service provider, if a substantial portion of the applicant's services or resources or both is provided to individuals not residing in the health service area in which the project is to be located.**

**University Health Services (UHS) and**
**Medical College of Virginia Hospitals (MCVH)**
**Petition to Show "Good Cause"**
**for Standing in the Review of:**

**COPN Request No. VA-5969**
**Sentara Norfolk General Hospital**
**Norfolk, Virginia**
**Addition of Liver Transplant Services**

University Health Services, Inc. ("UHS") and the Medical College of Virginia Hospitals ("MCVH"), collectively, "the Petitioner") seek to demonstrate "good cause" standing to participate as a party at the informal fact-finding conference ("IFFC") scheduled with respect to the certificate of public need application by Sentara Norfolk General Hospital to establish liver transplant services at the Sentara Norfolk General Hospital.

In order to show "good cause" and participate as a party with standing in the review of COPN Request Nos. VA-5969, the Petitioner must show that: "*(i) there is significant relevant information not previously presented at and not available at the time of the public hearing, (ii) there have been significant changes in factors or circumstances relating to the application subsequent to the public hearing, or (iii) there is a substantial material mistake of fact or law in the Department staff's report on the application or in the report submitted by the health systems agency.*"

The Petitioner first asserts that "*there is significant, relevant information not previously presented at and not available at the time of the public hearing*" which entitles the Petitioner to standing in the review of the proposal by SNGH to establish a liver transplant program.

In support of its assertion the Petitioner states that since the public hearing on the proposed project was conducted by the Eastern Virginia Health Systems Agency (EVHSA), it has reached a lease agreement with Bon Secours DePaul Hospital in the City of Norfolk for space in which its liver transplant physicians will provide pre- and post-operative care for liver transplant patients who are served in the MCVH liver transplant program. The MCVH liver transplant physicians expect to begin seeing patients in the near future. The Petitioner asserts that it does not believe that the infrequent pre- and post-operative visits to MCVH are burdensome for liver transplant patients, and they clearly do not constitute public need for another liver transplant program. However, the Petitioner asserts that it is interested in making services as convenient as possible to MCVH liver transplant patients and that this new clinic will serve as an alternative to the proposed project, which information was not available at the time of the public hearing. The Petitioner argues that this clinic alternative to the proposed Project provides virtually all of the proposed Project's purported benefits with none of its risks or adverse consequences.

While the development of an outpatient clinic in another local area hospital (e.g., DePaul) does allow for some of the travel time and expense of patients who now travel to Richmond for post-operative liver transplant services to be reduced, it does not provide the liver transplant service itself within a two-hour driving time of a significantly large population as would the proposed project. The placement of the liver transplant service at the SNGH facility would provide liver transplant services in a health planning region of

the state which currently has none. This proposed clinic does not effect a significant change in the manner in which actual transplant services are currently delivered by the MCVH transplant center. The primary transplant services will still require travel by residents of the SNGH tertiary service area to Richmond to receive the liver transplants, and a number of follow-up trips to Richmond for post-operative services. The petitioner's assertion that its potential opening of a clinic for liver patients in Norfolk constitutes "significant relevant information not previously presented at and not available at the time of the public hearing" should be rejected.

The Petitioner next asserts *(2) there have been significant changes in factors or circumstances relating to the application subsequent to the public hearing.* In support of this claim the Petitioner also relies upon its stated intention to establish a clinic at the Bon Secours DePaul Hospital in Norfolk for liver transplant patients. Aside from the fact that the alleged development of the clinic by MCVH liver transplant physicians has no relationship to the application of SNGH, for the same reasons and rationale stated above, this assertion of the Petitioner should be rejected.

Thirdly, the petitioner asserts that *(3) there is a substantial material mistake of fact or law in the department staffs report on the application or in the report submitted by the regional health planning agency* which entitles the Petitioner to standing in the review of the proposal by SNGH to establish a liver transplant program.

In support of this assertion the Petitioner claims that the staff reports of the Eastern Virginia Healths Systems Agency (EVHSA) and the Division of Certificate of Public Need contain certain statements and omissions which constitute substantial, material mistakes of fact or law, notwithstanding the fact that they reached the right result, and that these errors entitle the Petitioner to standing in the review of the proposal by SNGH to establish a liver transplant program. The Petitioner offers five arguments in support of this assertion.

1. The Petitioner argues that the EVHSA Staff Report failed to recognize and appropriately consider the substantial adverse effect the proposed project will have on liver transplant research activities and training programs at MCVH.

The EVHSA staff report devoted significant attention to the potential impact that creation of the new liver transplant service may have upon the service provided by MCVH. Whether the report captured the full impact that MCVH alleges that the new program will have upon MCVH's liver transplant program seems to be the subject for the Petitioner's concern;; however, the actual degree of impact remains to be seen and cannot be determined to be a mistake of fact or law in the EVHSA staff report. This argument does not identify a substantial material mistake of fact or law the report submitted by the regional health planning agency. This argument is rejected.

2. The Petitioner argues that the EVHSA Staff Report failed to recognize and appropriately consider the substantial adverse effect on patients that will result from the loss of flexibility in waiting list management due to the creation of a second liver transplant program that would be served by LifeNet, the organ procurement organization (OPO) that currently serves only one liver transplant program - the program at MCVH.

The Petitioner's argument regarding increased patient mortality because a second liver transplant program would be established in the same area that is served by LifeNet, the single Organ Procurement Organization (OPO), thereby creating a dual waiting list which would not be able to be "managed" by MCVH, and thus cause increased waiting list mortality, is not convincing. MCVH allegedly experiences a wait list mortality rate of slightly over 5% compared to the national average wait list mortality of approximately 14%. MCVH attributes its lower waitlist mortality rate to the fact that, as the single liver transplant center in the LifeNet OPO, it has total control over which of its patients on the wait list will receive the next available liver transplant service. If a second liver transplant program is established in the area, then both programs would necessarily have to work from an agreed-upon protocol to determine who would receive the next liver transplant. MCVH believes that its current policy of transplanting the patient most in need may be in jeopardy and lead to increased mortality among its waitlist patients. This argument does not identify a substantial material mistake of fact or law in the report submitted by the regional health planning agency. This argument is rejected, especially since the OPO, not the institution, makes the objective organ-assignment determinations.

LifeNet presently serves both institutions for the purpose of procuring and distributing hearts, kidneys, lungs and pancreases. The distribution of livers to persons in need of transplants is no more important than the distribution of the other important life-prolonging organs. The protocol for the distribution of these other vital organs has been satisfactorily agreed upon by both institutions, each of which participates on the LifeNet governing board, and the same can be expected for the procurement and distribution of livers. If waitlist mortality should increase, the policy for which patient gets the liver transplant will need to be refined. There is no reason that one can automatically conclude that waitlist mortality will increase with two programs. The OPO is the organization that will, by law, govern the liver transplantation, just as it does the transplantation of other vital organs.

This argument does not identify a substantial material mistake of fact or law in the report submitted by the regional health planning agency. This argument is rejected.

3. The Petitioner argues that the DCOPN Staff Report significantly overestimates the number of pre- and post operative physician visits required to be made by liver transplant patients, and thereby significantly overestimates the benefits of the Project.

The decision to approve or deny the application is not concerned with over or under estimates of numbers of pre and post operative visits for liver transplant patients, although it has been expressed as a concern among those who traveled more than two hours to services. Clearly, such visits are determined by the condition of the patients; wide variances from the average would not be surprising. Whether the DCOPN staff overestimated the average number of visits is not a significant error. The simple truth of the matter is that whoever lives more than two hours from the location of their liver transplant will have to travel to get to the transplant center multiple times. The SMFP rule is that liver transplant services should be available to 95% of the population within two hours' driving time. The MCVH transplant program is not available within the two-hour driving time for more than 400,000 persons in the SNGH service area (PDs 20 and 22). Therefore, in eastern Virginia, the location of SNGH, more than 6% of the state's population resides in excess of two hours' driving time of the nearest liver transplant facility, MCVH, and it is not located within the same Health Planning Region as the population at risk.

This argument does not identify a substantial material mistake of fact or law in the report submitted by the Division of Certificate of Public Need staff. This argument is rejected.

4. The petitioner argues that the DCOPN Staff Report fails to recognize and appropriately consider the substantial adverse affect the Project will have on liver transplantation research activities at MCVH.

It is not uncommon for institutions to collaborate in research projects and protocols and certainly, if a large volume of patients is required for the research concerning liver transplants, one could expect such collaboration between MCVH and SNGH, both of which would be served by the same OPO. There is no reason to expect research at MCVH to be affected by the initiation of liver transplant services at SNGH. Furthermore, any impact of the proposed project upon the research programs of MCVH should not be significant, especially in view of the slow projected start-up of the SNGH program of six, twelve and fifteen patients, respectively, in the first three years of operation.

This argument does not identify a substantial material mistake of fact or law the report submitted by the Division of Certificate of Public Need staff. This argument is rejected.

5. The Petitioner argues that the DCOPN Staff Report erroneously asserts that it is reasonable to conclude that MCVH's liver transplant charges have been and will be increasing at a rate (5% per year) similar to that projected by the applicant.

The DCOPN staff did erroneously conclude that MCVH's liver transplant charges would increase at a rate of 5% per year, which is similar to the charges proposed by the applicant; however, the assumption was not a significant error. It was a mere harmless error. There are several comparable solid organ transplant programs to compare between the two institutions and it is reasonable to believe that the SNGH charge structure will be comparable to the MCVH charge structure. SNGH has lower charges than MCVH in its other solid organ transplant programs, and it is reasonable to expect the liver transplant program charges will not be substantially different from those of the existing transplant services.

This argument does not identify a substantial material mistake of fact or law in the report submitted by the Division of Certificate of Public Need staff. This argument is rejected.

**Recommendation**

The Petitioner has not provided the necessary "good cause" threshold proofs that would entitle the Petitioner with "standing" to participate in the review of the proposed project. The Petitioner should be advised that its petition is rejected.

Respectfully submitted,

Raymond O. Perry

Raymond. O. Perry, M.P.H.
Adjudication Officer

## CHAPTER 230.

## STATE MEDICAL FACILITIES PLAN.



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**Research and Practice References**

39 Am Jur 2d, Health §§ 1, 3-4 (introductory—powers).

40 Am Jur 2d, Hospitals and Asylums §§ 1-5 (in general), 6-13 (management and operation), 14-19.5 (liability for injuries—in general), 20-21, 23-25 (liability for injuries—public hospitals), 26-36 (liability for injuries—public hospitals).

13A Am Jur Pl & Pr Forms (Rev), Hospitals, Forms 1-10 (licensing and regulation), 21-24, 26-29 (management and operation), 41-51 (liability for injuries—in general), 61-69, 71-78, 80-91 (liability for injuries—injury to patient—negligence in treatment), 111-121, 123-124 (liability for injuries—injury to patient—failure to safeguard patients from physical and health hazards), 131-140 (liability for injuries—injury to patient—administration of improper or defective substance), 151-156 (liability for injuries—injury to patient—condition of premises and equipment), 161-165 (liability for injuries—injury to others), 171-175.1 (liability for injuries—nursing homes; rest homes).

18 Am Jur Trials 103, Hospital Emergency Room Accidents.

19 Am Jur Trials 431, Defending Hospital—Negligence of Physician-Employee.

25 Am Jur Trials 185, Hospital Recovery Room Accidents.

29 Am Jur Trials 591, Hospital Liability for Nursing Medication Errors.

32 Am Jur Trials 1, Due Process Considerations in Suspension of Hospital Staff Privileges.

51 Am Jur Trials 375, Trial Report: Negligent Pediatric Care.

4 Am Jur Proof of Facts 473, Diathermy.

6 Am Jur Proof of Facts 131, Hospital Records.

7 Am Jur Proof of Facts 479, Malpractice.

8 Am Jur Proof of Facts 401, Neurological Examination.

9 Am Jur Proof of Facts 241, Physicians and Surgeons.

9 Am Jur Proof of Facts 375, Plastic Surgery.

9 Am Jur Proof of Facts 641, Pulmonary Function Tests.

9 Am Jur Proof of Facts 719, Radiation Injuries and Nuclear Energy.

10 Am Jur Proof of Facts 479, Shots, Injections, and Other Needling Procedures.

Liability of hospital, physician, or other medical personnel for death or injury to mother or child caused by improper procedures during vaginal delivery. 4 ALR5th 210.

Liability of hospital, physician, or other medical personnel for death or injury to mother or child caused by improper treatment during labor. 6 ALR5th 490.

Liability of hospital, physician, or other medical personnel for death or injury to mother or child caused by improper diagnosis and treatment of mother relating to and during pregnancy. 7 ALR5th 1.

Licensing and regulation of practice of physical therapy. 8 ALR5th 825.

Medical malpractice: Who are "health care providers," or the like, whose actions fall within statutes specifically governing actions and damages for medical malpractice. 12 ALR5th 1.

Arbitration of medical malpractice claims. 24 ALR5th 1.

## 12 VAC 5-230-10. Definitions.

The following words and terms, when used in Chapters 230 (12 VAC 5-230-10 et seq.) through 360 (12 VAC 5-360-10 et seq.) shall have the following meanings, unless the context clearly indicated otherwise:

"*Accessibility*" means the ability of a population or segment of the population to obtain appropriate, available services. This ability is determined by economic, temporal, locational, architectural, cultural, psychological, organizational and informational factors which may be barriers or facilitators to obtaining services.

"*Acceptability*" means to the level of satisfaction expressed by consumers with the availability, accessibility, cost, quality, continuity and degree of courtesy and consideration afforded them by the health care system.

"*Availability*" means the quantity and types of health services that can be produced in a certain area, given the supply of resources to produce those services.

"*Continuity of care*" means the extent of effective coordination of services provided to individuals and the community over time, within and among health care settings.

"*Cost*" means all expenses incurred in the production and delivery of health services.

"*Quality of care*" means to the degree to which services provided are properly matched to the needs of the population, are technically correct, and achieve beneficial impact. Quality of care can include consideration of the appropriateness of physical resources, the process of producing and delivering services, and the outcomes of services on health status, the environment, and/or behavior.

**Statutory Authority**

§§ 32.1-12 and 32.1-145 and 32.1-102.2 of the Code of Virginia.

**Historical Notes**

Derived from VR355-30-100 § 1; eff. July 1, 1993.

**Editor's Note**

This chapter comprises part of the State Medical Facilities Plan, which appears in Chapter 230 (12 VAC 5-230-10 et seq.) through Chapter 360 (12 VAC 5-360-10 et seq.).

## 12 VAC 5-230-20. Preface.

Virginia's Certificate of Public Need law defines the State Medical Facilities Plan as the "planning document adopted by the Board of Health which shall include, but not be limited to, (i) methodologies for projecting need for medical

facility beds and services; (ii) statistical information on the availability of medical facility beds and services; and (iii) procedures, criteria and standards for the review of applications for projects for medical care facilities and services." (§ 32.1-102.1 of the Code of Virginia.)

Section 32.1-102.3 of the Code of Virginia states that, "Any decision to issue or approve the issuance of a certificate (of public need) shall be consistent with the most recent applicable provisions of the State Health Plan and the State Medical Facilities Plan; provided, however, if the commissioner finds, upon presentation of appropriate evidence, the provisions of either such plan are inaccurate, outdated, inadequate or otherwise inapplicable, the commissioner, consistent with such finding, may issue or approve the issuance of a certificate and shall initiate procedures to make appropriate amendments to such plan."

Subsection B of § 32.1-102.3 of the Code of Virginia requires the commissioner to consider "the relationship" of a project "to the applicable health plans of the board" in "determining whether a public need for a project has been demonstrated."

This State Medical Facilities Plan is a comprehensive revision of the criteria and standards for COPN reviewable medical care facilities and services contained in the Virginia State Health Plan established from 1982 through 1987, and the Virginia State Medical Facilities Plan, last updated in July, 1988. This Plan supersedes the State Health Plan 1980 - 1984 and all subsequent amendments thereto save those governing facilities or services not presently addressed in this Plan.

**Statutory Authority**
§§ 32.1-12 and 32.1-145 and 32.1-102.2 of the Code of Virginia.

**Historical Notes**
Derived from VR355-30-100 § 2; eff. July 1, 1993.

## 12 VAC 5-230-30. Guiding principles in certificate of public need.

The following general principles will be used in guiding the implementation of the Virginia Medical Care Facilities Certificate of Public Need (COPN) Program and have served as basis for the development of the review criteria and standards for specific medical care facilities and services contained in this document:

1. The COPN program will give preference to medical facility and service development approaches which can document improvement in the cost-effectiveness of health care delivery. Providers should strive to develop new facilities and equipment and use already available facilities and equipment to deliver needed services at the same or higher levels of quality and effectiveness, as demonstrated in patient outcomes, at lower costs.

2. The COPN program will seek to achieve a balance between appropriate levels of availability and access to medical care facilities and services for all the citizens of Virginia and the need to constrain excess facility and service capacity.

3. The COPN program will seek to achieve economies of scale in development and operation, and optimal quality of care, through establishing limits on the development of specialized medical care facilities and services, on a statewide, regional, or planning district basis.

4. The COPN program will give preference to the development and

maintenance of needed services which are accessible to every person who can benfit from the services regardless of ability to pay.

5. The COPN program will promote the elimination of excess facility and service capacity. The COPN program will promote the conversion of excess facility and service capacity to meet identified needs. The COPN program will not facilitate the survival of medical care facilities and services which have rendered superfluous by changes in health care delivery and financing.

**Statutory Authority**
§§ 32.1-12 and 32.1-145 and 32.1-102.2 of the Code of Virginia.

**Historical Notes**
Derived from VR355-30-100 § 3; eff. July 1, 1993.

## CASE NOTES

The State Medical Facilities Plan need not be adopted by lengthy public promulgation process, where the Plan consists only of the numerical projections and methodologies by which the statistics are derived and where the adoption of the Plan does not involve the exercise of any agency discretion. Johnston-Willis v. Kenley, (1988) 6 Va App 231, 369 SE2d 1.

# CHAPTER 280.

# ORGAN TRANSPLANTATION SERVICES.

**Research and Practice References**

40 Am Jur 2d. Hospitals and Asylums §§ 6-13 (management and operation), 14-16, 17-19 (liability for injuries—in general), 20-21, 23-25 (liability for injuries—public hospitals), 26-35 (liability for injuries—public hospitals).

13A Am Jur Pl & Pr Forms (Rev). Hospitals. Forms 21-24, 26-27, 29 (management and operation), 43-51 (liability for injuries—in general), 61-63, 65-66, 69, 71-72, 75-78, 80-91 (liability for injuries—injury to patient—negligence in treatment), 116-117 (liability for injuries—injury to patient—failure to safeguard patients from physical and health hazards), 131-132, 134-135, 138, 140 (liability for injuries—injury to patient—administration of improper or defective substance), 151-156 (liability for injuries—injury to patient—condition of premises and equipment).

7 Am Jur Proof of Facts 479, Malpractice.

11 Am Jur Proof of Facts 331, Transfusions.

12 Am Jur Proof of Facts 453, Anesthesia.

16 Am Jur Proof of Facts 155, Surgical Malpractice—Foreign Bodies.

27 Am Jur Proof of Facts 1, Medical Malpractice—The Locality Rule.

4 Am Jur Proof of Facts 2d 333, Physician's Guarantee of Medical Results.

8 Am Jur Proof of Facts 2d 145, Failure to Inform Patient of Nature and Hazards of Surgery.

8 Am Jur Proof of Facts 2d 579, Surgeon's Failure to Exercise Supervision and Control Over Anesthetist.

10 Am Jur Proof of Facts 2d 605, Surgeon's Failure to Discover Breakage of Surgical Instrument

15 Am Jur Proof of Facts 2d 711, Physician's Failure to Obtain Informed Consent to Innovative Practice or Medical Research.

6 Am Jur Proof of Facts 3d 1, Anesthesia Malpractice.

26 Am Jur Proof of Facts 3d 185, Discovery Date in Medical Malpractice Litigation.

**Annotations**

Locality rule as governing hospital's standard of care to patient and expert's competency to testify thereto. 36 ALR3d 440.

Tort liability of physician or hospital in connection with organ or tissue transplant procedures. 76 ALR3d 890.

Tests of death for organ transplant purposes. 76 ALR3d 913.

## PART I.

## DEFINITIONS.



## 12 VAC 5-280-10. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

"*Department*" means Virginia Department of Health.

"*Donor organ/organ system*" means an organ/organ system retrieved from a cadaver or living donor, and processed under appropriate rules and protocols, for the purpose of surgical transplantation into a recipient selected in accordance with established guidelines and protocols.

"*Health care financing administration (HCFA) medicare requirements*" means those clinical, certification and administrative requirements and standards set by the HCFA of the United State Department of Health and Human Services to establish eligibility for Medicare program reimbursement.

"*Minimum survival rates*" means the lowest percentage of those receiving transplants who survive at least one year or for such other periods of times as

specified by the department. Minimum survival rates not specified in these standards shall be established by the department as experience permits.

"*Minimum utilization*" means the number of transplants expected to be performed annually. Minimum utilization requirements not specified in these standards shall be established by the department as experience permits.

"*Organ, organ system*" means any of the number of clinically distinct components of the human body containing tissues performing a function for which it is especially adapted. Distinct organ/organ systems include, but are not limited to, kidney, heart, heart/lung, liver, and pancreas.

"*Organ transplantation*" means a set of medical procedures performed to remove surgically a defined diseased or nonfunctioning organ/organ system from a patient and replace it with a healthier functioning donor organ/organ system.

**Statutory Authority**
§§ 32.1-12 and 32.1-145 and 32.1-102.1 of the Code of Virginia.

**Historical Notes**
Derived from VR355-30-105 § 1.1; eff. July 1, 1993.

**Editor's Note**
This chapter comprises part of the State Medical Facilities Plan, which appears in Chapter 230 (12 VAC 5-230-10 et seq.) through Chapter 360 (12 VAC 5-360-10 et seq.).

PART II.

CRITERIA AND STANDARDS.



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## 12 VAC 5-280-20. Acceptability; consumer participation.

Providers of organ transplantation services should provide a program of patient and family education regarding the nature of the patient's organ disease and the treatment of the patient and family in the management of the organ pre- and post-transplantation.

**Statutory Authority**
§§ 32.1-12 and 32.1-145 and 32.1-102.1 of the Code of Virginia.

**Historical Notes**
Derived from VR355-30-105 § 2.1; eff. July 1, 1993.

## 12 VAC 5-280-30. Accessibility; travel time; access to available organs.

A. Organ transplantation services, of any type, should be accessible within two hours driving time, under normal conditions, of 95% of Virginia's population.

B. Providers of organ transplantation services should demonstrate to the satisfaction of the department that they have clearly defined patient/organ recipient policies based solely on medical criteria.

**Statutory Authority**
§§ 32.1-12 and 32.1-145 and 32.1-102.1 of the Code of Virginia

**Historical Notes**
Derived from VR355-30-105 § 2.2; eff. July 1, 1993.

## 12 VAC 5-280-40. Availability; regionalization of services; conditional approval; HCFA medicare requirements.

A. There should be no more than one transplantation program for each organ system in a health planning region.

B. Approval of organ transplantation programs shall be conditioned upon a facility's meeting both minimum volume and survival standards. Failure to meet these standards within two years of initiation of the service may be cause for revocation of the certificate of public need.

C.1. Proposals to establish new transplantation services should demonstrate compliance with all Medicare program coverage criteria within two years of the initiation of the program.

2. Proposals to expand existing transplantation programs should demonstrate that existing organ transplantation services comply with all applicable federal Health Care Financing Administration criteria for Medicare program coverage.

**Statutory Authority**
§§ 32.1-12 and 32.1-145 and 32.1-102.1 of the Code of Virginia.

**Historical Notes**
Derived from VR355-30-105 § 2.3; eff. July 1, 1993.

## 12 VAC 5-280-50. Continuity of care; discharge planning procedures and follow-up care.

A. Providers of organ transplantation services should have written procedures and policies for discharge planning and follow-up care for the patient and family which are part of the institution's overall discharge planning program.

B. Providers of organ transplantation services should have established protocols for referring physicians and the organ transplantation service to assure adequate post-operative diagnostic evaluation for transplant patients.

**Statutory Authority**
§§ 32.1-12 and 32.1-145 and 32.1-102.1 of the Code of Virginia.

**Historical Notes**
Derived from VR355-30-105 § 2.4; eff. July 1, 1993.

## 12 VAC 5-280-60. Cost and charges.

The total cost (direct and indirect) for providing all organ transplantation services should be comparable to other similar service providers in the health planning region and the state.

**Statutory Authority**
§§ 32.1-12 and 32.1-145 and 32.1-102.1 of the Code of Virginia.

Historical Notes
Derived from VR355-30-105 § 2.5; eff. July 1, 1993.

## 12 VAC 5-280-70. Quality; minimum utilization; minimun survival rate; service proficiency; staffing; services.

A.1. Proposals to establish, expand or replace organ transplantation services should demonstrate that a minimum number of transplants will be performed annually. The minimum number required by organ system is

Kidney....25

Heart....12

Heart/Lung....12

Liver....12

Pancreas....12

2. Successful transplantation programs are expected to perform substantially larger numbers of transplants annually. Performance of minimum transplantation volumes does not necessarily indicate a need for additional transplantation capacity or programs.

3. Preference will be given to expansion of successful existing services, either by enabling necessary increases in the number of organ systems being transplanted or by adding transplantation capability for additional organ systems, rather than developing other programs that could reduce average program volume.

B.1. Facilities should demonstrate that they will achieve and maintain minimum transplant patient survival rates. Minimum one year survival rates, listed by organ system, are:

Kidney 90-95%

Heart 70-80%

Heart/Lung (none set)

Liver 50-60%

Pancreas 80-90%

2. Survival rates beyond one year should be consistent with the Health Care Financing Administration (HCFA) Medicare program requirements, or with applicable professional society recommended standards acceptable to the department where there are no HCFA criteria.

C. Proposals to add additional organ transplantation services should demonstrate at least two years successful experience with all existing organ transplantation systems.

D.1. All physicians that perform transplants should be board certified by the appropriate professional examining board, and should have a minimum of one year of formal training and two years of experience in transplant surgery and post-operative care.

2. Organ transplantation services should have a complete team of surgical, medical and other specialists, with at least two years experience in the proposed organ transplantation system.

E.1. Providers of organ transplantation services should document that they participate in a regional and national organ donor network. The facility should have written policies and procedures governing organ and tissue procurement.

2. Providers of organ transplantation services should have an ongoing approved medical education program.

3. Providers of organ transplantation services should collect and submit to the department transplantation program operating statistics, including patient and procedure volumes, mortality data and program cost and charges.

F. Providers of organ transplantation services should demonstrate that they have direct and immediate access to a histocompatibility testing laboratory that meets the American Society for Histocompatibility and Immunogenetics (ASHI) standards.

**Statutory Authority**
§§ 32.1-12 and 32.1-145 and 32.1-102.1 of the Code of Virginia.

**Historical Notes**
Derived from VR355-30-105 § 2.6; eff. July 1, 1993.

## Documents Incorporated by Reference

American Society for Histocompatibility and Immunogentics (ASHI) Standards.

The community gastroenterologists who will be medically managing the liver transplant population have established practices serving the Norfolk, Virginia Beach, and Chesapeake geographic areas. Therefore, the majority of the liver transplant population is expected to reside in those cities south of the Hampton Roads and Monitor/Merrimac tunnels. This assumption is supported by similar city of residence distributions in the existing organ transplant programs within the Center.

The projection of annual liver transplant volumes of 25-30 patients was based on estimates from the gastroenterologists. This group estimated how many patients each physician referred from their practice for liver transplants. These individual physician estimates were summed to arrive at the projected annual liver transplant volumes. The proforma volume estimates of six transplants in the first year, twelve in the second year, and fifteen in the third year of program implementation were conservative based on the expectation that any new transplant program must develop its waiting list, as well as, its physician referral patterns.

## LIVER TRANSPLANTATION PROGRAM PLAN

The Center proposes to expand its organ transplantation program to include liver transplants. There are approximately 25-30 adult patients (within the Center's primary market) that Sentara physicians refer out of the region and/or State for liver transplants each year. Based on information furnished by MCV's liver transplant program, there are also a significant number of patients referred to their center by Hampton Roads physicians who do not practice at Sentara. The Center assumes the accessibility of a liver transplant program in Hampton Roads will attract patient referrals from both Sentara and non-Sentara physicians. The Center expects to perform six transplants the first year of operation, twelve in year two, and fifteen in year three.

Although there are several liver transplant programs within a day's drive of SNGH, the frequency and intensity of the care afforded this chronically ill population makes it imperative that these patients be treated close to their homes, where family and friends can provide the levels of support required for their conditions. Discussions with patients, physicians, health care providers, community organizations, etc. have indicated a keen interest and support for implementation of a liver transplant program in Norfolk, Virginia. The letters of support included in this application provide documentation of that support. The Transplant Center at Sentara Norfolk General Hospital has provided financial data that

the expected survival rate as the rate one expects if a program performs at the level of the national average after adjusting for the particular combination of risk factors for the recipients as that program. The survival data for the Kidney Transplant Program at SNGH was not statistically different from the expected national UNOS rates.

As part of the Sentara Health System's commitment to improving the health status for the citizens of Hampton Roads, a focus on providing a continuum of care has been a priority for the last 25 years. Each of the organ transplant programs was established so that patients who were stricken with kidney, heart, or lung failure were able to receive the advanced levels of care they needed in close proximity to their home environments. As a result of the chronic disease conditions that afflict these patients, it is important that they remain in the vicinity of their family and friends for the extensive support systems that transplant patients require. Patient accessibility to a consistency of care in treating progressive end-stage organ failure is the premise on which the implementation of a liver transplantation program is proposed.

for organ-specific transplant programs? If such (non-Medicare) annual volume standards exist, please provide them for each type of organ transplant program.

7. On an annual basis for the 1992-95 period, please indicate the number of kidney, heart, single lung, double lung, and heart-lung transplants that were done each year at SNGH and the corresponding patient survival rates for each category.

F. In Year II it is projected that there will be 12 liver transplants. How many of them are projected to be indigent (non-insured) and Medicaid? How were those estimates arrived at?

SECTION V

A. Please specify which insurance programs and managed care/HMO programs presently pay for liver transplants (Medicare, Medicaid, BC/BS, etc.)

H.1. Attachment V.H.3. shows a total direct expense figure for Yr. II of $1,440,373 when the actual total amounts to $105,000 more, or $1,545,373. Please provide a revised proforma which shows correct amounts in all categories.

2. The Notes to Attachment V.H.3. refer to "Patient Listed" and "Patient Evaluated" average charges, as well as a "Transplant Average Charge". For patients who actually receive transplants, would the average total charge be *the sum* of the transplant, evaluation, and listing average charges? Do any of those charges include the professional physician fee, or is that extra?

3. In a revised proforma, please show separately net revenues and costs related to evaluations, listings, and transplants. *(If this question appears unreasonable or unduly time-consuming to respond to, please discuss with us.)*

VDH/DCOPN, SAC

5.


**EASTERN VIRGINIA HEALTH SYSTEMS AGENCY, INC.**

18 KOGER EXECUTIVE CENTER / SUITE 232

NORFOLK, VIRGINIA 23502

Area Code (804) 461-4834

ANDREW B. DAMIANI
President

PAUL M. BOYNTON
Executive Director


August 21, 1996

00226

RECEIVED

AUG 22 1996

Office of Health Facility Regulation / VA Dept of Health

Mr. Howard P. Kern
Chief Administrative Officer
Sentara Southside Hospitals
600 Gresham Drive
Norfolk, Virginia 23507

RE: COPN Request No. VA-5969
Sentara Norfolk General Hospital
Norfolk, Virginia
Addition of Liver Transplant Services

Dear ~~Mr. Kern~~ Howard:

Enclosed please find our review schedule on the Interested Parties Notification Form for the project referenced above. This information will be sent to all Planning District 20 and 21 hospitals, existing liver transplant programs in Virginia, and the Norfolk city government.

Should you have any questions about the schedule, please let me know. We look forward to seeing you on September 16th at the public hearing.

Sincerely,

Paul M. Boynton
Executive Director

cc: Sandra J. Miller
Laura G. Aaron, Esquire
Paul E. Parker
Samuel A. Clement

Enclosure

EASTERN VIRGINIA HEALTH SYSTEMS AGENCY, INC.
18 KOGER EXECUTIVE CENTER / SUITE 232
NORFOLK, VIRGINIA 23502
Area Code (804) 461-4834

ANDREW B. CAMIANI
President

PAUL M. BOYNTON
Executive Director

August 21, 1996

00227

TO: Interested Parties

FROM: P.M. Boynton, Executive Director, EVHSA

SUBJECT: Notification of Certificate of Public Need Project Review

The following project will be reviewed by this agency pursuant to Virginia's Certificate of Public Need Law. The project application is available at the EVHSA office for public inspection. Comments on the project may be made at the public hearing scheduled below or sent in writing to the EVHSA office at the address shown above. Written texts of comments presented at the public hearing are greatly appreciated.

| | |
|---|---|
| TYPE OF REVIEW: | Standard 120 Day Non-Competing Review in P.D. 20 |
| PROJECT REQUEST NUMBER: | COPN Request No. VA-5969 |
| PROJECT APPLICANT: | Sentara Norfolk General Hospital (SNGH)<br>600 Gresham Drive<br>Norfolk, Virginia 23507 |
| PROJECT DESCRIPTION: | SNGH seeks to establish a liver transplantation service at SNGH's transplant center. The center currently performs kidney, heart, lung, and heart/lung transplants and the liver program will utilize the hospital's existing ORs and recovery facilities. The liver program is projected to perform 6 transplants during its first year of operation, and 12 transplants in the second year of operation. |
| PROJECT COSTS: | Capital--$61,900 Financing--$0 |
| PUBLIC HEARING: | September 16, 1996, 11:00 a.m.<br>Conference Room A<br>Norfolk International Airport<br>Norfolk, Virginia |
| EVHSA BOARD ACTION: | November 12, 1996, 1:30 p.m.<br>Conference Room A<br>Norfolk International Airport<br>Norfolk, Virginia |
| WRITTEN COMMENTS DUE: | September 30, 1996 |

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RECEIVED

SEP 16 1996

Office of Health Facilities
Regulation / VA Dept. of Health

September 16, 1996

Virginia Commonwealth University

HOSPITAL ADMINISTRATION

401 North 12th Street
P.O. Box 980510
Richmond, Virginia 23298-0510

804 786-4682
FAX 804 371-0170
TDD 1 800 828-1120

Mr. Paul Parker, Director
Division of Certificate of Public Need
Health Facilities Regulation
3600 West Broad Street #216
Richmond, Virginia 23230

Re: COPN Request No. VA-5969

Dear Mr. Parker:

Please accept our formal opposition to Sentara Norfolk General Hospital's COPN Request Number VA-5969 to establish liver transplant services. The Medical College of Virginia Hospitals and MCV Associated Physicians strongly oppose this application based on the negative impact another program will have on mortality and transplantation costs for the citizens of Virginia. Further, an additional program will compromise transplant research taking place at MCV, jeopardize transplant training occurring at MCV, and decrease MCV's ability to medically manage the transplant waiting list to optimize patient outcomes.

MCV has a long-standing history of serving patients with end-stage liver disease from the Tidewater area, and many patients have documented the quality and convenience of the care they received in letters sent to the Eastern Virginia Health Planning Agency.

Since there exists ample capacity for liver transplant services within easy access to patients from the Tidewater area, ***there is no public need for an additional program in Planning District 19***. Following is an elaboration on the specific points of our opposition. In addition, attached are copies of a slide presentation made to Medical Staff and Administrative leadership from Sentara on September 3, 1996; copies of letters written by Sentara physicians, copies of a slide presentation which will be made at the public hearing on September 16, 1996 in Norfolk; and a copy of a letter written to Sentara Administration, at their request, to outline possible scenarios for collaboration to enhance what they recognized and affirmed as the high quality liver transplant services provided by MCV to patients living in the Tidewater area.

State Medical Facilities Plan for Organ Transplantation: Section IV.E.2.2
Distance As A Barrier To Transplant Services

Sentara Health System's principal formal argument for approval of a new liver transplant program is the inconvenience associated with travel time between the Tidewater area and Richmond. The State Medical Facilities Act for Transplantation Services states that transplant services *should* be available within two hours to all patients of Virginia. Sentara asserts in their application that the closest providers (MCV, UVA and Fairfax) are located more than two hours away from the majority of patients in Sentara's service area. As such, Sentara implies that an inconvenience exists sufficient to warrant an additional program.

The closest liver transplant service to the Tidewater area is MCV. The next closest is UVA. For a majority of the population in Sentara's service area the distance to MCV is less than 100 miles. According to the American Automobile Association (AAA), the travel time from Norfolk to Richmond is 1.5 hours and the travel time from Virginia Beach to Richmond is 2 hours.

State Medical Facilities Plan for Organ Transplantation: Section IV.E.2.3
Availability

Sentara supports its position regarding a new liver transplant program in part by referencing Section 2.3.A. of the Plan. The section states that "There should be no more than one transplantation program for each organ system in a health planning region." Sentara states that no such service exists in the planning region. Though this is true, *the standard does not require, nor does it suggest, that the absence of a transplant service in a planning region is cause for starting a new one*.

According to UNOS, in calendar year 1995, 21 people who reside in the Tidewater region received liver transplants. Eleven of the 21 received transplants in UNOS regions other than region 11. Specifically, 4 patients received transplants in region 2 (Northeastern U.S.) and 7 patients received transplants in region 4 (Southwestern U.S.). This clearly demonstrates that *distance is not a significant access barrier for most of the residents of the Tidewater region who are in need of liver transplantation.*

Access to liver transplant services is more than simply a function of distance. The availability of organs, historical referral patterns, and managed care contractual relationships with transplant centers outside the service area determine where and when an individual receives a liver transplant. For those patients who will receive services from a local provider, MCV is well positioned to provide liver transplant services, and has done so successfully for more than a decade. *The most dramatic improvements in access to liver transplantation for the residents of Virginia can be accomplished through initiatives directed at improving the rate of organ donation.*

Finally, MCV has offered in writing to provide services to Sentara and Tidewater patients that would help mitigate the issue of traveling to Richmond for some pre- and post- operative care. MCV has offered to arrange for telemedicine services as well as the establishment of a satellite transplant hepatology practice in the tidewater area.

**State Medical Facilities Plan for Organ Transplantation: Section IV.E.2.5**
**The Cost Of Liver Transplant Services**

Sentara states in its application that its cost and charges will be comparable with other transplant providers, and that Sentara is a low cost/low charge provider. Though Sentara's *charge* structure may compare to other providers, initiation of a new program will undoubtedly require an investment in fixed costs, thereby substantially increasing the overall *cost* per procedure in the region. The creation of a new liver transplant program will not likely increase the number of transplants, but will increase the cost to be borne by citizens and/or payors.

Reflecting on the establishment of a liver transplant program at MCV allows us to speak from experience on the significant investment required to build a quality program. Some examples of the fixed cost associated with a program are the transplant surgeon's salary (typically guaranteed for some period of time by the sponsoring hospital), specialty nurse coordinators, specialized lab technicians, financial coordinators, hepatology practice support, operating room equipment and setups, administrative personnel specific to the program, and data management resources. The expenses associated with these fixed costs can total in the hundreds of thousands of dollars.

MCV believes that the addition of a new liver transplant program in Virginia would serve only to dilute the existing transplant population and force the allocation of significant fixed costs to fewer patients.

**State Medical Facilities Plan for Organ Transplantation: Section IV.E.2.6**
**Quality**

Probably the most compelling argument for or against any new clinical service is the potential of that service to improve clinical outcomes. As with many other extremely complicated procedures, the clinical outcome for liver transplants improves as the number of procedures performed increases.

The United Network for Organ Sharing (UNOS) is the primary procurer of solid organs for transplant. According to UNOS, 12 liver transplants must be performed per year in order for a transplant program to receive UNOS certification.

Sentara Health System projects performing six transplants in year one, twelve in year two, and fifteen in year three. MCV believes that these projections are highly optimistic. Capturing 100% of the stay-at-home market would require referring physicians to sever referral relationships with MCV physicians that have existed for decades, all payors covering patients from the region to change contractual relationships, and for patients to all prefer transplant services at a young program. MCV believes this is highly unlikely.

MCV has performed liver transplants since 1984. During that period our volume has increased to a current rate of over 75 per year. MCV has been able to achieve a 2 year survival rate of 79% and a 5 year survival rate of 68%. Both rates are superior to national averages.

An important indicator of the quality of MCV's liver transplant program is the liver transplant waiting list death rate. According to UNOS, the 1994 national average was 7.8%. The MCV liver transplant waiting list death rate is 3.8%. MCV believes this significant difference can be attributed to MCV's exceptional ability to medically manage a large waiting list. The skill set and experience necessary to achieve such a low waiting list death rate was developed over a period of years, and is assisted by the diversity of acuity afforded by a larger list. Low waiting list mortality and superior patient survivals are achieved through a delicate balance of timing transplant, as influenced by the independent variables of deteriorating patient health, donor-recipient match, and waiting time.

Though predicting mortality is difficult, MCV believes that mortality associated with liver transplants will be high for a new program. MCV initiated liver transplant services 1984. The one year survival rates for years one and two was 50%. Henrico Doctors Hospital launched a new liver transplant program in 1990. That year, five patients were transplanted but four of the five died. Though the program still technically exists, no liver transplants have been performed at Henrico Doctors Hospital since 1990. As stated previously, the implementation of a new liver transplant program will likely not result in an increase in the number of liver transplants performed in Virginia. Redistributing the liver transplant population over multiple programs will result in fewer procedures at each center. The opportunity for existing programs to improve proficiency by performing high volumes of liver transplants essentially evaporates. Now a mature program performing an annualized rate of 75 liver transplants, MCV has improved its one year survival from 50% to 82%, far in excess of the national average.

*Exposing patients from the Tidewater area to unnecessary mortality due to program start-up is unethical given the close proximity of a highly successful program such as MCV.*

Training Healthcare Professionals

MCV is an academic medical center with a multi-faceted mission including the provision of high quality medical care to the citizens of Virginia. The training of physicians, nurses, and allied health professionals is an equally important component of our mission. *The initiation of this project has the potential to reduce MCV's ability to provide training in liver transplantation by reducing program volumes required for training and fellowship certification.* As one of only two state-sponsored liver transplant training sites in Virginia, it is imperative that the MCV program not be threatened by the proliferation of unnecessary transplant programs.

Improving Transplant Outcomes Through Clinical Research

Medical research is the third component of MCV's mission. At no time in the history of medicine in the United States has the threat to research at academic medical centers been more severe. The pressure to reduce the cost of health care is intense. Most payors do not recognize the value of research and do not reimburse at levels sufficient to maintain these programs.

It has been demonstrated repeatedly that significant advancements in transplant technology occur primarily at research-based transplant programs. The transplant physicians and surgeons at MCV have been involved in pioneering cutting edge transplant therapies. Such involvement includes the development and refinement of rejection suppression drug therapy, hepatocyte transplantation, and segmental liver transplantation surgery. These advancements can continue only if patient volumes are sufficient to sustain a program with a threefold mission.

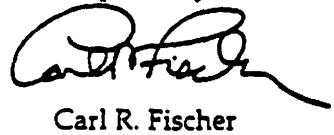
*Proliferation of transplant programs further erodes the ability to conduct research in critical areas of medical care. Sentara's liver transplant proposal is an additional threat to that ability while adding little to meaningful transplant research in Virginia.*

SUMMARY

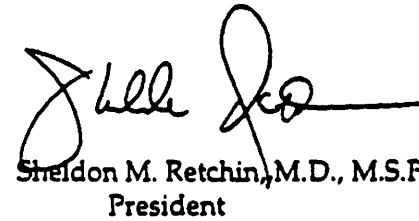
In summary, MCV believes not only that no public need exists for another liver transplant program in this region, but that Sentara's justification for initiating a new liver transplant program is inadequate and that the decision to pursue such a path is ill-advised. The travel time for the vast majority of Tidewater liver transplant candidates to MCV is less than the stated two hours. It is understood throughout the industry that the clinical and financial risks of developing a new liver transplant program are quite high. The advent of such a new program will inevitably lead to increased costs, poor clinical outcomes, unnecessary deaths, fewer training opportunities, and reduced research capability.

Clearly the only real benefit provided by this application for services will accrue to the applicant, and it does not address any unmet need. We therefore urge the Eastern Virginia Health Planning Agency, the Office of Resources Development, and the State Department of Health to deny this application.

Respectfully,



Carl R. Fischer
Executive Director
Medical College of Virginia Hospitals



Sheldon M. Retchin, M.D., M.S.P.H.
President
MCV Associated Physicians

Attachments

cc: Paul Boyton
Mike Byrne
Andrew A. Lasser, Dr.P.H.
Scott Eldredge
Marc P. Posner, M.D.
Robert A. Fisher, M.D.
Mitchell Shiffman, M.D.
Brian Letourneau
Marcos Irigaray

*GASTROENTEROLOGY, LTD.*

00236

BERTON W. ASHMAN, M.D.
ALAN P. GANDERSON, M.D.
JAMES W. RAWLES, JR., M.D.
JAN A. JANSON, M.D.

1101 FIRST COLONIAL ROAD, SUITE 20
VIRGINIA BEACH, VIRGINIA 23454
PHONE (804) 481-4817
FAX (804) 481-7138

August 20, 1996

Dr. Richard L. Hurwitz
Virginia Vascular Associates
880 Kempsville Rd., #1000
Norfolk, VA 23502

Dear Rick:

Thank you for your letter regarding the tentative plan for establishing a liver transplant program in Hampton Roads. While initially this seemed to be an appealing idea (primarily for reasons of convenience), I subsequently have had some reservations.

The majority of our liver transplant patients currently go to MCV, where the service has been excellent. Fortunately, this institution is really not very far away and has a very well-established and successful liver transplant program. While I do not doubt that the surgical and technical aspects of the procedure can be mastered here in Tidewater, I am not at all confident that the current situation in Tidewater lends itself well to the establishment of the other components necessary for a successful liver transplant program.

The medical aspects of liver transplant evaluation and management would require a full-time dedicated hepatologist, preferably allied with a major academic institution. I do not think that community gastroenterologists can function effectively in this role.

We must also consider that the effectiveness and success of the liver transplant program depend to a great extent on the depth of its experience. I think that dilution of this experience by establishment of an additional liver transplant center in our region does not serve our patients well.

At the present time, the availability of liver transplants is limited primarily by the availability of transplantable livers. A second transplant program, with additional hospital beds, equipment & physicians, will do nothing to change the one limiting factor. In addition, it may diminish the overall quality and effectiveness of this procedure in our area.

-continued-

Dr. Richard Burwitz
August 20, 1996
Continued - page 2

I would, therefore, recommend that the plans for a liver transplant program in Hampton Roads be shelved for the present time.

Sincerely,

James W. Rawles, Jr., M.D.

JWR/jr:js

cc: Dr. Mitchell Shiffman
Chief, Hepatology Section
Medical College of Virginia

# GASTROENTEROLOGY, LTD.

00241

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July 8, 1996

Dr. Richard Burwitz
Virginia Vascular Associates
880 Kempsville Rd., #1000
Norfolk, VA 23502

Dear Rick:

Thanks for your letter of 6/27/96. Unfortunately, due to a heavy day after being on-call, I was unable to attend the meeting to discuss a possible liver transplant program at Sentara Norfolk General Hospital.

I have certain concerns that you should know about. I believe that there are at least three centers in Virginia which are already performing transplants. Forming a fourth center, I believe, would dilute our regional centers' experiences. To wit, I do not believe there is enough pathology to support a liver transplant center in Norfolk.

Thank you for your attention to this matter. Please don't hesitate to contact me if you wish any further discussion.

Sincerely,

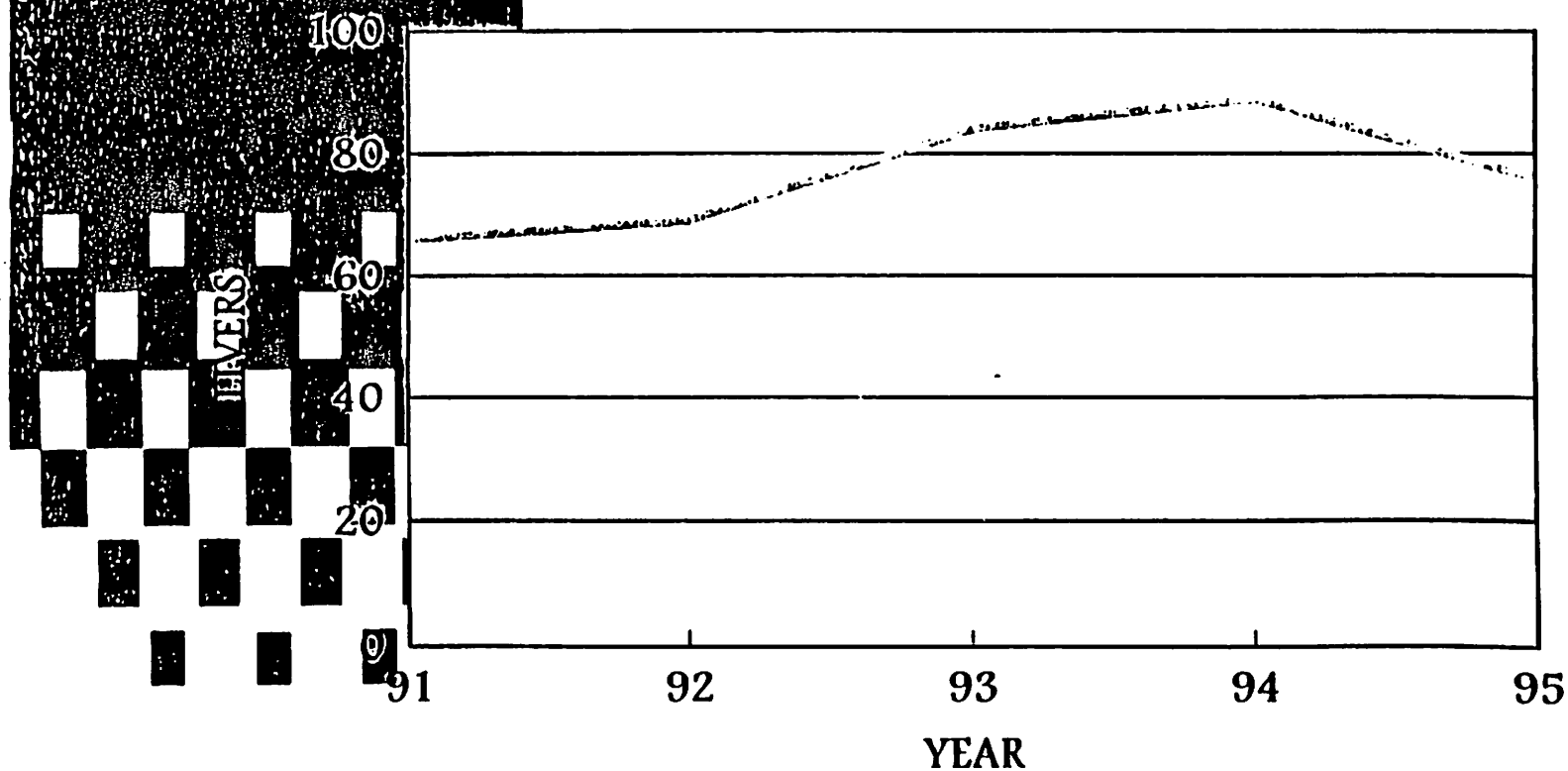
Jan A. Janson, M.D.

JAJ:js

cc: Dr. Mitchell Shiffman, Medical College of Virginia
Dr. Michael Ryan

# MCV LIVER TRANSPLANT PROGRAM

## LIVER DONATIONS IN VIRGINIA



# MCV LIVER TRANSPLANT PROGRAM

## *DEDICATED PROGRAM RESOURCES*

| | |
|---|---|
| Transplant Surgeons | 4 |
| Transplant Hepatologists | 4 |
| Nurse Coordinators | 3 |
| Transplant Administrator | 1 |
| Secretaries | 2 |
| Psychologist | 1 |
| Social Worker | 1 |
| Dietician | 1 |
| Financial Coordinators | 2 |
| Data Entry Specialists | 2 |
| Program Support Tech | 1 |
| Transplant Info Mgr | 1 |

## Section II.H.

How long would it be from the date of COPN approval until the liver transplant service is ready to accept the first patient?

An experienced liver transplant surgeon must have SNGH medical staff privileges and be relocated to the Tidewater area before the first patient can be accepted. If the liver transplant surgeon is available, SNGH will be able to accept its first liver transplant patient thirty days from the date of Certificate of Public Need (COPN) approval. The United Network for Organ Sharing (UNOS) application for conditional approval to perform liver transplants will be submitted to coincide with COPN approval.

## Section III.B

Projected total patient days for the 644 beds at SNGH for the two years following completion of this project (p.7) are different from the total computed by adding patient days across all inpatient service categories. For 1997, the difference is 2,126 patient days, and for 1998 the difference is 2,084 patient days. Please explain the difference or revise the projected patient days.

A revised projected patient days is attached.

## Section IV.A.1.

Please discuss where the liver transplant surgeon will be recruited from; why he/she is willing to leave that facility to come to SNGH; and why he/she is willing to do a relatively low volume business (12 procedures in Year II) compared with U.VA. And MCV.

There are currently two surgical practices in the Norfolk/Virginia Beach/Chesapeake area that are recruiting experienced liver transplant vascular surgeons. Candidates are being recruited from throughout the United States. The availability of state-of-the-art diagnostic and treatment facilities, the Eastern Virginia Medical School (EVMS) teaching and research environment, and the desirability of the Hampton Roads metropolitan area should make the recruitment of a liver transplant surgeon relatively easy.

As discussed in the program narrative previously submitted with the COPN application, the three year liver transplant volume projections of 6 in year one, 12 in year two, and 15 in year three are conservative estimates. A liver transplant program at SNGH would be expected to perform 25-30 transplants annually based on the current volumes of patients in the Tidewater area who are referred for liver transplantation.

## Section IV.A.2

**Will the liver transplant surgeon who is recruited for SNGH have any type of "success rate" clause, relating to morbidity and mortality rates, stated in his/her contract with SNGH?**

The liver transplant surgeon is being recruited by the private practice physician community. Therefore, we anticipate the employment contract will be with the physician practice and not with SNGH or Sentara.

## Section IV.A.3.p.6.

**Who are the three GI physicians "who have committed to medically manage liver transplant patients"? Please provide their curriculum vitae.**

The Curriculum Vita for each of the three GI physicians who have committed to medically manage the liver transplant patients are attached.

## Section IV.A.4.p.7.

**What is an "intensivist"?**

An intensivist is an Internal Medicine Physician who is boarded in Critical Care Medicine by the American Board of Internal Medicine or the American Board of General Surgery.

## Section IV.B.1.

**Of the 25-30 Sentara patients receiving liver transplants elsewhere on an annual basis, as identified by Sentara physicians, how many were specifically referred to MCV, to U.VA., and to other facilities in 1995?**

A July 18, 1996 letter written by Dr. Mitchell L. Shiffman to all gastroenterologists in the Tidewater Medical Community indicates 112 patients have been referred to MCV from the Tidewater area in the last three years.[1] Of these 112 patients, 35 were transplanted. Thus, according to Dr. Shiffman's data, MCV transplants 12 patients per year from the Tidewater region. Physicians have estimated an additional 5 patients are transplanted annually at UVa. There are also patients referred to centers such as Pittsburgh, but the numbers of patients referred to centers outside the State was not available from the physicians.

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[1]Dr. Shiffman is Chief of the Hepatology Section and Medical Director of the Liver Transplant Program at MCV. In his letter, Dr. Shiffman did not detail the specific geographic areas or the zip codes of the patients that he considered Tidewater area patients.

Data provided by the UNOS Research Department indicates 18 patients from the SNGH primary service area received liver transplants in 1994 and 21 patients received transplants in 1995.[2] Of these 21 patients, only 10 were transplanted in UNOS region II, which includes the Virginia Centers. Data identifying the facilities at which the transplants were performed is privileged information and is not available from UNOS.

## Section IV.B.2.

### To which liver transplant program are the majority of patients from the Hampton Roads area referred?

Based on physician feedback regarding their referral patterns, it is believed the majority of patients from the Hampton Roads area are currently referred to UNOS Region 11 transplant centers.

## Section IV.B.3.

### Are children ever candidates for liver transplants? If so, to which transplant program are they referred?

Children are candidates for liver transplants. The EVMS GI physicians who practice at the Children's Hospital of the Kings Daughters (CHKD) have indicated they currently refer their pediatric liver transplant patients to the University of Virginia (UVa). It is not known if all GI physicians refer their pediatric patients to UVa.

## Section IV.D.

### Please explain why SNGH (with kidney, heart, lung, and heart-lung transplant programs in place for some time) has waited until now to propose doing liver transplants?

The Transplant Center Leadership has evaluated the implementation of a liver transplant program since 1991. The decision was made to first implement the lung and heart/lung transplant program in 1993-94. Under the SMFP, it is suggested that organ transplant programs demonstrate at least two years successful experience with existing organ transplants.

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[2]This data was compiled from the zip codes of patients whose records were submitted to the UNOS registry. The Research Department indicated that not all patients in the registry had zip code data submitted

MCV HOSPITALS

Virginia Commonwealth University

DEPARTMENT OF SURGERY

00331

RECEIVED

SEP 20 1996

Certificate of Public Need
Regulation / VA Dept. of Health

Mr. Paul M. Boynton
Executive Director
Eastern Virginia Health System Agency
1800 Koger Executive Center, Suite 232
Norfolk, VA 23502

September 17, 1996

RE: Certificate of Public Need
Request Number VA 5969

Dear Mr. Boynton:

Out of dutiful respect to your admonition regarding debate during the course of the Public Hearing yesterday, in spite of great temptation on my part, I chose not to rise to speak at the end of the hearing, but wish to offer at this time additional comments and data germane to our opposition to the C.O.N. request for an additional Liver Transplant Program in the State of Virginia. Included also, is our "official response" to your request for clarification and additional data regarding transplant center volume and outcomes, and the numbers of out-of-state MCV liver transplant recipients.

I have been involved with Transplantation in the State of Virginia since my arrival to Richmond, as a Surgical Faculty member in the Division of Transplantation Surgery, Department of Surgery at the Medical College of Virginia in 1983. I have been an intimate witness to the history of transplantation as it has unfolded and involved the disintegration of a premier Heart Transplantation Program (1989) at the Medical College of Virginia and proliferation of Liver and Kidney Transplant Programs throughout the State over the past 13 years. I would offer you this brief historical perspective in hopes that it may further illuminate the issues.

The Medical College of Virginia Transplant Program is one of the three original Transplant Programs in the U.S. (the other two were in Denver and Boston) and was pioneered by the late Dr. David Hume, Chairman of Surgery at MCV in 1962. In the last 34 years, well over 1200 renal transplants, 350 liver transplants, 400

heart transplants and 30 simultaneous kidney-pancreas transplants have been done at MCV. The Heart Transplant Program was begun in 1968, and is the second longest continuous Heart Program in the world (Stanford is the first), pioneered by Dr. Richard Lower, who performed some of the seminal experimental work which eventuated in successful clinical human heart transplantation.

Liver transplantation actually begun at MCV in 1969 for a brief 3 year interval, but was dropped for the next twelve years until overall results improved as a consequence of the introduction of Cyclosporine immunosuppression. The modern MCV Liver Transplant Program was begun by Drs. H.M. Lee, Mendez-Picon and myself as principals in 1984. It was reorganized in 1991 with the departure of Dr. Mendez-Picon, and semi-retirement of Dr. H.M. Lee, under the direction of myself and Dr. Mitchell Shiffman. Over the next several years, we recruited an additional three experienced, well-trained liver transplant surgeons, as well as additional hepatologists. As the national stature and notoriety of our Hepatology group grew in their field, we have been able to attract large numbers of patients seeking their tertiary medical care for end-stage liver disease at MCV. This has provided us with a liver transplant waiting list of 60-75 patients at the present time, which is the single most important driving force behind our yearly liver transplant recipient volume, since there remains throughout the world, a scarcity of donor solid organs for transplantation. Obviously then, any new Liver Transplant Program in our OPO region will participate in a "common OPO waiting list" which prioritizes organ allocation according to waiting time among other things. The program with the largest waiting list, and longest waiting times will attract the most donor organs for its recipients under the current sharing arrangements mandated by UNOS. This will more seriously disadvantage a new, small program than if it were the only program in the OPO, and thus will prolong the time to which a Liver Transplant Program which is starting up will achieve reasonable transplant volume. This will be true regardless of present referral patterns. The point I am making is that Sentara may well be a bit naïve in thinking they

will build their program in only a few short years. Reflected also in Dr. Roberts' paper (Attachment II), is the current movement in UNOS, and supported by the American Society of Transplant Surgeons, to broaden organ distribution/allocation regions and to consolidate and centralize transplant centers. Addition of a new, superfluous liver transplant program to a cachement area already well served by a mature, high volume liver transplant center is thus anathema to the current trend in national healthcare planning for transplantation.

We have transplanted livers into 62 recipients in FY 95, and so far this calendar year, we have already performed 47 liver transplants. Annualized, we are predicting 70-75 liver transplants will be performed at MCV in 1996. This is a direct function of the size of our waiting list, use of "reduced size" livers, as well as our aggressive posture towards using what were once believed to be "marginal donor" livers, in an effort to expand the donor pool as well as reduce waiting list mortality. This aggressive stance toward marginal donors is likewise a function of a "mature" experienced program. We have been successful in reducing our waiting list mortality, at no increase in our "primary liver nonfunction" rate, and our survivals, as you heard yesterday, exceed the national averages for liver transplantation.

A combination of factors accounts for our current highly successful liver transplant endeavor, which as you also heard yesterday, struggled, as all start-up liver programs do, in its first few years. Our surgical and medical teams have continued to amass experience and expertise in this field as a result of continuing increasing liver transplant volumes, the teams have matured and consolidated their efforts over the past 5-6 years as they have worked together. There have been tangible, definite improvements in surgical and anesthetic technique; better, more immunespecific immunosuppressive medications; marked improvements in organ preservation; more accurate and complete preoperative patient assessment and evaluation as our understanding of end-stage liver disease has improved and expanded. We have been able to accomplish this not only as a result of our own commitment and dedication to the program, but with fundamental support from the Academic Medical Center,

MCV Hospital Administration, the Medical School and as a direct result of our overall academic mission which includes teaching and research. The Liver Transplant Program required significant financial assistance, which it generously received from MCV Hospital, in its start up phase, because, as you may know, the University Hospital Consortium benchmark "break-even" point for Liver Transplant is approximately 20/year. The Liver Transplant Program is currently fiscally responsible, even in light of our continuing commitment to provision of indigent care. MCV Hospital provides the majority of indigent patient care in the State of Virginia, and as such is willing to underwrite several indigent liver transplant slots each year. (Interestingly, MCV Hospital has even been willing to allow us to add some 30-40 indigent renal transplant recipient candidates to our renal transplant waiting list over the past several years from the Tidewater Area, who were deferred for transplant in Norfolk for financial reasons.)

Simultaneous kidney-pancreas transplant was first offered at MCV in 1994, as the results of this procedure had improved considerably and a true need was perceived to offer this therapy for Type I Diabetic ESRD patients in the Richmond-Tidewater Area (no other program existed). This program is both clinically and financially successful, even at low transplant volumes.

The proliferation of what have euphemistically been termed "boutique" transplant programs has been a national phenomenon over the past 5 years. In this vein, the situation with Heart Transplantation in Virginia offers some instruction. In 1988, Dr. Richard Lower retired from cardiac surgery and was replaced by a new Chairman of Surgery at MCV who is a Cardiac Surgeon. This rapidly resulted in the exodus of three MCV cardiac surgeons, trained by Dr. Lower in heart transplant, and the splintering of the MCV Heart Transplant Program into two additional programs: one at Henrico Doctors Hospital (Richmond) and one at Sentara Norfolk General. The only other Heart Transplant Program in Virginia in 1988 was Fairfax; UVA had not yet begun its program. MCV, prior to 1989, was the second largest Heart Transplant

Program in the country, doing about 80 heart transplants/year, and generating significant high quality clinical and basic science research in the field of heart transplantation as a direct result of the activity of its Heart Transplant Program. By the end of 1989, there were five programs in Virginia, and the number of heart transplants in the state that year dropped precipitously. In point of fact, the total number of heart transplants/year in the state of Virginia has not significantly increased (1988-1994, UNOS Data, see attachment I) in spite of the proliferation of programs. This is not surprising in light of the incredible proliferation of Heart Transplant Programs throughout the U.S. during this time interval and given the overall scarcity of donor hearts. Unfortunately, as a member of the Board of Directors of LifeNet OPO, I was forced to bear witness to two years of "heart wars" over organ distribution/allocation between the three Heart Transplant Centers in Central and Eastern Virginia, the institutional "self-serving" nature of which engendered much bad publicity for Transplantation in general. Sentara was (is) a firm believer in "local primacy" and felt that donor hearts recovered in Norfolk should be transplanted only into Norfolk residents. Fortunately, UNOS (and the OPTN, Federal Government) forced a "common list" throughout the OPO for hearts shortly thereafter, which went a long way towards equalization of access to donor hearts for the heart recipients in the LifeNet cachement area (see attachment II). This is the impetus behind Dr. Barnhart's question during his statement at the Hearing regarding the make-up of our liver list - in fact, ***85% of our liver recipients are citizens of the State of Virginia, and only 60% of the donors are Virginians,*** over the past three years.

As you can readily see from Attachment I, each of the now five Heart Transplant Centers in the State of Virginia is doing an average of 15-20 heart transplants/year - barely enough to maintain proficiency and "economies of scale", let alone any meaningful clinical research or teaching. Specifically, the numbers for three centers (Sentara Norfolk General-Kings Daughters Hospitals, Henrico Doctors Hospital, MCV-McGuire VAH), arising

out of one (MCV-McGuire), are depicted below (taken from Attachment I): (Fairfax and UVA are in different cachement areas; Fairfax is in a different UNOS region altogether and services mainly the Northern VA/D.C. area)

Numbers of Heart Transplants/Year by Center in Central/Eastern Virginia

| YEAR | 88 | 89 | 90 | 91 | 92 | 93 | 94 |
|---|---|---|---|---|---|---|---|
| Sentara NGH-KDH | 0 | 10 | 23 | 24 | 11 | 10 | 17 |
| Henrico Doctors Hospital | 0 | 1 | 10 | 11 | 17 | 12 | 9 |
| MCV McGuire VAH | 73 | 29 | 32 | 35 | 22 | 14 | 16 |
| TOTAL: | 73 | 40 | 65 | 70 | 50 | 36 | 42 |

One can reasonably ask, what have we really accomplished here? Aside from assuaging surgeon's egos and satisfying the "free market economy" principle, the total number of heart transplants has remained unchanged, almost certainly the direct and indirect costs of heart transplantation in Virginia have remained unchanged or increased substantially, and no center is doing enough transplants to support clinical and basic science research, or teaching. Unfortunately, even at this time, some six years later, the three centers are unable to collaborate in any meaningful way such that the possibility of research and teaching remains elusive. One of the only saving graces is that at least quality of outcome has been maintained, but at what overall human and financial costs? Moreover, this data strongly suggests that in light of the stable total number of heart transplants performed over the six year interval in

Virginia, the capacity in the State for Heart Transplant Programs has probably been exceeded.

The situation for Liver Transplantation over the past six years is only slightly different; the data would suggest that we have reached a point where additional facilities for Liver Transplantation are not only unnecessary, but would seriously undermine the ability of existing programs to maintain their high quality outcomes, research and teaching initiatives. Attachment III shows similar data for Liver Transplant Programs in Virginia over the past six years. There has been an increase in the numbers of liver transplants in the state with addition of programs at UVA (1988) and Fairfax (1992), however, over the past three years (including Attachment IV - Virginia Transplant Council Statistics, 1995), this number has reached a steady-state plateau, indicating the driving force is now only the numbers of available donor organs. The numbers of transplants performed by each of the three centers is high enough to support research and teaching, as well as maintain quality outcomes and contain overall costs.

Included at your request, Mr. Boynton, are data pertinent to center volume of transplants vs outcome for both hearts and livers. (See Attachments V (p. 876, Table 85-11), VI, VII, VII, IX). These data suggest a modest, but real and statistically significant (UNOS data, Hunsicker 2 papers) improvement in survival associated with midrange center volume, which then tapers off as programs grow too large and inefficient.

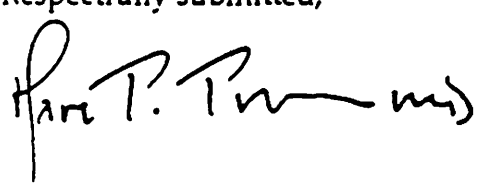
Finally, as Program Director of an Academic Medical Center Transplant Program, in addition to all of our other opposing arguments to granting a C.O.N. which would establish another Liver Transplant Program in Virginia, I would like to make a strong plea in the service of ongoing research and healthcare professional training, both of which are intimately related to center volume of transplant activity. Because of the number of patients to whom we are able to offer liver transplantation each year, we have been able to conduct clinical trials looking at new immunosuppressive modalities, antimicrobial prophylactic

regimens, methods of liver allograft preservation, antiviral protocols for treatment of post-transplant viral infections (e.g. Hepatitis B), utility of liver cell transplantation as a bridge to whole organ replacement in patients with acute, fulminant liver failure who otherwise would have died, etc. (see Attachment X - MCV Transplant Program Bibliography), all of which has, and continues to contribute clinically to our knowledge and practice in the field of liver transplantation in an exceptionally meaningful way. Furthermore, it is as a direct consequence of our volume of liver transplants that we are able to provide quality professional education and training experience to our medical students, housestaff, fellows, attending physician colleagues, etc. relevant to the field of liver transplantation. There is no question that an additional (private sector, especially) liver transplant program in Virginia will do nothing but seriously erode our ability to satisfy our Academic Mission, and in my opinion, if only for this reason alone, would be ethically unconscionable. In our present 1996 milieu of the healthcare market economy in this country, our ability to continue academic pursuits in consort with provision of clinical care is already seriously threatened. Thus, it is that much more critical that we have the continued support of the Virginia State Health Planning System if we are to be enabled to take the Academic Transplant Center into the next millennium.

9.

Thank you very much for this opportunity to provide you with this additional data, as well as my thoughts and opinions, in the course of our strong opposition to the request by Sentara to be granted a C.O.N. for a new Liver Transplant Program in Virginia.

Respectfully submitted,



Marc P. Posner, M.D., F.A.C.S.
Professor and Chairman,
Division of Transplantation Surgery
Director, Medical College of Virginia
Transplant Program

cc: Mr. Paul Parker
Director
Division of Certification of Public Need
Health Facilities Regulation
3600 W. Broad St., #216
Richmond, VA 23230

Mr. Samuel Clement
Project Analyst
Division of Certification of Public Need
Commonwealth of Virginia Department of Public Health
P.O. Box 2448
Richmond, VA 23218

## Table 68
## Transplants by State and Transplant Center -- 1988 to 1994

00340

### Heart Transplants

| State | Transplant Center | 1988 | 1989 | 1990 | 1991 | 1992 | 1993 | 1994 |
|---|---|---|---|---|---|---|---|---|
| Utah | Latter-Day Saints Hospital - Salt Lake City | 21 | 24 | 24 | 22 | 19 | 12 | 11 |
| | Primary Childrens Medical Ctr - Salt Lake City | 0 | 0 | 0 | 1 | 7 | 7 | 9 |
| | University of Utah Hosp - Salt Lake City | 31 | 31 | 35 | 19 | 15 | 11 | 15 |
| | VA Medical Center - Salt Lake City | 19 | 24 | 18 | 20 | 19 | 16 | 4 |
| | Total | 71 | 79 | 77 | 62 | 60 | 46 | 39 |
| Virginia | Childrens Hosp Kings Daughter - Norfolk * | 0 | 0 | 7 | 3 | 3 | 1 | 3 |
| | Fairfax Hosp - Falls Church | 9 | 11 | 12 | 10 | 12 | 19 | 22 |
| | Henrico Doctors Hospital - Richmond | 0 | 1 | 10 | 11 | 17 | 12 | 9 |
| MCV | McGuire VA Medical Center - Richmond | 27 | 11 | 12 | 10 | 7 | 6 | 12 |
| | Medical College of Virginia - Richmond | 46 | 18 | 20 | 25 | 15 | 8 | 4 |
| | Sentara Norfolk General - Norfolk * | 0 | 10 | 16 | 21 | 8 | 9 | 14 |
| | Univ of Va Hosp & Childrens Rehab - Charlottesville | 0 | 3 | 20 | 25 | 25 | 22 | 27 |
| | Total | 82 | 54 | 97 | 105 | 87 | 77 | 91 |
| Washington | Childrens Hospital & Med Ctr - Seattle | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | Sacred Heart Medical Center - Spokane | 0 | 0 | 18 | 15 | 9 | 13 | 16 |
| | University Hospital - Seattle | 17 | 13 | 20 | 24 | 21 | 19 | 14 |
| | Total | 17 | 13 | 38 | 39 | 30 | 32 | 31 |
| Wisconsin | Childrens Hosp of Wisconsin - Milwaukee | 0 | 0 | 0 | 1 | 0 | 1 | 1 |
| | John L. Doyne Hospital - Milwaukee | 6 | 8 | 11 | 9 | 4 | 2 | 5 |
| | St Luke's Medical Center - Milwaukee | 22 | 22 | 29 | 27 | 27 | 28 | 24 |
| | University of Wisconsin Hosp - Madison | 13 | 15 | 9 | 16 | 19 | 42 | 57 |
| | Total | 41 | 45 | 49 | 53 | 50 | 73 | 87 |

* SENTARA HEART PROGRAM

Source: UNOS Scientific Registry data as of October 7, 1995.

10

FROM: LIVER TRANSPLANTATION, KLINTMALM + SOLLINGER, EDS. PHYSICIANS & SCIENTISTS PUBLISHING CO. INC. GLENVIEW, ILLINOIS, 1996

# Prioritization and Distribution of Organs for Liver Transplantation

*John P. Roberts*

## Introduction

Liver transplantation has always been governed by the availability of donor organs. Lack of a legal definition of brain death hindered early efforts to obtain organs for transplantation. Donation was deferred until cardiac function ceased. The donors were observed (sometimes for days) until their hearts stopped. The femoral vessels were quickly cannulated and extracorporeal perfusion was instituted. Following perfusion the organs were removed for transplantation. The time interval between donor death and reperfusion of the organs was generally two to three hours, ensuring that the donor organs could only be recovered in the transplant center or a center nearby. Because of the small number of patients in whom transplantation was considered, there was little need to decide between waiting recipients.

Today, with a firm definition of brain death, a person who is brain dead can be recognized quickly as a potential donor. A call goes to a specialized organization which sends a coordinator to the donor hospital to obtain consent from the family and manage the donor until organ recovery. A series of phone calls is made to those transplant centers with patients who are waiting for transplants and a potential recipient is found. After allocation of the organs, the donor is taken to the operating room. Dissection of the major vessels and the liver is performed. The liver is perfused with a preservation

solution that allows successful preservation for up to 24 hours. Afte removal, the liver may be flown across the country for implantatior in a patient thousands of miles away.

These radical changes required changes in both the legal and medical system. Probably the most profound change had to do with the passage by states of brain death laws in the 1970s and the adoption of the 1978 Uniform Determination of Death Act. These allowed the identification of individuals who were brain dead but whose hearts remained beating. The use of brain dead donors with beating hearts permitted the optimal preservation of the organs. The Uniform Anatomical Gift Act in 1968 allowed for the next of kin to donate the decedent's organs and provided the legal mechanisms for the donation processes to occur.

In 1984 The National Organ Transplant Act created a national organ sharing system that was to be managed by the National Organ Procurement and Transplantation Network (OPTN). The network consisted of organ procurement organizations (OPOs) and transplant centers. The OPOs were responsible for procuring and distributing the organs to the transplant centers. The OPTN awards a contract to an organization that will administer the network. This contract was subsequently awarded to the United Network for Organ Sharing (UNOS). Subsequent legislation has required that all OPOs be federally certified and have a service area that is of sufficient size to assure maximum effectiveness and efficiency.

This legislation has led to the improvement in the process of organ procurement and distribution. Despite these improvements, serious organ shortages persist and have led to painful discussions about how these organs should best be distributed among those who are waiting.

## The Current System

Two elements determine the allocation of livers for transplantation. The first is the system of prioritization, currently comprised of two factors: the length of time a patient has been waiting and the degree of illness. The prioritization system determines to which patient,

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## Table 66
## Transplants by State and Transplant Center -- 1988 to 1994

### Liver Transplants

| State | Transplant Center | 1988 | 1989 | 1990 | 1991 | 1992 | 1993 | 1994 |
|---|---|---|---|---|---|---|---|---|
| Utah | Latter-Day Saints Hospital - Salt Lake City | 12 | 18 | 16 | 21 | 16 | 19 | 29 |
| | Total | 12 | 18 | 16 | 21 | 16 | 19 | 29 |
| Virginia | Fairfax Hosp - Falls Church | 0 | 0 | 0 | 0 | 4 | 14 | 18 |
| | Henrico Doctors Hospital - Richmond | 0 | 0 | 0 | 5 | 0 | 0 | 0 |
| | Medical College of Virginia - Richmond | 21 | 18 | 16 | 27 | 31 | 37 | 33 |
| | Univ of Va Hosp & Childrens Rehab - Charlottesville | 1 | 17 | 54 | 51 | 36 | 66 | 62 |
| | Total | 22 | 35 | 70 | 83 | 71 | 117 | 113 |
| Washington | Childrens Hospital & Med Ctr - Seattle | 0 | 0 | 1 | 5 | 5 | 11 | 4 |
| | University Hospital - Seattle | 0 | 0 | 29 | 50 | 43 | 52 | 56 |
| | Total | 0 | 0 | 30 | 55 | 48 | 63 | 60 |
| Wisconsin | Childrens Hosp of Wisconsin - Milwaukee | 1 | 2 | 6 | 8 | 3 | 5 | 5 |
| | Froedtert Memorial Lutheran - Milwaukee | 15 | 10 | 28 | 18 | 29 | 24 | 18 |
| | University of Wisconsin Hosp - Madison | 58 | 71 | 84 | 68 | 58 | 71 | 60 |
| | Total | 74 | 83 | 118 | 94 | 90 | 100 | 83 |

Source: UNOS Scientific Registry data as of October 7, 1995.

ATTACHMENT v

85

00353

# Effect of Liver Transplantation on Local, Regional, and National Health Care

Roger W. Evans, PhD

Liver transplantation is an expensive surgical procedure, and as such, it raises a variety of complex social, economic, legal, ethical, and health policy questions.[1-3] For example, transplantation has been criticized as too costly relative to other health-care needs, and, in an era of international health-care reform, disease prevention and health promotion are intuitively appealing.[4-7] Not surprisingly, fiscal restraint has prompted many critics to complain that organ transplantation underscores what is wrong rather than what is right with health care today.

It is unlikely that the criticism will end soon. Highly visible expensive procedures from which few people benefit will face a serious challenge in the months and years ahead. However, instead of looking inward to find a defense, the transplant community must adopt an external proactive response, forcing public health officials to balance their concerns about transplantation with broader health-care policy initiatives. For example, although prevention is an important consideration, it clearly adds to rather than decreases health-care expenditures.[8,9] It is inappropriate to promote health-care prevention on grounds that it will decrease expenditures. Instead, as argued by Russell, cost-effectiveness analyses of prevention provide little evidence of savings.[8,9] Cost-effectiveness studies, which estimate the net costs and net benefits of interventions, show that preventive care usually increases medical expenditures. Furthermore, there are many medical and surgical procedures with long-term economic implications that rival those of transplantation and with net benefits that are substantially less. Thus, as a symbol, a dollar sign can be deceiving.

Against this backdrop, we need to cultivate an understanding of the local, regional, and national implications of liver transplantation. By joining two paradigms—one concerning the cost of illness and the other, technology assessment—we can begin to anticipate the way in which the international health-care debate will take shape.[10-16] This debate will surely focus on the role of technology and the practice of medicine in an increasingly constrained health-care environment. To the chagrin of many physicians and surgeons, the most significant health policy issues we now face are nonclinical. These issues will be raised by local, regional, and national regulatory authorities who intend to challenge technology and dictate clinical practice. Accountability will be a primary consideration because clinical freedom has assumed a price society is neither willing to pay nor able to afford.[17]

Both administrators and health services researchers will play a critical role in shaping the future of health care. Inept surgeons who have been inclined to shoot from the hip, present anecdote as science, and ignorantly dabble in politics will have no valuable contribution to make. The system they have created to serve their own interests will now reject them acutely. Thus, in many respects, the future of transplantation may be as grim as it once was bright.

## COST OF ILLNESS

Liver transplantation raises difficult questions as to the value of a human life.[18-24] Valuing a life remains an onerous task because we often relate the cost of health care to an episode of illness rather than analyzing expenditures longitudinally. For example, a liver transplant, from the date of surgery to the date of hospital discharge, now costs approximately $195,220 (Table 85-1). Meanwhile, lifetime medical costs average approximately $225,000 per person.[25] Comparing these figures, we get a sense of the disproportionate share of total resources expended to effect a liver transplant, the recipient of which goes on to incur additional costs of nearly $18,000 annually each year after transplantation. In effect, the liver transplant recipient consumes more health-care resources in 1 year than the average person consumes in a lifetime. Moreover, the life expectancy of the liver transplant recipient is much shorter, the longest survivor having lived 23 years after



FROM: TRANSPLANTATION OF THE LIVER
BUTTH KLINTMALM EDS. W.B. SAUNDERS Co. Philadelphia 1991

TABLE 85-8 Total inpatient hospital charge by diagnosis-related group for Olmsted County residents, 1991

| DRG | Description | No. of Patients | Total Charges, $ | Length of Stay, days |
|---|---|---|---|---|
| 373 | Vaginal delivery without complicating diagnoses | 1296 | 2,207,044 | 2.5 |
| 112 | Percutaneous cardiovascular procedures | 185 | 2,066,129 | 5.4 |
| 106 | Coronary artery bypass with cardiac catheterization | 59 | 2,027,126 | 14.5 |
| 209 | Major joint and limb reattachment procedures | 141 | 1,936,071 | 10.6 |
| 462 | Rehabilitation | 87 | 1,729,850 | 35.0 |
| 148 | Major small- and large-bowel procedures with complicating conditions | 96 | 1,656,897 | 15.4 |
| 430 | Psychoses | 187 | 1,640,935 | 17.0 |
| 483 | Tracheostomy except for mouth larynx or pharynx disorder | 12 | 1,209,399 | 59.4 |
| 89 | Simple pneumonia and pleurisy at age greater than 17 years with coronary care | 216 | 1,067,670 | 5.9 |
| 127 | Heart failure and shock | 210 | 1,038,448 | 6.0 |

DRG = diagnosis-related group.

broader sense, it is a process of policy research that examines the short- and long-term consequences of individual medical technologies and thereby becomes the source of information needed by policymakers in formulating regulations and legislation, by industry in developing products, by health professionals in treating and serving patients, and by consumers in making personal health decisions. The results of any technology assessment may have differing implications for the patient, the institution, third-party payers, physicians, administrators, health-care professionals, and society. The scope of a comprehensive technology assessment should include many of the following issues: need, demand, supply, benefit, outcomes, cost-effectiveness, appropriateness, social considerations, ethical implications, and legal ramifications.

Elsewhere I have provided detailed analyses of various aspects of a technology assessment of liver transplantation.[1] I elaborate on some of these here because of their implications for policymakers. In particular, I want to address the matter of cost-effectiveness because this issue will continue to fuel much of the debate as to the relative priority of liver transplantation given other health-care needs. This task will spark controversy because it forces us to come to grips with economics-based moral and ethical dilemmas that few people have been willing to confront objectively. There are, after all, more dubious ways to spend the health-care dollar than on transplantation. Furthermore, as noted previously, despite its attraction, health promotion and disease prevention may also have a cost for which society is neither willing nor able to pay. A few examples will provide a little health policy "food" for thought.

Liver transplantation is an expensive surgical procedure, the beneficiaries of which will continue to incur substantial posttransplantation expenses (see Table 85-9). Liver transplantation is not a cure, and, in the words of Lewis Thomas, it is little more than a "halfway technology."[49] As such, liver transplantation presents some interesting technology assessment challenges; it has diffused rapidly in the hands of many surgeons whose credentials are often questioned. In 1981, 26 liver transplantations were performed at one program. In 1992, more than 3000 liver transplantations were performed at 105 programs. As shown in Table 85-10, patient outcomes were highly variable in 1988, although a detailed analysis indicated that there was but a modest association among liver transplant volume, outcomes, and charges (Table 85-11).[50, 51] Nonetheless, these data and others like them have led to spirited debate as to the selection of transplant patients and the designation of qualified transplant programs.

In the United States, many third-party payers, transplant surgeons, and transplant physicians have speculated as to how inept patient selection in the hands of unqualified surgeons has diminished the relative cost-effectiveness of liver transplantation. Although the rhetoric is more profound than the data, there is reason to be concerned

TABLE 85-9 Summary of liver transplantation procedure charges, 1993

| Element of Cost | Minimum, $ | 25th Percentile, $ | 50th Percentile, $ (Median) | 75th Percentile, $ | Maximum, $ |
|---|---|---|---|---|---|
| Hospital charges | 26,911 | 90,316 | 139,322 | 254,504 | 1,803,068 |
| Minor organ acquisition charges | 6,394 | 17,150 | 21,800 | 28,783 | 87,908 |
| Surgeon fees | 9,373 | 20,085 | 20,085 | 25,876 | 102,569 |
| Other professional fees | 208 | 7,532 | 13,987 | 26,345 | 179,042 |

TABLE 85-10 Distribution of liver transplant centers according to actual one-year patient survival rates, 1988

| Survival Rate, % | Transplant Centers | |
|---|---|---|
| | Number | % |
| .000-.500 | 19 | 35.8 |
| .501-.600 | 4 | 7.5 |
| .601-.650 | 7 | 13.2 |
| .651-.700 | 5 | 9.4 |
| .701-.750 | 6 | 11.3 |
| .751-.800 | 3 | 5.7 |
| .801-.850 | 2 | 3.8 |
| .851-.900 | 2 | 3.8 |
| .901-.950 | 2 | 3.8 |
| .951-1.000 | 3 | 5.7 |

From Evans RW, Manninen DL, Dong FB. The National Cooperative Transplantation Study: Final Report. Seattle, WA, Battelle Seattle Research Center, 1991.

TABLE 85-12 Liver transplantation procedure charges based on status before surgery

| Status Before Transplantation | Total Charges, $ | LOS, days | One-Year Survival, % |
|---|---|---|---|
| On life support | | | 36.4 |
| | 211,711* | 50* | |
| Intensive care | | | 64.3 |
| Hospitalized | 154,077 | 42 | 69.6 |
| Homebound | | | 73.9 |
| | 114,797† | 25† | |
| Not hospitalized or homebound | | | 82.9 |
| Overall | 145,795 | 33 | 63.8 |

*Combined figure for on life support and intensive care statuses. Financial data were obtained for too few cases to permit a detailed breakdown based on all categories of status before transplantation.
†Combined figure for homebound and not hospitalized or homebound statuses. Financial data were obtained for too few cases to permit a detailed breakdown based on all categories of status before transplantation.
From Evans RW, Manninen DL, Doug FB. The National Cooperative Transplantation Study: Final Report. Seattle, WA, Battelle Seattle Research Center, 1991.

even about the "expert" opinion that endorses the concept that only the sickest of patients should receive liver transplants.[52] As the proponents argue, these patients may derive the greatest short-term benefit; however, they do so at tremendous expense. As shown in Table 85-12, when all ndidates are considered, the sickest patients actually .ve the poorest 1-year survival rate and incur the highest transplant procedure charges.[1] Clearly, there is a continuum of care, and the objective is to identify that point in the disease trajectory that offers the patients with end-stage liver disease the opportunity to benefit both optimally and cost-effectively.[53-61] The cost of salvaging the patient who is near dead cannot justify the surgical challenge or mask the intent to allocate donor livers disproportionately to high-volume transplant centers that have become increasingly cost-ineffective as a result of policies that favor the listing of patients who are too sick to benefit from liver transplantation. Likewise, those programs that perform transplantation in patients who are relatively healthy and can benefit from alternative forms of therapy cost-effectively should not be accorded priority over patients for whom other treatment options have been exhausted. Clearly, a balance must be struck, and research into the optimal timing of transplantation will better define at which point the cost utility of liver transplantation is most favorable.

TABLE 85-11 Liver transplant program volume, outcome, and charge relationship, 1988

| Transplant Volume | One-Year Patient Survival | Average Procedure Charges |
|---|---|---|
| <25 procedures | 59.0 | — |
| 25-70 procedures | 67.2 | — |
| >70 procedures | 64.3 | — |
| <30 procedures | — | $138,452 |
| 30-70 procedures | — | 150,447 |
| >70 procedures | — | 154,632 |

ta modified from Evans RW, Manninen DL, Doug FB. The National Cooperative Transplantation Study: Final Report. Seattle, WA, Battelle Seattle Research Center, 1991; Evans RW. Executive Summary: The National Cooperative Transplantation Study (report BHARC-100-91-020). Seattle, WA, Battelle Seattle Research Center, 1991.

Unfortunately, amidst the debate as to patient selection, the liver transplant community has become self-serving, often placing institutional needs ahead of those of the patients they serve. From the perspective of technology assessment, the results will be disastrous. Rather than looking for methods by which to improve the overall cost-effectiveness of liver transplantation, some spokespersons have taken it on themselves to destroy that which so many other people have labored so hard to achieve. In some cases, the volume of patients required to fuel individual surgical egos will eventually ensure the demise of transplantation. Health-care policymakers are neither in the position nor of the mindset to listen to those persons whose narrow views reflect an incomplete appreciation of the broader health-care issues that policymakers confront daily.

Competing demands for increasingly scarce resources is a problem the international community faces. Deciding which demands are deserving of attention is not easy. It is clear, however, that the medical profession is considered to be too narrowly focused on fragmented objectives that serve no useful societal purpose. Rather than presenting themselves as adversaries, members of the medical profession, of which the transplant community has been a vocal

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ɪ, must come to grips with the economic mandate to ich they are being asked to respond. Armed with data, her ' 'n rhetoric, transplant professionals must en- ivo inform the debate that now engulfs them. The itical favor the transplant community has enjoyed hin the United States is about to vanish as a result of sguided efforts that will yield no measurable public ılth gain. In this regard, various aspects of our practices ɪ the research we pursue should be carefully targeted to ectives with long-term benefits. These must recognize . economic reality within which medicine is now prac- ɜd. The frivolous luxuries of yesterday can no longer be tified today. The issues we chose to ignore in decades ɪt are foremost today.

Although there is reason to be concerned, there is little ɪis for despair. There are many public health issues, luding the acquired immunodeficiency syndrome :DS) epidemic, that will challenge our humanity as we pple with the value of a human life. For example, in ɔ2, the United States spent more than five times as ıch money in treating AIDS and human immunodefi- ncy virus than did on all transplant procedures.[62-65] As ɔwn in Table 85-13, expenditures for AIDS continue to rease, with few measurable benefits. Currently, we :nd about $102,000 on each person with AIDS, who, in n, lives approximately 460 days. The survival data for nsplantation are far more impressive but, because of ɪg-term survival, the aggregate expenditures for trans- ntation will continue to increase (see Table 85-14). In ociety in which the kiss of death now seems to have ɪre ' 'e than the gift of life, it is difficult to say what lies :ac ı respect to health-care reform.[66]

## ɪCUSSION

a paradigm for change, technology assessment has ıch to offer. We can, indeed, make the services we pro- e more cost-effective if we choose to accept the fact that surgical challenge must be tempered by economic ıstraint. The days of the traveling medicine show are w over, and we have entered an era wherein we must ısider both clinical benefits and economic costs when make decisions related to the relative worth and utility health-care technology. Regardless of how it is prac- ɜd, medicine will become more regulated by local, re- nal, and national authorities. While national policy- kers endeavor to decide the constraints within which

ɜLE 85-13 Expenditures for the treatment of HIV and AIDS

| ɜcription | Amount |
|---|---|
| ıual expenditures per person with HIV | $ 10,000 |
| ıual expenditures per person with AIDS | $ 38,300 |
| time costs per person with AIDS | $102,000 |
| ɜl expenditures for AIDS | |
| ɔ92 | $10.3 billion |
| ɔ9ɜ | $15.2 billion |

= human immunodeficiency virus. AIDS = acquired immunodeficiency ɜome. Data modified from references 62-65.

TABLE 85-14 Persons with AIDS and transplant recipient survival rates

| Condition/Treatment | One Year, % | Three Year, % |
|---|---|---|
| AIDS | 56 | 17 |
| Kidney tranplant | 95 | 91 |
| Heart transplant | 82 | 75 |
| Liver transplant | 75 | 67 |

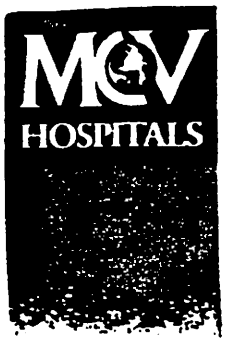
AIDS = acquired immunodeficiency syndrome.

we will practice, regional and local authorities address issues related to the delivery of specialty services. In some countries liver transplantation programs have been heavily regulated, whereas in others, including the United States, a laissez-faire approach has manifested itself in gross competition.[67-69] On the one hand, this may have undermined the true cost-effectiveness of the procedures we provide, but, on the other hand, one must have serious reservations as to the cost efficiency of transplant programs that have been granted monopoly status. Regulation also has a price, and any effort to limit the providers of specialized services should incorporate performance criteria based on carefully conducted technology assessments.

As these remarks imply, there is clearly a need for national guidelines in all areas of transplantation. We should begin with explicit criteria for transplant centers, the selection of transplant recipients, and the procurement of donor organs. Outcome data should be reported in a uniform manner, with appropriate adjustments for patient case mix.[70, 71] However, with explicit patient selection guidelines, case mix will become a less significant consideration and, most importantly, cannot be used to justify inefficient high-volume transplant centers in which the number of procedures performed annually is confused with both efficiency and proficiency. In an effort to address various issues related to the total costs of illness, including the social costs identified previously, it is time to give concerted attention to the geographic regionalization of transplant centers.[69] Regionalization would not be an adequate basis of monopolies. Instead, each transplant program would be required to meet stringent performance criteria. Furthermore, given the scarcity of donor organs, all transplant programs would be carefully monitored on the basis of cost and outcome data. Physician and surgeon involvement in this activity would be minimal, with much work being shifted to administrators and health services researchers who are appropriately qualified and more able to evaluate the performance of the health-care system.

Finally, embedded in this discussion is a generalized concern with continuous improvement as an underlying operational orientation for health-care reform.[72-77] However, I begin with the assumption that excellence is not good enough and mediocrity is intolerable. Medicine can no longer exempt itself from the practices that have been central to industry. The struggle to improve is consistent with the technology assessment paradigm. We must develop, implement, and evaluate methods by which medi-

12.



Virginia Commonwealth University

HOSPITAL ADMINISTRATION
401 North 12th Street
P O Box 980510
Richmond, Virginia 23298-0510

804 786-4682
FAX 804 371-0170
TDD 1 800 828-1120

October 16, 1996

00410
RECEIVED
OCT 17 1996
Office of Health Facilities
Regulation / VA Dept. of Health

Mr. Samuel Clement
Division of COPN
3600 West Broad Street
Suite 216
Richmond, VA 23230

Dear Sam:

As we discussed, I am enclosing a copy of a report generated by LIFENET, the local organ procurement agency for the Richmond and Tidewater region. This report compares the number and types of organs procured during 1995 and the projected 1996 volumes.

I believe this report serves to support our contention that the number of livers donated in our procurement region is inadequate to support the existing capacity of the region to perform liver transplantations. So far in 1996, MCV has performed 51 liver transplants. We expect to perform more than 75 by the end of the year. The projected recovery of livers in our procurement region for 1996 is approximately 46. If the number of projected liver procurements is accurate, we will be forced to import almost half of the livers we use in our program.

The initiation of a new liver transplant service will further dilute the ability of LIFENET to meet the organ donation needs our region. It will force MCV to import an even greater number of organs from outside our region. Costs will rise and clinical outcomes will be jeopardized.

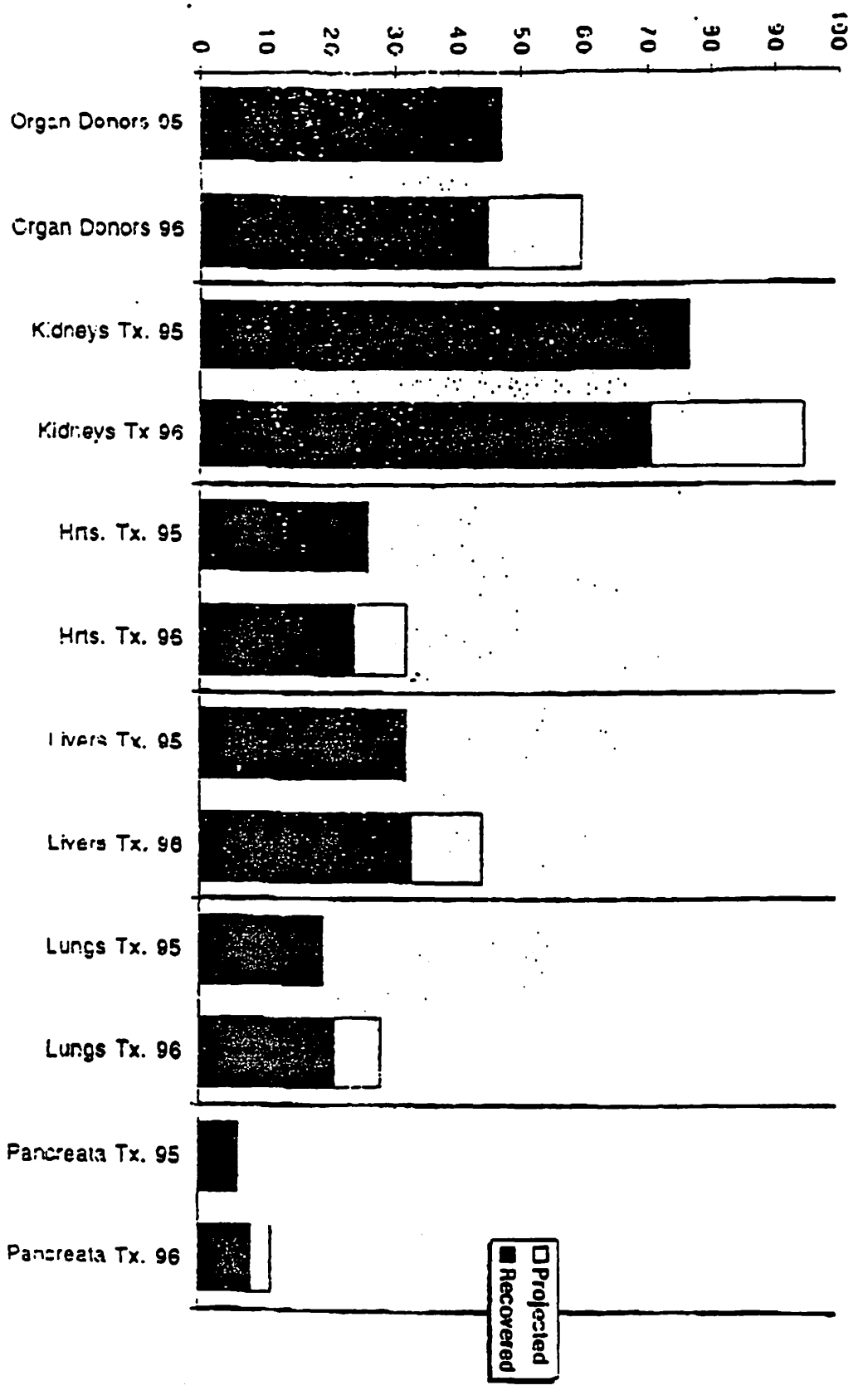
I hope this information assists you in evaluating the Sentara COPN. Please contact me if you are in need of additional information.

Sincerely yours,

Brian E. Letourneau
Service Line Administrator

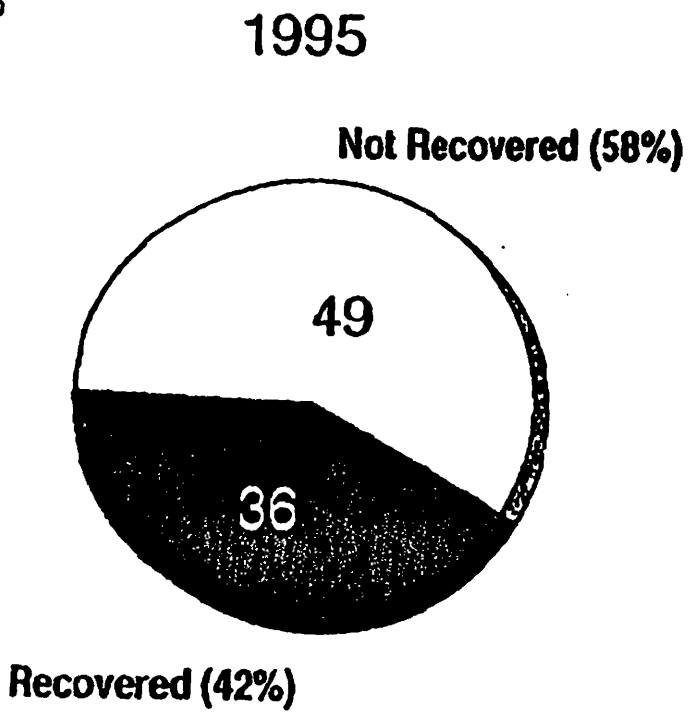
cc: Robert Fisher, M.D.
Scott Eldredge

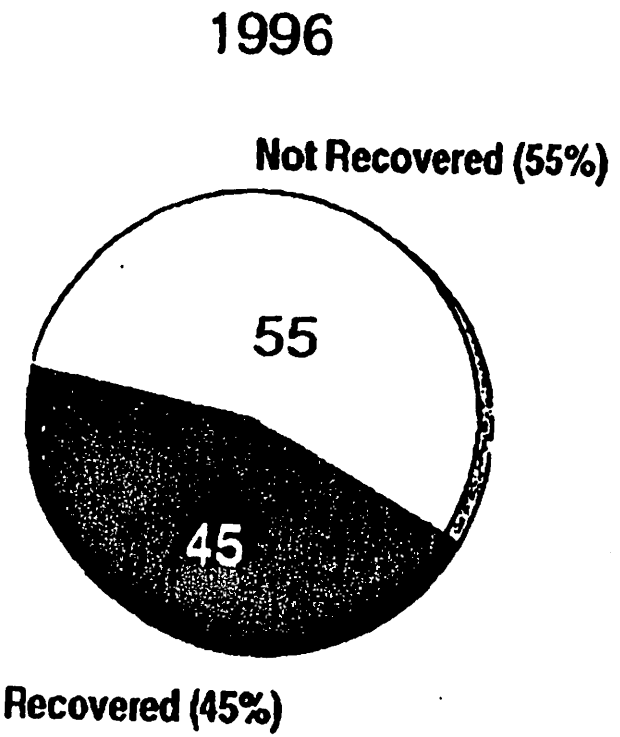
00411


Total Number of Transplants 1995 vs 1996 Projected
100
90
80
70
60
50
40
30
20
10
0
Organ Donors 95
Organ Donors 96
Kidneys Tx. 95
Kidneys Tx 96
Hrts. Tx. 95
Hrts. Tx. 96
Livers Tx. 95
Livers Tx. 96
Lungs Tx. 95
Lungs Tx. 96
Pancreata Tx. 95
Pancreata Tx. 96
Projected
Recovered

# Suitable Organ Donors
(January-September)

00412



EASTERN VIRGINIA HEALTH SYSTEMS AGENCY, INC.
18 KOGER EXECUTIVE CENTER / SUITE 232
NORFOLK, VIRGINIA 23502
Area Code (804) 461-4834

ANDREW B. DAMIANI
President

PAUL M. BOYNTON
Executive Director

14.

00416

November 13, 1996

Paul E. Parker, Director
Division of COPN
Virginia Department of Health
3600 W. Broad St., Suite 216
Richmond, VA 23230

RECEIVED
NOV 14 1996
Office of Health Facilities
Regulation / VA Dept. of Health

RE: COPN REQUEST NO. VA-5969
SENTARA NORFOLK GENERAL HOSPITAL
NORFOLK, VIRGINIA
ESTABLISH LIVER TRANSPLANT SERVICE

Dear Mr. Parker:

Please be advised that our Board of Directors voted yesterday 6-3 to recommend approval of the project referenced above. The reasons for the vote were that the project would improve the availability and geographical accessibility to liver transplant services for P.D. 20 residents and that having a liver transplant service would round out the complement of transplant services that are presently provided at Sentara Norfolk General Hospital.

Should you have any questions about the Board's recommendation or about out staff report, which was previously transmitted to you, please let me know.

Sincerely,

Paul M. Boynton
Executive Director

cc: Laura G. Aaron, Esquire
Edward L. Berdick
Sandra J. Miller
Wendy V. Brown
Samuel A. Clement
Andrew B. Damiani

EASTERN VIRGINIA HEALTH SYSTEMS AGENCY, INC.
18 KOGER EXECUTIVE CENTER / SUITE 232
NORFOLK, VIRGINIA 23502
Area Code (804) 461-4834

ANDREW B. DAMIANI
President

PAUL M. BOYNTON
Executive Director

00417

November 1, 1996

Mr. Edward L. Berdick
Chief Operating Officer
Sentara Southside Hospitals
Sentara Norfolk General Hospital
600 Gresham Drive
Norfolk, Virginia 23507

RE: COPN REQUEST NO. VA-5969
SENTARA NORFOLK GENERAL HOSPITAL
NORFOLK VIRGINIA
ESTABLISH LIVER TRANSPLANT SERVICE

Dear Ed:

Enclosed please find our staff report, and the minutes of the public hearing, for the project referenced above. As you know, our Board of Directors will consider this request when it meets at 1:30 p.m. on November 12, 1996 in Conference Room A at Norfolk International Airport.

Since EVHSA staff are recommending denial of this project, you and/or other representatives of the project will be allowed a total of 20 minutes to make a presentation on it, after which the EVHSA staff will have 20 minutes to make a presentation on the staff's report. After both presentations, the Board members may ask questions of the applicant and staff before taking action on the project.

Should you have any questions about the Board meeting procedures, or about the staff report, please let me know.

Sincerely,

Paul M. Boynton
Executive Director

cc: Laura G. Aaron, Esquire
Sandra J. Miller
Paul E. Parker
Wendy V. Brown
Samuel A. Clement

Enclosures

EASTERN VIRGINIA HEALTH SYSTEMS AGENCY, INC.
18 THE KOGER CENTER, SUITE 232
NORFOLK, VIRGINIA 23502

TYPE OF REQUEST: Standard 120 Day Review in P.D. 20

COPN REQUEST NUMBER: VA-5969

PROJECT APPLICANT: Sentara Norfolk General Hospital
600 Gresham Drive
Norfolk, Virginia 23507

PROJECT DESCRIPTION: Establish Liver Transplantation Service

PROJECT COSTS: Capital -- $61,900 Financing -- $0 (Reserves)

## I. PROJECT SUMMARY AND RELATED INFORMATION

Sentara Norfolk General Hospital (SNGH) seeks COPN approval to establish a liver transplantation service at its Transplant Center. Kidney, heart, lung, and heart/lung transplants are presently performed at that center, and the liver transplant program would use existing operating rooms and recovery facilities located at SNGH. Specifically, SNGH has 27 licensed ORs, and 2 of those that are presently used for vascular surgeries and kidney transplants would also be used for liver transplants. SNGH has also projected a volume of 6 liver transplants in the first operational year, 12 in the second year, and 15 in the third year.

Following the transplant surgery, patients will initially go to SNGH's 8-bed Vascular ICU and, as their condition improves, they will be moved from there to an 8-bed Vascular Stepdown Unit. Pre and post liver transplant patients will be evaluated and/or treated in SNGH's Outpatient Transplant Center. Also, 5 additional ORs at SNGH are used for heart, lung, and heart/lung transplants as well as for cardiac bypass surgeries.

SNGH indicates that, once an experienced liver transplant surgeon is relocated to the Norfolk area, SNGH can accept its first liver transplant patient 30 days from the date a COPN for the project is approved. Physician related costs are not a matter of public record and are not part of the annual operating costs that are provided in the financial projections included in COPN applications. However, even without the physician costs, the annual operating costs for the new transplant service are projected to be about $1.2 million in Year I and $1.94 million in Year II. The transplant surgeon would be employed by a physicians group and not by SNGH.

In its Completeness Question responses, SNGH indicates that, while it is projected that only 6, 12, and 15 transplants would be done in the first three years of operation respectively, "SNGH would be expected to perform 25-30 annually based on the current volumes of patients in the Tidewater area who are referred for liver transplantation." While a patient may be referred and evaluated for a possible transplant, it should be understood that the patient may not receive a transplant because of lack of availability of livers or lack of need or suitability for a transplant. Indeed, SNGH projects that in Years I-II the number of patients evaluated will be 16 times the number of transplants performed.

Information provided by the University of Virginia for Calendar Year 1996 shows that its program did 29 transplants (as of 9/30/96) of which 5 (17.2%) were from HSA V, and information provided by the Medical College of Virginia indicates it did 51 transplants in 1996 (as of 10/22/96) of which 18 (35%) were from HSA V. Thus, in 1996 a total of 23 HSA V patients had liver transplants at MCV and UVA combined. In that regard, there are 3 liver transplant centers in Virginia (UVA, MCV, and Fairfax Hospital), and in 1995 11 HSA V patients received transplants in other states according to the United Network for Organ Sharing (UNOS). The 23 transplants done so far at UVA/MCV combined in 1996 would almost equal the 25-30 SNGH thinks it might do eventually. Indeed, for SNGH to have reached a volume of 25-30 transplants in 1996, SNGH would have had to capture all of the UVA/MCV patients from HSA V and/or made up the difference by capturing some of the HSA V patients who received transplants outside of Virginia. Of the 23 HSA V transplants done at MCV/UVA, 14 or 60.9% came from P.D. 20 (SNGH's primary service area) which is slightly below P.D. 20's 64.5% portion of HSA V's population.

The application indicates that 25.0 FTEs are presently associated with SNGH's Transplant Center (not including physicians) of whom 5 or 20% are administrative staff, 8 or 32% are RNs, and another 8 or 32% are laboratory medical technologists. The liver transplant service is projected to require an additional 2.5 FTEs including 1.0 FTE RN, 1.0 FTE CVS (cardiovascular services) technician, and a 0.5 medical social worker. Notably, for Year II SNGH has projected that salaries and benefits for the 2.5 FTEs will amount to only $80,331 or 4.1% of total expenses projected ($1,941,185) while "patient care costs" will amount to $1,245,562 or 64.2% and "indirect costs" (overhead) will amount to $500,812 or 25.8%.

The application also states that the new staff needed for the transplant program will be recruited internally if possible via transfer from other departments and, if that fails, normal external recruiting methods (ads in newspapers, professional journals, etc.) will be used. Because of the small number of new staff that would be needed for this project, there should be no negative impact on other health care providers in the Norfolk area if SNGH has to recruit externally to fill the positions.

The application further states that SNGH's kidney transplant program was begun in 1972 (prior to the COPN law becoming effective July 1, 1973), while the heart, lung, and heart/lung programs were established in 1989, 1992, and 1993 respectively. Thus, both the heart and lung programs were established during the July 1, 1989 to June 30, 1992 period of deregulation. However, while both the heart and lung transplant programs were properly registered with the state during the period of deregulation, there appears to be no record that the heart/lung program was ever properly registered. Thus, historically all of SNGH's transplant programs have been established without COPN review.

Moreover, the Completeness Question responses indicate that, while both the kidney and heart transplant programs at SNGH are Medicare certified, neither the lung nor heart/lung transplant programs presently have Medicare certification "due to the limited availability of organs for transplant." It is observed that there is, indeed, a limited availability of organs available for transplant but, if anything, that very scarcity argues for fewer transplant programs with proportionally higher volumes, than for more transplant programs with lower volumes.

In that regard, the 1995 Annual Report of the Organ Procurement and Transplant Network (part of UNOS) indicates that, up to a point, there is a strong positive relationship between volume and outcome. Specifically, 1-3 year survival rates consistently increase when liver transplant centers go from 1-23 transplants, to 24-45 transplants, and then to 46-92 transplants annually. However, they drop off somewhat when the centers have more than 92 transplants annually. Also, the 1994 UNOS Report of Center Specific Graft and Patient Survival Rates shows that, of 20 centers nationally that did just 1-12 transplants during the 10/1/87-12/31/91 period, 7 or 35% had actual one year survival rates that were below 60%. The minimum standard for one year liver transplant survival is a rate of 50-60% in the Stated Medical Facilities Plan (SMFP).

The application states that all of SNGH's transplant programs have exceeded the minimum one year survival rates required by the Stated Medical Facilities Plan . The one year survival rate data SNGH provided is shown in Table I below.

TABLE I

| Program | Patients | Time Period | SNGH | SMFP |
|---|---|---|---|---|
| Kidney | 291 | 1990-1995 | 94.0% | 90-95% |
| Heart | 44 | 1992-1995 | 95.4% | 70-80% |
| Lung* | 15 | 1992-1995 | 66.0% | None |

*Includes survival rates for single lung, double lung, and heat/lung.

Table I shows that SNGH has apparently had good one year outcomes with its high volume kidney transplant program and its substantially lower volume heart transplant program. However, its lung transplant program has had a much lower survival rate, and the program technically averaged only 5 transplants per year.

However, that average of 5 transplants annually is probably misleading since the application also states that in a recent 12 month period 10 lung and heart/lung transplants were performed, suggesting that in the remainder of the 1992-95 period only 5 were performed, or an average of 2.5 per year. The Medicare standard for lung transplants is a minimum of 10 per year while the SMFP standard is 12 per year, as it is for liver transplants.

Notably, the 291 kidney transplants would be an average of 73 per year and well above both the Medicare and SMFP minimum standards of 25 per year. However, the 44 heart transplants would be an average of about 15 per year and much closer to the Medicare and SMFP minimums of 12 per year.

In view of the relatively low average annual volume of heart transplants and the apparently very low level of lung and heart/lung transplants, it is not surprising that very low annual volumes for liver transplants (6/12/15 in Yrs. I-III respectively) have been projected. Notably, the Medicare and SMFP minimum standards for liver transplants are both 12 per year, and the SMFP additionally states both that "Successful transplantation programs are expected to perform substantially larger numbers of transplants annually" and that "Performance of minimum transplantation volumes does not necessarily indicate a need for additional transplantation capacity or programs." (Emphasis added.)

SNGH's stated major reason for establishing a liver transplant program is that it would increase geographic access to the service for patients residing in SNGH's primary service area (PSA) which is P.D. 20 and especially the Urban Tidewater area of Norfolk, Portsmouth, Virginia Beach, and Chesapeake. In that regard, the application states that "As a result of the chronic disease conditions that afflict these patients, it is important that they remain in the vicinity of their family and friends for the extensive support systems that transplant patients require," and that "Patient accessibility to a consistency of care in treating progressive end-stage organ failure is the premise on which the implementation of a liver transplantation program is proposed."

However, it is also the case that patients from the P.D. 20 area who have received their actual liver transplants at MCV have apparently received quite adequate postoperative care from physicians and related providers (including Sentara providers) in the P.D. 20 area, as was testified to by some witnesses appearing at the public hearing on this project. It was also observed at the hearing that the SMFP's geographic accessibility standard is that transplant services be within 2 hours driving time, under normal conditions, of 95% of Virginia's (not a single planning district's) population. That standard is satisfied for at least 95% of the residents of P.D. 20, and the American Automobile Association indicates that the driving time to Richmond from the 4 jurisdictions in the Urban Tidewater area is in the 1.5-2.0 hours range.

The application also states that SNGH's financial projections "will position the (Transplant) Center to provide liver transplantation at equal or lower cost to the closest Virginia transplant centers . . ." However, those projections indicate that (not including an average patient listing charge of almost $9,000, an average patient evaluation charge of over $1,000, and physician fees) the average liver transplant charge at SNGH would be $152,123 in Year I and $159,729 in Year II. (NOTE: The listing charge includes additional evaluation charges such as MRI/CT fees.)

In contrast, Attachment I shows that, based upon what the hospitals reported to Virginia Health Information (VHI) for 1995, the average charge for a liver transplant (not including physician and listing/evaluation fees) was $134,182 at MCV, $109,917 at UVA, and $119,523 at Fairfax Hospital. Thus, at all 3 facilities the average charges were substantially below what SNGH has projected it will charge for the first two years of operation of its liver transplant program. Financial projections for this project are specifically reviewed in Section II, Item H (pp. 8-9).

For the record it is observed that SNGH has a licensed capacity of 644 acute care (including psychiatric) beds. In the 1993-95 period SNGH has also experienced declining overall inpatient occupancy rates of 62.8%, 61.2%, and 57.0% respectively. SNGH is also the only Level I (highest level) trauma center in HSA V.

## II. REQUIRED STATE CONSIDERATIONS

State COPN law and regulations require that 20 factors be considered by the state's Health Commissioner when determining that a public need exists for a project, and the consistency of this project with those Required Considerations is reviewed below.

**A. THE RECOMMENDATION AND REASONS THEREFOR OF THE APPROPRIATE REGIONAL HEALTH PLANNING AGENCY.**

The EVHSA Board of Directors will review this project at its November 12, 1996 meeting, and the recommendation of the EVHSA staff may be found in Section III (p.11).

**B. THE RELATIONSHIP OF THE PROJECT TO THE APPLICABLE HEALTH PLANS OF THE REGIONAL HEALTH PLANNING AGENCY, THE VIRGINIA HEALTH PLANNING BOARD, AND THE STATE BOARD OF HEALTH.**

Neither the EVHSA nor the Virginia Health Planning Board have any plans which apply to this project. Rather, the only relevant plan is the current edition of the State Medical Facilities Plan (SMFP), and the portion of that plan which has relevance for this project is the Organ Transplantation Services component, which is Virginia Regulation VR-355-30-105.

Section 2.2.A. of that SMFP component, which provides Accessibility standards, states regarding travel time:

> A. Travel Time
>
> Organ transplantation services, of any type, should be accessible within two hours driving time, under normal conditions, of 95% of Virginia's population. (Emphasis added.)

Notably, for most of the residents of P.D.s 17 (Northern Neck), 18 (Middle Peninsula), and 21 (Peninsula) the liver transplant program located at MCV is about one hour or less driving time one-way. Moreover, for at least 95% of the residents of P.D. 20 and especially the Urban Tidewater area of Norfolk, Virginia Beach, Chesapeake, and Portsmouth, the driving time one-way to MCV is in the 1.5-2.0 hour range. Thus, while the SNGH project might improve geographic accessibility to liver transplant services for P.D. 20 residents, no geographic accessibility problem exists based upon the SMFP standard and, thus, geographic access is not a compelling reason for approving the SNGH project based on that standard.

Also, Section 2.5. of the SMFP component regarding Cost states the following:

> Cost and charges—The total cost (direct and indirect) for providing all organ transplantation services should be comparable to other similar service providers in the health planning region and the state. (Emphasis added.)

There are no other providers of liver transplant services in HSA V, but there are 3 providers in the state (MCV, UVA, Fairfax Hospital). As Attachment I shows, for the 12 month period ending June 30, 1995 the overall average charge for a liver transplant ranged from $109,917 at UVA to $134,182 at MCV. In contrast, the financial projections SNGH has submitted show that in Year I the average transplant charge would be $152,123 while in Year II it would be $159,729 (not including patient listing, patient evaluation, and physician charges). Thus, in Year II (1998) SNGH's average transplant charge would be $25,547 and 19% higher than MCV's was in 1995. (NOTE: Cost data is proprietary information and not available to the public.)

Further, not including physician costs, total SNGH expenses with just 6 liver transplants in Year I would amount to $1,187,860 of which 25.7% ($305,506) would be for overhead while in Year II with just 12 transplants total expenses not including physician costs would be $1,941,185 of which 25.8% ($500,812) would be for overhead. Thus, well over $1.0 million in Year I and over $2.0 million in Year II would be spent on SNGH's expenses and the expenses of the yet-to-be-hired transplant surgeon, and those expenses would be paid for by the public with only 6/12 transplants being done respectively in each year. But if those transplants were done at MCV, no new transplant surgeon or other staff would have to be hired, and charges would predictably be substantially less based upon the data shown in Attachment I.

Section 2.6.A.1. of the Quality standards states that proposals to establish liver transplant services should demonstrate that a "minimum number of transplants will be performed annually" and that minimum for liver transplants is 12, not the 6 SNGH has projected for Year I. Thus, while SNGH has projected that it would achieve 12 transplants in Year II, the fact that it would achieve only 6 in Year I makes the project appear to be not consistent with Section 2.6.A.1 of the SMFP component.

Furthermore, as noted in Section I, patient origin information for liver transplant patients served at UVA and MCV in 1996 shows that 14 came from P.D. 20. Thus, if virtually all of SNGH's liver transplant patients were to come from P.D. 20 and, more specifically, from the 4-city Urban Tidewater area of P.D. 20 in Years I-II, SNGH would probably have to capture the majority of liver transplant patients from P.D. 20 who would be expected to go to MCV and to a much lesser extent to UVA.

In that regard, for 1996 (as of 10/22/96) MCV had 12 or 23.5% of its 51 liver transplant patients come from P.D. 20. Thus, had SNGH's proposed liver transplant program been in service in 1996 and captured all of those patients, the impact upon MCV's transplant volume would have been substantial and automatically increased the average cost per transplant case and probably the charge per case as well, and that would have been in addition to the costs and charges SNGH's program and the transplant surgeon and any other new specialists would have added to the system.

Additionally, Section 2.6.A.2. regarding Quality states the following:

> 2. Successful transplantation programs are expected to perform substantially larger numbers of transplants annually. Performance of minimum transplantation volumes does not necessarily indicate a need for additional transplantation capacity or programs. (Emphasis added.)

That standard was specifically included in the SMFP component to discourage the development of low volume transplant programs because data for other types of transplant programs had shown there was often a relationship between volume and outcome and that, the higher volume a transplant program had, the better would probably be the outcomes. In that regard, Attachment II provides utilization information for the liver transplant programs at MCV, UVA, and Fairfax Hospital for the 1991-96 period, and Attachment III shows the 3 month, and 1-3 year national survival rates for programs of various sizes that were provided in the 1995 Annual Report of the Organ Procurement and Transplant Network which is a part of UNOS.

As Attachment II shows, MCV and UVA have consistently had high liver transplant volumes while only in 1995 and 1996 did Fairfax Hospital reach volumes of over 24 transplants per year. In that regard, Attachment III shows that nationally survival rates increase as the volumes at transplant centers increase and reach the 24-92 range, although when a volume of more then 92 transplants annually is achieved survival rates tend to decrease somewhat.

Regarding survival rates also, Section 2.6.B.1. of the Quality standards states facilities with liver transplant programs should demonstrate that they will achieve and maintain a minimum one year survival rate of 50-60%. The 1994 UNOS Report of Center Specific Graft and Patient Survival Rates, which included data on liver transplant centers for the October 1, 1987 to December 31, 1991 period, showed that of the 14 centers that did a total of 1-6 liver transplants (timeframe was not specified), 7 or 50% had actual one year survival rates less than 60%. Further, 8 or 57% of those facilities had actual one year survival rates which equaled or exceeded 50%, but 6 or 43% had actual survival rates of less than 50%.

Thus, based solely on those percentages, SNGH would perhaps have a slightly better than even chance of achieving the SMFP minimum survival rate standard of 50-60% in Year I. Further, regarding the 6 centers which did 7-12 transplants (again, timeframe not specified), the UNOS data indicates that all had actual one year survival rates which exceeded 60%. Thus, for Year II it would appear that SNGH would probably be able to comply with the SMFP's minimum 50-60% survival rate standard. However, in contrast, MCV had one year actual survival rates of 81% for the 1991-94 period and 85% for the 1995-96 period.

Additionally, Section 2.3.B. of the Availability standards states:

> B. Conditional Approval
>
> Approval of organ transplantation programs shall be conditioned upon the facility's meeting both minimum volume and survival standards. Failure to meet these standards within two years of initiation of the service may be cause for revocation of the certificate of public need. (Emphasis added.)

This standard seems to conflict with Section 2.6.A.1. of the Quality Standards which says nothing about having two years to meet the minimum volume of 12 liver transplants annually and Section 2.6.B.1. which says that "Facilities should demonstrate that they will achieve and maintain minimum transplant patient survival rates." However, the important point is that Section 2.3.B. only applies after a public need has been demonstrated for the project. (NOTE: Medicare requires that for a program to be certified it must achieve 12 transplants in each of two consecutive years.)

Thus, it is Section 2.6.A.2. of the Quality standards (quoted earlier) which is controlling, and it states "Performance of minimum transplantation volumes does not necessarily indicate a need for additional transplantation capacity or programs." Consequently, since there is no public need for the SNGH project based upon the SMFP's geographic accessibility standard, and since no other compelling public need argument has been made for the project, and because the SNGH project is not apparently a less costly alternative to other transplant programs in the state and especially to MCV's, SNGH's project would appear not to be consistent with Section 2.6.A. based on the record.

Finally, the project does appear to comply with the Acceptability and Continuity of Care standards, as well as with the portion of the Accessibility standard relating to "patient access to available organs" of the SMFP component, but those standards are not repeated here for the sake of brevity. Nevertheless, based upon this project's apparent inconsistency with the Cost standard and with Section 2.6.A.2. of the Quality standard, the project at best appears to be only partially consistent with the SMFP component.

C. THE RELATIONSHIP OF THE PROJECT TO THE LONG-RANGE DEVELOPMENT PLAN, IF ANY, OF THE PERSON APPLYING FOR THE CERTIFICATE.

The application states that SNGH "does not have a long range plan which specifically addresses the development of the Transplantation Center." It adds that, "Adding liver transplants to the Center have long been discussed and planned to provide services locally and conveniently to the more than 25-30 adults who are referred out of the region for transplants each year."

D. THE NEED THAT THE POPULATION SERVED OR TO BE SERVED BY THE PROJECT HAS FOR THE PROJECT.

The SMFP does not have a population-based formula to determine public need for transplant programs, but (as discussed in Item B above) it does have a geographical accessibility standard of having transplant programs be within 2 hours one-way driving time for 95% of the population of Virginia (not just of a single planning district). As noted, for most of the residents of P.D.s 17, 18, and 21 the MCV liver transplant program is an hour or less one-way drive and for at least 95% of the residents of P.D. 20 and Urban Tidewater (SNGH's primary service area) the driving time is in the 1.5-2.0 hour range.

Further, as also noted in the Item B discussion, the SMFP is very clear that high volume transplant programs are encouraged and low-volume programs are discouraged. The proposed SNGH liver transplant program would be a low volume program, with only 6, 12, and 15 liver transplants projected in its first 3 years of operation respectively. In contrast, all 3 of the present liver transplant programs including MCV are high volume programs.

As has also been noted earlier, the only major argument SNGH has made for its program is that it would improve geographic access for P.D. 20 and especially Urban Tidewater residents. While that is technically true, there is no geographic access problem based upon the SMFP standard, and since the SNGH proposed program is also apparently not a low cost alternative to the MCV program, it must be concluded that there is no demonstrated population-based public need for this project.

E. THE EXTENT TO WHICH THE PROJECT WILL BE ACCESSIBLE TO ALL RESIDENTS OF THE AREA PROPOSED TO BE SERVED.

The proposed program will have the same geographic and financial accessibility for potential SNGH patients as do the other transplant programs at SNGH. However, it is also noted that Medicaid does not reimburse for liver transplants for its adult enrollees. Thus, in Virginia, no matter what hospital operates a liver transplant program, there is essentially a dual-standard of care which discriminates against Medicaid patients over 21 years of age

On the other hand, Medicare will reimburse for transplants done in Medicare approved centers, but SNGH has projected 6, 12, and 15 liver transplants in Years I-III respectively. In 1996 9.2% of P.D. 20's population of 1,093,292 or 100,531 were 65 years old or over with most of them being eligible for Medicare.

Thus, for the first 3 years of operation, about 100,000 elderly people would probably not have financial accessibility through Medicare to SNGH's liver transplant program, which would be almost twice the number of people of all ages who would be added to P.D. 20's population during the entire 1996-2000 period. As noted earlier, SNGH's lung and heart/lung transplant programs are not presently Medicare certified, and for liver transplants Medicare requires that programs achieve 12 transplants in each of two consecutive years to obtain certification.

In any case, for Year II SNGH projects having one indigent and one Medicaid liver transplant patient (not stated whether adult or pediatric). SNGH's Completeness Question responses also state that "Insurers such as Trigon, Cigna, Aetna, etc., reimburse for liver transplants if the subscriber has transplant as a covered service." (Emphasis added.) Also, for 1996 (as of 10/22/96) MCV served 4 indigent patients (including 1 Medicaid adult) which was 7.8% of its 51 transplant patients.

F. THE AREA, POPULATION, TOPOGRAPHY, HIGHWAY FACILITIES, AND AVAILABILITY OF THE SERVICES TO BE PROVIDED BY THE PROJECT IN THE PARTICULAR PART OF THE HEALTH PLANNING REGION IN WHICH THE PROJECT IS PROPOSED.

There will be no change in the area, topography, and highway facilities in P.D. 20 or the Urban Tidewater area as a result of this project. P.D. 20 and the Urban Tidewater area have excellent road systems which include several interstates as well as four lane highways. In the 1996-2000 period the P.D. 20 population is projected to grow by 53,670 people, but most of that growth (67.4% and 36,197 people) will occur in Virginia Beach. Chesapeake will also account for 27.6% (14,809 people) of that growth. In other words, 95% of P.D. 20's growth in the 1996-2000 period will occur in Virginia Beach and Chesapeake.

As noted earlier, there are 3 liver transplant programs in Virginia at MCV, UVA, and Fairfax Hospital. There is no liver transplant program located in HSA V, but the MCV program is within 2.0 hours or less driving time for at least 95% of the residents of P.D. 20 and within an hour or less driving time for most residents of P.D.s 17, 18, and 21. Thus, there is no geographic access or availability problem based upon the SMFP standard.

G. LESS COSTLY AND MORE EFFECTIVE ALTERNATIVE METHODS OF REASONABLY MEETING IDENTIFIED HEALTH SERVICE NEEDS.

For just the first two years of operation of a very low volume program, doing 6 transplants in Year I and the SMFP's minimum of 12 in Year II, SNGH's operating costs including overhead are projected to total $3,129,045 and that does not include any charges and costs relating to physicians including the liver transplant surgeon who will be hired by a private physicians group in the Norfolk area. That is a great deal of money to spend, and ultimately to be paid for by the public, just to have a liver transplant program located in P.D. 20 when a high volume program, which would not need to recruit a new surgeon, is available for most of HSA V residents within 2 hours or less driving time in Richmond at MCV.

So far in 1996, 23 HSA V residents (14 from P.D. 20) received liver transplants at MCV (12) and UVA (2) while in 1995 11 HSA V residents received liver transplants at out-of-state facilities. That suggests that HSA V patients and their physicians generally have little difficulty with liver transplants being done, not only outside of HSA V, but also outside of the state. Further, the 12 P.D. 20 liver transplants done at MCV so far in 1996 amounts to 23.5% of the 51 transplants MCV has done this year.

Thus, had the proposed SNGH program been in operation in 1996 and captured all of MCV's P.D. 20 liver transplant business, that 23.5% reduction in volume would have substantially increased the overall average cost for a liver transplant at MCV which would probably have, in turn, increased MCV's overall average charge per transplant. As noted earlier, MCV's overall average charge in 1995 of $134,182 (Attachment I) is substantially less than the average charges of $152,123 and $159,729 per transplant (not including patient listing and evaluation charges, and physician fees) that SNGH has projected for Years I-II respectively. Thus, the least costly and most effective alternative to the SNGH project appears to be not to do it at all, which thereby avoids injecting millions of dollars of additional costs and charges annually into the HSA V system.

## H. THE IMMEDIATE AND LONG-TERM FINANCIAL FEASIBILITY OF THE PROJECT.

At just $61,900 the capital cost of this project is small, and since that cost will be funded from SNGH's accumulated reserves, the immediate financial feasibility of the project is assured. However, the real cost to the HSA V system is the operating costs of the project and the physician related costs, including having a new transplant surgeon come to P.D. 20. Only the projected operating costs at SNGH are stated in the application (as is typical for all COPN applications), and those costs are shown in Table II below.

TABLE II

| Item | YEAR I | YEAR II |
|---|---|---|
| Transplants | 6 | 12 |
| Patients Listed | 48 | 96 |
| Patients Evaluated | 96 | 192 |
| | | |
| Gross Revenues | $1,425,091 | $2,992,692 |
| Net Revenues | 927,718 | 1,969,420 |
| Total Costs | 1,187,860 | 1,941,185 |
| Profits | ($260,142) | 28,234 |
| Profit % Net | - 28.04% | 1.4% |
| | | |
| Transplant Avg. Charge | $152,123 | $159,729 |
| Listing Charge | 8,558 | 8,986 |
| Evaluation Charge | 1,058 | 1,111 |

Table II is instructive in several ways. First, it shows that the number of patients listed for liver transplants is expected to be 8 times the number of patients actually transplanted in each year. Second, it shows that the number of patients evaluated for a transplant is projected to be 16 times the number of those actually transplanted. Notably, MCV's present waiting list has 64 patients on it (as of 10/22/96), including both Virginia and out-of-state patients, but SNGH has projected 96 in Year II which is 32 patients and 50.0% more than MCV presently has. That may not be reasonable.

Third, the patient listing charges in Years I-II are almost $9,000 and when combined with the patient evaluation charges of over $1,000 would add $9,616 in Year I and $10,097 in Year II to a transplant patient's bill. Notably, UNOS charges only $350 for listing but, according to SNGH, the SNGH listing charge includes charges for additional patient evaluation procedures like MRI/CT. Fourth, with the transplant charges and volumes shown in Table II, for Year I gross revenues (charges) from just transplants would be $912,738 and in Year II they would be $1,916,748. That means that in Year I $512,353 would have to come from patient listings and evaluations while in Year II $1,075,944 would.

As Table II also shows, even if SNGH achieves its projected volumes of actual transplants, patient listings, and patient evaluations, in Year I SNGH still manages to lose $260,142 while in Year II SNGH only gains $28,234 which is a net loss of $231,908 for the first 2 years of operation. Further, for Year III SNGH has anticipated only 15 actual transplants and no financial projections have been provided. (NOTE: Year III projections are not required in the COPN application.)

Thus, on the basis of its own financial projections, SNGH's project is not financially feasible in its first two years of operation (in the sense of being able to breakeven) and that is assuming that it is able to achieve its projected volumes of transplants, listings, and evaluations. Moreover, if SNGH does not achieve those volumes, the aggregate Year I-II loss could be much greater than $231,908.

Notably, any losses would have to be subsidized by the profits SNGH makes from transplant related patients and other patients whose medical conditions do not require liver transplants, listings, or evaluations, and if the losses proved to be substantial, pressure could grow to increase non-transplant related charges at SNGH, as well as transplant related charges. In any case, those losses, as well as SNGH's costs and the physician/surgeon related costs, are simply expenses for which SNGH has not demonstrated any public need.

I. THE RELATIONSHIP OF THE PROJECT TO THE EXISTING HEALTH CARE SYSTEM OF THE AREA IN WHICH THE PROJECT IS PROPOSED.

Not applicable. There are no liver transplant programs in HSA V, and the program at MCV in Richmond is within 2 hours driving time one-way for most of the residents of HSA V, which is consistent with the SMFP's travel time standard.

J. THE AVAILABILITY OF RESOURCES FOR THE PROJECT.

As noted, the $61,900 capital cost for this project is small and can be easily paid for out of the accumulated reserves of SNGH. In terms of human resources, the application indicates that only 2.5 FTE personnel will be needed, in addition to the 25.0 FTE existing Transplant Center personnel, to staff the liver transplant program. Of those 2.5 FTEs, 1.0 FTE will be an RN, 1.0 FTE a cardiovascular services technician, and 0.5 FTE a medical social worker. SNGH believes all of the 2.5 FTEs can be recruited internally through transfers from other departments at SNGH, and because of the small number of new staff required, even if SNGH had to recruit outside of the hospital, there would be no substantial negative impact on other P.D. 20 health care providers.

K. THE ORGANIZATIONAL RELATIONSHIP OF THE PROJECT TO NECESSARY ANCILLARY AND SUPPORT SERVICES.

Because SNGH currently operates heart, lung, kidney, and heart/lung transplant programs, there should be no problems in providing the necessary ancillary and support services needed for the proposed liver transplant program.

L. THE RELATIONSHIP OF THE PROJECT TO THE CLINICAL NEEDS OF HEALTH PROFESSIONAL TRAINING PROGRAMS IN THE AREA IN WHICH THE PROJECT IS PROPOSED.

Not applicable.

M. THE SPECIAL NEEDS AND CIRCUMSTANCES OF AN APPLICANT FOR A CERTIFICATE SUCH AS A MEDICAL SCHOOL, HOSPITAL, MULTIDISCIPLINARY CLINIC, SPECIALTY CENTER, OR REGIONAL HEALTH SERVICES PROVIDER, IF A SUBSTANTIAL PORTION OF THE APPLICANT'S SERVICES OR RESOURCES OR BOTH IS PROVIDED TO INDIVIDUALS NOT RESIDING IN THE HEALTH PLANNING REGION IN WHICH THE PROJECT IS TO BE LOCATED.

Not applicable.

N. THE NEED AND AVAILABILITY IN THE HEALTH PLANNING REGION FOR OSTEOPATHIC AND ALLOPATHIC SERVICES AND FACILITIES AND THE IMPACT ON EXISTING AND PROPOSED INSTITUTIONAL TRAINING PROGRAMS FOR DOCTORS OF OSTEOPATHY AND MEDICINE AT THE STUDENT, INTERNSHIP, AND RESIDENCY TRAINING LEVELS.

Not applicable.

O. THE SPECIAL NEEDS AND CIRCUMSTANCES OF HEALTH MAINTENANCE ORGANIZATIONS.

Not applicable.

**P. THE SPECIAL NEEDS AND CIRCUMSTANCES FOR BIOMEDICAL AND BEHAVIORAL RESEARCH PROJECTS WHICH ARE DESIGNED TO MEET A NATIONAL NEED AND FOR WHICH LOCAL CONDITIONS OFFER SPECIAL ADVANTAGES.**

Not applicable.

**Q. THE COSTS AND BENEFITS OF THE CONSTRUCTION ASSOCIATED WITH THE PROPOSED PROJECT.**

Not applicable. No renovation or new construction costs are associated with this project.

**R. THE PROBABLE IMPACT OF THE PROJECT ON THE COSTS OF AND CHARGES FOR PROVIDING HEALTH SERVICES BY THE APPLICANT FOR A CERTIFICATE AND ON THE COSTS AND CHARGES TO THE PUBLIC FOR PROVIDING HEALTH SERVICES BY OTHER PERSONS IN THE AREA.**

As has been noted, for 1996 (as of 10/22/96) MCV did 51 liver transplants of which 18 or 35.3% were for HSA V patients. Thus, had the proposed SNGH program been operational in 1996 and captured just 12 or the 23.5% of MCV's business that was from P.D. 20, it could of had a very substantial negative impact on MCV's average cost per transplant and, thus, placed substantial pressure on MCV to increase its charges as well. As discussed in Item H, MCV's 1995 average charge per transplant was $134,182 (Attachment I), and SNGH's Year I charge of $152,123 would be 13.4% and $17,941 higher than MCV's, while SNGH's Year II charge of $159,729 would be 19.0% and $25,547 higher than MCV's.

Further, for 1996 (as of 9/30/96) information from UVA indicates that, of 29 total liver transplants done, 5 or 17.2% were for HSA V patients. Thus, had SNGH's proposed program been in operation and captured all of UVA's HSA V patients, UVA would have experienced an increase in its overall average cost per transplant and, thus, pressure to increase charges as well. Attachment I shows that UVA's average charge per transplant in 1995 was the lowest of the 3 hospitals in Virginia providing liver transplant services. In that regard, SNGH's projected average charge for Year I would be $42,206 and 38.4% higher than UVA's 1995 average charge of $109,917 while SNGH's projected average charge for Year II would be $49,812 and 45.3% higher.

Also, SNGH's proposed costs and charges are discussed in detail in Item H (pp.8-9) and shown in Table II (p.8). As noted in that discussion, SNGH has projected a net loss of $231,908 if it achieves all of its projections for transplants, patient listings, and patient evaluations, but if it does not achieve those projections, then the loss could be substantially higher. Any substantial losses for the proposed liver transplant program would predictably be passed on in the form of higher charges to either or both transplant related patients and non-transplant related patients at SNGH. Notably, both UVA and MCV are also on record as opposing this project.

**S. IMPROVEMENTS OR INNOVATIONS IN THE FINANCING AND DELIVERY OF HEALTH SERVICES WHICH FOSTER COMPETITION AND SERVE TO PROMOTE QUALITY ASSURANCE AND COST EFFECTIVENESS.**

Not applicable.

**T. IN THE CASE OF HEALTH SERVICES OR FACILITIES PROPOSED TO BE PROVIDED, THE EFFICIENCY AND APPROPRIATENESS OF THE USE OF EXISTING SERVICES AND FACILITIES IN THE AREA SIMILAR TO THOSE PROPOSED.**

There are no liver transplant programs in HSA V, but there are 3 in the state at UVA, MCV, and Fairfax Hospital. Utilization for all 3 programs is shown in Attachment II, and both the UVA and MCV programs have served HSA V residents in recent years, while Fairfax has not.

As Attachment II shows, all of the programs have experienced high utilization while, in contrast, the proposed SNGH program would be a high cost but low utilization program with 6, 12, and 15 transplants in the first three years of operation. Moreover, even for SNGH to achieve those levels of utilization it would have to capture business from MCV where so far in 1996 35.3% of its transplants have been for HSA V residents, and from UVA where so far in 1996 17.2% of its transplants have also been for HSA V residents. Thus, in all likelihood the proposed SNGH program would simply reduce the efficiency and increase the costs and charges of the MCV and UVA programs while also adding quite substantial new costs to the P.D. 20 and HSA V system.

## III. EVHSA STAFF RECOMMENDATION

It is recommended that the EVHSA Board of Directors recommend to the State Health Commissioner that COPN Request No. VA-5969, submitted by Sentara Norfolk General Hospital to establish a liver transplant service, be denied for the following reasons:

1.) The proposed project is not consistent with the State Medical Facilities Plan in substantial respects.

2.) There is no geographic access or availability problem in HSA V for liver transplant services based upon the SMFP's geographic access standard and the proposed project's charges are not consistent with the SMFP's cost standards.

3.) The proposed project would be a low volume/high cost program which would needlessly inject additional costs/charges into the HSA V system.

4.) A less costly and more appropriate and effective alternative exists to the proposed project which is to continue to have HSA V patients receive liver transplants at the Medical College of Virginia and other facilities.

5.) The proposed project would drive up the costs and, potentially, the charges for liver transplant services at MCV and UVA, where transplant charges in 1995 were substantially below those projected for the proposed project.

6.) The proposed project could potentially reduce the financial access of adult Medicaid patients and other uninsured patients to liver transplant services by reducing utilization of the high volume programs at MCV and UVA.

7.) For the 1991-96 period, the MCV program has had actual one year survival rates which appear to be higher than what might be expected from the proposed SNGH program with projected volumes of 6 and 12 transplants in the first two years of operation.

8.) HSA V Medicare patients would probably not have financial access to the proposed program for the first three years of operation because the program would need to obtain Medicare certification.

## ATTACHMENT I

## 1995 LIVER TRANSPLANT AVERAGE CHARGES

| Insurers | MCV | UVA | Fairfax |
|---|---|---|---|
| AETNA | $127,065 (4) | $ 134,482 (2) | $130,622 (3) |
| Blue Cross/ Blue Shield | 134,084 (5) | 127,530 (14) | – |
| Champus | 127,083 (6) | – | – |
| Cigna | 101,552 (1) | – | – |
| Foreign | – | 90,590 (1) | – |
| Indigent/Charity Care | – | 109,236 (1) | – |
| Medicaid | – | 132,800 (2) | – |
| Medicare | 207,529 (2) | 115,823 (13) | 88,833 (3) |
| Metropolitan | 217,206 (1) | – | – |
| Other Commercial | 126,146 (8) | 97,540 (13) | 106,937 (8) |
| PPO-Unspecified | – | – | 277,502 (1) |
| Self Pay | – | 77,424 (1) | – |
| State Government | – | 66,098 (1) | – |
| Travelers | – | 58,185 (2) | – |
| Unknown | 113,877 (10) | 100,312 (3) | – |
| Overall Average | $ 134,182 (37) | $ 109,917 (53) | $119,523 (15) |

Source: VHI information provided by the HSA of Northern Virginia for period July 1, 1994 to June 30, 1995.

## ATTACHMENT II

## VIRGINIA LIVER TRANSPLANT CENTERS UTILIZATION

## 1991-1996

Number of Transplants by Center

| Year | Medical College of Virginia | University of Virginia | Fairfax Hospital | |
|---|---|---|---|---|
| 1991 | 27 | 51 | Not Open | [illegible] |
| 1992 | 31 | 36 | 4 | 7 |
| 1993 | 37 | 66 | 14 | 11 |
| 1994 | 33 | 63 | 18 | 14 |
| 1995 | 39 | 53 | 36 | 18 |
| 1996* | 65 | 39 | 55 | [illegible] |

* 1996 Data is annualized using year-to-date data ending September 30, 1996 for all transplant centers. (As of September 30, 1996: Actual transplants were MCV - 49, UVA - 29, and Fairfax Hospital - 41 transplants.)

Source: Transplant Center Adminstrations.

ATTACHMENT III

## PATIENT SURVIVAL RATES RELATIVE TO PROGRAM VOLUME

| CENTER VOLUME | 3 MONTH SURVIVAL | 1 YEAR SURVIVAL | 2 YEAR SURVIVAL | 3 YEAR SURVIVAL |
|---|---|---|---|---|
| 0-23 | 81.4 | 75.8 | 72.3 | 69.1 |
| 24-45 | 84.7 | 79.1 | 75.1 | 72.4 |
| 46-92 | 87.2 | 82.3 | 79.0 | 77.1 |
| 93-159 | 88.1 | 81.7 | 77.5 | 74.9 |
| 160+ | 86.6 | 79.6 | 75.5 | 72.1 |

SOURCE: Organ Procurement and Transplant Network, 1995 Annual Report

developing tertiary services, 2) the established clinical outcomes of the Transplant Center, 3) the proven capability of the transplant team of physicians and staff, and 4) the commitment of the liver specialist physicians to develop this program,.

# Certificate of Public Need Application

Sentara Norfolk General Hospital

Transplant Center requests approval to

**expand** its organ transplant program to

include liver transplantation.

# Tertiary Services provided by Sentara Health System

00443

- **Organ Transplantation**
- Genitourinary Reconstructive Surgery
- Multidisciplinary Cancer Clinic
- Microsurgical Research Center
- Level 1 Trauma Center
- Nightingale Air Ambulance
- Perinatal Intensive Care

# Tertiary Services

- **Tertiary Services** are defined as those services which are provided by **only one** health care entity in a region such as a State Planning District.
- **Sentara Norfolk General Hospital** continues to be the **largest provider** of tertiary services for the Planning District for Hampton Roads.
- Organ Transplantation is **one of the many** tertiary services Sentara provides for Hampton Roads.

# Case Mix Index for Regional Virginia Hospitals

00444

| Hospital | 1994 | 1995 |
|---|---|---|
| SNGH | 1.474 | 1.4743 |
| UVA | 1.442 | 1.4767 |
| MCV | 1.323 | 1.40393 |
| Fairfax | 1.134 | 1.1459 |
| Henrico | 1.236 | 1.3394 |

Source: 1994 and 1995 Annual Report
Efficiency and Productivity

# Region Served by Sentara Health System

# Transplant Team Participation

00445

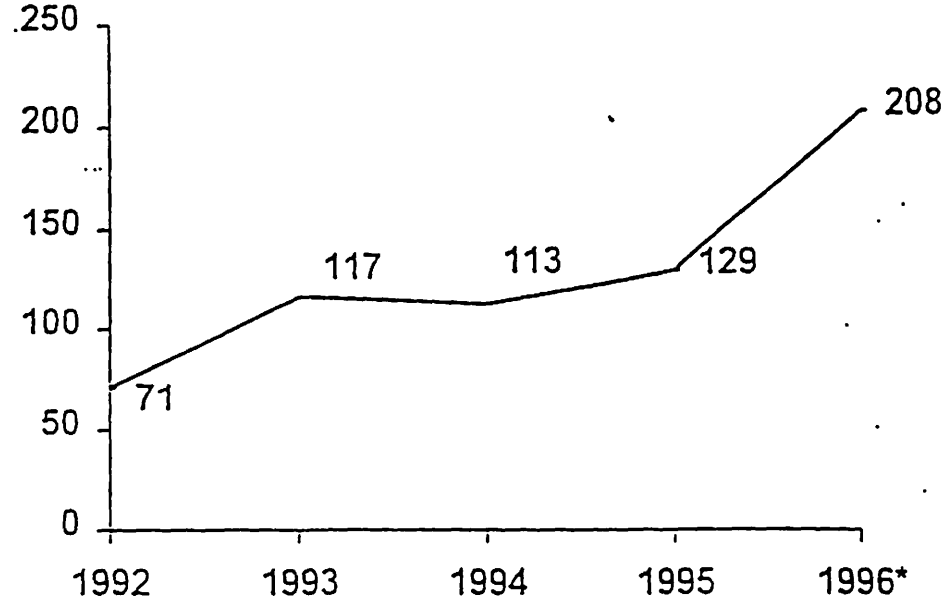
- Administration
- Anesthesiology
- Cardiology
- Cardiovascular Surgery
- Chaplaincy
- Finance
- Immunology
- Infectious Disease
- Nephrology
- Nursing
- Pathology
- Pharmacy
- Psychiatry
- Pulmonary Disease
- Radiology
- Rehabilitation
- Social Services
- Urology
- Vascular Surgery

# Sentara Norfolk General Hospital Organ Transplant Program History

| Organ | Start Year |
|---|---|
| Kidney | 1972 |
| Heart | 1989 |
| Lung | 1992 |
| Heart/Lung | 1993 |

# 5 Year Virginia Liver Transplant Volumes

00446




* Annualized from 4 months actual data.

Source: UNOS

# 1996 Virginia Liver Transplant Programs

| Program | Start Year |
|---|---|
| Medical College of Virginia | 1983 |
| University of Virginia | 1988 |
| Henrico Doctor's Hospital | 1991 |
| Fairfax Hospital | 1992 |

## Patients in the Southeastern Virginia / Northeastern North Carolina Region Receiving Liver Transplants

00447

| Year | No. Transplants |
|---|---|
| 1994 | 19 |
| 1995 | 22 |

Source: UNOS

## Liver Transplant Waiting List and Median Waiting Times

| Year | No. Patients | Days |
|---|---|---|
| 1988 | 2140 | 33 |
| 1989 | 2880 | 40 |
| 1990 | 3643 | 45 |
| 1991 | 4131 | 67 |
| 1992 | 4760 | 106 |
| 1993 | 5484 | 146 |
| 1994 | 6211 | 171 |
| Current* | 6758 | n/a |

*as of 7/31/96

# Projected Volumes for Sentara's Liver Transplant Program

00448

| | |
|---|---|
| Year 1 | 6 |
| Year 2 | 12 |
| Year 3 | 15 |

# New Liver Transplant Center Volume Growth

| Program | 1993 | 1994 | 1995 | 1996* |
|---|---|---|---|---|
| Univ of Mary | - | 1 | 17 | 27 |
| Carolinas | - | 7 | 10 | 21 |
| Univ of Calif | 3 | 10 | 13 | 32 |
| Loma Linda | 3 | 12 | 24 | 52 |

*Annualized on 4 mos ...

# Current Liver Research

00449

| | |
|---|---|
| Investigators: | The Virginia Cooperative Hepatitis Treatment Group |
| Principal Investigator: | Mitchell L. Shiffman, MD<br>Medical College of Virginia<br>Richmond, Virginia |
| Co-Investigators: | Vinod K. Rustgi, MD<br>Falls Church, Virginia |
| | Steven Cauldwell, MD<br>Charlottesville, Virginia |
| Satellite Sites: | Michael Ryan, MD<br>Norfolk, Virginia |
| | Others to be named |

# Benefits of a Liver Transplant Program within the Hampton Roads Region

- Less medical risk in transferring acutely ill patients
- Reduce problems of non-optimal communication
- Reduce lapses in the continuum of care
- Ease of patient follow-up
- Decrease the cost of care attributable to duplication of services, tests, procedures
- Eliminate the cost of transferring acutely ill

# Sentara Health System
# Operating Principle

00450

$$\frac{\uparrow \text{Quality} + \uparrow \text{Service}}{\downarrow \text{Cost}} = \uparrow \text{Value}$$

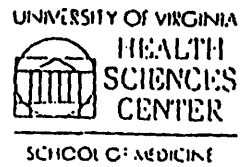
ATTACHMENT C

# MCV LIVER TRANSPLANT PROGRAM

## OVERVIEW

- Started 1984
- Re-organized 1991
  - # Transplants: 201
  - % Re-transplants: 9.0%
  - Waiting list mortality: 3.8%
- Specialized techniques developed:
  - Human hepatocyte transplantation
  - Segmental and living related transplantation

ATTACHMENT I.




October 31, 1996

Paul Boynton
Assistant Vice President
Eastern Virginia Health Systems

Mr. Boynton:

We appreciate the opportunity to respond to the COPN review for Sentara's request for a liver transplant program.

Under Section 32.1 of the Code of Virginia, established in 1973, the COPN code language has been to control health care costs by constraining the supply of medical care facilities and services. Using the authority of that codified intent, it is our belief that the needs of the patient population needing liver transplantation in the Commonwealth is very adequately met with current program offerings. Currently, live transplant centers serving the Commonwealth are also producing outcomes that reflect their clinical success as well as their patient capacity. The University of Virginia, for example, was the first Center from Baltimore to Atlanta to receive Medicare accreditation for liver transplantation, based on survival and outcome. It is our belief, therefore, that supply needs in quantity and quality are currently being met and that additions to this network are duplicative with no benefit that is substantive to quality.

Enclosed is a profile of our Liver Transplant Data, including survival rates and faculty profiles with length of dedication to liver transplant procedures, only.

Of further concern to an academic medical center such as ours is unnecessary duplication of a service that erodes our ability to provide clinical applications of translational research. Academic medical faculty's thoughtful explorations of the factors that insure better science in transplantation promote the likelihood of a better future for all transplant patients in the Commonwealth. Transplant is a multidisciplinary service; people will go across the country for this expertise in a complicated surgical and medical procedure with its attendant need for expertise in medical management of lifelong immunology.

Thank you for your courtesy in insuring that our view was heard.

Sincerely,

Robert M. Carey, M.D.
James Carroll Flippin Professor
Of Medical Science and Dean

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004272

# LIVER TRANSPLANT DATA

...ant Volumes:

| | LIVER | KIDNEY |
|---|---|---|
| | 18 YTD July 9th | 43 YTD July 9th |
| | 34 | 39 |
| | 62 | 41 |
| | 66 | 52 |
| | 56 | 55 |
| | 51 | 58 |
| | 34 | 62 |
| | 17 | 43 |
| | 1 | 25 |

...TRANSPLANT:

...ing physician-in-charge of the liver transplant team.

| | Liver Transplant Surgeon-In-Charge | Liver Transplant Physician-In-Charge |
|---|---|---|
| | Timothy L. Pruett, MD | Same |
| | Director of Transplantation | Same |
| | Surgery | Same |
| ...fication | See attached | |
| ...ployment | July 1, 1987 | |
| ...Date Liver Transplant ...at this Institution | 2/23/88 - present | |
| ...ns at this Institution | 75 | |
| ...Date Liver Transplant ...at other Institutions | NA | |
| ...ns at other Institutions | NA | |
| ...ions where Transplant ...med | NA | |
| ...Allocated to Liver ...tion Program | 50% | |

All other physicians on the liver transplant team.

| Liver Transplant Surgeon Profiles | | | |
|---|---|---|---|
| Name | Specialty | Board Certified | # Years Performing LiverTransplants |
| Christopher McCullough, MD | Surgery | Yes | 6 years |
| Michael Ishitani, MD | Surgery | Yes | 3 years |

| Liver Transplant Physician Profiles | | | |
|---|---|---|---|
| Name | Specialty | Board Certified | # Years Monitoring Liver Transplants |
| Stephen Caldwell, MD | Gastroenterology | Yes | 5 years |
| Stephen Hickston, MD | Gastroenterology | Yes | 3 years |

Survival rates for liver transplants:

| | Kaplan-Meier 1 Yr Survival | Kaplan-Meier 2 Yr Survival | Kaplan-Meier 3 Yr Survival |
|---|---|---|---|
| Patient | 83.76% | 82.08% | 76.37% |
| Graft | 73.19% | 77.43% | 72.69% |

Survival rates for pediatric liver transplants:

| | Kaplan-Meier 1 Yr Survival | Kaplan-Meier 2 Yr Survival | Kaplan-Meier 3 Yr Survival |
|---|---|---|---|
| Patient | 81.82% | 81.82% | 81.82% |
| Graft | 66.67% | 66.67% | 66.67% |

Medicare Certification: December 7, 1992

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C04/8

SNGH Liver Transplant
Service Area Patients Obtaining Services

| | 1994 | 1995 | 1996[1] |
|---|---|---|---|
| Region 2 | 0 | 4 | 1 |
| Region 4 | 0 | 7 | 0 |
| Region 11 | 18 | 10 | 26 |
| **Totals from Area** | **18** | **21** | **27** |

Source: UNOS Research Department

[1] Annual projections based on actual volume of 17 patients who received liver transplants between January 1, 1996 and July 31, 1996.

## Survival Rates of Liver Transplant Program With Annual Volumes Between 6 and 25

### Facilities At or Above SMFP Standards

| # Transplants | Center | |
|---|---|---|
| 6 | Children's Hospital - Seattle | 100 |
| 8 | The Children's Hospital - Columbus | 75.00 |
| 9 | LSU - Willis Knighton | 77.80 |
| 10 | Children's - Denver | 80.00 |
| 11 | Egleston Children's | 63.60 |
| 12 | Le Bonheur Children's | 72.70 |
| 11 | Vanderbilt | 72.70 |
| 16 | Medical University - S.C. | 81.30 |
| 16 | Henry Ford | 68.80 |
| 16 | Texas Children's | 62.50 |
| 17 | Children's Hospital - Wisc. | 76.50 |
| 18 | Jewish Hospital - Louisville | 66.70 |
| 21 | NYU Medical Center | 81.00 |
| 23 | V.A. Hospital - Portland | 60.90 |
| 23 | St. Louis Children's | 52.20 |

### Facilities Below SMFP Standards

| | | |
|---|---|---|
| 6 | Columbia Presbyterian | 0.00 |
| 20 | University of Illinois | 40.00 |
| 24 | Yale | 37.50 |
| 24 | Wilford Hall USAF | 45.80 |

**Fifteen of Nineteen Facilities are at or above the SMFP Survival Rate Standard.**

Source: 1994 UNOS Report of Center Specific Graft and Patient Survival Rates (most recent data available summarizes transplant activity from October 1, 1987 through December 31, 1991)

Comparison of Small and Large Liver Transplant Programs Within a Market Area
"Bigger Does Not Mean Better"

| Market | Program | # Transplants | Survival Rate |
|---|---|---|---|
| Los Angeles | Adams-Sinai | 97 | 76.3 |
| Los Angeles | Univ. of California | 679 | 62.7 |
| Denver | Children's Hospital | 10 | 80 |
| Denver | Univ. of Colorado | 106 | 78.3 |
| Atlanta | Egleston Childrens | 11 | 63.6 |
| Atlanta | Emory | 113 | 64.8 |
| Indianapolis | Indiana Univ. Med. Center | 121 | 61.2 |
| Indianapolis | Methodist Hospital | 51 | 66.7 |
| Boston | Children's-Boston | 35 | 71.4 |
| Boston | Mass General | 89 | 67.4 |
| Boston | New England Deaconess | 188 | 62.8 |
| Boston | New England Med. Center | 111 | 67.9 |
| St. Louis | Barnes/Childrens | 144 | 59 |
| St. Louis | Cardinal Glennon Childrens | 5 | 80 |
| St. Louis | St. Louis Childrens | 23 | 52.2 |
| St. Louis | St. Louis University | 43 | 51.2 |
| Columbus | Ohio State | 79 | 70.9 |
| Columbus | Children's Columbus | 8 | 75 |
| Philadelphia | Albert Einstein | 1 | 100 |
| Philadelphia | Children's Philadelphia | 49 | 42.9 |
| Philadelphia | University of Pennsylvania | 103 | 57.8 |
| Philadelphia | St. Christopher's Childrens | 59 | 74.6 |
| Philadelphia | Thomas Jefferson | 82 | 59.8 |
| Memphis | LeBonheur Childrens | 11 | 70.3 |
| Memphis | University of Tennessee | 53 | 66 |
| Houston | Texas Children's | 16 | 62.5 |
| Houston | The Methodist Hospital | 40 | 45 |
| Houston | University of Texas | 28 | 53.6 |
| Seattle | Children's - Seattle | 6 | 100 |
| Seattle | University of Washington | 78 | 73.1 |
| Milwaukee | Children's - Wisconsin | 17 | 76.5 |
| Milwaukee | Froedtert Memorial | 72 | 56.9 |

Source: 1994 UNOS Report of Center Specific Graft and Patient Survival Rates (most recent data available summarizes transplant activity from October 1, 1987 through December 31, 1991).

## SNGH Liver Transplant and Disease Management
## Fixed Cost of Operation

| | Year 1 | Year 2 |
|---|---|---|
| Capital Cost | $9,480[1] | $9,480[1] |
| Fixed Salary and Benefit Expense | $46,556[2] | $64,264[2] |
| Annual Fixed Cost of Program | $56,036 | $73,744 |
| Cost/Transplant | $9,339 | $6,145 |
| Cost/Patient Listed | $1,167 | $768 |
| Cost/Patient Evaluated | $584 | $384 |

[1] Based on capital expenditure of $61,900 depreciated on a straight line bases over 6.5 years.

[2] Based on the incremental staffing expenses that will be incurred by the program. Variable expenses have not been included.

Charge Comparisons:
Selected Charges

| | SNGH | UVA | MCV | Fairfax |
|---|---|---|---|---|
| Semi Private Room-base | $268.00 | $360.00 | $379.00 | $279.00 |
| ICU/CCU-base | $570.00 | $755.00 | $1,435.00 | $1,085.00 |
| OR | $380.67 | $500.70 | $915.00[1] | $517.00 |
| CABG | $15,567.29 | $44,152.86 | $51,881.37 | $48,057.00 |

Source: 1994 Annual Survey of Hospital Charges, Virginia Health Services Cost Review Council

[1] Hourly rate reported.

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00535


WITH OFFICES IN:

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TELECOPIER (86 20) 8331 3675


IN
JAN. 22, 1997

January 20, 1997

*Via Facsimile and Mail*

Mr. Sam Clement
Division of Certificate of Public Need
Office of Health Facilities Regulation
Virginia Department of Health
3600 West Broad Street, Suite 216
Richmond, Virginia 23230

Re: ***COPN Request No. Va-5969***
***Sentara Norfolk General Hospital***
***Norfolk, Virginia***
***Establish Liver Transplant Service***

Dear Sam:

This follows up on our recent discussions about your proposed meeting with MCV to discuss aspects of the referenced project. On behalf of my client, I wish to express our objection to such a meeting. We understand that you have already had one such meeting with MCV regarding this project. In addition, MCV has submitted written comments outlining its position on this project. MCV is not a party to this proceeding. Under the circumstances, MCV has been given much more process than is due under the law. We respectfully ask that you not attend another meeting with MCV about this project which will only result in further delay in issuing the staff recommendation on this project. If a meeting is held, we would expect that Sentara be given notice and an opportunity to observe and respond to any information that is provided.

Sincerely,

Laura G. Aaron

cc: Sandra J. Miller
Christine Burge

# REQUIREMENTS FOR ASTS ACCREDITATION OF TRANSPLANT SURGERY FELLOWSHIP TRAINING PROGRAMS

In February 1995, the Council of the ASTS, upon recommendation by the Education Committee, agreed upon the following requirements for ASTS accreditation of transplantation surgery fellowship training programs.

## Duration of Training:

Regardless of the intensity of exposure to clinical transplantation, there is a consensus that transplant surgery training programs should be two years in duration.

## Content of Training:

The scope and depth of transplantation has changed dramatically in the recent years with heavy emphasis on multi-organ transplantation expertise. There is stronger emphasis for fellowship trainees to have experience in kidney, liver, pancreas transplantation, as well as multi-organ procurement. Although the following requirements are listed for each organ transplant individually, it is ideal that exposure to transplant surgery approaches all requirements.

Kidney Transplantation: A minimum of one year of clinical experience at an institution performing a minimum of 60 kidney transplants annually, during which the transplant surgery fellow participates in all activities of kidney transplantation (i.e. provision of vascular access, organ procurement, and at least 30 transplant operations as primary surgeon or co-surgeon over the two year fellowship) is mandatory.

Liver Transplantation: Clinical liver transplantation fellowship programs are encouraged in institutions having an adequate case load and opportunity for long-term follow-up. The Council of the ASTS judge that the institution should perform at least 50 liver transplants annually. Adequate transplant fellow experience over the two year fellowship is a minimum of 40 liver transplants either as primary surgeon or first assistant. The liver transplantation experience should also include adequate training in multi-organ procurement (kidneys, livers, pancreases) with 25 procedures as primary or co-surgeon required during the two year fellowship duration.

Pancreas Transplantation: Clinical pancreas transplantation is sufficiently complex and unique that fellowship training is encouraged in institutions having an adequate case load. The Council of the ASTS judges that the fellowship training institution should perform at least 20 pancreas transplants annually. Adequate transplant surgery fellow experience over the two year fellowship is a minimum of 15 pancreas transplants, either as a primary surgeon or first assistant.

Multi-Organ Transplantation: Programs are encouraged to seek approval for training in kidney, liver, and pancreas transplantation, either as individual institutions or by amalgamating with another. Broad and intensive clinical exposure to kidney, liver, and pancreas transplantation, as well as multi-organ procurement is sought.

Multi-Organ Procurement: Training in multi-organ procurement is essential and transplant surgery fellow experience over the two year fellowship is a minimum of 25 multi-organ procurements, either as primary surgeon or first assistant.

## The Application Process:

If you have questions or added input, please contact Hugh Auchincloss, Jr., M.D., Chair, ASTS Education Committee, Department of Surgery/Transplantation, Massachusetts General Hospital, 32 Fruit Street, White 510-B, Boston, Massachusetts 02114. Upon receipt of the application form and after a preliminary review, a site visit will be scheduled. The site visit team will arrange an agenda with the transplant program to ascertain the strength of institutional support for the transplant program and to help optimize the transplant surgery fellowship potential at that center. Our intention is to be helpful and constructive.

Hugh Auchincloss, Jr., M.D.
Chair, Education Committee

Rev 6/13/96

# DEPARTMENT OF HEALTH

## *Staff Summary, Analysis, and Recommendation*

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## Staff Summary

**Applicant.** Sentara Norfolk General Hospital (SNGH). Sentara Norfolk General Hospital, part of Sentara Health System, is licensed for 644 beds and is located on the west side of downtown Norfolk. It is one of the Commonwealth's major tertiary-care hospitals and the primary trauma-care center for the Hampton Roads area and adjacent areas of northeastern North Carolina. SNGH is the principal teaching hospital for undergraduate and graduate medical students at the Eastern Virginia Medical School (EVMS), which shares the Eastern Virginia Medical Center campus with SNGH.

**Project Description.** The application states in part:

> Sentara Health System proposes to expand its Transplant Center to include liver transplantation. The Transplant Center is located at Norfolk General Hospital and has been in existence for twenty-five years....The Center currently performs kidney, heart, lung, and heart/lung transplants....
>
> ....There are approximately 25-30 adult patients (within the Center's primary market) that Sentara physicians refer out of the region and/or state for liver transplants each year. Based on information furnished by MCV's liver transplant program, there are also a significant number of patients referred to their center by Hampton Roads physicians who do not practice at Sentara. The Center assumes the accessibility of a liver transplant program in Hampton Roads will attract patient referrals from both Sentara and non-Sentara physicians. The Center expects to perform six transplants the first year of operation, twelve in year two, and fifteen in year three....
>
> To implement this proposed program, a surgeon with liver transplant experience will be recruited into one of the private surgical-practice groups within the region. It is expected this individual will immediately meet the minimum UNOS transplant surgeon criteria for implementation of a liver transplant program. Medical support for this patient population will be provided by gastroenterologists (GI) within the community who have experience in liver transplantation in their medical training at facilities such as the University of Wisconsin, Yale, and the Medical College of Virginia. The three GI physicians who have committed to medically manage liver transplant patients will also obtain any additional training necessary to provide optimal medical care for these patients. Several of the GI physicians are also involved with research clinical studies that offer patients access to the most advanced treatments available.
>
> Other physicians available within the community to support the liver program include Dr. Scott Stanley, a surgical pathologist, who completed his medical training at the University of Minnesota in their liver transplantation program. Dr. Martha Mooney, an infectious disease specialist who supports the kidney, heart, and lung transplant programs, will also provide support for the liver transplant program. SNGH has several intensivists on its medical staff who will provide support to the transplant physicians as well. Also, several members of the anesthesia practice which supports Sentara Norfolk General Hospital's surgery program have had experience with liver transplants in their medical training and fellowships.
>
> Because the Center performs kidney, heart, lung, and heart/lung transplants, there are only incremental operating costs associated with this program expansion. The administrative and clerical staff that support the current organ transplant programs will also support the proposed liver transplant program. Additional program and hospital staff needed to support the program include a full-time RN Transplant Coordinator, a part-time Licensed Clinical Social Worker, and a full-time CVS technician to operate the intraoperative cell-saver. These additional salary dollars have been detailed in the Financial Data section of this application.
>
> There are no additional inpatient bed requests or facility construction associated with this proposal. Liver transplant patients would be incorporated into the current vascular step-down and intensive care units within SNGH. The actual transplantation surgical procedure would be performed within the surgical suites at SNGH. Some of the more costly equipment used to support this complicated procedure (such as the

bypass pump and the intraoperative cell saver) is already available at SNGH, due to other tertiary-care programs located at the hospital.

Upon discharge, patients will initially be followed in the Transplant Outpatient Clinic located on the fifth floor of SNGH. It is assumed that patients will be followed in the Clinic for three months post-discharge. Any follow-up care required after this period will be coordinated with the patient's primary care and/or referring physician. The Transplant Outpatient Clinic presently supports the outpatient needs for the kidney, heart, and heart/lung programs. Thus, the liver transplant outpatients will utilize the existing Transplant Center examination rooms, waiting rooms, etc. Long-term follow-up on these patients will comply with standard protocols and procedures in place within the liver transplant program and will include at least an annual examination.

Reimbursement for liver transplantation is expected to be from sources similar to the existing organ transplant programs. Current facility contracts with insurers such as Aetna, Cigna, Blue Cross, Met Life, and MetraHealth Travelers include the ability for patients to have transplant services provided at SNGH. Patients covered by the Sentara insurance products that provide coverage for transplant services will also have the ability to have liver transplant services provided at SNGH. The liver transplant program expects to perform transplants on patients without the ability to pay, as part of Sentara's charitable mission of improving the health of citizens in the Hampton Roads community.

In summary, the application proposes to add a fifth organ transplant service, liver transplants, to the existing array of four transplant services now available at SNGH, the oldest being kidney transplants, begun in 1972. Because of the existing organ transplant programs, the applicant believes the patient care services and most of the medical skills and expertise necessary to care for liver transplant patients are already available at SNGH. However, an experienced liver transplant surgeon would have to be recruited.

Since this would be an addition, involving a modest number of patients, to an established organ transplant program, new costs associated with this project are expected to be minimal. No facility expansion, facility renovation, or bed additions are included in this application. The application's projected capital costs for this project are:

| | |
|---|---|
| Direct construction costs | $0 |
| Equipment | $54,400 |
| Legal fees | $7,500 |
| Total Projected Capital Costs | $61,900 |

The project will be financed with accumulated reserves.

**Applicant's Justification.** As justification for this project, the application states in part:

The proposal to expand the organ transplant services at SNGH to include liver transplant procedures will address the need of a substantial population to have improved access to liver transplant services. At present, liver transplants are available through three providers in the Commonwealth: MCV in Richmond, UVA in Charlottesville, and Fairfax Hospitals. All of these providers are located more than two hours away from a substantial portion of the population that SNGH proposes to serve. In fact, because of geographic barriers such as the Hampton Roads and Monitor-Merrimac bridge-tunnels, travel times often exceed two hours by a substantial margin. SNGH proposes to make liver transplant services available to this population by expanding its current successful organ transplant program to offer liver transplant services.

There is a substantial population from the greater Tidewater region in need of improved access to liver transplant services. On an annual basis, SNGH physicians who have committed to support the SNGH program refer 25 to 30 patients to MCV for liver transplants. SNGH believes that there is a substantial

number of patients referred outside of the region by other area physicians who would obtain liver transplant services in the area if they were available. SNGH proposes to make the service available so area residents who need liver transplants can be treated close to home.

The frequency and intensity of the services provided in conjunction with a liver transplant make it imperative that patients be treated close to their homes when possible. While a transplant candidate waits for an organ to become available, the patient must come to the transplant center on a regular basis for examination and diagnostic testing. Even if the wait for an organ is long, the patient must keep up with the schedule of visits to maintain eligibility for the organ. After the transplant procedure, the patient must return for examination by the transplant team at least twice weekly for six to twelve weeks. Diagnostic tests and other procedures also need to be performed during this time. If care is not available in a reasonably accessible location, these repeated medical episodes can cause extreme financial hardship for patients and their families in terms of lost wages, travel and lodging expenses. These added stresses compound what is already an extremely anxiety-ridden event.

SNGH proposes to eliminate some of the stress and disruption encountered by transplant patients who must travel outside the region to obtain care. SNGH is uniquely situated to bring liver transplant services to this region of the Commonwealth. As the region's only organ transplant provider and the region's only academic center for medical teaching, SNGH already has in place the systems, policies and procedures to support the liver transplant service. Further, SNGH already has much of the equipment necessary for the performance of transplants. Accordingly, SNGH can bring this needed service to the region at a very low capital cost and be cost competitive with the other programs in the state.

....Discussions with patients, physicians, health care providers, community organizations, etc. have indicated a keen interest and support for implementation of a liver transplant program in Norfolk, Virginia. The letters of support included in this application provide documentation of that support. The Transplant Center at Sentara Norfolk General Hospital has provided financial data that it believes will position the Center to provide liver transplantation at equal or lower cost to the closest Virginia transplant centers, in addition to providing consistent and expert health care in the patient's home environment. For these two reasons, the Sentara Health System is requesting approval to add the availability for liver transplantation to its organ transplantation program.

Thus, the application justifies the project on these principal bases:

- The number of residents of the SNGH service area who receive liver transplants each year would constitute an adequate caseload for establishment of liver transplant services at SNGH. Based on known referrals for liver transplants by physicians who practice at SNGH and estimated referrals by other physicians in the SNGH service area, SNGH believes it would attract a caseload meeting the volume standards for initiation and maintenance of liver transplant services.

- A substantial portion of the SNGH service area is two hours or more from the nearest provider of liver transplant services, MCV Hospitals in Richmond. The program of care for a liver transplant patient typically involves months of pre-operative evaluation and monitoring and six to twelve week of twice-weekly postoperative evaluation and monitoring. Because of the number of these outpatient visits, as well as the operation and inpatient recovery period, travel outside the patient's home area for these services constitutes a significant additional burden of time and expense for the patient and his family.

- SNGH is an established provider of transplant services for four other organs. SNGH already has in place the facilities, administrative services, patient care services, and most of the special physician and nursing-care skills necessary to perform liver transplants and provide care for these patients. Therefore, this project would involve modest new costs, require few new personnel, and require few changes in SNGH's present patient care operation.

Support for and Opposition to The Project. A considerable number of written and oral statements supporting and opposing this application have been presented to the Virginia Department of Health and to the Eastern Virginia Health Systems Agency (EVHSA), as part of the application material, at the EVHSA public hearing, and in separate correspondence. Of particular note is an extensive statement of opposition to the application submitted to the Department of Health jointly by Medical College of Virginia Hospitals (MCVH) and MCV Associated Physicians (letter dated September 16, 1996, with attachments).

Establishment of a liver transplant program at SNGH would likely result in a significant (perhaps 15%-20%) reduction in patient volume and revenue of the existing liver transplant program at MCVH. For this reason, and because MCVH has extensive experience in liver transplantation, MCVH's views regarding this application are noted at various points in this project review.

MCVH's views on the SNGH application are summarized in the following quotation from their letter of September 16, 1996 to the Department of Health.

> The Medical College of Virginia Hospitals and MCV Associated Physicians strongly oppose this application based on the negative impact another program will have on mortality and transplantation costs for the citizens of Virginia. Further, an additional program will compromise transplant research taking place at MCV, jeopardize transplant training occurring at MCV, and decrease MCV's ability to medically manage the transplant waiting list to optimize patient outcomes.
>
> MCV has a long-standing history of serving patients with end-stage liver disease from the Tidewater area, and many patients have documented the quality and convenience of the care they received in letters sent to the Eastern Virginia Health Planning Agency.
>
> Since there exists ample capacity for liver transplant services within easy access to patients from the Tidewater area, *there is no public need for an additional program in Planning District [20].* (emphasis original)

Thus, the MCVH letter notes a number of points of opposition, analysis of which is central to this project review. MCVH believes liver transplant patients from the Tidewater area are already being well cared for and that establishment of the SNGH liver transplant program would have the following negative effects:

- Increase mortality.
- Increase transplant costs.
- Compromise transplant research at MCV.
- Jeopardize transplant training at MCV.
- Decrease MCV's ability to medically manage the transplant waiting list for optimal outcomes.

The opposing views of SNGH and MCVH largely frame the issues for this project review. They are summarized in Table A below.

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*Table A*
**PRINCIPAL POINTS IN SUPPORT OF AND IN OPPOSITION TO ESTABLISHMENT OF A LIVER TRANSPLANT PROGRAM AT SENTARA NORFOLK GENERAL**

| SNGH Points in Support | MCVH Points in Opposition |
|---|---|
| Travel from the SNGH area to MCVH is burdensome for liver transplant patients and families. For some parts of the SNGH service area, travel time to MCVH exceeds the SMFP standard of two hours. | Access to MCVH from the SNGH service area is "easy". Patients have testified to the convenience and the quality of care at MCVH. |
| The number of liver transplant patients from the potential SNGH service area for liver transplantation constitutes an adequate caseload for a new program. | MCVH has ample capacity to serve the existing and future caseload from the SNGH area. The possibility that SNGH would meet minimum volume standards is not a sufficient reason to establish a new liver transplant program. |
| SNGH is a long-established provider of transplant services and has had excellent results with existing transplant programs. | A new liver transplant program would have higher mortality and morbidity than MCVH's existing program. |
| A liver transplant program at SNGH would eliminate the medical risk of transferring acutely ill patients from SNGH to MCVH. It would reduce problems of non-optimal communication and lapses in the continuum of care. | Dividing one larger caseload into two smaller ones diminishes the opportunity to manage the overall pool of patients for optimal outcomes. |
| SNGH is an established provider of transplant services for other organs. Establishment of this program would require few new resources and little new cost. | A new program will result in higher overall costs and higher cost per case for liver transplant services in Virginia. |
| A liver transplant program at SNGH would eliminate the cost of transferring acutely ill patients from SNGH to MCVH. | |
| A liver transplant program at SNGH would eliminate the costs associated with duplicate performance of services, tests, and procedures, which often occurs when patients begin their liver care under a Sentara physician and then enter the transplant program at MCVH. | |
| | Reduction in MCVH transplant volume would negatively affect transplant training at MCVH. |
| | Reduction in MCVH transplant volume would negatively affect transplant research at MCVH. |

Of note also is a letter of October 31, 1996 from Robert M. Carey, M.D., Dean, University of Virginia School of Medicine, to the Eastern Virginia Health Systems Agency (attachment L to the minutes of the EVHSA public hearing, September 16, 1996). Dr. Carey indicated opposition to this application, stating in part:

> ...Using the authority of that codified intent [of the Code of Virginia relating to certificates of public need], it is our belief that the needs of the patient population needing liver transplantation in the Commonwealth are very adequately met with current program offerings. Currently, liver transplant centers serving the Commonwealth are also producing outcomes that reflect their clinical success as well as their patient capacity. The University of Virginia, for example, was the first center from Baltimore to Atlanta to receive Medicare accreditation for liver transplantation, based on survival and outcome. It is our belief, therefore, that supply needs in quantity and quality are currently being met and that additions to this network are duplicative with no benefit that is substantive to qualify....
>
> Of further concern to an academic medical center such as ours is unnecessary duplication of a service that erodes an ability to provide clinical applications of translational research. Academic medical faculty's thoughtful explorations of the factors that insure better science in transplantation promote the likelihood of a better future for all transplant patients in the Commonwealth.

## Staff Analysis

*(NOTE: A summary of key issues and findings appears at the end of this analysis on pages 66-68.)*

**4.1. In determining whether a public need exists for a proposed project, the following factors shall be taken into account when applicable:**

**4.1.A. The recommendation and the reasons therefor of the appropriate regional health planning agency.**

By letter of November 13, 1996, the Executive Director, Eastern Virginia Health Systems Agency advised:

> Please be advised that our Board of Directors voted yesterday 6-3 to recommend approval of [COPN Request No. VA-5969]. The reasons for the vote were that the project would improve the availability and geographical accessibility to liver transplant services for P.D. 20 residents and that having a liver transplant service would round out the complement of transplant services that are presently provided at Sentara Norfolk General Hospital.

**4.1.B. The relationship of the project to the applicable health plans of the regional health planning agency, the Virginia Health Planning Board and the Board of Health.**

*Virginia State Medical Facilities Plan* "Organ Transplantation Services, Part II, Criteria and Standards":

Acceptability.
*SMFP Standard:* **Consumer Participation - Providers of organ transplantation services should provide a program of patient and family education regarding the nature of the patient's organ disease and the treatment of the patient and family in the management of the organ pre- and post-transplantation.**

The application states that "as an existing provider of organ transplantation services,...SNGH already has appropriate education programs in place." The application includes examples of patient education material and copies of policy and procedure statements regarding patient education for kidney transplant patients. SNGH subsequently furnished DCOPN a draft "Liver Transplant Protocol", which prescribes staff activities for patient and family education.

The application meets this standard.

Accessibility.
*SMFP Standards:*

A. **Travel Time.**

**Organ transplantation services, of any type, should be accessible within two hours driving time, under normal conditions, of 95% of Virginia's population.**

For the highest-level hospital services (e.g., certain trauma services, neonatal intensive care, transplantation, and others), SNGH can claim a service area covering Virginia Planning Districts 20, 21, and 22, as well as

several counties in northeastern North Carolina. (Several years ago, the Commonwealth's designation of planning districts merged PD 20, southside Hampton Roads, with PD 21, the Peninsula, to form PD 23, Hampton Roads. However, for many purposes of health systems analysis, it is useful to maintain the distinction between PD 20, southside Hampton Roads, and PD 21, the Peninsula. This distinction is maintained here.)

Populations in 2000 of the various components of the potential SNGH service area for transplant services are projected by the Virginia Employment Commission as follows:

***Table B***
**PROJECTED POPULATION IN 2000**
**OF JURISDICTIONS POTENTIALLY IN THE SNGH SERVICE AREA FOR LIVER TRANSPLANTS**

| Jurisdiction (from west to east) | 2000 Population | Percent of SNGH Area | Closest Point to MCV | Popu. Center to MCV | Popu. Center to SNGH |
|---|---|---|---|---|---|
| Southampton & Franklin | 25,390 | 1% | 55 | 70 | 50 |
| Isle of Wight | 30,477 | 2% | 65 | 75 | 35 |
| Suffolk | 59,482 | 3% | 75 | 85 | 18 |
| Chesapeake | 188,999 | 11% | 90 | 105 | 10 |
| Portsmouth | 102,961 | 6% | 90 | 95 | 7 |
| Norfolk | 256,094 | 15% | 85 | 92 | 4 |
| Virginia Beach | 483,559 | 28% | 95 | 102 | 10 |
| Total - PD 20 | 1,146,962 | 66% | | | |
| James City & Williamsbg. | 56,837 | 3% | 40 | 50 | 50 |
| York & Poquoson | 62,374 | 4% | 40 | 65 | 35 |
| Newport News | 184,787 | 11% | 55 | 70 | 30 |
| Hampton | 142,110 | 8% | 70 | 75 | 25 |
| Total - PD 21 | 446,108 | 26% | | | |
| Total - Hampton Roads | 1,593,070 | 92% | | | |
| Accomack | 32,405 | 2% | 150 | 165 | 75 |
| Northampton | 12,496 | 1% | 120 | 135 | 45 |
| Total - PD 22 | 44,901 | 3% | | | |
| Northeastern NC | 100,000 (est.) | 6% | | | |
| Total All Areas | 1,737,971 | 100% | | | |

Sources: (1) Populations from Virginia Population Projections 2010, Virginia Employment Commission, June 1993. (2) Mileages computed from 1994-95 VDOT Official State Map and American Map Corporation Delaware Maryland Virginia West Virginia Road Map.

This SNGH service area for the highest-level hospital services (hereafter referred to as SNGH's potential service area for liver transplantation) encompasses approximately 1.7 million persons and 24% of the total Virginia population. Within this area, all points except portions of James City County are closer to SNGH than to MCVH.

At present, the accessibility standard for liver transplant services is not met for approximately 25%-30% of Virginia's population: most of southwest Virginia (Health Planning Region 3) and part of eastern Virginia (Health Planning Region 5). In eastern Virginia, approximately 400,000 persons (all of PD 22 and perhaps one-half of the populations of Virginia Beach and Chesapeake) reside more than two hours driving time from MCVH.

Implementation of this project would bring an additional approximately 400,000 Virginia residents, about six percent of the state's population, within the SMFP's accessibility standard for liver transplant services. It would also materially improve accessibility for approximately 100,000 North Carolina residents, whose

nearest source of liver transplant services is Chapel Hill or Durham, approximately 100 miles from the center of the northeastern North Carolina area which uses tertiary-care hospital services at SNGH.

B. **Patient Access to Available Organs.**

**Providers of organ transplantation services should demonstrate to the satisfaction of the Department that they have clearly defined patient/organ-recipient policies based solely on medical criteria.**

The application states, "As a participant in the organ donor network, SNGH already has these policies and procedures in place." The application includes copies of transplant candidate selection policies for kidney, heart, and lung transplants. These policies describe the medical and psychosocial criteria for determining patient suitability for receiving a transplant. The Manager, SNGH Transplant Center, advised that the GI Advisory Team of SNGH's Transplant Leadership Council has prepared a first draft and is now working to refine organ-recipient policies for liver transplantation, which presents some especially difficult issues of patient suitability.

The application meets this standard.

Availability.
*SMFP Standards:*

A. **Regionalization of Services.**

**There should be no more than one transplantation program for each organ system in a health planning region.**

SNGH is the only provider of organ transplant services in Virginia Health Planning Region 5.

The application meets this standard.

B. **Conditional Approval.**

**Approval of organ transplantation programs shall be conditioned upon a facility's meeting both minimum volume and survival standards. Failure to meet these standards within two years of initiation of the service may be cause for revocation of the certificate of public need.**

If this application is approved, the approval will incorporate this condition, and this condition will be stated on the Certificate of Public Need.

C. **HCFA/Medicare Requirements.**

1. **Proposals to establish new transplantation services should demonstrate compliance with all Medicare program coverage criteria within two years of the initiation of the program.**

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Medicare program coverage criteria for liver transplant services specify: (1) a minimum annual volume of transplants (12, same as SMFP standard) and (2) minimum patient survival rates for one year and for two years post-transplant (77% one-year survival, 60% two-year survival).

If this application is approved, the approval will incorporate as a condition, stated on the Certificate of Public Need, that within two years of initiation the SNGH liver transplant program will achieve the minimum annual volume standard and the minimum *one-year* survival standard required for Medicare certification. (Compliance with the Medicare two-year survival standard cannot be demonstrated until more than two years have passed since initiation of the liver transplant program.)

2. **Proposals to expand existing transplantation programs should demonstrate that existing organ transplantation services comply with all applicable federal Health Care Financing Administration criteria for Medicare program coverage.**

SNGH's existing organ transplant services are: (1) kidney, (2) heart, (3) lung, and (4) heart-lung.

The application states that SNGH's kidney and heart transplant programs hold Medicare (and UNOS) certification. The application speaks *collectively* of SNGH's lung and heart-lung transplant programs (although they are categorized separately by UNOS for statistical purposes and categorized separately by SNGH in reporting average charges and average costs for transplant services). The application states:

> This program was certified by UNOS in 1996 but has not achieved Medicare certification due to low annual transplant volumes attributable to limited availability of suitable organs. Recently the Center performed ten lung, heart/lung transplants in a twelve-month period, as required by Medicare for certification. The Center will need to perform ten lung, heart/lung transplants throughout this next year to meet Medicare certification.

Assuming, as implied above, that Medicare views lung and heart-lung transplant services in the same facility as a *single service for certification* and that the minimum twelve-month volume for certification is a total of ten lung and heart-lung transplants, the following is noted (also see Table 2 attached):

- Five lung and/or four heart-lung transplant services are operating in Virginia. UVAH, McGuire VA, MCVH, and SNGH perform lung and heart-lung transplants. Fairfax Hospital performs lung transplants, but has not performed a heart-lung transplant (through 1995).

- SNGH was the last of the five Virginia facilities to begin lung and/or heart-lung transplant services. SNGH's first lung transplant was in 1992, and their first heart-lung transplant was in 1993.

- Through 1995, *only UVAH* had performed ten or more lung and heart-lung transplants in a single calendar year, which UVAH did in each year 1991 through 1995.

- After UVAH, the next highest (calendar-year) annual volume (through 1995) of lung and heart-lung transplants was six, performed by MCVH in 1993 and by Fairfax Hospital in 1994.

- SNGH performed five lung and heart-lung transplants in calendar year 1995, with a higher number in more recent (non-calendar-year) twelve-month periods, according to the application.

Accordingly, SNGH has *not* met the annual volume requirement for Medicare certification of their *lung and heart-lung* transplant service. However, SNGH's performance is essentially the same as three of the four other providers of this service in Virginia, and SNGH is making progress toward the minimum annual volume requirement for Medicare certification of their lung and heart-lung transplant service.

The application demonstrates substantial conformance with this standard.

**Continuity of Care.**
***SMFP Standards:***

**Discharge planning procedures and follow-up care:**

**A. Providers of organ transplantation services should have written procedures and policies for discharge planning and follow-up care for the patient and the family which are part of the institution's overall discharge planning program.**

The application states, "As an existing provider of organ transplant services, SNGH already has such policies and procedures in place." The application includes copies of discharge planning and post-discharge policies and procedures for kidney, heart, and heart/lung transplant patients. SNGH subsequently furnished DCOPN a draft "Liver Transplant Protocol", more fully described below, which addresses discharge planning and post-discharge concerns for liver transplant patients.

The application meets this standard.

**B. Providers of organ transplantation services should have established protocols for referring physicians and the organ transplantation service to assure adequate post-operative diagnostic evaluation for transplant patients.**

The application states, "As an existing provider of organ transplant services, SNGH already has such policies and procedures in place." The application includes copies of post-transplant evaluation protocols for kidney and lung transplant patients. SNGH subsequently furnished DCOPN a draft "Liver Transplant Protocol", which addresses the following matters from the day of operation through the day of discharge:

- Expected outcomes
- Teaching of the patient and family
- Consults
- Treatments
- Tests
- Medications
- Diet
- Activity
- Spiritual and psychosocial concerns
- Discharge planning and post-discharge concerns

The application meets this standard.

**Cost.**

***SMFP Standard:*** **Cost and Charges - The total cost (direct and indirect) for providing all organ transplantation services should be comparable to other similar service providers in the health planning region and the state.**

**COMPARISON OF OVERALL NET REVENUE AND COSTS AMONG VIRGINIA'S MAJOR TERTIARY-CARE HOSPITALS**

The application states, "SNGH is typically a low cost, low charge provider." Table C compares SNGH's case-mix indices, net patient revenue, and costs with those of the other major tertiary-care hospitals in Virginia, all of which offer transplant services for one or more solid-organ systems.

*Table C*
**COMPARISON OF CASE MIX, NET PATIENT REVENUE, AND COSTS AMONG MAJOR TERTIARY-CARE HOSPITALS IN VIRGINIA–1994**

| Hospital | All-Patient Case Mix | Medicare Case Mix | Net Reve. Per Adj. Admiss. | Cost Per Adj. Admiss. | Net Reve. Per Adj. Pat. Day | Costs Per Adj. Pat. Day |
|---|---|---|---|---|---|---|
| UVA | 1.48 | 1.70 | 10,057 | 10,838 | 1,550 | 1,671 |
| Fairfax | 1.15 | 1.62 | 6,830 | 6,327 | 1,483 | 1,373 |
| Roanoke Mem. | 1.56 | 1.70 | 8,664 | 8,332 | 1,220 | 1,173 |
| MCV | 1.40 | 1.71 | 9,833 | 9,946 | 1,478 | 1,495 |
| Avg. of Above | 1.40 | 1.68 | 8,846 | 8,861 | 1,433 | 1,428 |
| SNGH | 1.47 | 1.98 | 7,600 | 7,153 | 1,165 | 1,097 |
| *SNGH % of Avg.* | *105%* | *118%* | *86%* | *81%* | *81%* | *77%* |

Source. Virginia Health Services Cost Review Council, Hospital and Nursing Home Industry Trends, 1995. Data for 1994 is the most recent published data.

Table C shows that SNGH has *higher* case-mix indices (both all-patient and Medicare case mix) than the *average* for the four other major tertiary-care hospitals, but SNGH has 14% to 23% *lower* net revenue and costs per patient day and per admission (with both admissions and patient days adjusted to reflect each hospital's volume of outpatient services). This data indicates that SNGH is serving a slightly more demanding case mix of patients, but using less resources and receiving less revenue to do so, than the four other major tertiary-care hospitals, on the average.

Indeed, SNGH's net revenue and costs *per patient day* are lower than any of the other four hospitals. SNGH's net revenue and costs *per admission* are 11% and 13% higher than at Fairfax Hospital, but this probably reflects Fairfax Hospital's high volume of obstetric and pediatric admissions. These are typically much shorter stays and therefore lower cost than other admissions (as can be inferred from Fairfax Hospital's comparatively low *all-patient* case-mix index). Table C fully supports the application's assertion that "SNGH is typically a low cost, low charge provider."

Although relevant and important to consider, the above information on SNGH's *overall* revenue and cost performance does not specifically address the SMFP standard regarding the "cost and charges" of a proposed liver transplant program.

## CHARGES FOR LIVER TRANSPLANT SERVICES.

**Information Provided by the Applicant on Charges of Existing Programs.** The applicant's response to completeness questions states:

> The only charge information available for non-Sentara programs is the average liver transplant charges incurred for patients covered by Sentara Insurance products. Average transplant charges for May 1, 1995-April 30, 1996 were $427,990. These charges include professional fees, evaluation, surgery, and post-operative care for 12 months post surgery.

If taken at face value, this reported average charge would make the proposed SNGH liver transplant program (charges described in Tables D and E below and in Table 1 attached) look very modestly priced, indeed. However, the above-quoted statement omits many essential facts necessary for reliable interpretation:

- How many patients are included in this statistic? Probably no more than three or four.
- Did one or more of these cases involve some unusual circumstances (such as graft failure and retransplant during the period of the charge data) that make this case(s) unrepresentative and thus skew the average?
- What was the *range* of charges among the individual cases?
- What proportion of the total charges was for *hospital services*, which are the only services covered by the projected SNGH charge data (described below)?
- What amount was *actually paid* (i.e., the gross charges *less contractual adjustments*) by Sentara for these cases?

In view of these questions not addressed by the applicant, this data must be disregarded in review of this application.

**Data from Virginia Health Information on Charges for Liver Transplant Hospitalizations.** However, limited information is available on charges for liver transplant services at the three existing programs in Virginia. The EVHSA staff report on this application reported average charges, by hospital and payer, for liver transplant hospitalizations for the period July 1, 1994 to June 30, 1995. The data was obtained from the Health Systems Agency of Northern Virginia, who prepared it from a basic data file supplied by Virginia Health Information, Inc. (VHI). *(NOTE: VHI explicitly disclaims any responsibility for the accuracy of results obtained by others using VHI data files.)*

According to the EVHSA staff report (and consistent with the structure of the VHI data file), these figures do not include patient listing, patient evaluation, and physician fees. These figures are *hospital* charges only and only for the *inpatient stay during which the transplant was performed.* Hospital charges for services provided on an *outpatient* basis or charges for any inpatient stay *other than for the transplant procedure* are not included in these figures. As can be computed from attached Table 1, SNGH's projected annual gross revenue from *transplant hospitalizations* is about 64% of total projected annual gross revenue from the complete liver transplant program, including patient listing and patient evaluation charges as well as transplant hospitalization charges.

The EVHSA staff report provided the following information on average charges for hospital stays for liver transplants during the period July 1, 1994 to June 30, 1995:

- Fairfax Hospital $119,523 (for 15 transplants), range among payers: $88,833 - $277,502
- UVAH $109,917 (for 53 transplants), range among payers: $77,424 - $134,482
- MCVH $134,182 (for 37 transplants), range among payers: $101,552 - $217,206

Based on this data, the EVHSA staff report stated: "Thus in Year II (1998) SNGH's average transplant charge [$159,729] would be $25,547 and 19% higher than MCV's was in 1995." Although this comparison is correct in its math, it is not reasonable for analysis to compare 1994-95 charges with 1998 charges. Inflation is a fact of life, not least in health care, and must be taken into account for review of this application, just as it was taken into account by SNGH in preparing their pro forma.

The SNGH pro forma included in the application (reproduced in attached Table 1) incorporates a five-percent increase in charges from year 1 to year 2. It is reasonable to believe that the three existing liver transplant programs have been increasing their charges at a rate similar to that projected by SNGH. Inflating their reported average charges forward for three and one-half years (from 1994-95 to 1998) at a compounded average annual rate of five percent (total increase of 18.6%) yields the following comparison with SNGH's projected average charge for 1998.

*Table D*
**COMPARISON OF PROJECTED HOSPITAL CHARGES IN 1998 FOR INPATIENT STAYS FOR LIVER TRANSPLANTS**

| Hospital | Average Charge 7/1/94-6/30/95 | Projected 1998 Average Charge (at 5% annual inflation for existing programs) | Percent of SNGH 1998 Projected Charge |
|---|---|---|---|
| Fairfax Hosp. | 119,523 | 141,754 | 88.7% |
| UVA Hosp. | 109,917 | 130,362 | 81.6% |
| MCV Hosp. | 134,182 | 159,140 | 99.6% |
| Sentara NGH | not applic. | 159,729 | |

Source. Average charge data for 1994-95 from EVHSA staff report on COPN Request No. VA-5969, 11/12/96. Projected 1998 charges, except SNGH, by DCOPN.

As shown in Table D, there is *no difference* in the average charge for the *transplant hospitalization* between SNGH and *MCVH*, when the VHI 1994-95 charge information from the existing liver transplant programs is put on a comparable basis with SNGH's proposed 1998 charge for liver transplant hospitalizations. SNGH's projected charge in 1998 is about 11% higher than the projection in Table D of the 1998 average charge at *Fairfax* and about 18% higher than the projection of the 1998 average charge at *UVAH*. Given the large range of 75% or more from the lowest charge to the highest charge of each existing provider in 1994-95, it is doubtful that the projected charge differences of 11% and 18% between SNGH and two other providers are of much practical significance.

Analysis of Net Revenue. More important for analysis is that the amounts in Table D are *charges*, rather than *revenue actually collected or expected to be collected*. Charges for hospital inpatient services are essentially a fiction. Virtually no payer actually pays charges or is expected to pay charges. The actual transaction amount--that which really counts--is not reported by hospitals to VHI and is not available for this project review. Furthermore, the relationship between charges (gross revenue) and the actual amount collected (net revenue) varies substantially among individual hospitals and among services within a hospital. It is not possible to use reported charges for a particular kind of hospital stay to accurately estimate net revenue for that service. Therefore, while SNGH's pro forma projects net revenue for their

proposed liver transplant program as a whole, net revenue data from the other liver transplant programs in Virginia is not available, with one limited exception.

Included in material provided to the Department, as part of MCVH's statement of opposition to this application, was a set of slides used by MCVH representatives in a presentation to SNGH management in September 1996. One of these slides noted the existence of an MCVH "case rate" for complete liver transplant services provided to patients covered by Sentara health plans. According to the slide, the case rate is now set at $156,500 and covers these services:

- Hospital and MD fees pre-transplant, including pre-transplant hospitalizations.
- Hospital and MD fees transplant hospitalization.
- Hospital and MD fees post-transplant for one year and 30 days of immunosuppressive treatment.

This case rate from MCVH is offered to various health care payers, including Sentara insurance plans, through United Resources Network, a broker of health care services to the insurance industry. As a contractually-established rate for services, the case rate represents the *actual transaction amount*, i.e., net revenue. With the important qualifications noted below, it is a valid (and current) number to compare with SNGH's projected 1997 average net revenue for a liver transplant case. The MCVH case rate compares with SNGH's pro forma net revenue (adjusted to add back 3.0% of gross revenue allowed for bad debt) for 1997 as shown in Table E below:

***Table E***
**COMPARISON OF PROJECTED 1997 SNGH NET REVENUE WITH MCVH CURRENT CASE RATE FOR LIVER TRANSPLANT SERVICES**

| SNGH Service | SNGH 1997 Gross Revenue (Charge) | SNGH 1997 Net Revenue (68.1%) | MCVH Case Rate | SNGH Net Revenue as % of MCVH Case Rate |
|---|---|---|---|---|
| Patient evaluation | 1,058 | 720 | Not applicable | Not applicable |
| Patient listing | 8,558 | 5,828 | Not applicable | Not applicable |
| Transplant hospitaliz. | 152,123 | 103,596 | Not applicable | Not applicable |
| *TOTAL* | *161,739* | *110,144* | *156,500* | *70.4%* |

Sources: (1) SNGH gross revenues from COPN application. (2) Calculation of net revenue per type of service by DCOPN (3) MCVH case rate from slides for MCVH presentation to SNGH, September 1996.

Although the comparison in Table E involves *net* revenue figures, which are economically meaningful (in contrast to *gross* revenue figures), it is nonetheless a flawed comparison for two reasons. The most important deficiency of the comparison is that the SNGH figures do not include physician fees (except for pathology services), which *are* included in the MCVH case rate. DCOPN has no information with which to adjust the SNGH projections to make them more comparable to the MCVH case rate.

The second deficiency of the comparison in Table E is that the SNGH allowance for contractual adjustments for liver transplant services (31.9% in year 1) was apparently based on current *hospital-wide* experience. Current hospital-wide experience may not be a good predictor of the contractual allowance percentage that would be found in a particular very small and very specialized program not yet in operation In summary, from this comparison and making some very rough allowance for physician fees, it can only be said that the SNGH net revenue from liver transplant services would apparently be somewhere in the vicinity of the MCVH case rate.

Accordingly, *with respect to charges and net revenue*, it cannot be said either that this application has demonstrated conformance or has not demonstrated conformance with the "cost" standard in the State Medical Facilities Plan. Nonetheless, in the absence of meaningful service-specific charge data, the good *overall* net revenue performance of SNGH, relative to the other major tertiary-care hospitals in Virginia, as shown in Table D above, is a significant point in favor of this application.

## COSTS OF THE LIVER TRANSPLANT PROGRAM

Information on the *costs* (i.e., the expenses) of specific patient stays or specific services in Virginia hospitals is not reported externally. Therefore, it is not possible to make a comprehensive comparison of SNGH's projected costs for liver transplant services with the costs of existing liver transplant programs in Virginia.

In material presented to the EVHSA public hearing (September 16, 1996) in opposition to this application, MCVH cited "over $1,500,000 in fixed wages" attributable to their liver transplant program. According to the minutes of the public hearing, "[Dr. Fisher] then showed the fixed cost of the liver transplantation team with wages at $1.5 million which would be duplicated at SNGH to perform the small projected volume which he stated could easily be accommodated at the established programs in the state." In addition to wages for various non-physician personnel, the cited fixed wages at MCVH included "surgeons (guaranteed salary)" and "hepatologists (practice support)".

SNGH Projected Expenses. In contrast to MCVH's cited fixed wages (including physician compensation) exceeding $1.5 million, SNGH's application cites *incremental* wages and benefits, attributable to the proposed liver transplant program, approximating only $80,000. While this projected incremental personnel expense does not include compensation of any physicians (either surgeons or hepatologists, as they will be part of the private practice community and their compensation not a responsibility of SNGH), it does show that the extensive duplication of personnel costs predicted by MCVH is not projected by SNGH. SNGH does not project extensive duplication of (non-physician) personnel costs, because SNGH expects to draw on the personnel resources already available to the existing transplant programs at SNGH, which are performing more than 50 transplants per year.

The following are important points about SNGH's projected expenses for the proposed liver transplant program (see attached Table 1 for detail of projected expenses):

- Of the approximately $2.0 million of total expenses projected for year 2 (1998), approximately $500,000 or about 25% represents "indirect expenses" or allocation to the new program of "overhead" expenses (e.g., building costs, administration, general support services) that *already exist at SNGH*. Accordingly, these projected expenses of the proposed liver transplant program do not represent additions to, or duplications of, any expenses already in the health care system. These expenses are essentially irrelevant to this analysis.

- The remaining approximately $1.5 million of total expenses projected by SNGH for year 2 includes relatively little in the way of expenses which are *duplicative* of expenses that *must continue to be incurred* by existing liver transplant programs, regardless of whether SNGH establishes a program.

- ◊ The depreciation expense of $9,480 per year for the equipment (retractors, infuser, freezer, etc.) to be added by this project is both fixed and *duplicative*.

- ◊ The projected "other" expense of $105,000 in year 2, said to be for "continuing education, marketing, etc.", is not inherently fixed but is *duplicative*.

- ◊ The projected salary and benefits expenses of $80,331 (transplant coordinator, 0.5 FTE social worker, plus call pay for technician personnel) are not truly fixed but are *at least partially and perhaps entirely duplicative* of expenses that *must continue to be incurred* at existing liver transplant programs.

  - It is unknown whether a reduction of perhaps 10-15 liver transplant cases (15%-20%) at MCVH would permit any reduction in personnel costs of MCVH's liver transplant program. It would appear, though, that a 15%-20% reduction in program volume at MCVH *should* permit *some* reduction in MCVH's liver transplant personnel costs, which MCVH has stated to be $1.5 million (including physician compensation). However, it seems quite unlikely that development of a liver transplant program at SNGH would reduce volume at any existing program, other than MCVH, to an extent that would permit any reduction of that other program's personnel expenses.

  - On balance, for this review it is assumed that approximately one-half, about $40,000, of SNGH's stated incremental personnel costs *is duplicative* of personnel costs in other programs, specifically MCVH. (This implies that if MCVH were to experience a 15%-20% reduction in liver transplant program volume, MCVH would be expected to reduce their associated personnel expenses by three percent, but no more.)

- ◊ The projected $1.25 million of "patient care costs" at SNGH in year 2 consists of all those expenses associated with the direct care of the patient during the evaluation, listing, and transplant hospitalization phases of the patient's treatment. These expenses include nursing and therapy services, counseling, imaging, laboratory, pharmacy, medical supplies, room expense, dietary services, and any other patient care service.

  - "Patient care costs" include *variable*-cost elements (e.g., medical and housekeeping supplies, drugs, raw food, on-call nursing and therapy time, etc.), that change directly and proportionately with the volume of patient services provided. Patient care costs also include *fixed*-cost elements (e.g., overhead and core-staff components of the various ancillary patient service departments, plant and support costs allocated directly to the nursing care unit, etc.), that do not change unless the volume of patient services changes dramatically. Although patient-care costs are categorized as "direct expenses" in the SNGH pro forma, these costs are by no means entirely *variable* costs. A significant, but undetermined portion of "patient care costs" identified in the SNGH pro forma are fixed over a considerable range of patient service volume, already exist at SNGH, and would *not be increased* by the introduction of liver transplant services.

  - By definition, the *variable*-cost elements in "patient care costs" are *not duplicative* of any costs which *must* continue to be incurred at existing liver transplant programs. Since the application states that the proposed liver transplant program would produce no

*incremental* fixed costs, beyond those specifically identified (detailed above), it appears that none of the "patient care costs", whether variable or fixed, should be viewed as *duplicative* of costs that *must* continue to be incurred at existing liver transplant programs.

- The application cites two opportunities for *reduction* of patient care costs as a result of establishing a liver transplant service at SNGH. The cost of medically transferring acutely ill patients from SNGH to MCVH for transplantation would be eliminated. Also eliminated would be the cost of duplicating certain procedures and activities, which the applicant says are duplicated now when liver transplant patients are transferred from care by SNGH physicians to care by MCVH physicians. Since the application provides no quantification of these events, they cannot be given any material weight in this review.

The foregoing suggests that approximately $165,000 (depreciation, "other", and one-half of the specifically identified salaries and benefits) or about 8.5% of SNGH's projected total expenses in year 2 for the liver transplant program *are duplicative* of expenses that *must* continue to be incurred at existing liver transplant programs, regardless of whether SNGH establishes a program.

SNGH projects serving 300 "patients" in year 2, comprising 12 transplants, 96 listings, and 192 evaluations. (Although the projected numbers of listings and evaluations seem unreasonably high, as discussed on pages 53-54, they are accepted here for analysis of the pro forma, which is based on them.) These are not 300 different individuals but rather 300 separate phases of liver transplant care provided to some unknown but smaller number of individuals, probably approximating the number of patients evaluated, projected at 192 in year 2. These are the people who would "benefit" from the incremental cost, estimated above to be $165,000 in year 2, resulting from establishment of the proposed program at SNGH. On this basis, the incremental cost of the proposed program, per individual benefited in year 2, is roughly $1,000.

Alternatively, a number of "transplant-equivalent" patients can be calculated using the per-patient charge data in the SNGH pro forma. As proposed for year 2, a patient *listing* bears a charge of $8,986 or 5.6% of the charge for the transplant procedure, while a patient *evaluation* bears a charge of $1,111 or 0.7% of the charge for the transplant procedure. Using these proportions, the 96 patient listings and 192 patient evaluations projected for year 2 convert to 6.1 "transplant-equivalent" patients, for a total of 18.1 "transplant-equivalent" patients projected for year 2. On this basis, the incremental cost of the proposed program, per "transplant-equivalent" patient projected in year 2, is about $9,000.

<u>Physician Services Costs.</u> Unaddressed in the foregoing discussion of costs is the cost of physician services as an element of the proposed SNGH program. The application explains that SNGH will have no responsibility for compensating, subsidizing, or guaranteeing any minimum level of income for any existing physicians on the SNGH medical staff or any physicians newly recruited to the SNGH medical staff as a result of establishing the proposed liver transplant program. Although physician compensation or support is not an element of expense for SNGH, the cost of physician services is still an element of expense within the health care system that should be noted in this project review.

As with the hospital costs discussed above, the key question regarding the cost of physician services is the extent, if any, of *incremental* physician costs that will result from this project and will be *duplicative* of costs that *must continue to be incurred* in connection with existing liver transplant programs. However, very little that is solid can be said on this point.

If this project is implemented, the private-practice community associated with SNGH will recruit at least one new physician, a liver transplant surgeon, to the community. This will result in an increase in physician fee revenue and physician support costs *within eastern Virginia*. Whether this new physician will cause an increase in physician fee revenue and physician support costs *within the state* can only be speculated. If this physician is recruited from *within* Virginia, then no net effect on the state would be expected. If this physician is recruited from *outside* the state, but his/her arrival causes a redistribution of transplant volume among programs within the state, so that a physician already here leaves the state, then also no net effect on the state would be expected.

If, as seems most likely, this physician is recruited from outside the state and this causes no departure of a physician already here, then, as a minimum, incremental and *duplicative* physician *support* costs (office costs, staff, etc.) would result. However, there is no particular reason to think that *incremental and duplicative* physician *fee payments* would result. The charges generated by this new physician would presumably reflect either *redistribution* of patient volume and associated charges *within* the state or reflect *addition* of patient volume and associated charges *to* the state. If, as seems most likely, establishment of a liver transplant program at SNGH reduced volume by 15%-20% at MCVH, MCVH might be required to maintain income levels of some physicians associated with their program. To whatever extent this occurred, it would be a *duplicative* cost, i.e., a net addition to health care costs in Virginia.

Neither the application nor any subsequent communication from SNGH or MCVH has provided specific information regarding possible duplication of expenses for physician services, although the potential for this problem was implied in MCVH's presentation to the EVHSA public hearing on this project.

## SUMMARY OF FINDINGS AND CONCLUSIONS REGARDING COSTS AND CHARGES

The availability, quality, precision, and relevance of data to address the SMFP's "cost" (actually costs and charges) standard for this service are so limited that directly addressing the standard is hardly possible.

Data on *gross charges* is available for the transplant hospitalization only, which is about two-thirds of SNGH's projected annual total gross revenue from the proposed liver transplant program. When appropriately analyzed, i.e., when inflation adjustments are made, the gross charges data indicates that there is no material difference between SNGH's proposed 1998 charge for the transplant hospitalization and the projected (by DCOPN) 1998 gross charge at the three other programs in Virginia. There is not even a one-percent difference between SNGH and MCVH. (See Table D above.)

However, gross charges are not meaningful figures and cannot readily be translated into meaningful figures, i.e., actual transaction amounts, net revenue. One limited measure of net revenue is available for MCVH's liver transplant program. This is a case rate offered to several health care payers, including Sentara insurance plans. The MCVH case rate is compared with SNGH's projected net revenue from liver transplant services (Table E above), but even this comparison is deficient and inconclusive.

SNGH's projected *costs* for the proposed liver transplant program are contained in the application and have been analyzed. However, there is virtually no basis for comparing them with costs of the other liver transplant programs in Virginia, since cost data for them is not available. The EVHSA staff report on this application, as well as extensive comments in opposition submitted by MCVH, emphasized the view that the proposed liver transplant program at SNGH would result in a large *duplication* of costs for liver transplant services within Virginia.

However, the DCOPN analysis finds that when the expense elements presented in the SNGH pro forma are carefully analyzed, with due regard for hospital cost allocation procedures and the true extent of variable vs. fixed costs, very little of the expenses presented in the SNGH pro forma constitute duplication of any costs which *must continue to be incurred* by existing liver transplant programs, if a new program is established at SNGH.

Specifically, DCOPN finds that about $165,000 or 8.5% of SNGH's projected year 2 (1998) costs are duplicative of costs which must continue to be incurred by existing liver transplant programs, if a new program is established at SNGH. These estimated duplicative costs amount to about $9,000 per "transplant-equivalent" patient (a measure of patient volume combining SNGH's projected listings, evaluations, and transplant hospitalizations according to their relative charges) or about $1,000 per "patient", counting each listing, each evaluation, and each transplant performed as a "patient".

Because the cost and charge standard specific to this application cannot be well addressed, due to the lack of meaningful and comparable data among liver transplant programs, it is relevant to note SNGH's superior *overall* performance with respect to net revenue and costs, as reported by the Virginia Health Services Cost Review Council and summarized in Table C above.

It cannot be said that this application demonstrates--or even that it is possible to demonstrate--conformance with the SMFP cost standard for the proposed liver transplant service. However, the balance of evidence indicates that the proposed SNGH program would meet the cost standard, if adequate data for assessment were available. The DCOPN analysis also finds that *duplicative* costs embodied in this project (with some uncertainty as to the extent of duplicative *physician services* costs, which are *not* within the SNGH project costs) are *not large* by any comparative standard.

Quality:
*SMFP Standards:*

**A. Minimum Utilization.**

**1. Proposals to establish, expand, or replace organ transplantation services should demonstrate that a minimum number of transplants will be performed annually. The minimum number required by organ system is:**

| | |
|---|---|
| **Kidney** | **25** |
| **Heart** | **12** |
| **Heart/Lung** | **12** |
| **Liver** | **12** |
| **Pancreas** | **12** |

TRANSPLANT PROGRAM VOLUMES IN VIRGINIA--1988-1995

Before applying the minimum utilization standard to review of the proposed liver transplant program at SNGH, useful perspective--*including the degree to which the standard has been met or has not been met by existing transplant programs in Virginia*--can be gained from examining the trends in volume and distribution of activity among the various transplant programs now existing in Virginia, including those already established at SNGH.

Table 2 attached shows the details of this information for each Virginia transplant program and provides total statewide and nationwide transplant volume for each organ system for each year 1988-1995. Table 2 also provides the following statistics for each organ system:

- Average annual volume per Virginia transplant program in each year (among those programs which performed any transplants in that year).
- Average annual rate of change in volume, by program, statewide total, and nationwide total.
- SNGH transplant volume as a percent of statewide volume in each year.
- Virginia transplant volume as a percent of nationwide volume in each year.

The information in attached Table 2 is summarized in the following table:

***Table F***
**SUMMARY DATA ON VIRGINIA SOLID-ORGAN TRANSPLANT PROGRAMS--1988-1995**

| Type of Transplant | No. of Programs 1988 (or 1st yr.) | No. of Programs 1995 | Total Transplants 1988 (or 1st yr.) | Total Transplants 1995 | Avg. Program Vol. (1st yr. with usable data*) | Avg. Program Volume 1995 | SMFP Min. Ann. Vol. Standard | Cumu. Yrs. of Program Existence* < SMFP Std. | SNGH Volume 1995 |
|---|---|---|---|---|---|---|---|---|---|
| Kidney | 3 | 6 | 116 | 201 | 39 | 34 | 25 | 4 of 34 | 35 |
| Heart | 3 | 7 | 82 | 72 | 27 | 10 | 12 | 21 of 47 | 13 |
| Lung | 1 | 5 | 3 | 28 | 3 | 7 | w/hrt.-lung | w/hrt.-lung | 4 |
| Heart-Lung | 2 | 3 | 2 | 1 | 1 | 1 | 12 | 22 of 26 | 1 |
| Pancreas | 1 | 3 | 1 | 19 | 5 | 6 | 12 | 12 of 12 | not appl. |
| Liver | 2 | 3 | 22 | 129 | 18 | 43 | 12 | 0 of 18 | not appl. |
| Total | 12 | 27 | 226 | 450 | 19 | 17 | not appl. | 59 of 137 | 53 |

Source: Basic data from Table 2, attached. Additional calculations by VDH DCOPN.
*Note: Excluding program start-up years, which are usually partial years.

<u>Transplant Program Volume Trends and Distribution.</u> Table 2 attached and Table F above support the following observations:

<u>Kidney Transplants.</u> Kidney transplants are by far the most frequent solid-organ transplant procedure in Virginia. Kidney transplants increased nearly 75% in Virginia from 1988 to 1995. However, due to the emergence of new providers, *average annual volume per kidney transplant program* in Virginia was lower in 1995 than in 1988. Nonetheless, all kidney transplant programs in Virginia, except Roanoke Memorial, had 1995 volume well above the <u>State Medical Facilities Plan</u> (SMFP) minimum annual volume standard of 25.

From 1988 through 1995, there were 34 "program-years" (a program-year means one program in operation for one year) of kidney transplant activity in Virginia, excluding program start-up years. In four (12%) of these (post start-up) program-years, volume was *below* the SMFP standard of minimum annual volume.

<u>Heart Transplants.</u> Heart transplants in Virginia are less than 40% as numerous as kidney transplants, and their number has been essentially constant. Yet, Virginia has more programs (seven) for heart transplants than for any other organ system. (One program, McGuire VA Medical Center, serves a restricted population.) There were only three heart transplant programs in Virginia in 1988 (Fairfax, McGuire, and MCVH). Since 1990 there have been seven, including SNGH. UVA Hospitals

started its heart transplant program in 1989, and by 1991 UVAH had become the largest program in the state and remains so today.

Reflecting the substantial increase from 1988 to 1995 in the number of heart transplant programs in Virginia, *average annual volume per program* has decreased sharply. In 1995, heart transplant volume at Fairfax, UVA Hospitals, McGuire VA, and SNGH equaled or exceeded the SMFP minimum annual volume standard of 12, while MCVH, Children's Hospital of the Kings Daughters, and Henrico Doctors were below the SMFP standard of minimum annual volume. Average annual volume per heart transplant program in Virginia ranged from 10 to 13 during the last three data years, essentially matching but not exceeding the SMFP standard of minimum annual volume.

From 1988 through 1995, there were 47 program-years of heart transplant activity in Virginia, excluding program start-up years. In 21 (47%) of these (post start-up) program-years, volume was *below* the SMFP standard of minimum annual volume.

**Lung Transplants.** The first lung transplant program in Virginia appeared at UVA Hospitals in 1990. Two years later there were five lung transplant programs in Virginia, the number today, which includes SNGH. Among these five programs, only UVAH has ever had more than six lung transplants in a single (calendar) year (through 1995). The annual number of lung transplants in Virginia increased sharply after the UVAH program was established in 1990. However, in the last four calendar years, the total number of lung transplants statewide appears to have stabilized between 25 and 30, and the *average annual volume per program* has stabilized around six. The SMFP provides no standard of minimum annual volume specifically for lung transplants, which are included with heart-lung transplants below.

**Heart-Lung Transplants.** There are four heart-lung transplant programs in Virginia (UVAH, McGuire VA, MCVH, and SNGH). However, heart-lung transplants are very rare. No more than four were performed in Virginia in any year from 1988 to 1995. For application of a standard of minimum annual volume, lung transplants and heart-lung transplants are combined.

From 1988 through 1995, there were 26 program-years of lung and heart-lung transplant activity in Virginia, excluding program start-up years. In 22 (85%) of these years, volume was *below* the SMFP standard of minimum annual volume.

**Pancreas Transplants.** Before 1992, UVA Hospitals was the only provider of pancreas transplants in Virginia. In 1992, Fairfax Hospital established a pancreas transplant program, as did MCV Hospitals, although MCVH's first pancreas transplant did not occur until 1993. Presumably as a result of the new programs, neither UVAH nor either of the other two Virginia pancreas transplant programs ever achieved (through 1995) the SMFP minimum annual volume standard of 12. However, Virginia and the nation have experienced a high rate of increase in the annual volume of pancreas transplants. If continued, and if no new programs are established in Virginia, the rate of increase in pancreas transplants would bring one or more of the Virginia programs up to the SMFP standard.

From 1988 through 1995, there were 12 program-years of pancreas transplant activity in Virginia, excluding program start-up years. In all program-years, volume was *below* the SMFP standard of minimum annual volume.

Liver Transplants. In 1988, MCVH performed a moderate volume (21) of liver transplants and accounted for all but one of the liver transplants performed in Virginia. In the same year, UVAH established a liver transplant program, and within two years UVAH greatly surpassed MCVH's volume. Still, MCVH's liver transplant volume remained well above the SMFP minimum annual volume standard of 12. Although Henrico Doctors Hospital performed liver transplants during the single year of 1991, for all practical purposes there were only two liver transplant programs in Virginia until 1992, when Fairfax Hospital established one.

There remain only three liver transplant programs in Virginia today. Yet, the liver is the second most commonly transplanted organ in Virginia and nationwide. Nationwide, the annual volume of liver transplants has been increasing about nine percent per year, and in Virginia about 16% per year. In Virginia, the annual volume of liver transplants has been increasing more rapidly than that of any other organ system being transplanted, except the pancreas. Each existing liver transplant program in Virginia is performing at least three times the SMFP minimum annual volume standard of 12.

From 1988 through 1995, there were 18 program-years of liver transplant activity in Virginia, excluding program start-up years. In none of these (post start-up) program-years was liver transplant volume *below* the SMFP standard of minimum annual volume. This is the highest rate of compliance with the SMFP standard of any of the five organ systems for which the SMFP provides a standard of minimum annual volume per transplant program.

Transplant Programs at SNGH. The following highlights transplant program experience at SNGH from 1988 to 1995:

**Kidney.** From 1988 through 1990, SNGH had the largest kidney transplant program in Virginia. Since then, SNGH's annual volume has declined only slightly, but SNGH's *share* of the state total declined from 43% to 20% between 1988 and 1995, as new providers (Roanoke Memorial, Fairfax, and Henrico Doctors) emerged.

**Heart.** SNGH began their heart transplant program in 1989, as did Henrico Doctors and UVAH. Since inception of their program, SNGH has experienced annual heart transplant volume generally approximating the SMFP minimum annual volume standard of 12.

**Lung.** Like all other lung transplant programs in Virginia, except UVAH, SNGH has performed only a handful of lung transplants each year. For application of a standard of minimum annual volume, lung transplants and heart-lung transplants are combined.

**Heart-Lung.** Like all three other heart-lung transplant programs in Virginia, SNGH has performed a very minimal number of these transplants. SNGH has performed two to four lung and heart-lung transplants combined, each year, well below the SMFP minimum annual volume standard of 12.

**Pancreas.** SNGH does not have a pancreas transplant program, although nationwide pancreas transplants are slightly more numerous than lung transplants and about eleven times as numerous as heart-lung transplants.

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**Liver.** Establishment of a liver transplant program at SNGH is the subject of this COPN application. If SNGH had a liver transplant program which drew SNGH's 1995 share (17.6%) of statewide *kidney and heart* transplants, annual liver transplant volume at SNGH would be approximately 25, or about twice the SMFP minimum annual volume standard of 12.

**Summary of SNGH Transplant Experience.** SNGH is a well-established and experienced provider of transplant services. In 1988, SNGH was one of only five hospitals in Virginia providing transplant services and was second (after MCVH) in the volume of transplants. In 1988, the kidney was the only organ transplanted at SNGH. Heart, lung, and heart-lung transplant services were added at SNGH from 1989 through 1993. In 1995, SNGH was fourth in total volume among the eight Virginia hospitals offering transplant services for one or more organs. From 1988 to 1995, SNGH's annual transplant volume first increased and then declined back to about the 1988 level. During the same period, total statewide transplant volume more than doubled, reflecting the addition of a number of new transplant programs at other Virginia hospitals.

Summary of Transplant Program Experience in Virginia--1988-1995. In 1988, there were 11 solid-organ transplant programs in five Virginia hospitals covering five organ systems. In 1995, there were 27 transplant programs in eight Virginia hospitals covering six organ systems. The total number of transplants performed in Virginia hospitals doubled from 1988 to 1995, while total U.S. transplant volume increased about 60%. Four hundred fifty transplants of six organ systems were performed in Virginia facilities in 1995. (See Table F above and attached Table 2.)

In 1988, MCVH was by far the largest provider of transplants in Virginia. At that time, MCVH had three transplant programs (kidney, heart, and liver) and had twice the transplant volume of SNGH and four times the volume of UVAH. In 1995, UVAH was by far the largest provider of transplants, with six programs and about 70% more volume than MCVH or Fairfax Hospital, the next two highest-volume transplant facilities.

Current transplant volumes and rates of increase in volume differ considerably among the six solid-organ systems being transplanted in Virginia. Liver transplants are the second most numerous type (after kidneys), with 155 in Virginia in 1996. Among the six organ systems, liver transplants have shown the highest rate of increase in annual volume in Virginia. In spite of the comparatively high volume of liver transplants and the high rate of increase in volume, there are only three liver transplant programs in the state. This compares with six kidney transplant programs and seven heart transplant programs. In 1996, the average annual volume of the three liver transplant programs in Virginia was 52, more than four times the SMFP *minimum* utilization standard.

All Virginia solid-organ transplant programs combined had 137 program-years of operation from 1988 through 1995, excluding program start-up years and viewing lung and heart-lung programs together. In 59 (43%) of these program-years, transplant volume was *below* the SMFP standard of minimum annual volume. Every Virginia provider of transplant services has had several program-years of operation below the SMFP standard of minimum annual volume for one or more of the organ systems transplanted there.

However, after the start-up year, none of the three liver transplant programs in Virginia has operated below the SMFP minimum annual volume standard of 12. In 1996 (see Table G below), each of the three existing

liver transplant programs performed at least three times the SMFP's (and HCFA's) standard of minimum annual volume for a liver transplant program.

## PROJECTED UTILIZATION OF A LIVER TRANSPLANT PROGRAM AT SNGH

Assessment of the application's conformance with the SMFP's minimum utilization standard of 12 liver transplants per year (page 9) involves at least three questions:

- How likely is the proposed liver transplant program to meet the minimum utilization standard in the *first year*, or at least soon, after establishment of the program?

- If the proposed program may not meet the minimum utilization standard in the *first year*, but is likely to meet the standard in the second or third year, is a possible shortfall in the first year a significant consideration?

- How great and how certain is the presumed relationship between program volume and quality of outcomes, since this presumed relationship is the basis for the standard? If there seems a reasonable probability that the minimum utilization standard will not quite be met in the first or subsequent years, is this an overwhelmingly negative factor in assessment, or only one of many considerations? Similarly, if the minimum utilization standard seems likely to be met, but just barely so, is this a basis for only a qualified or weak endorsement of the application.

Utilization of a liver transplant program at SNGH would depend upon these factors:

- The incidence or rate of liver transplants within the population from which SNGH may draw patients.
- SNGH's ability to attract liver transplant cases arising *within* the population of SNGH's potential service area for liver transplantation.
- SNGH's ability to attract liver transplant cases from the population *outside* SNGH's potential service area for liver transplantation.

**The Incidence or Rate of Liver Transplants Within the Population.** Available evidence on this point includes the following:

1. The EVHSA staff report states:

> Information provided by the University of Virginia for calendar year 1996 shows that its program did 29 transplants (as of 9/30/96) of which 5 (17.2%) were from HSA V, and information provided by the Medical College of Virginia indicates it did 51 transplants in 1996 (as of 10/22/96) of which 18 (35%) were from HSA V. Thus, in 1996 a total of 23 HSA V patients had liver transplants at MCV and UVA combined.

2. The application states:

> ....There are approximately 25-30 adult patients (within the Center's primary market) that Sentara physicians refer out of the region and/or state for liver transplants each year. Based on information furnished by MCV's liver transplant program, there are also a significant number of patients referred to their center by Hampton Roads physicians who do not practice at Sentara.

*and:*

On an annual basis, SNGH physicians who have committed to support the SNGH program refer 25 to 30 patients to MCV for liver transplants. SNGH believes that there is a substantial number of patients referred outside of the region by other area physicians who would obtain liver transplant services in the area if they were available.

*and:*

The projection of annual liver transplant volumes of 25-30 patients was based on estimates from the gastroenterologists. This group estimated how many patients each physician referred from their practice for liver transplants. These individual physician estimates were summed to arrive at the projected annual liver transplant volumes. The pro forma volume estimates of six transplants in the first year, twelve in the second year, and fifteen in the third year of program implementation were conservative based on the expectation that any new transplant program must develop its waiting list, as well as its physician referral patterns.

3. The applicant's responses to completeness questions stated:

   A July 18, 1996 letter written by Dr. Mitchell L. Shiffman [Medical Director, Liver Transplant Program, MCVH] to all gastroenterologists in the Tidewater Medical Community indicates 112 patients have been referred to MCV from the Tidewater area [definition of Tidewater area not indicated] in the last three years. Of these 112 patients, 35 were transplanted. Thus, according to Dr. Shiffman's data, MCV transplants 12 patients per year from the Tidewater region. Physicians have estimated an additional five patients are transplanted annually at UVA. There are also patients referred to centers such as Pittsburgh, but the number of patients referred to centers outside the state was not available from the physicians.

4 The applicant's responses to completeness questions further stated:

   Data provided by the UNOS Research Department indicates 18 patients from the SNGH primary service area [identified in the application as most of PD 20, southside Hampton Roads] received liver transplants in 1994, and 21 patients received transplants in 1995. Of these 21 patients [in 1995], only ten were transplanted in UNOS Region 11 [VA, NC, SC, KY, TN]. Data identifying the facilities at which the transplants were performed is privileged information and is not available from UNOS....This data was compiled from the zip codes of patients whose records were submitted to the UNOS registry. The Research Department indicated that not all patients in the registry had zip code data submitted.

5. Nationwide in 1994 there were 3,652 liver transplants (see attached Table 2) or about 14 per million U.S. population. Since this rate has been increasing recently about eight percent per year, the 1997 rate of liver transplants can be estimated at approximately 17 per million population. As shown in Table B above, SNGH's potential service area for liver transplantation encompasses a population of approximately 1.7 million. Applying the estimated liver transplant rate of 17 per million population to the SNGH service-area population of 1.7 million yields an estimated 1997 rate of 29 liver transplants per year from the population of SNGH's potential service area for liver transplantation.

These five items of information are *generally* consistent, but not entirely so. They differ with respect to identification of geographic areas and with respect to "referrals" vs. actual transplants. The first item quoted above refers to HSA V. HSA V includes the Northern Neck and Middle Peninsula, whose approximately 130,000 residents are far more likely to use Richmond hospitals than hospitals in the Norfolk area. The second item quoted above speaks of *Sentara* physicians "referring" 25-30 (adult) patients per year from the Center's *primary market area* (stated in the application to be southside Hampton Roads, most of PD 20), plus *non*-Sentara physicians referring an unspecified number of others. The geography is clear,

but the total number is unstated. More important, "referrals" do not equal transplants and apparently are much greater in number than transplants.

The third item quoted above refers to actual transplants, rather than just referrals. Dr. Schiffman's reference to "Tidewater" was later clarified to mean an area comprising 95 zip codes (233XX through 237XX). Based on a map provided, these zip codes appear to cover all of PD 20 except Southampton County, all of PD 21 except Williamsburg and James City County, and all of PD 22 (Virginia eastern shore). Dr. Schiffman's statement establishes a *minimum* (only those performed at MCVH) of 12 liver transplants per year among "Tidewater" residents. Additional information in this item suggests the full number of transplants (at all facilities) per year of "Tidewater" residents is considerably higher, perhaps twice as great as the 12 performed at MCVH, reported by Dr. Schiffman.

The data in the fourth item quoted above is based on incomplete zip code identification of patients. The degree of data incompleteness is unknown but could be significant. This item establishes a *minimum* of 18-21 liver transplants per year among "SNGH service-area" residents, but "SNGH service area" is not defined in this case. In view of the incomplete zip code data, the *full* number may be 25-30 (11 *outside* of UNOS Region 11, plus a presumed 12 at MCVH, plus five or so at UVAH, plus a possible few at Duke, Fairfax, or other facilities *within* UNOS Region 11).

The fifth item above is straightforward but speculative, since it applies nationwide experience to a condition that may have large regional variations. This item establishes 29 transplants per year from SNGH's potential service area for liver transplantation.

SNGH's Ability to Attract Cases Arising within their Potential Service Area. Patients regularly travel outside their state or their region of the state for high-level medical services. Accordingly, the number of transplants performed *by transplant programs* in Virginia does not match perfectly the number of transplants performed *on the population* of Virginia. Nonetheless, historical trends in volume at Virginia's three existing liver transplant programs provide insight into the ease or difficulty SNGH might have in achieving adequate volume in the next several years.

*Table G*
**NUMBER OF LIVER TRANSPLANTS AT VIRGINIA FACILITIES AND U.S. TOTAL**

| Year | MCVH | UVAH | MC+UV | *Pct. Chg.* | Fairfax | Total VA | *Pct. Chg.* | Total US | *Pct. Chg.* |
|---|---|---|---|---|---|---|---|---|---|
| 1988 | 21 | 1 | 22 | — | No prog. | 22 | — | 1,713 | — |
| 1989 | 18 | 17 | 35 | 59% | No prog. | 35 | 59% | 2,201 | 28% |
| 1990 | 16 | 54 | 70 | 100% | No prog. | 70 | 100% | 2,690 | 22% |
| 1991 | 27 | 51 | 78 | 11% | No prog. | 78 | 11% | 2,954 | 10% |
| 1992 | 31 | 36 | 67 | -14% | 4 | 71 | -9% | 3,064 | 4% |
| 1993 | 37 | 66 | 103 | 54% | 14 | 117 | 65% | 3,440 | 12% |
| 1994 | 33 | 62 | 95 | -7% | 18 | 113 | -3% | 3,652 | 6% |
| 1995 | 39 | 53 | 92 | -4% | 37 | 129 | 14% | NAV | NAV |
| 1996 (prel.) | 66 | 37 | 103 | 12% | 53 | 156 | 21% | NAV | NAV |
| Average | 32 | 42 | 74 | 21% | 25 | 88 | 28% | - | 13% |

Sources: (1) Transplant volumes for 1988-1994 from Tables 10 and 66, 1995 Annual Report of the Organ Procurement and Transplantation Network, UNOS (2) Data for 1995 is from the Virginia Transplant Council (revised March 1966). (3) Data for 1996 is preliminary data from the Virginia Transplant Council. (4) "NAV" = data not available.

Table G shows that the Fairfax program has experienced very substantial and consistent growth since it was established in 1992. However, volume at MCVH and University of Virginia Hospitals (UVAH) *combined*

has shown only moderate and inconsistent growth since 1991, averaging about six percent per year from 1991 to 1996. Recent growth in the total US volume of liver transplants was about eight percent per year from 1991 to 1994. The relatively modest average annual growth rate of liver *donations* in Virginia, about five percent per year (data not shown here), and the moderate average annual growth rate of liver transplants at the two programs closest to SNGH, suggest that underlying trends in growth of liver transplant activity cannot be relied upon as a major force to spur rapid growth in utilization at SNGH.

This data indicates that, if SNGH is to achieve more than minimal liver transplant volume in the next several years, most of that volume would have to come from reducing the current volume of existing liver transplant programs, presumably mainly those closest--MCVH and UVAH, especially MCVH. The possible adverse effects of SNGH diversion of volume from MCVH are noted elsewhere in this review.

In addition to possible adverse effects on existing liver transplant programs by diversion of their volume to SNGH, there is the question of SNGH's *ability* to divert volume from well-established programs, especially MCVH. The MCVH liver transplant program is one of the first three in the nation and apparently enjoys an excellent reputation and good outcome statistics. The MCVH program is recognized by a number of large health care payers and showed a sharp gain in volume in 1996 (see Table G above). MCVH physician specialists have long-established referral relationships with physicians all around the state, perhaps especially in northside Hampton Roads (PD 21). These referral relationships are strengthened by the fact that many physicians in Virginia received their undergraduate or graduate medical education at MCV.

On the other hand, SNGH and its parent Sentara are dominant health care entities in a metropolitan region of approximately 1.6 million people, with affiliated or owned hospitals and other facilities stretching from Williamsburg to Virginia Beach. As described previously, SNGH is a well-established provider of transplant services in general. The Eastern Virginia Medical School, with which Sentara is closely linked, cannot compare in volume of graduates or national recognition with MCV, but the presence of EVMS and the growing ranks of graduates from EVMS's medical school and residency programs strengthen the likelihood that community physicians throughout eastern Virginia and northeastern North Carolina will refer patients to specialist physicians practicing at SNGH.

All these considerations of history, geography, and national reputation suggest there is little prospect of SNGH soon approaching the volume of liver transplants now performed at MCVH. At the same time, these considerations also suggest that SNGH has good reason to expect to attract, over time, a majority of liver transplant patients residing in the greater Hampton Roads and immediately adjacent areas. The evidence presented here suggests this number would be *at least* 10-15 patients per year, within the first few years.

**SNGH's Ability to Attract Cases from Outside the Normal Service Area.** Liver transplantation is not an especially new activity of medical practice, and referral relationships for liver transplants are presumably well established by now. SNGH is not blessed with any particular locational advantages relative to a statewide, multi-state, or nationwide market. More important, SNGH is not part of an academic medical center with national prominence in transplantation or related areas of medical practice and research. Aggressive marketing and pricing with health care payers or the recruitment of an especially prominent liver transplant surgeon could give SNGH drawing power beyond its normal tertiary-care service area.

However, on balance it must be assumed that SNGH's liver transplant volume will depend almost entirely on SNGH's ability to draw patients from its potential liver transplant service area of Hampton Roads, plus the Virginia eastern shore and northeastern North Carolina. If SNGH provided *all* liver transplants received

by the population of this area, but had *no inflow* of liver transplant patients from other areas, SNGH would provide about 30 liver transplants per year, based on the current nationwide rate of liver transplantation.

**Summary of Findings and Conclusions Regarding Projected Utilization of a Liver Transplant Program at SNGH.** It seems relatively late in the evolution of transplant services to be establishing a liver transplant program now. While the volume of liver transplants is growing more rapidly than the volume of other transplant services in Virginia, a disproportionate share of that growth is attributable to Fairfax Hospital, rather than MCVH and UVAH, from whose potential future caseload SNGH would be expected to draw more than half its liver transplant patients.

Nonetheless, various pieces of evidence reviewed above suggest that SNGH could be expected to provide at least 10-15 liver transplants per year, after allowing time for establishment of physician referral relationships and development of a list of patients waiting for organs. As noted above in the review of statewide transplant activity, if SNGH's liver transplant service were to attract the same 17.6% share that SNGH had in 1995 of statewide *kidney and heart transplants* combined, SNGH would perform about 25 liver transplants per year.

The project is judged to be very unlikely to meet the SMFP minimum annual volume standard of 12 within the first year, but judged likely to meet the standard within two or three years.

## THE RELATIONSHIP BETWEEN VOLUME OF TRANSPLANTS AND OUTCOMES IN LIVER TRANSPLANT PROGRAMS

It is widely accepted that for complex surgical procedures there is a favorable relationship between surgical volume and surgical outcomes at a facility. That is, higher volume of a procedure at a facility is associated with better outcomes for the patients who have undergone the procedure there. This accords with the common-sense wisdom that "practice makes perfect", and it is an important concern of this project review. However, the existence of a volume-outcome relationship *specific to liver transplantation* must be verified, and the nature and magnitude of the relationship must be investigated.

It should also be observed that, to the extent there is an association between higher volume and better outcomes at a facility, causation may run *from* quality *to* volume, as well as or instead of causation running only *from* volume *to* quality. Favorable outcome experience for a particular kind of complex surgery at a particular hospital—or just a hospital's good reputation in general—may lead to higher volumes of the complex surgery being performed at that (already good) hospital.

Also, in assessing the likely quality of a new program of complex surgery at a hospital, there is reason to consider that hospital's *overall* quality experience, to the extent it can be assessed, as well as considering the likely volume of cases for the new program of complex surgery. By the same token, the rate of growth of the new program will likely be affected by the hospital's overall quality reputation, as well as by more tangible factors relating to the size of the service area and the incidence of need for the procedure within the service-area population.

Regardless of the extent to which quality promotes volume or volume promotes quality, data relating volume of cases and quality of outcomes, by hospital, for liver transplants has been produced by the United Network for Organ Sharing (UNOS) as part of its contract with the Division of Organ Transplantation, Health Resources and Services Administration, US Department of Health and Human Services (USDHHS)

The data to be discussed here was prepared by Erick B. Edwards, Ph.D., Chief Biostatistician of UNOS, and was published in 1995 as Summary of 1994 Report of Center-Specific Graft and Patient Survival Rates. Attached to this project review are two data tables (Table 3 and Table 4), prepared by the Division of Certificate of Public Need, which display Mr. Edwards' data and provide various statistical summaries of it.

Explanation of the UNOS 1994 Center-Specific Data. Before discussing conclusions that may be drawn from the UNOS data displayed in Table 3 and Table 4 attached to this report, several key points about the data should be noted:

1. Volumes shown are *not annual* volumes. They are the numbers of transplants during the period October 1, 1987 through December 31, 1991. The 1987 beginning date is when UNOS became responsible, under contract with USDHHS, for collecting data on all organ transplants performed within the United States. The 1991 ending date for the data set was necessary to provide time for the required follow-ups to determine patient status and then process, analyze, and publish the data.

   Thus, the data shown in attached Table 3 and Table 4 covers a period of 4-1/4 years. For those programs in operation during the whole period, *average annual* volume could be computed by dividing the reported number of transplants by 4-1/4. However, many of the programs shown were not in operation the whole period. Accordingly, the number of transplants is a valid indicator of the *cumulative* experience of a program but not in every case a valid measure of the *annual* experience of a program.

2. The survival data shown relates to the survival of the *graft*, that is the transplanted organ, which is not the same as the survival of the patient. If the original graft fails, the patient may be retransplanted and survive. However, graft survival is a commonly used measure of transplant outcomes and is highly correlated with patient survival. Also, the graft survival statistic reflects the rate of re-transplantation, which it is desirable to minimize.

3. Most important, two measures of survival are reported in the referenced UNOS report. First is the *actual* survival percentage for each program. Second is the "*expected*" survival percentage for each program, computed by Dr. Edwards of UNOS. Computation of the expected survival percentage for a program took into account the effect on graft survival of several "covariates" (the *year of transplant* and several specified *donor and recipient* conditions) as they were represented in that program's transplant caseload.

   The impact on graft survival of each covariate was statistically estimated by Mr. Edwards from analysis of the overall national data. The statistically estimated impact of each factor was then applied to each transplant case to obtain the expectation (probability) of survival for that transplant. The statistically estimated survival probability for each transplant was then summed across a program's caseload to obtain the overall *expected* graft survival percentage for that program.

   Thus, a program's expected survival percentage is just the overall national survival experience for transplant cases *with the same year of transplant and same specified donor and recipient characteristics* as represented in this program's transplant caseload. A program's *expected* survival percentage is based entirely on the characteristics of the program's transplant *cases* and excludes any consideration of the characteristics of the facility's *program of care*.

4. Dr. Edwards then compared a program's *actual* survival percentage with its *expected* survival percentage and calculated the "statistical significance" of the difference, i.e., the probability that the *observed* difference between actual and expected survival percentages represented a *true* difference, rather than random or chance variation. The "p" value is the customary measure of statistical significance. Its inverse, "1-p", is more readily interpretable. "1-p" represents the probability that the observed difference reflects a *true* difference and one which is in the *direction indicated.*

   For example, University of Pittsburgh-Presbyterian Hospital has an observed difference of 2.4 percentage points of actual survival exceeding expected survival. This difference is not large, but because it is based on so many cases (1705), it is highly *statistically* significant. The observed difference between actual and expected survival for Presbyterian Hospital has a 99% probability of being a *true* difference, rather than the result of random variation in the data. In comparison, LeBonheur Children's Hospital of Memphis has an identical observed difference (2.4 percentage points actual over expected survival). However, this difference is based on many fewer cases, 11. Its probability of being a *true* difference, rather than the result of random variation in the data, is only 14% (so that there is an 86% probability that the true difference is 0 or in the *other direction.*)

5. To assess the practical importance of these results for real-world decision making, it is necessary to consider both the *magnitude* of the observed difference between a program's actual and expected survival percentages and the *statistical significance* of the difference (i.e., the probability that the observed difference is true and not just random variation). One way of combining both measures is to multiply a program's observed difference between actual and expected survival by the probability (1-p) of that difference. The final column of Attached Table 3 provides such a calculation. In this manner, a large difference based on few observations is given the same weight as a small difference based on many observations. Also, results are not discarded merely because they fail to meet arbitrary standards of statistical significance customarily used in academic work (such as $p < .05$ or $p < .01$).

<u>Analysis of the UNOS 1994 Center-Specific Data.</u> DCOPN's analysis of the UNOS data presented in the attached tables offers the following findings and conclusions:

1. When the 88 liver transplant programs in the UNOS report are arrayed according to *volume of liver transplants* during the 4-1/4 year data period (as in attached Table 3), it is visually apparent that both *positive* performances (i.e., *actual* survival *greater* than expected) and *negative* performances (i.e., *actual* survival *less* than expected) are distributed throughout the list. There is no visually obvious clustering of positive or negative performances anywhere along the range of liver transplant volumes. A comparison of survival percentages among five groups of transplant programs, grouped according to volume of transplants during the period 10/1/87-12/31/91, is provided by Table K below.

2. When the 88 programs are arrayed according to their *probability-weighted difference* of actual vs. expected survival (as in Table H below and in attached Table 4), the following is noted:

- Thirty-four programs had a *positive* probability-weighted difference, i.e., a higher percentage of actual survival than of expected survival.
  - ◊ The median volume of transplants at these "positive" programs, *over a period of up to 4-1/4 years*, was 63.
  - ◊ Nine of the 34 "positive" programs had 25 or fewer transplants, *over a period of up to 4-1/4 years*.

- Ten programs had a probability-weighted difference of *zero*, i.e., no difference between actual survival and expected survival.
  - ◊ The median volume of transplants at these "no difference" programs, *over a period of up to 4-1/4 years*, was 5.
  - ◊ Seven of the 10 "no difference" programs had 25 or fewer transplants, *over a period of up to 4-1/4 years*.

- Forty-four programs had a *negative* probability-weighted difference, i.e., a lower percentage of actual survival than of expected survival.
  - ◊ The median volume of transplants at these "negative" programs, *over a period of up to 4-1/4 years*, was 45.
  - ◊ Seventeen of the 44 "negative" programs had 25 or fewer transplants, *over a period of up to 4-1/4 years*.

- Programs with *positive* differences were *less likely to be low-volume* (9 of 34 or 26% had 25 or fewer transplants) than were programs with *negative* differences (17 of 44 or 39% had 25 or fewer transplants). However, programs with low volume were *nearly equally divided* between positive and zero differences combined (16 low-volume programs in this group) and negative differences (17 low-volume programs in this group).

- These results are summarized in the Table H below.

***Table H***
**DISTRIBUTION OF LIVER TRANSPLANT PROGRAMS BY PROBABILITY-WEIGHTED ONE-YEAR GRAFT SURVIVAL PERFORMANCE AND VOLUME OF TRANSPLANTS (10/1/87-12/31/91)**

| Program One-Year Graft Survival Performance (probability-weighted diff.) | Number of Programs (all volumes) | Median Volume of Programs in This Group | No. of Programs with 25 or Fewer Transplants ("small") | "Small" Programs As Percent of This Group |
|---|---|---|---|---|
| Actual survival > expected | 34 | 63 | 9 | 26% |
| Actual survival = expected | 10 | 5 | 7 | 70% |
| Actual survival < expected | 44 | 45 | 17 | 39% |
| All programs | 88 | 45 | 33 | 38% |

NOTES: (1) Basic data taken from Summary of 1994 Report of Center-Specific Graft and Patient Survival Rates, Edwards, E B, UNOS, 1995 (see attached Table 4). (2) Probability-weighted survival and medians computed by VDH, DCOPN.

3. DCOPN performed several simple regression analyses on the arrayed data, with results as shown in Table I below.

***Table I***
**RESULTS OF SIMPLE LINEAR REGRESSION ANALYSIS ON UNOS CENTER-SPECIFIC RESULTS FOR LIVER TRANSPLANTS–10/1/87-12/31/91**

| Programs Analyzed (center volume as independent variable) | Dependent (Y) Variable | R Square | Slope Coefficient | P-Value Slope |
|---|---|---|---|---|
| All programs (88) | Actual one-year graft survival | .009 | .0088 | .37 |
| same | Diff.–actual minus exp. survival | .03 | .0157 | .10 |
| same | Prob.-wgt. diff.–act. minus exp. | .04 | .0145 | .05 |
| All exc. 10 lgst. + 10 sm. (68) | Actual one-year graft survival | .006 | .0210 | .53 |
| same | Diff.–actual minus exp. survival | .04 | .0481 | .11 |
| same | Prob.-wgt. diff.–act. minus exp. | .05 | .0535 | .06 |
| Facil. from 25 to 250 trans. (46) | Actual one-year graft survival | .001 | .0072 | .82 |
| same | Diff.–actual minus exp. survival | .02 | .0234 | .40 |
| same | Prob.-wgt. diff.–act. minus exp. | .02 | .0255 | .32 |

NOTES: (1) Basic data taken from Summary of 1994 Report of Center-Specific Graft and Patient Survival Rates. Edwards, E.B., UNOS, 1995. (see attached Table 3) (2) Regression analyses performed by VDH, DCOPN.

The regression results can be summarized as follows:

- For each of the three groupings of programs analyzed, *actual* one-year survival percentages showed the smallest relationship with transplant program volume. In each case, transplant program volume explained less than one percent of the variation among transplant programs in *actual* survival percentages. Stronger statistical relationships were produced by using the *difference between actual and expected* survival percentages.

- All nine regressions produced a *positive* slope coefficient. This means that all nine regressions showed a positive relationship between liver transplant program volume and the one-year graft survival statistic. That is, the greater the volume at a program, the better the survival statistics.

- All nine regressions showed a *very small* relationship between transplant program volume and one-year graft survival statistics. The *strongest* result was found in analysis of the *probability-weighted difference* between actual and expected survival for *all programs excluding the ten largest and ten smallest*. Even here, transplant program volume explained *only five percent* of the variation among the programs in the survival statistic. Therefore, from the perspective of these analyses, factors *other than transplant program volume* accounted for 95% or more of the variation among liver transplant programs in one-year graft survival for transplants performed during the period 10/1/87-12/31/91.

- Among the three groupings of programs analyzed, the *weakest* results were obtained when analyzing the group of programs with volumes ranging from 25 liver transplants to 250 liver transplants (over the 4-1/4 year data period). These weak results show that transplant program volume offered *essentially no explanation* of variation in the survival statistic among these 46 programs, which omitted the 31 smallest and the 11 largest.

  - ◊ Of particular relevance to this COPN review is that this range of program volume included the data for MCVH and UVAH and would include *annual* volumes recently reported for MCVH, UVAH, and Fairfax Hospital. This range of program volume

would also include even the lowest level of volume projected by SNGH. Accordingly, this analysis indicates that the likely differences in volume among the applicant and the three existing liver transplant programs in Virginia are statistically expected to have *essentially no bearing* on graft survival percentages.

◊ Specifically, using the slope coefficient of .0255 produced by the regression analysis, and assuming SNGH performs *50 fewer* liver transplants per year than MCVH would perform in the absence of an SNGH program, this analysis indicates that--strictly on the basis of transplant volume--SNGH would be statistically expected to have a one-year graft survival percentage which is *1.28 percentage points lower* than that of MCVH.

Summary of Findings and Conclusions from the 1994 UNOS Center-Specific Data. The analysis presented here of the 1994 UNOS center-specific transplant data offers the following main points regarding a relationship between transplant program volume and transplant graft survival:

- When the 88 liver transplant programs included in the UNOS report are arrayed in order of *liver transplant volume* during the 4-1/4-year data period (as in attached Table 3), there is no visually obvious clustering of good or poor-performing programs at any place along the array. Programs with better-than-expected survival rates and programs with worse-than-expected survival rates are found across the entire range of volume. Visual inspection of the data does not show a clear or strong relationship between transplant program volume and graft survival percentage.

- When the 88 programs are arrayed according to their *probability-weighted difference* of actual vs. expected survival (as in attached Table 4), the following is noted:

  ◊ Within the group of programs with one-year graft survival *better* than expected, the *median* transplant volume was 63 (over the 4-1/4-year data period.)
  ◊ Within the group of programs with one-year graft survival *less* than expected, the *median* transplant volume was 45 (over the 4-1/4-year data period.)
  ◊ The 33 programs with 25 or fewer transplants (over the 4-1/4-year data period) were nearly equally divided between those with *actual survival equal to or better than expected* (16 of 33 "small" programs) and those with *actual survival less than expected* (17 "small" programs).

- A series of simple (one independent variable) regression analyses performed by VDH DCOPN found:

  ◊ All nine regressions showed a *positive, but very small* statistical relationship between transplant program volume and the one-year graft survival statistic.
  ◊ Even in the strongest case, transplant program volume explained *only five percent* of the variation among programs in the one-year graft survival statistic.
  ◊ The most relevant of the nine regression analyses indicates that SNGH's smaller volume would be statistically expected to result in a one-year graft survival percentage at SNGH which is *1.28 percentage points lower* than that of MCVH.

In short, DCOPN's analysis of the 1994 UNOS center-specific data for liver transplant programs found that there is a statistical relationship between liver transplant program volume and the one-year graft survival percentage. However, the relationship is so small--and for many of the analyses, so uncertain--that the

volume-outcome relationship is of doubtful *practical* significance. It appears that liver transplant program volume explains, at most, *only five percent* of variation in transplant graft survival among programs. Therefore, while transplant volume cannot be disregarded in considering this application, *other factors related to the operation of the transplant program will have far more effect in determining graft survival.*

The conclusions offered above, asserting a very limited volume-outcome relationship for liver transplant programs, are fully consistent with the analysis and conclusions of Mr. Edwards of UNOS and his co-investigators, who examined the effect of transplant program volume on graft survival for all kidney, liver, heart, and pancreas transplants performed during the 27-month period October 1, 1987-December 31, 1989. In "Effect of Center Size and Patient-Mix Covariates on Transplant Center-Specific Patient and Graft Survival in the United States" (Transplantation Proceedings, Vol. 25, No. 1, February, 1993, pp. 1318-1320), Mr. Edwards et al stated:

> To examine the impact of center volume on graft and patient survival, we divided the centers into five quintiles based upon center volume....For all organ transplants other than kidneys, there was a clear center size effect, with the centers of the smallest [lowest-volume] quintiles having significantly less good outcomes (2.0 to 3.5 times more likely for a graft to fail than in the reference fourth [next-to-highest-volume] quintile) than centers in the other quintiles. It should be noted that these [lowest-volume quintile] centers had few transplants--fewer than 6 livers, 9 hearts, or 4 pancreases over the 27-month period of the study. (emphasis added) The largest liver transplant centers had a [statistically] significantly better outcome than the smaller centers, and there was trend in this direction for pancreas transplant centers. There was little other evidence of a substantial center size effect in centers of the four largest quintiles.

*also:*

> Our results indicate that a large fraction of the variation in center-specific rates is due to chance alone. Even with numbers of procedures on the order of 500, centers with the same real success rate may have observed success rates that vary over a range of at least 7%....
>
> It has been suggested that center volume itself directly affects center success rates, with better results in the more experienced, larger centers. Our data suggest that this effect may be overestimated. We did find an excess risk of graft loss in the smallest liver, thoracic, and pancreas centers ranging from 2.0 to 3.5 times that in the reference fourth [next-to-highest-volume] quintile. However, these [smallest] centers were small indeed, each having performed fewer than 9 transplants over the 27-month period of the study. There was no indication of a substantial center size effect above this low threshold; there was no apparent size effect at all in kidney transplant centers. (emphasis added)
>
> Inclusion of transplant covariates known to be important in prediction of individual transplant outcomes was variably successful in explaining the differences between centers. The greatest effect was with the liver transplant centers, with a reduction in center-to-center variability by 41%....Clearly much of the variability between centers remains unexplained.

## CONTRASTING VIEWS IN THE EVHSA STAFF REPORT

The findings and conclusions stated above and detailed in the attached Table 3 and Table 4 describe a very small, though positive statistical relationship between liver transplant program volumes and graft survival percentages. This evidently small relationship between program volume and graft survival is in conflict with various statements in the prior record of this project review. For example, the EVHSA staff report on this application stated as follows:

> ..[The] limited availability of organs for transplants...argues for fewer transplant programs with proportionally higher volumes, [rather than] for more transplant programs with lower volumes.
>
> In that regard, the 1995 Annual Report of the Organ Procurement and Transplant Network (part of UNOS) indicates that, up to a point, there is a strong positive relationship between volume and outcome. Specifically, 1-3 year survival rates consistently increase when liver transplant centers go from 1-23 transplants to 24-45 transplants, and then to 46-92

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transplants annually. However, they drop off somewhat when the centers have more than 92 transplants annually. Also the 1994 UNOS Report of Center-Specific Graft and Patient Survival Rates shows that, of 20 centers nationally that did just 1-12 transplants during the 10/1/87-12/31/91 period, 7 or 35% had actual one year survival rates that were below 60%. The minimum standard for one year liver transplant survival is a rate of 50%-60% in the State Medical Facilities Plan (SMFP).

*also:*

Regarding survival rates also, Section 2.6.B.I of the [SMFP] Quality standards states facilities with liver transplant programs should demonstrate that they will achieve and maintain a minimum one year survival rate of 50%-60%. The 1994 UNOS Report of Center Specific Graft and Patient Survival Rates, which included data on liver transplant centers for the October 1, 1987 to December 31, 1991 period, showed that of the 14 centers that did a total of 1-6 liver transplants (time frame was not specified), 7 or 50% had actual one year survival rates less than 60%. Further, 8 or 57% of those facilities had actual one year survival rates which equaled or exceeded 50%, but 6 or 43% had actual survival rates of less than 50%.

Thus, based solely on those percentages, SNGH would perhaps have a slightly better than even chance of achieving the SMFP minimum survival standard of 50%-60% in Year I. Further, regarding the 6 centers which did 7-12 transplants (again, time frame not specified), the UNOS data indicates that all had actual one-year survival rates which exceeded 60%. Thus, for Year II it would appear that SNGH would probably be able to comply with the SMFP's minimum 50%-60% survival rate standard. However, in contrast, MCV had one year actual survival rates of 81% for the 1991-94 period and 85% for the 1995-96 period.

The second data source (UNOS's 1994 Report of Center Specific Graft and Patient Survival Rates) cited in the above quotations from the EVHSA report is the same data source used for the preceding DCOPN analysis. The DCOPN analysis concluded that the statistical relationship between liver transplant program volume and one-year graft survival is *very small*, though positive. Tables 3 and 4 attached to this report present the key detail from the UNOS report regarding liver transplant one-year graft survival percentages. While the EVHSA statement correctly reports the UNOS numbers, additional context is needed for accurate interpretation.

First, the UNOS 1994 report cited in the quoted EVHSA statement (and used for the DCOPN analysis) covers a period of 4-1/4 years. The 20 lowest-volume programs performed from one to eleven transplants *over a period of up to 4-1/4 years* (depending on when the program started), *not annually*. The *annual* volume was no more than one, two, or three transplants for most programs in this lowest-volume group for most years in the period covered by the UNOS report. It is not accurate for the EVHSA report to say "time frame not specified" and then to treat these volumes--which cover a period of up to 4-1/4 years--as though they were *annual* volumes.

**Annual Liver Transplant Volumes in Twenty Lowest-Volume Programs.** Table J below shows the *actual annual* volumes from 1988 through 1991 for each of the *20 lowest-volume* programs in the UNOS 1994 Report of Center Specific Graft and Patient Survival Rates.

*Table J*
**ANNUAL VOLUME OF LIVER TRANSPLANTS--1988-1991***
**AND ONE-YEAR GRAFT SURVIVAL--10/1/87-12/31/91**
**FOR TWENTY LOWEST-VOLUME CENTERS IN UNOS 1994 CENTER-SPECIFIC REPORT**

| Liver Transplant Center | Volume 10/1/87*-12/31/91 | Vol. 1988* | Vol. 1989 | Vol. 1990 | Vol. 1991 | *Average* Volume (years w/activity) | *Actual* % Survival (10/1/87-12/31/91) | *Difference* Actual - Expected Survival | *Probabil.-Weighted* Difference |
|---|---|---|---|---|---|---|---|---|---|
| Egleston Children's - Atlanta | 11 | 0 | 0 | 2 | 9 | 5.5 | 63.6 | -14.4 | -10 8 |
| Le-Bonheur Child.-Memphis | 11 | 1 | 3 | 4 | 3 | 2.75 | 72.7 | 2.4 | 0.3 |
| Vanderbilt U. Med. Ctr. | 11 | 0 | 0 | 0 | 11 | 11 | 72.7 | 5.5 | 1.8 |
| The Child. Hosp. - Denver | 10 | 0 | 0 | 3 | 7 | 5 | 80.0 | 5.5 | 1.8 |
| LSU Willis-Knighton M. Ctr. | 9 | 0 | 0 | 0 | 9 | 9 | 77.8 | 1.3 | 0.1 |
| The Child. Hosp. - Columbus | 9 | 1 | 1 | 6 | 1 | 2.25 | 75.0 | 3.1 | 0.5 |
| Columbia Presby. Med. Ctr.* | 6 | 0 | 3 | 2 | 1 | 2 | 0 | -69.8 | -69.1 |
| Child. Hosp. & M.C. - Seattle | 6 | 0 | 0 | 1 | 5 | 3 | 100 | 25.7 | 22.1 |
| Tampa Gen. Hosp. | 5 | 5 | 0 | 0 | 0 | 5 | 20.0 | -51.3 | -48.7 |
| Glennon Cardinal Mem. Hosp. | 5 | 0 | 3 | 1 | 1 | 1.67 | 80.0 | 10.2 | 0.0 |
| Henrico Doctor's Hosp.* | 5 | 0 | 0 | 0 | 5 | 5 | 20.0 | -57.0 | -55.9 |
| North Carolina Mem. Hosp. | 4 | 0 | 0 | 0 | 4 | 4 | 75.0 | 10.2 | 0.0 |
| Howard Univ. Hosp. | 3 | 0 | 2 | 0 | 1 | 1.5 | 0 | -57.5 | -48.9 |
| Louisiana State Univ. Hosp.* | 3 | 3 | 0 | 0 | 0 | 3 | 66.7 | -5.9 | 0.0 |
| St. Luke's Hosp. of K.C.* | 3 | 0 | 0 | 0 | 3 | 3 | 50.0 | -31.4 | -10 4 |
| Univ. of Miss. Med. Ctr.* | 3 | 0 | 2 | 1 | 0 | 1.5 | 66.7 | -12.6 | 0.0 |
| Stanford Univ. Med. Ctr. | 2 | 0 | 0 | 0 | 2 | 2 | 100 | 19.6 | 0.0 |
| Univ. Hosp.-UCSD Med. Ctr. | 1 | 0 | 0 | 0 | 0 | 2 | 0 | -78.3 | -44 6 |
| Univ. Hosp. Okla. City | 1 | 0 | 0 | 0 | 1 | 1 | 0 | -77.4 | -42.6 |
| Albert Einstein Med. Ctr.-Phila. | 1 | 0 | 0 | 0 | 1 | 1 | 100 | 31.5 | 0.0 |
| Average (facil. w/activity) | 5.5 | 2.5 | 2.3 | 2.5 | 4.0 | 3.6 | 56.0 | -17.0 | -15.2 |
| Median (facil. w/activity) | 5 | 2.5 | 2.5 | 2.0 | 3.0 | 3.0 | 69.7 | -2.3 | 0.0 |

*Notes: (1) Data on annual volumes taken from Table 66, 1995 Annual Report of the Organ Procurement and Transplantation Network, UNOS, 1995, other data from Table 3 attached; additional computations by VDH DCOPN. (2) The total data period covered is 10/1/87-12/31/91. Activity in the final quarter of 1987 is included here as 1988. (3) Programs marked with an asterisk suspended or terminated their liver transplant program following the period covered by this data.

Table J supports the following findings:

- The average annual volume for the 20 lowest-volume programs, *omitting* the years in which they had *no* transplant activity, was only 3.6

- Only two (LSU and Vanderbilt) of the 20 lowest-volume programs in the UNOS 1994 center-specific report had *average annual volumes of six or greater* during the period covered by the data, 10/1/87-12/31/91. Both of these programs had better-than-expected one-year graft survival percentages.

- Five of these 20 lowest-volume programs (including Henrico Doctors Hospital) suspended or terminated liver transplant services following the data period. Each of these programs had lower-than-expected one-year graft survival. These programs may have had problematic operating circumstances, which simultaneously contributed to low volume, poor graft survival, and cessation of the program. The representativeness of their data and its relevance to assessment of this application from SNGH are questionable.

- Notwithstanding the extremely low volume of these programs, their ~~median~~ actual one-year graft survival was 69.7%. This is better than the median actual one-year graft survival of 66.8% among all 88 programs in the UNOS study. The median difference between actual and expected survival (as calculated by UNOS and described above) for the 20 lowest-volume programs was -2.3 percentage points. As further described below, this median difference was *better* than the median difference found for each of the next three *higher-volume* groups of liver transplant programs, which groups included MCVH and UVAH.

As demonstrated earlier in this review, transplant program volume is *not determinative* of graft survival percentage. Program volume is not even a factor of *much* statistical effect on graft survival, especially when the very-highest-volume and very-lowest-volume programs are removed from the analysis.

Even if transplant program volume did have a large statistical association with graft survival, it would be of doubtful validity to predict SNGH's performance on the basis of the experience of the 20 lowest-volume programs in the UNOS 1994 report, shown in Table J above. SNGH is projecting a first-year volume of six transplants, with moderate growth thereafter, a projection which appears reasonable. It is unwarranted to infer that SNGH's results should be expected to parallel those of the 20 lowest-volume liver transplant programs in the UNOS 1994 report, *70% of which programs had average annual volume of four transplants or less*.

In addition, the numbers of transplants in the 20 lowest-volume programs were too small to give much statistical significance to their results. Ten of the 20 programs had *actual* survival percentages *lower* than their *expected* survival percentages. Of these ten low-volume programs with less-than-expected survival, only four had results which were statistically significant at a 75% or higher confidence level, only two at a 95% or higher confidence level.

Survival Statistics for Five Volume Groups of Liver Transplant Programs. Table K below displays the one-year graft survival statistics for five volume groups of liver transplant programs, based on the data in the UNOS 1994 report of center-specific results. Table K provides additional insight into the relative performance of the group of 20 lowest-volume liver transplant programs, referred to in the EVHSA report.

***Table K***
**COMPARISON OF ONE-YEAR GRAFT SURVIVAL STATISTICS FOR LIVER TRANSPLANT CENTERS GROUPED BY VOLUME OF TRANSPLANTS–10/1/87-12/31/91**

| Number of Transplants Per Program (10/1/87-12/31/91) | Total No. Trans. in Category | *Median* Actual Survival | *Median* Difference Actual minus Expected Surv. | *Average* Actual Survival | *Average* Difference Actual minus Expected Surv. |
|---|---|---|---|---|---|
| 1-11 (20 facil.) | 108 | 69.7 | -2.3 | 56.0 | -17.0 |
| 16-40 (20 facil.) | 495 | 65.4 | -2.4 | 63.3 | -5.8 |
| 41-82 (18 facil.) | 1,058 | 66.4 | -3.6 | 64.3 | -3.7 |
| 84-188 (18 facil.) | 2,112 | 64.2 | -3.9 | 65.1 | -3.1 |
| 221-1705 (12) | 5,863 | 70.0 | +2.7 | 69.7 | +3.2 |
| All programs (88) | 9,634 | 66.8 | -1.8 | 63.1 | -6.1 |

NOTES. (1) Basic data taken from Summary of 1994 Report of Center-Specific Graft and Patient Survival Rates. Edwards, E.B., UNOS, 1995 (see attached Table 3). (2) Grouping of programs and computation of medians and averages by VDH, DCOPN.

Table K supports the following findings and conclusions:

- The group of 20 lowest-volume centers had poor results when viewed by the *average* statistics for the group, but not when viewed by the *median* statistics. For the 20 lowest-volume programs, the *average difference* between the *actual* one-year graft survival percentage and the *expected* survival percentage (as calculated by UNOS and described above) was a negative 17.0 percentage points, a very large difference. However, the *median* difference between actual and expected one-year graft survival was a much smaller -2.3 percentage points. This is still an unfavorable difference, but it is *less* unfavorable than the median difference for the next three groups of higher-volume programs.

- As the EVHSA report states, seven of the 20 lowest-volume programs had one-year graft survival percentages below 60%. At the same time, and not noted in the EVHSA report, the *median* actual one-year graft survival percentage of 69.7% for these 20 lowest-volume programs was *better than the median of 66.8% for all 88 programs* in the UNOS report (see attached Table 3 for program-specific detail).

- Twelve of the 20 lowest-volume programs had a one-year graft survival percentage *better than the median* for those 18 programs which performed from 84 to 188 liver transplants during the 4-1/4 year UNOS data period. This group of higher-volume programs included MCVH and UVAH. The *median difference* (-2.3) between actual and expected survival rates for the 20 lowest-volume programs was actually *slightly smaller (i.e., better)* than the median difference (-3.9) between actual and expected survival for the 18 liver transplant programs which performed from 84 to 188 transplants (see attached Table 3 for program-specific detail).

- In terms of the *median difference* between actual survival and expected survival, the second-highest-volume group (which included MCVH and UVAH) performed more poorly than did any other group. In terms of the *average difference* between actual survival and expected survival, the second-highest-volume group performed better than any of the three lower-volume groups. However, the second-highest-volume group still had an unfavorable average difference (-3.1 percentage points) between actual survival and expected survival.

- As suggested by the sharp differences between the average and the median statistics for the lowest-volume group, the asserted poor performance of very-low-volume liver transplant programs is a result of especially poor outcomes at just a few of these programs. As can be seen in attached Table 3, seven of these 20 lowest-volume programs had actual survival rates of 50% or lower (but ten had survival rates of 72.7% or higher).

- The *median* statistics in the above table suggest only a small and uncertain relationship between a liver transplant program's volume and its one-year graft survival percentage. However, the *average* statistics in the above table suggest a clearer relationship between a transplant program's volume and its one-year survival percentage.

- SNGH's projected liver transplant volume would put SNGH in the second or third volume group shown in the above table. <u>There is little basis in this data to conclude that SNGH should be expected--simply on the basis of volume--to have less favorable outcomes than MCVH and</u>

UVAH, whose volumes put them in the fourth volume group, where the median (but not the average) one-year survival statistics were the *poorest* of any of the groups.

**Summary of Findings and Conclusions from Analysis of Survival for Programs Grouped by Transplant Volume.** When liver transplant programs are grouped as above by volume of transplants, and survival experience is then compared among the volume groups, the particular conclusion that emerges, regarding any relationship between program volume and survival percentage, is considerably affected *by which measure of central tendency* is used to describe and compare the groups of programs. If groups are described and compared by use of group *averages*, there emerges a clear and consistent pattern of higher survival percentages with increased program volume of transplants.

However, if the volume groups are described and compared by use of group *medians*, there does *not* emerge a clear and consistent pattern of higher survival percentages with increased program volume of transplants. The group of 12 *highest-volume* programs showed the *best* survival performance, but the group of 18 *next-highest-volume* programs showed the *worst* performance, while the group of 20 *lowest-volume* programs showed the *second-best* survival performance.

Grouping observations (liver transplant program volumes and survival percentages in this instance) and comparing group averages may be an unreliable method of determining trends and correlations, when the groups are small and contain a great deal of *intra*-group variation, as is true with this data. A few extreme values in a group can seriously bias the average for the group, as can the selection of boundaries for each group. Therefore, some other technique, such as regression analysis, or some measure of central tendency other than the average should be employed.

When the UNOS 1994 center-specific data is viewed in these alternative ways, only a very small relationship is seen between program volume of transplants and percentage of graft survival. It is clear that program volume is a very weak predictor of patient outcomes and that *other factors at the facility, along with patient and donor characteristics, carry nearly all the weight in determining patient outcomes*.

**Comparison of the UNOS 1994 Center-Specific Report and the UNOS 1995 Annual Report.** Analysis of the UNOS 1994 center-specific report of liver transplant activity seems clearly to demonstrate that transplant program volume has very little to do with patient outcomes, and almost no effect on patient outcomes across the broad middle range of programs by volume. In the foregoing analysis, this middle range of programs by volume included MCVH and UVAH and would include the projected volumes at SNGH. In addition, as quoted above, the author of the UNOS report, writing in the journal Transplantation Proceedings, stated "this effect [of center volume on outcome] may be overstated" and "there was no indication of a substantial center size effect above this low threshold [nine transplants over a 27-month period]."

Nonetheless, as the EVHSA staff report (quoted above) stated, and as expressed in various statements from MCVH submitted for inclusion in this project review, data tables in UNOS's 1995 Annual Report of the U.S. Scientific Registry of Transplant Recipients and the Organ Procurement and Transplantation Network do suggest a clear positive relationship between liver transplant program volume and graft survival.

Table L below compares one-year graft survival percentages according to liver transplant program volume measured in two different ways and for two different but overlapping time periods.

***Table L***
**COMPARISON OF ONE-YEAR GRAFT SURVIVAL STATISTICS FOR LIVER TRANSPLANT CENTERS GROUPED BY TWO MEASURES OF VOLUME: TOTAL TRANSPLANTS PER PROGRAM–10/1/87-12/31/91 AND NUMBER OF TRANSPLANTS AT THE FACILITY IN THE PRIOR TWELVE MONTHS–10/1/87-12/31/93**

| *Transplants Performed 10/1/87-12/31/91* | | | | | | *Transplants 10/1/87-12/31/93* | | |
|---|---|---|---|---|---|---|---|---|
| Total Number of Transplants per Program (10/1/87-12/31/91) | Total No. Trans. in Category | *Median* Actual One-Yr. Survival | *Median* Difference Actual minus Expected Surv. | *Average* Actual One-Yr. Survival | *Average* Difference Actual minus Expected Surv. | No. Trans. at Facil. in Prior 12 Mon. | Total No. Trans. in Category | One-Year Graft Survival |
| 1-11 (20 facil.) | 108 | 69.7 | -2.3 | 56.0 | -17.0 | 0-23 | 3,073 | 66.9 |
| 16-40 (20 facil.) | 495 | 65.4 | -2.4 | 63.3 | -5.8 | 24-45 | 2,885 | 70.3 |
| 41-82 (18 facil.) | 1,056 | 66.4 | -3.6 | 64.3 | -3.7 | 46-92 | 2,971 | 71.8 |
| 84-188 (18 facil.) | 2,112 | 64.2 | -3.9 | 65.1 | -3.1 | 93-159 | 2,922 | 72.5 |
| 221-1705 (12) | 5,863 | 70.0 | +2.7 | 69.7 | +3.2 | 160+ | 2,954 | 67.8 |
| *All programs (88)* | *9,634* | *66.8* | *-1.8* | *63.1* | *-6.1* | | *14,805* | *69.1* |

NOTES: (1) Basic data taken from Summary of 1994 Report of Center-Specific Graft and Patient Survival Rates, Edwards, E.B., UNOS, 1995 (see attached Table 3), and from Table 44, 1995 Annual Report of... the Organ Procurement and Transplantation Network, UNOS
(2) Grouping of programs for 10/1/87-12/31/91 and computation of group medians and averages by VDH, DCOPN.

The left-hand side of Table L and the right-hand side of Table L suggest very different conclusions about the relationship of liver transplant program volume to one-year graft survival percentage. The *left-hand* side of Table L (which is the same as Table K) shows an inconsistent and unclear relationship between liver transplant program volume and one-year graft survival, especially across the middle three groups of programs. UVAH and MCVH are in the fourth volume group, with 84-188 transplants during the period 10/1/87-12/31/91.

The *right-hand* side of Table L suggests a clear relationship between transplant program volume and one-year graft survival, up to and including the fourth group of programs (93-159 transplants in the prior twelve months). At 1996 volume, MCVH would be in the middle group, and UVAH would be in the second-lowest-volume group. (See Table G above.)

There are important differences between what is measured and reported on the left-hand side and on the right-hand side of Table L. These differences appear to explain why the two sides of Table L suggest different conclusions about the relationship of liver transplant program volume to one-year graft survival percentage.

Differences in Measurement. The principal differences in measurement between the left-hand and right-hand sides of Table L are:

1. The left-hand side of Table L groups programs according to total liver transplant volume *over a period of 4-1/4 years* (although many programs were not in operation at the beginning of the period). This is only a rough measure of *annual* volume, but a good measure of *cumulative* liver transplant experience at the facility.

2. The right-hand side of Table L does *not* involve a grouping of *programs*, but instead a grouping of liver transplant *cases*, according to the volume of liver transplants in the program *within the 12 months prior to each case*. Transplants performed at a particular program are likely to appear in

*more than one* volume category on the right-hand side of Table L, depending on when the transplant was performed.

For example, at UVAH, some 1990 liver transplants were in the lowest-volume (least favorable) category; most 1991 and 1992 transplants were in the middle-volume (second most favorable) category; and some 1993 transplants were in the second-lowest-volume (second least favorable) category. Thus, the right-hand side of Table L groups cases according to a program's *recent* experience, but the classification of a program is variable and is only a rough indicator of *cumulative* experience.

3. Taken as a whole, the data on the left-hand side of Table L is *older* than the data on the right-hand side. The 6-1/4-year period (10/1/87-12/31/93) on the right-hand side includes the 4-1/4-years (10/1/87-12/31/91) on the left-hand side, but the right-hand side adds two more years and about 50% more procedures. This fact explains some of the observable differences between the left-hand and right-hand sides of Table L.

The UVAH example above demonstrates that, as a new program grows over time, transplants performed there in *later* years fall into *higher-volume* categories. The average date of transplant in the lowest-volume category on the right-hand side of Table L *(covering 6-1/4 years)* is probably significantly *earlier* than the average date of transplant in the second volume category, which in turn is probably somewhat earlier than the average date of transplant in the third (middle) volume category. Thus, higher-volume categories on the right-hand side of Table L tend to represent *more recent* transplants, as well as representing transplants in *more experienced* programs. There is no evident way of separating the effect of *date of transplant* from the effect of *program experience* on the results in the right-hand side of Table L. It is possible that just date of transplant, by itself, explains most or all of the differences among survival percentages shown on the right-hand side of Table L.

It is evident that the date of transplant is an important factor in explaining differences in survival statistics among liver transplants. One-year graft survival for liver transplants performed in 1988 was 64.3%. It rose to 73.4% in 1993 (Table 18, 1995 Annual Report of...the OPTN, UNOS). This difference of 9.1 percentage points in survival between 1988 and 1993 is greater than the difference of 5.6 percentage points between the least favorable and most favorable volume groups on the right-hand side of Table L. This suggests that differences in average transplant date *could* account for most or nearly all of the differences in survival percentages among transplant volume categories on the right-hand side of Table L.

Differences in Statistics Reported. In addition to differences in measurement, there are differences between the two sides of Table L in the construction of the statistics being reported.

1. The right-hand side of Table L reports the actual (unadjusted) survival percentage averaged across the *individual transplant cases* in a particular volume category. This survival percentage is constructed directly from the data for the approximately 3,000 individual cases in each volume category. It is therefore a precise portrayal of the composite survival experience of individual transplants in the category.

2. The left-hand side of Table L reports the median and the average survival percentage among the *12-20 programs* in each volume category. The median and average for each volume category are not constructed directly from *individual* case data, but from program-wide survival percentages,

with each program given equal weight in the calculation regardless of program size. Thus, the statistics on the left-hand side of Table L are not an absolutely precise portrayal of the composite survival experience of the *individual* transplants in the category. This explains some of the observable differences between the left-hand and right-hand sides of Table L.

3. The most important distinction between the statistics on the two sides of Table L is that the left-hand side deals with the *difference between the actual survival percentage for a liver transplant program and its "expected" survival percentage*, while the right-hand side deals only with the actual survival percentage. The source, meaning, and construction of the "expected" survival percentage are explained on pages 18-19 above. Important to note again here is that *the year of transplant* was one of the factors ("covariates") of each transplant case that Dr. Edwards of UNOS took into account when determining a liver transplant program's "expected" survival rate.

Summary of Findings and Conclusions from Comparison of Statistics in the Two UNOS Reports. The data in the UNOS 1995 annual report (cited in the EVHSA staff report and in statements of opposition presented by MCVH), which relates liver transplant program volume and survival percentage, is *unadjusted* to reflect any differences among the programs in the characteristics of their cases (the "covariates" described earlier). Therefore, the consistent and sizable relationship between volume and outcome which appears in the 1995 annual report data seems far less likely to be true than the *virtual absence* of a relationship between program volume and outcome found from analysis of the *case-mix-adjusted* data in the 1994 center-specific report, a finding evidently supported by other investigation cited earlier in this review.

Granted, analysis of *medians* and analysis of *averages* for volume groups of programs, using the 1994 report's case-mix-adjusted data, do not lead to identical conclusions. When the *median* difference between actual and "expected" survival is viewed across five volume groups of programs, only a weak and inconsistent relationship between program volume and survival percentage is found. However, when the *average* difference between actual and "expected" survival is viewed across five volume groups of programs, there appears to be a consistent and stronger relationship between program volume and survival percentage.

Grouping observations (liver transplant program volumes and survival percentages in this instance) and then comparing group averages may be an unreliable method of determining trends and correlations, when the groups are small and contain a great deal of *intra*-group variation, as is true with this data. A few extreme values in a group can seriously bias the average for the group, as can the selection of boundaries for each group. Therefore, some other technique, such as regression analysis, or some measure of central tendency other than the average should be employed.

When the UNOS 1994 case-mix-adjusted data is viewed in these alternative ways, only a very limited relationship is found between a program's volume of transplants and percentage of graft survival. It seems clear that liver transplant program volume is a very weak predictor of patient outcomes and that *other factors at the facility, along with patient and donor characteristics, carry nearly all the weight in determining patient outcomes.*

**2. Successful transplantation programs are expected to perform substantially larger numbers of transplants annually. Performance of minimum transplantation volumes does not necessarily indicate a need for additional transplantation capacity or programs.**

The meaning of this standard may be unclear. The applicant interpreted it as a standard relating utilization of existing transplant programs *at the applicant's facility* to a request to add a new transplant program at the applicant's facility. The application states:

> With the exception of lung transplants, which are limited due to availability of organs, the existing transplant services at SNGH exceed minimum volume standards by substantial margins:
>
> SNGH transplants May 1, 1995 - April 30, 1996:

| | |
|---|---|
| Kidney | 39 |
| Heart | 17 |
| Heart/lung | 6 |

(Actually, while the SNGH *kidney* transplant program has operated for many years at 1.5 to two times the SMFP minimum annual volume standard of 25, the SNGH *heart* transplant program has usually operated just above or just below the SMFP minimum annual volume standard of 12. Fourteen heart transplants were performed at SNGH in calendar year 1996.)

A more appropriate interpretation of this standard is that it relates the volume of existing transplant programs *serving a given population* to a request to establish an additional program for the *same type of transplant service to serve the same population*. The standard indicates that increased need within the population for a particular transplant service may be able to be met by increasing transplant volume at existing programs rather than necessarily establishing an additional program.

As described above (pages 26-28), it appears that perhaps 40%-50% of liver transplant patients from SNGH's potential liver transplant service area are now transplanted at MCVH, with perhaps another 10%-20% transplanted at UVAH. Liver transplant volumes at MCVH and UVAH are therefore the most relevant to this standard. Table 2 attached and Table G above show that for several years the MCVH liver transplant program has operated at about three times the SMFP minimum annual volume standard and the UVAH program at about five times the SMFP minimum annual volume standard (until 1996 when the volume relationship between MCVH and UVAH reversed).

A liver transplant program at SNGH seems likely to perform at least 10-15 transplants per year in its first several years (see page 28). This level of volume at SNGH would likely reduce MCVH's annual volume by no more than 10-15 transplants and no more than 15%-20%. Establishment of a liver transplant program at SNGH would likely have only a minimal effect on volume at UVAH, perhaps reducing it by a handful of cases and no more than 10%. Accordingly, establishment of a liver transplant program at SNGH would still leave the MCVH and UVAH programs with volume several times as great as the SMFP (and Medicare) minimum annual volume standard of 12.

In 1994, there were 3,652 liver transplants nationwide, performed by 102 liver transplant programs. Nationwide *average* program volume was 36. *Median* program volume was lower. Even with the establishment of a new liver transplant program at SNGH, the existing programs at MCVH and UVAH (and certainly at Fairfax Hospital) would continue to have annual volumes at least as great as average program volume nationwide and greater than the volume of more than one-half of the liver transplant programs in the country.

In summary, the existing liver transplant programs in Virginia are now performing well above the standard of minimum annual volume and would continue to do so after the establishment of a new program at

SNGH. Also, as shown in attached Table 2 and Table G above, the statewide and nationwide numbers of liver transplants are increasing steadily each year. Any reduction in existing program volumes caused by establishment of a new program at SNGH would almost certainly be made up by normal volume growth within two or three years.

In this sense, the establishment of a liver transplant program at SNGH would not seriously reduce volume at any existing program and would not reduce any existing program to "low" volume. (However, see review criteria 4.1.G and 4.1.L below for discussion of other possible effects of likely volume reduction at MCVH). Yet, it is also clear that, without establishing a new liver transplant program at SNGH, moderate growth of existing programs, leaving them still in the middle range of program size, would meet the foreseeable future needs of Virginians for liver transplant services for a number of years.

On balance, consideration of this review standard neither strengthens nor weakens the case for this application.

3. **Preference will be given to expansion of successful existing services, either by enabling necessary increases in the number of organ systems being transplanted or by adding transplantation capability for additional organ systems, rather than developing other programs that could reduce average program volume.**

Interpretation of this standard would be clear if this application sought to establish a transplant service at a facility *not* already providing *any* transplant service. In the present context, though, interpretation of this standard is not clear. The standard gives preference to expansion of "successful existing services...by adding transplantation capability for additional organ systems...." The SNGH application proposes to do just that.

On the other hand, the standard opposes "developing other programs that could reduce average program volume." The most reasonable interpretation of "program" is *one* specific organ system, not the collection of transplantation services for *several* organs that may exist at a given hospital. If approved, this application would "reduce average program volume" among the liver transplant programs in Virginia. As discussed under the preceding standard, average program volume would be reduced from 52 to 38 (at 1996 volume), but this reduction would disappear in several years, as overall liver transplant volume continued to grow.

On balance, consideration of this review standard neither strengthens nor weakens the case for this application.

**B. Minimum Survival Rates.**

1. **Facilities should demonstrate that they will achieve and maintain minimum transplant patient survival rates. Minimum one-year survival rates, listed by organ system, are**

| | |
|---|---|
| **Kidney** | **90-95%** |
| **Heart** | **70-80%** |
| **Heart/lung** | **(none set)** |
| **Liver** | **50-60%** |
| **Pancreas** | **80-90%** |

With respect to this standard, the application states:

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> All the organ transplant programs have exceeded the minimum one year survival rates, as required by the Virginia Medical Care Facilities Certificate of Public Need (COPN) patient survival criteria. The actuarial survival rates for each of the programs are detailed below.

| Program | Number | Time Period | SNGH 1 yr. | COPN Std. |
|---|---|---|---|---|
| Kidney | 291 | 1990-1995 | 94% | 90-95% |
| Heart | 44 | 1992-1995 | 95.4% | 70-80% |
| Lung | 15 | 1992-1995 | 66% | none |

> The actuarial one year survival rates for the kidney transplantation program include cadaver, as well as living donor survival rates. Also, the one year survival rates for the lung program include survival rates for single lung, double lung, and heart/lung.

According to the data provided, SNGH's existing transplant programs more than meet the *minimum* one-year patient survival rates stated in the SMFP. Granted, the SMFP standard is several years old, and the cited survival rates might no longer be considered adequate minimum standards. However, specifically relevant to SNGH, nationwide kidney and heart transplant one-year patient survival rates increased less than two percentage points from 1988 to 1993. This suggests that the SMFP minimum standards for kidney and heart transplant survival may still be appropriate. *Nationwide* one-year patient survival rates for transplants performed in *1993* were:

- Kidney 94.9% (weighed average for cadaveric and living donor transplants)
- Heart 82.3%
- Lung 76.3% (weighted average for lung and heart-lung transplants)

The reported SNGH *kidney* transplant one-year patient survival rate matches the national kidney one-year patient survival rate, while the SNGH *heart* transplant one-year survival rate exceeds the national rate by 13 percentage points. The SNGH one-year patient survival rate for *lung and heart-lung transplants combined* is 10.3 percentage points below the national rate. The comparatively poor results for SNGH's combined lung and heart-lung transplants are of doubtful statistical significance due to the small number of procedures (15). With just one more survivor, SNGH's one-year patient survival rate for lung and heart-lung transplants combined would have been within three percentage points of the national rate.

Also of value in assessing the quality of SNGH's existing transplant programs are SNGH's survival statistics as reported in UNOS's 1994 Report of Center Specific Graft and Patient Survival Rates. This report, previously described on pages 27-29, showed the following for kidney and heart transplants performed at SNGH, Fairfax Hospital, MCVH, and UVAH between October 1, 1987 and December 31, 1991. (Lung and heart-lung programs were not in operation at SNGH during the data period.)

***Table M***
**COMPARISON OF ONE-YEAR SURVIVAL STATISTICS FOR KIDNEY AND HEART TRANSPLANTS (10/1/87-12/31/91)**

| Transplant Service | *Number of* Transplants (10/1/87-12/31/91 | *Actual* One-Year Patient/Graft Survival* | *Expected* One-Year Patient/Graft Survival* | *Difference* Actual Minus Expected | "p" Value of Difference | 1-"p" | Probability-Weighted Difference (diff. X (1-"P")) |
|---|---|---|---|---|---|---|---|
| ***Fairfax*** | | | | | | | |
| Heart | 43 | 93.0% | 84.9% | 8.1 | .13 | .87 | 7.0 |
| Kidney | no service | | | | | | |
| ***MCVH*** | | | | | | | |
| Heart | 117 | 81.2% | 81.7% | -0.5 | .83 | .17 | -.0 |
| Kidney | 192 | 88.0% | 80.4% | 7.6 | .01 | .99 | 7.5 |
| ***UVAH*** | | | | | | | |
| Heart | 45 | 80.0% | 83.0% | -3.0 | .58 | .42 | -1.3 |
| Kidney | 190 | 82.1% | 82.8% | -0.7 | .80 | .20 | -0.1 |
| ***Avg. Above*** | | | | | | | |
| Heart | 68 | 84.7% | 83.2% | 2.2 | NMF | NMF | 1.9 |
| Kidney | 191 | 85.1% | 81.6% | 3.5 | NMF | NMF | 3.7 |
| ***SNGH*** | | | | | | | |
| Heart | 47 | 83.0% | 82.8% | 0.2 | .99 | .01 | 0 |
| Kidney | 243 | 76.5% | 78.3% | -1.8 | .49 | .51 | -0.9 |

Sources: Heart statistics from 1994 Report of Center Specific Graft and Patient Survival Rates, UNOS, 1995. Kidney statistics from Summary of 1994 Report of Center-Specific Graft and Patient Survival Rates, Edwards, E.B., UNOS, 1995. Additional computations by VDH, DCOPN.

*Note: Heart survival statistics relate to *patient* survival. Kidney survival statistics relate to *graft* survival (as kidney *patient* survival statistics were not readily available). See pages 27-29 for explanation of the "expected" survival rate and other aspects of the source data.

Table M and the prior analysis show that SNGH has achieved very satisfactory one-year survival rates with their existing transplant programs. This experience offers reason to believe that SNGH would likely achieve *at least* the SMFP's minimum one-year liver transplant patient survival rate (50%-60%, which seems too low in light of current results nationwide), if a liver transplant program is established at SNGH.

Notwithstanding the favorable inferences that can be drawn from SNGH's very satisfactory results with their established transplant programs, the start-up experience of a new transplant program may still be a valid concern. In their public comments opposing this application at the EVHSA public hearing, representatives of MCVH stated:

- In MCVH's start-up year (1984), the one-year survival rate was 50%.
- In Henrico Doctors Hospital's start-up year (1990), the one-year survival rate was 20%. Four out of five patients died and the program was discontinued.
- The mortality associated with a start-up program is extremely high....
- SNGH's start-up liver transplant mortality might be 40%, while MCVH's current one-year mortality is 19%.

Regarding these points raised by MCVH, the following is noted:

- MCVH was one of the first three liver transplant programs in the country. Such pioneering efforts in most fields involve far greater frequency of failure than is experienced after the field is established. MCVH's pioneering work in liver transplantation reflects and adds to the prominence

of MCVH among the nation's academic medical centers, but the results of these pioneering efforts are a questionable indicator of results that can be expected today.

- Liver transplant survival rates have increased steadily over the years. For example, the national liver transplant one-year patient survival rate was 77.1% in 1988 and was 81.6% in 1993, an improvement of nearly one percentage point per year. It seems unreasonable to contend that 1984 experience is a reliable guide to results that can be expected today, thirteen years later.

- During the period 1988-1991, Henrico Doctors Hospital and at least four others (noted on page 37 above) established and then soon terminated liver transplant programs, apparently due to low volume and/or high mortality. During the same period, many other liver transplant programs were started and experienced survival rates equal or superior to those of established liver transplant programs, according to the findings of UNOS's 1994 Report of Center Specific Graft and Patient Survival Rates. See Table J above for the varied experience of some very-low-volume programs (including Henrico Doctors) which began operation during the period 1988-1991.

- DCOPN asked MCVH the following questions about their statements on start-up program mortality and their implied prediction that a liver transplant program at SNGH might experience one-year patient mortality of 40% during the start-up period.

  - ◊ **"Is 1984 mortality experience a useful guide for 1997?"** This question was not answered.

  - ◊ **"What was the national one-year survival rate for *established* liver transplant programs in 1984?"** This question was not answered, and it was suggested that a special research request be made to UNOS. However, since MCVH was one of the first three liver transplant programs in the country and began operation in 1984, it seems likely there was virtually *no* experience of *established* liver transplant programs in 1984.

  - ◊ **"What is the experience of *recent* start-up liver transplant programs, and how does it compare with established programs?"** MCVH responded that they are "unable to answer this questions at this time, but [are] pursuing several avenues to obtain the data necessary to prepare a response." This question was sent to MCVH on December 4, and no substantive response has yet been received.

  - ◊ **"What is the basis for estimating Sentara start-up, one-year liver transplant mortality at 40%. Is this based on *recent* national experience with start-up liver transplant programs?"** MCVH responded that "this estimate is based on MCV's and University of Virginia's start-up experience. As noted above, MCVH's start-up experience was a national pioneering effort thirteen years ago and cannot be considered a reliable predictor of current start-up results. UVAH's specific start-up experience was not stated in any presentation or document available to DCOPN. UVAH began liver transplantation in 1988. UVAH's overall one-year patient survival rate for 1988-1991 was slightly *better* than "expected", according to UNOS's 1994 Report of Center-Specific Graft and Patient Survival Results. *There is no evidence here of excessive liver transplant mortality during UVAH's start-up period.* although it may have occurred and be obscured by superior results in the immediately following years.

- Considering the foregoing, there appears to be no substantiation of MCVH's contention and no other reason to believe that a liver transplant program at SNGH would be likely to experience excessive mortality during its start-up period.

The application and analysis of related information satisfactorily demonstrate that SNGH will achieve and maintain a one-year survival rate for liver transplant patients which meets or exceeds the SMFP standard of 50%-60%. The application meets this standard.

2. **Survival rates beyond one year should be consistent with the Health Care Financing Administration (HCFA) Medicare program requirements, or with applicable professional-society-recommended standards acceptable to the Department where there are no HCFA criteria.**

The application does not directly address this standard. The Department has not recognized (and is not aware of) liver-transplant survival standards from any professional society. The HCFA Medicare program requirement for liver-transplant patient survival beyond one year is 60% for *two-year* patient survival.

Since the applicant does not yet have a liver transplant program, specific conformance with this standard cannot be demonstrated for liver transplantation. However, the applicant has supplied the following information (communication from Manager, SNGH Transplant Center, February 19, 1997) regarding two-year patient survival rates for SNGH's existing transplant programs:

- Kidney transplant two-year patient survival (for transplants 1990-95): 90% vs. no HCFA standard
- Heart transplant two-year patient survival (for transplants 1992-95): 95.4% vs. 65% HCFA
- Lung and heart-lung transplant two-year patient survival (for transplants 1990-95): 66% vs. 62% HCFA standard

Since the applicant's existing transplant programs exceed HCFA two-year minimum patient survival standards, it is likely that a liver transplant program at SNGH would also exceed the relevant HCFA two-year minimum patient survival standard.

The application is judged to be consistent with this standard.

C. **Service Proficiency.**

**Proposals to establish additional organ transplantation services should demonstrate at least two years successful experience with all existing organ transplantation systems.**

With respect to this standard, the application states:

> As indicated above, with the exception of lung transplants not meeting minimum volume standards due to availability of organs, the organ transplant program at SNGH satisfies this standard.

By "successful experience", this standard presumably refers to achieving both acceptable *utilization* and acceptable *survival rates* in existing transplant services. SNGH's experience with existing transplant programs and the applicable standards are summarized in Table N below.

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*Table N*
**COMPARISON OF SNGH TRANSPLANT PROGRAM EXPERIENCE WITH MINIMUM UTILIZATION AND PATIENT SURVIVAL STANDARDS**

| Transplant Service | Year Service Began | Avg Ann. Volume 1995-96 | SMFP Standard | HCFA Standard | One-Year Pat. Surviv. 1992-95 | SMFP Standard | HCFA Standard | National One-Year Surv. ('93) |
|---|---|---|---|---|---|---|---|---|
| Kidney | 1972 | 35 | 25 | 25 | 94% | 90%-95% | 90% | 94.9% |
| Heart | 1989 | 14 | 12 | 12 | 95.4% | 70%-80% | 73% | 82.3% |
| Lung, Heart-Lung | 1992 | 6 | 12 | 10 | 66.7% | none | 69% | 76.3% |

Sources: Volume data from Table 2 attached and communication from Virginia Transplant Council. HCFA standards and SNGH survival data from the COPN application.

Table N shows that SNGH has met both the utilization and the patient survival standards for their *kidney* and *heart* transplant programs. These programs also achieved one-year patient survival rates for 1992-95 which equaled or exceeded the national one-year patient survival rates for 1993. SNGH's *lung and heart-lung* transplant programs (combined) have not achieved either the utilization standard or the one-year patient survival standard applicable to the lung and heart-lung service.

SNGH's combined lung and heart-lung transplant volume has been increasing, and the HCFA standard of 10 such transplants per year was met for a recent twelve-month period (although this volume must be achieved for two twelve-month periods to qualify for Medicare certification of the program). SNGH is the state's second largest provider of lung and heart-lung transplants, after UVAH.

The 2.3 percentage point difference, between SNGH's combined lung and heart-lung one-year patient survival rate and the HCFA standard, is clearly not statistically significant. The same is true for the larger difference between the SNGH experience and the national experience.

The application meets this standard.

**D. Staffing.**

**1. All physicians that perform transplants should be board certified by the appropriate professional examining board, and should have a minimum of one year of formal training and two years of experience in transplant surgery and post-operative care.**

With respect to this standard, the application states, "SNGH will recruit specialists that meet or exceed these standards."

The application meets this standard.

**2. Organ transplantation services should have a complete team of surgical, medical, and other specialists, with at least two years experience in the proposed organ transplantation system.**

With respect to this standard, the application states:

> SNGH has surgical, medical, and other specialty physicians on staff with liver experience. Some of the physicians may need to attend refresher training to update them on recent advances in liver transplantation.

*also:*

> To implement this proposed program, a surgeon with liver transplant experience will be recruited into one of the private surgical-practice groups within the region. It is expected this individual will immediately meet the minimum UNOS transplant surgeon criteria for implementation of a liver transplant program. Medical support for this patient population will be provided by gastroenterologists (GI) within the community who have experience in liver transplantation in their medical training at facilities such as the University of Wisconsin, Yale, and the Medical College of Virginia.

The application meets this standard to the extent reasonable for a facility that does not yet have a liver transplant program in operation.

**E. Systems Operations.**

**1. Providers of organ transplantation services should document that they participate in a regional and national organ donor network. The facility should have written policies and procedures governing organ and tissue procurement.**

SNGH is a founding member of the Hampton Roads Coalition on Donations, a regional network whose purpose is to promote public awareness of organ/tissue donation. The application includes a copy of SNGH's policies and procedures regarding requesting and handling organ and tissue donations.

The application meets this standard.

**2. Providers of organ transplantation services should have an ongoing approved medical education program.**

The application states, "As a provider of transplant services, SNGH already has in place an ongoing approved medical education program." All physicians associated with SNGH's transplant programs participate in continuing medical education (CME) programs, for which CME hours are assigned by the Eastern Virginia Medical School. SNGH also furnished DCOPN an outline of a liver transplant education program and a schedule of certain liver transplant education and training activities for October 1996 through January 1997. These activities included visits by SNGH medical and administrative staff to four existing liver transplant programs in Virginia and other states.

The application meets this standard.

**3. Providers of organ transplantation services should collect and submit to the Department transplantation program operating statistics, including patient and procedure volumes, mortality data, and program cost and charges.**

The application states, "SNGH will collect and submit to the Department operating statistics including patients and procedure volumes, mortality data, and program costs and charges."

Except for data on program *costs*, the various data elements cited in this standard are already collected by the Virginia Transplant Council (a unit of the Department), the United Network for Organ Sharing (UNOS), or Virginia Health Information (VHI). However, direct submission of this data to the Department by the transplant program will make complete data more easily accessible and more quickly available to the Department than the current arrangements permit.

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The application meets this standard.

**F. Support Services.**

**Providers of organ transplantation services should demonstrate that they have direct and immediate access to a histocompatibility testing laboratory that meets the American Society for Histocompatibility and Immunogenetics (ASHI) standards.**

SNGH operates within the hospital an HLA immunology laboratory, which is accredited by ASHI until 1999 (based on a recent inspection) in the following areas:

- serologic typing class I
- serologic typing class II
- disease association studies
- histocompatibility testing for transplantation as follows:
  - renal, cadaveric
  - renal, living-related
  - non-renal

The application meets this standard.

**4.1.C. The relationship of the project to the long-range development plan, if any, of the person applying for a certificate.**

The application states that SNGH does not have a long-range plan that specifically addresses development of the Transplantation Center, which already encompasses transplant services for kidneys, hearts, lungs, and heart-lung combinations. The application states that addition of liver transplant services to the present set of transplant services has been under discussion and planning for a long time.

It appears that, from an institutional perspective (which is not the same as public need), it is very logical to add liver transplantation to SNGH's existing group of transplant services. As shown in attached Table 2 and discussed on page 21 above, liver transplantation is the second most common solid-organ transplant procedure in Virginia and in the nation. The number of liver transplants per year is growing considerably faster in Virginia and in the nation than is the number of heart or kidney transplants. Each of the three existing liver transplant programs in Virginia has annual volume at least three times the standard of minimum annual volume in the SMFP or used by HCFA for Medicare certification.

These considerations suggest that *if* there is reason to add another transplant service in Virginia at this time, *liver transplantation is the service to add and SNGH is the place to add it.* Indeed, it is reasonable to ask why SNGH has not sought to establish liver transplant services before now, and this was among the completeness questions asked of SNGH following initial review of the application. The applicant responded:

> The Transplant Center leadership has evaluated the implementation of a liver transplant program since 1991 The decision was made to first implement the and heart-lung transplant program in 1993-94. Under the SMFP, it is suggested that organ transplant programs demonstrate at least two years successful experience with existing organ transplants.

physicians *not* on the Sentara medical staff, these established relationships will not instantly be dissolved in favor of referral to a Sentara transplant program.

In view of these considerations and the available data, DCOPN assumes that (1) the population of SNGH's potential service area for liver transplantation receives about 25-30 liver transplants per year and (2) within two to three years of its establishment, a Sentara liver transplant service would provide 10-15 of these transplants per year, with gradual growth into the future.

In addition to the patients who are transplanted in a given year, a larger number of patients are being managed on a waiting list, and a still larger number are evaluated each year for potential placement on the waiting list and eventual transplantation. In the application, SNGH estimates that, in year 2 of the service, twelve patients would be *transplanted*, 96 would be *listed*, and 192 would be *evaluated*. These projected ratios of *listed* and *evaluated* patients to *transplanted* patients seem quite high.

Since waiting-list mortality is less than ten percent (nationwide), nearly all persons on the waiting list will eventually be transplanted. Since nationwide average waiting-list time is roughly nine months (extrapolating the 1994 trend to 1997), there must be an approximate correspondence between the number of listings in one year and the number of transplants in the next year. Data presented by MCVH (at a meeting with SNGH representatives and subsequently provided to DCOPN and EVHSA) confirms this. The MCVH data also shows that annual *evaluations* at MCVH for liver transplantation have been roughly 50% greater than the number of *listings* in that year.

Accordingly, with allowance for future growth of transplant volume beyond year 2, the following projection of year 2 liver transplant service volume at SNGH seems more realistic than the projection in the application:

- 12 transplants, same as stated in the application
- 18 listings, rather than 96 stated in the application
- 27 evaluations, rather than 192 stated in the application

This constitutes the group of persons who would be the principal beneficiaries in year 2 of establishing a liver transplant service at SNGH. Increases of perhaps 20% per year would be expected over the next several years. These numbers *cannot* be summed to determine the number of *different individuals* served in a year. All of the transplants come from the listings, though mostly *not the same year's* listings, and all of the listings come from (the same year's) evaluations. Nonetheless, in assessing the potential benefit of this proposal, it is reasonable to consider transplants, listings, and evaluations separately.

**The Extent of Benefit.** The following Table P addresses the extent of benefit that might result from establishment of a liver transplant program at SNGH.

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Table O below shows the year of development and the location of solid-organ transplant services in Virginia. No new transplant services have been established in Virginia since 1993.

***Table O***
**CHRONOLOGY OF ESTABLISHMENT OF TRANSPLANTATION SERVICES IN VIRGINIA HOSPITALS**

| | Kidney | | | | | | Heart | | | | | | Lung & Heart-Lung | | | | | | Pancreas | | | | | | Liver | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Year Began -> | Pre '89 | '89 | '90 | '91 | '92 | '93 | Pre '89 | '89 | '90 | '91 | '92 | '93 | Pre '89 | '89 | '90 | '91 | '92 | '93 | Pre '89 | '89 | '90 | '91 | '92 | '93 | Pre '89 | '89 | '90 | '91 | '92 | '93 |
| Roa. Memor. | | | | | | ■ | | | | | | | | | | | | | | | | | | | | | | | | |
| Fairfax | | | | | ■ | | ■ | | | | | | | | | ■ | | | | | | | ■ | | | | | | ■ | |
| UVA Hosp. | ■ | | | | | | | ■ | | | | | | | ■ | | | | ■ | | | | | | ■ | | | | | |
| Henrico Doc. | | | ■ | | | | | ■ | | | | | | | | | | | | | | | | | | | | * | | |
| McGuire VA | | | | | | | ■ | | | | | | ■ | | | | | | | | | | | | | | | | | |
| MCV Hosp. | ■ | | | | | | ■ | | | | | | ■ | | | | | | | | | | ■ | | ■ | | | | | |
| Childrens KD | | | | | | | | | ■ | | | | | | | | | | | | | | | | | | | | | |
| Sentara NGH | ■ | | | | | | | ■ | | | | | | | | | ■ | | | | | | | | | | | | | |

Source: Table 2 attached. *Note: Henrico Doctors Hosp. established and terminated liver transplant service in 1991.

**4.1.D. The need that the population served or to be served by the project has for the project.**

Appropriate analysis of this criterion has three aspects: (1) the nature of the benefits; (2) the number of persons benefited; and (3) the extent (degree, frequency, or significance) of benefit received by those persons benefited.

The Nature of the Benefits. The application states the following potential benefits of establishing a liver transplant program at SNGH:

- Reduce travel time and expense for liver transplant patients and families who reside in the SNGH service area and now must travel to Richmond (or another, more distant program).
- Eliminate the medical risk and cost of transferring acutely ill patients from SNGH to MCVH.
- Reduce problems of non-optimal communication and lapses in the continuum of care that sometimes occur when patients are removed from the medical care community where they were treated prior to entering the transplant program at another location.
- Eliminate the costs, medical risks, and patient discomfort associated with duplicate performance of services, tests, and procedures, which often occurs when patients begin their liver care under a Sentara physician and later enter the transplant program at MCVH.

The Number of Persons Benefited. Consistent with preceding discussion (pages 7-8), the population to be served by the project is assumed to be the population of Virginia planning districts 20, 21, and 22, plus a population of approximately 100,000 in northeastern North Carolina. Of course, patients residing in the parts of this area most distant from SNGH are relatively less likely to use liver transplant services at SNGH and relatively more likely to use services at some other liver transplant program, even though the other program would be equally distant or more distant than SNGH. Also, referring physicians in the identified area have already established referral relationships for liver transplant services and, especially for

*Table P*

**EVALUATION OF BENEFITS OF ESTABLISHING A LIVER TRANSPLANT PROGRAM AT SNGH AS COMPARED TO PATIENTS FROM SNGH AREA BEING TREATED AT MCVH**
**(based on projected patient volume in year 2 of SNGH program)**

| Nature of Benefit | Description of Current Circumstances | No. Persons Benefited Per Year | Avg. No. Times Each Person Benefited/Yr. | Total Occasions of Benefit Per Year | Evaluation of Benefit of SNGH Location vs. MCVH |
|---|---|---|---|---|---|
| Reduce travel time and expense: | | | | | |
| Transplant evaluation | 3-day non-hospital stay in Richmond | 27 patients to be evaluated | 1 trip, avg. 1 overnight per trip | 27 trips, 27 overnights | 27 trips shortened<br>27 overnights eliminated |
| Pre-transplant exams | 1-day trip to Richmond | 18 patients on waiting list | 3 trips, 3 days | 54 trips, 54 days | 54 trips shortened<br>54 travel days shortened |
| Transplant hospitaliz. | 14-day inpatient stay in Richmond | 12 transpl. pat.<br>12 family mbr. | 1 trip, 14 visit-days by family member | 12 trips, 168 visit-days by family member | 12 trips shortened<br>84 (50%) overnights elim. |
| Post-discharge non-hosp. facility stays | 6-week stay at non-hosp. facility in Richmond | 12 transpl. pat.<br>12 family mbr.<br>10 (?) others | 30 trips by family mbr., others;<br>avg. 10 overnights | 360 trips by fam. mbr., others;<br>120 overnights | 360 trips shortened<br>120 overnights eliminated |
| Post-transplant outpatient visits | 2 times weekly - 6 weeks<br>1 time monthly - 9 mon.<br>trip to Richmond | 12 transplant patients | 21 trips, 21 days | 252 trips, 252 days | 252 trips shortened<br>252 travel days shortened |
| *Total reduced travel time and expense* | | | | 705 trips<br>231 overnights<br>666 days | 705 trips shortened<br>231 overnights eliminated<br>666 travel days shortened |
| Eliminate risk and cost of transferring acutely ill patients to MCVH | May have to transfer a hospitalized patient from SNGH to MCVH | a few--less than 12 | 1 | a few--less than 12 | significant for a few patients |
| Improve communications and continuity of care | Communication/continuity of care may suffer when patient goes to Richmond | 18 patients on waiting list | 1 | unknown | potentially significant for a few patients |
| Eliminate costs, medical risks, and patient discomfort from duplicated services, tests, and procedures | Services, tests, and procedures often duplicated when patient starts care in Hampton Roads and later enters MCVH program | up to 27 patients evaluated | unknown | unknown | unknown, probably minor relative to all costs, medical risks, and patient discomforts of liver transplantation |

Source: Information re. course of treatment and number of visits provided in letter from Manager, SNGH Transplant Center, December 20, 1996 and subsequent telephone conversations. Other information from COPN application and estimates by DCOPN staff.

Table P is an attempt, involving a number of arguable assumptions, to quantify the benefits that might accrue to patients and their family members if liver transplant services were received at SNGH as compared to receiving those services at MCVH. The benefits of reduced travel time and expense, as estimated in Table P, can be expressed in financial terms as follows:

- 705 trips shortened an average distance of 80 miles each way, at $0.15 per mile = $16,920
- 231 overnights eliminated at $35 per night = $8,085
- 666 travel days shortened at 3 hours per day, evaluated at $5 per hour = $9,990

  Total estimated value of benefits of reduced travel $34,995

This is necessarily an imprecise, debatable, and incomplete estimate of the nature and value of benefits associated with reduced travel for liver transplant services that would result from establishment of a program at SNGH. It is worth noting, however, that the total estimated financial value of benefits from reduced travel, approximately $35,000 in year 2, is only about 20% of the approximately $165,000 of new health system costs that DCOPN estimates would result in year 2 if this project is implemented.

As shown in Table P, reduced travel is not the only benefit expected to accrue from establishing liver transplant services at SNGH. However, the other benefits are not even crudely quantifiable from the information available. It is certainly conceivable, though, that the other benefits have a financial value more or less equivalent to the benefits of reduced travel.

Finally, all of these benefits have some potential to improve the psychological and physical well-being of patients and their families.

**4.1.E. The extent to which the project will be accessible to all residents of the area proposed to be served.**

Financial Accessibility. The applications states, "The liver transplant program expects to perform transplants on patients without the ability to pay, as part of Sentara's charitable mission of improving the health of citizens in the Hampton Roads community." In response to a completeness question, the applicant stated:

> Year two of the liver transplant proforma assumes one indigent patient and one patient with Medicaid coverage will be transplanted [among 12 projected liver transplants]. These projections were based on compilations of the current payor source for the SNGH Transplant Center.

Since Virginia Medicaid does not cover adult liver transplantation, presumably the cited Medicaid patient was evaluated as a no-revenue patient for purposes of the pro forma.

At the EVHSA public hearing, Dr. John Herre, a transplant cardiologist at SNGH and president-elect of the medical staff of Sentara Hospitals-Norfolk, stated:

> While many institutions have been unwilling even to consider solid organ transplantation for individuals without adequate insurance, Sentara has a long and consistent history of providing all necessary forms of care, including transplantation, to indigent patients. As a member of the heart transplant team, this has been particularly rewarding, as it has allowed medical need to supersede financial considerations. More than 200 patients have been evaluated for heart transplantation and no patient has been turned down for financial reasons.

According to information published by the Virginia Health Services Cost Review Council, in 1994 (last year of published data) SNGH provided charity care equal to 4.2% of gross revenue. This percentage of charity care was more than twice as great as the median of 2.0% among all HPR V hospitals.

It appears that *uninsured* and *Medicaid* patients would have reasonable financial access to liver transplant services at SNGH. Medicare patients would not have access until SNGH's liver transplant service received Medicare certification. This would require achieving annual volume of twelve transplants for two consecutive twelve-month periods. It seems likely this would not occur until the program had been in operation for about three years or more.

The access of *privately insured* patients would develop as their insurers recognize the SNGH program. Since SNGH is an established provider of other transplant services and has a very competitive cost and charge structure (see Table C above), it seems likely that most privately insured patients would reasonably soon have financial access to a liver transplant service at SNGH.

Geographic Accessibility. Relative to the distribution of population and considering the pattern of roadways and the impediments to travel created by the waterways, this location provides a high level of geographic accessibility for the population of the health planning region. See commentary under 4.1.F below.

**4.1.F. The area, population, topography, highway facilities and availability of the services to be provided by the project in the particular part of the health planning region in which the project is proposed.**

The proposed project would be the only site of liver transplant services within the health planning region. The many waterways running through Hampton Roads are a major factor affecting population distribution and highway travel within the area. SNGH is located within the Eastern Virginia Medical Center (EVMC) near downtown Norfolk, which approximates the geographical center of population in southside Hampton Roads. The EVMC lies at the eastern end of the Midtown Tunnel to Portsmouth, which connects via limited-access highway to I-664 to Newport News. EVMC is also within two miles of I-264 which runs from Virginia Beach to Suffolk and within two miles of the northern terminus of I-464 from Chesapeake.

Thus, interstate highway or equivalent connections link the Eastern Virginia Medical Center with all seven major cities of Hampton Roads. Relative to the distribution of population and considering the pattern of roadways and the impediments to travel created by the waterways, this location provides a high level of geographic accessibility for the population of the health planning region.

**4.1.G. Less costly or more effective alternate methods of reasonably meeting identified health service needs.**

This criterion involves two considerations: "less costly" and "more effective".

Less Costly. This consideration has been extensively addressed under the SMFP "cost" standard on pages 12-20 above. As described there, available data is not sufficient to reach a reliable conclusion as to whether an SNGH liver transplant program would or would not have higher net revenue or higher expenses per patient than the three existing programs in Virginia. However, the superior *overall* net revenue and cost performance of SNGH, as compared to other tertiary-care hospitals in Virginia (see Table C), certainly suggests that SNGH net revenue and expenses per liver transplant patient would not be higher than those of the existing programs.

Although the EVHSA staff report and comments by MCVH in opposition to this application contend that this project would result in a large duplication of existing health system costs, the DCOPN review finds little basis for these contentions. The applicant asserts, credibly, that since the liver transplant program would be only an addition to the existing, well-established transplant activity at SNGH, very little in the way of new resources would be required.

Based on the applicant's pro forma, DCOPN's analysis finds that approximately $165,000 (depreciation, "other", and one-half of the specifically identified salaries and benefits) *or about 8.5%* of SNGH's projected total expenses in year 2 for the liver transplant program *are duplicative* of expenses that *must* continue to be incurred at existing liver transplant programs, regardless of whether SNGH establishes a program.

Using the data and assumptions in the applicant's pro forma, a number of "transplant-equivalent" patients can be calculated, which encompasses projected patients actually transplanted, projected patients managed on a waiting list, and projected patients evaluated. On this basis, the incremental and duplicative cost of the proposed program, per "transplant-equivalent" patient projected in year 2, is about $9,000.

What must be offset against this duplicative cost per "transplant-equivalent" patient are the expense reductions that would be expected to result from establishment of a liver transplant program at SNGH. These are described on page 53-56 and in Table P above. They include reduced travel and lodging expense for patients and families. They also include some elimination of duplicative tests and other procedures and some reduction of emergency medical transfers.

However, it is hard to imagine that the identified expense reductions would equal the identified duplicative costs expected to result if this project is implemented. Accordingly, there would likely be *some* net additional cost placed into the health care system as a result of this project, although the amount would not be large by any comparative standard. On balance, it appears that it would be slightly *less costly* to meet the needs of the population for liver transplant services by continuing to rely on the existing services.

More Effective. Excluding the expense and convenience issues just discussed, it is hard to see that implementation of this project would materially improve the *effectiveness* with which liver transplant services are provided to the population of SNGH's potential service area. The effectiveness of the present service arrangements, specifically at MCVH, appears to be quite high, in terms of service availability, service accessibility, quality of care, patient outcomes, and patient satisfaction. This review finds no evidence that the proposed new liver transplant service at SNGH would be *more effective* than continuing to rely on present arrangements.

In fact, there is one consideration suggesting that it could be more effective for patients from SNGH's potential service area to continue to be served by MCVH rather than by a new program at SNGH. This consideration involves a single waiting list for liver transplantation, if MCVH remains, as now, the only liver transplant program in the area served by LifeNet, the organ procurement organization which would serve both MCVH and SNGH. Regarding this point, MCVH stated (MCVH response of 2/7/97 to questions submitted to MCVH by DCOPN, dated 12/4/96 and 12/6/96):

> ...Table 52 from the OPTN 1995 annual report...summarizes [nationwide] waiting-list mortality for the period of 1989-1994. As is evident, [nationwide] waiting-list mortality ranged between 7.8 and 9.2 percent per year during this time frame. Waiting-list mortality at MCVH during the period 1984 through 1990 exceeded 20 percent. The reasons for this were the small numbers of transplants performed at MCV during that period of time and the lack of a dedicated liver transplant surgeon and physician to manage these patients.
>
> Since 1991, with the creation of the current MCV transplant team including dedicated liver transplant surgeons and physicians, waiting-list mortality has fallen to an all-time low averaging 3.8 percent during the past six years....[with a range] from 0-5 percent per year....
>
> Our program is able to keep waiting-list mortality at this very low figure by careful follow-up and assessment of each patient's condition. Patients with liver disease progress and develop complications at variable rates. Some patients may not progress as fast as anticipated and may, therefore, await organ transplantation for 18 months or longer. In contrast, other patients may deteriorate more rapidly and/or are referred to our liver transplant center in a much more deteriorated state and require organ transplantation within days of being placed on the active liver transplant waiting list. By being the only liver transplant center served by our organ procurement organization ("OPO"), any organ donated locally can be used for the "sickest" patient on the waiting list, rather than the patient who has waited the longest period of time.

> In contrast, if a second liver transplant program at Norfolk/Sentara hospital were to become a reality, there would then be two liver transplant programs competing for organs within the same OPO. This would necessitate a common waiting list, and patients would then receive organs based upon waiting-list time rather than based upon actual disease severity.
>
> The anticipated effect of this would be to increase waiting-list mortality at both centers. For example, assume there are two patients, one listed at Norfolk/Sentara and the other at MCV, both at home awaiting hepatic transplantation. The patient at MCV has been on the waiting list for one year, is stable, and has good underlying hepatic reserve. In contrast, the patient at the Norfolk/Sentara program was recently placed on the waiting list with more advanced liver disease, but is not ill enough to require hospitalization. The next donated organ would go to the more stable patient at MCV who has waited longer, rather than the patient with more advanced liver disease at Sentara/Norfolk who has less waiting time.

This statement from MCVH seems clearly to show the following:

- MCVH has done a distinctly superior job of managing its liver transplant waiting list in recent years. The average program has not done nearly so well, and a *new* program would not be *expected* to do as well as MCVH is doing in minimizing waiting-list mortality.

- The organization and staffing of a program can make a great difference in program results in a relatively short time, even if other aspects of the environment remain about the same.

The above statement from MCVH does *not* seem clearly to show the following, although it may have been intended to do so:

- That there is a large and certain relationship between liver transplant volume and waiting-list mortality.

  MCVH's liver transplant volume averaged 18 during the years 1988-1990. These years were in the period of *high* waiting-list mortality (said to be 20+ percent) at MCVH, which was more than twice the national average (about 9 percent during the period 1988-90, earliest available data). In the next two years (1991-92), MCVH's liver transplant volume averaged 29, an average increase of 12 transplants, but waiting-list mortality fell by about three-fourths, to a level of five percent or less.

  It is difficult to believe that the increased activity associated with 12 more transplants per year would be the principal cause of such a dramatic reduction in waiting-list mortality. It seems likely that re-organization and re-staffing of MCVH's liver transplant program were the main factors in the dramatic improvement.

- That a new program would be highly unlikely to match the good waiting-list results at MCVH.

  It is plausible that experience would lead to superior results, but MCVH's dramatic improvement came from *losing much of their institutional experience and creating a new liver transplant team.* If MCVH could get such an improvement from a new team, why couldn't a new liver transplant program get good results from a new team, especially a new liver transplant team supported by an established overall transplant center?

The principal lesson of the MCVH experience with waiting-list mortality seems to be that personnel recruitment and organization, rather than volume of cases, are key to good results.

Yet, the above observations do not detract from the plausibility of MCVH's contention that a single-program waiting list in an organ procurement organization's area permits more effective management of the patients than would be possible with a two-program waiting list. Although DCOPN does not understand all the nuances of waiting-list management and organ-recipient matching, DCOPN nonetheless judges this factor to be a material point favoring denial of this application.

**Summary of "Less Costly" or "More Effective" Alternate Methods.** The foregoing indicates that the proposed project would be slightly more costly and might be less effective in one significant way than continuing to rely on present providers of liver transplant services, especially MCVH, to serve the population of SNGH's potential liver transplant service area.

**4.1.H. The immediate and long-term financial feasibility of the project.**

The EVHSA staff report states that, "on the basis of its own projections, SNGH's project is not financially feasible in its first two years of operation (in the sense of being able to break even)." The SNGH pro forma, reproduced as Table 1 attached, does show *negative* net income in the first year and much smaller *positive* net income in the second year, so that cumulative net income for the first two years is negative.

It seems unwarranted to conclude that a project is financially *in*feasible just because it is not "profitable" in its first year of operation and retains a cumulative operating deficit after the first two years. Very few enterprises could meet such a standard of financial feasibility. Based on SNGH's pro forma for the first two years, it is fairly clear that, *over a period of several years*, especially with gradually increasing volume, the SNGH liver transplant service would show *cumulative* net income which is *positive*.

Much more important for analysis, though, is that "net income", as shown on the SNGH proforma, bears little relationship to financial feasibility. What counts in an assessment of financial feasibility is whether the *marginal* (new) revenue from the liver transplant service would exceed the *marginal* cost of establishing and operating the service.

As far as is known, essentially *all* of the liver transplant service *revenue* (projected by the SNGH pro forma at approximately $2.0 million in year 2) would be *new* revenue to SNGH. In contrast, only a small portion of the *expenses* shown on the pro forma would be *new* expenses to SNGH. All of the *indirect* expenses (approximately $0.5 million in year 2) are *existing* ("fixed") expenses at SNGH, which now would be spread across one more cost center (thereby reducing the accounting "cost" of every other cost center in the transplant center or in the hospital). In addition, a large part--probably most--of the "patient-care" expenses (projected by the pro forma at approximately $1.2 million in year 2) are also existing (fixed) expenses at SNGH (see discussion on page 17 above). It is likely that well over $1.0 million of the projected year 2 expenses of the liver transplant service are existing (fixed) expenses at SNGH.

Accordingly, based on SNGH's pro forma, the *actual contribution to profit* (i.e., *marginal* revenue minus *marginal* cost) of the proposed liver transplant service would likely be well over $1.0 million in year 2 and would be substantial even in year 1. If SNGH's pro forma is anywhere close to accurate, the proposed liver transplant service would be hugely financially feasible right from the start.

**4.1.I. The relationship of the project to the existing health care system of the area in which the project is proposed.**

Evaluation of this criterion depends on interpretation of "the area in which the project is proposed." The customary interpretation of "area" is the planning district or the health planning region. In these contexts, this project would relate extremely well to the existing health care system. Since it would be unique within the area, this project would not duplicate any costs or disrupt any existing patterns of care within the area, and it would increase the accessibility and availability of health care services within the area.

However, "area" for this project might also be interpreted to encompass the state or at least the two contiguous health planning regions of central Virginia and eastern Virginia. In this context, this project would involve some (but comparatively small) degree of duplication of costs and would redirect some patterns of patient care within the area. This project might also have some detrimental effect on the research and training activities conducted at MCVH. These considerations are discussed in greater detail under 4.1.L below.

**4.1.J. The availability of resources for the project.**

The application states that very few new resources would be required to implement this project, because the proposed liver transplant service is only an addition to the existing transplant center at SNGH. All required resources for this project appear to be readily available and mostly already in place at SNGH.

**4.1.K. The organizational relationship of the project to necessary ancillary and support services.**

The project would be located in an environment where the necessary ancillary and support services are already present.

**4.1.L. The relationship of the project to the clinical needs of health professional training programs in the area in which the project is proposed.**

Discussion here will also address two other considerations: (1) the closely related concern of review criterion 4.1.N concerning the "impact on existing and proposed institutional training programs for doctors of osteopathy and medicine at the student, internship, and residency training levels" and (2) a concern, not directly addressed in any review criterion, regarding the potential impact of this project on *research* activities of existing transplantation programs, specifically research conducted in connection with MCVH's liver transplant program.

Many activities have some minimum feasible level of volume and some optimum level of volume which affects the efficiency and effectiveness with which the activity is performed. In opposing this application, MCVH has stated the concern that establishment of a liver transplant program at SNGH would reduce the volume of liver transplant patients served by MCVH and that this reduction would adversely affect the efficiency and effectiveness--and perhaps even the existence--of certain training and research activities at MCVH.

**Extent of Reduction in Liver Transplants at MCVH Likely to Be Caused by a New Program at SNGH.** Relative to this concern, this review has previously found the following:

- Estimated annual liver transplants *on residents* of SNGH's potential service area 25-30
- Projected annual liver transplants *at SNGH*, within a few years of establishment at least 10-15
- Current annual liver transplants *at MCVH* on residents of SNGH's area about 10-15
- Projected annual *loss* (next few years) of transplants *from MCVH to SNGH* no more than 10-15

Thus, a majority, but not all, of SNGH's liver transplant volume would be patients who would otherwise be transplanted at MCVH. This diversion to SNGH would be expected to reduce MCVH's annual volume by no more than 10-15 transplants, at least in the early years. This would be about 15%-20% of MCVH's expected future volume. Regarding their future volume, MCVH has stated (MCVH response of 2/7/97 to questions submitted to MCVH by DCOPN, dated 12/4/96 and 12/6/96):

> We expect that liver transplant volume at Medical College of Virginia will continue at its current pace of 60-75 liver transplants yearly for the foreseeable future. MCV's projected fiscal year 1997-98 volume is 75 liver transplants. This optimum volume is sufficient to sustain MCV's three-part mission of providing excellent patient care: conducting meaningful, productive clinical research; and providing teaching/training opportunities to medical professionals.....
>
> The addition of another liver transplant program in Virginia (Norfolk/Sentara) would divert patients from the Tidewater area away from the MCVH program. As such, [MCVH] program volume would be expected to decrease somewhat, although the exact impact cannot be determined at this time. A conservative estimate would be a 20 percent reduction in liver transplant volume once the Norfolk/Sentara program matures and can demonstrate good transplant outcomes.

Thus, MCVH's projection of volume loss to SNGH is about 12-15 liver transplants per year (a stated 20% reduction of otherwise projected annual volume of 60-75). If MCVH's assumptions hold, MCVH would perform about 50-60 liver transplants per year, after the SNGH program is fully established. *From 1988 through 1995, MCVH never performed as many as 40 liver transplants*, but in 1996 liver transplant volume rose to 66 (see attached Table 2 or Table G above). Therefore, even after the establishment of liver transplant services at SNGH, MCVH would still have higher volume than it ever had before 1966, if their assumptions hold. From this perspective, it is hard to see that a new liver transplant program at SNGH would harm any interest of MCVH.

However, MCVH's concern about loss of liver transplant volume should not be dismissed too easily. MCVH's maximum projection of 75 transplants per year (absent a new program at SNGH) could easily be too high. This projection represents a 14% gain over 1996 (66 transplants) and a near doubling of 1995 (39 transplants). If MCVH's future volume, absent an SNGH program, would be 60-65 (instead of the projected maximum of 75), and if SNGH took 15 or more of those cases, then MCVH volume would be reduced to less than 50 liver transplants per year, a circumstance which would be significant.

**Effect of Volume Reduction on Liver Transplant Training Programs at MCVH.** While 50 liver transplants would still be more than performed at MCVH in any year prior to 1996, important circumstances have recently changed, so that performing *less than 50* liver transplants per year would now be--but would not previously have been--detrimental to an MCVH training program. MCVH has advised (MCVH response of 2/7/97 to questions submitted to MCVH by DCOPN, dated 12/4/96 and 12/6/96):

> The MCVH liver transplant program is accredited by the American Society of Transplant Surgeons (ASTS) and the American Society of Transplant Physicians (ASTP). The minimum number of liver transplants

> necessary to maintain these accreditations is 50 per year....The ASTS requires that a Liver Transplant Program must perform a minimum of 50 liver transplants per year, continuously, to remain accredited as a Transplant Fellowship Training Program.

In a subsequent telephone conversation, MCVH explained that prior to 1996 the ASTS volume requirement was only 25, which permitted MCVH to be accredited in past years. Thus, if MCVH liver transplant volume were now to fall below 50 per year, which a new program at SNGH might well cause to happen, MCVH would lose accreditations and fellowship training opportunities which MCVH has had for a number of years. These accreditations apply to training of both liver transplant surgeons (ASTS) and transplant hepatologists (ASTP).

While the establishment of a liver transplant program at SNGH might well cause significant *harm to training programs at MCVH*, no evidence has been offered that establishment of a liver transplant program at SNGH would provide material *benefit to any training program at SNGH or at EVMS*. The application is silent on this point, and no later communication from SNGH addresses it either. The application and later correspondence include only one letter of support from EVMS (L.D. Britt, M.D., Chairman, EVMS Department of Surgery), and that letter speaks only of advantages for patient care of establishing the proposed service.

In this regard, MCVH stated (MCVH response of 2/7/97 to questions submitted to MCVH by DCOPN, dated 12/4/96 and 12/6/96):

> [SNGH does not], to our knowledge, have a surgical training program and their medical house staff would not participate in the care of liver transplant patients Recent guidelines regarding internal medical house staff training specifically eliminate transplantation as an area of training. Thus there is no specific educational mission to a proposed liver transplant program in Norfolk/Sentara Hospital.

It is difficult for DCOPN to evaluate all the ramifications of these circumstances. Nonetheless, DCOPN believes there is a significant public interest in the Commonwealth's largest medical school (and one of the nation's pioneer liver transplant centers) maintaining accreditation and fellowship opportunities in liver transplantation. Presumably, *UVAH* cannot do this, since UVAH's liver transplant volume fell to 37 in 1996, after declining for the two years prior.

On balance, DCOPN believes that the establishment of a liver transplant program at SNGH has a considerable likelihood (less than certain, but more than negligible) of harming transplant training programs at MCVH. This is judged to be a material factor favoring denial of this application.

**Effect of Volume Reduction on Liver Transplant Research at MCVH.** In a presentation made by MCVH personnel to SNGH senior management in September 1996 (copies of the presentation slides later provided to EVHSA and DCOPN), MCVH noted as a strength of their liver transplant program that certain "specialized techniques" had been developed there. DCOPN asked MCVH to amplify this point and place it in some context that might give it more meaning for review of the SNGH application. DCOPN asked MCVH these questions regarding the cited "specialized techniques" developed there (DCOPN questions to MCVH, dated 12/6/96):

- Do they set the MCVH program apart from most others?
- Does the development of these specialized techniques reflect a substantial research program at MCVH related to liver transplantation?

- Would research and/or developments like these at MCVH be significantly aided by a considerable increase in liver transplant volume or significantly harmed by a considerable decrease in liver transplant volume?

MCVH responded (response of 2/7/97):

> No technical or pharmacological advancements in transplantation have occurred outside of a research dedicated transplant university. Two major areas of transplant research involve inducing tolerance (the ability of a host to accept a foreign tissue without rejection) and reducing the complications of long-term immunosuppression drugs on patients and their transplanted organs.
>
> MCV is the only transplant center in the world to have successfully transplanted isolated human liver cells into a critically ill patient dying of liver failure. These cells stabilized the patients' condition and allowed them to receive whole-organ transplant several days thereafter. This technique was developed in the Liver Transplantation Research Laboratories. Two of the seven patients treated with this technology were referred to MCV from the Tidewater area. These two patients are alive and well today because of this ongoing research.
>
> To perform proper clinical trials, a large patient population of transplant recipients is necessary. The MCV program has several ongoing, randomized clinical trials to develop new and better immunosuppressant medications. Such clinical trials could not be performed if a new program at Norfolk Sentara reduced the number of patients transplanted at MCV by more than 20%.

The MCVH response is persuasive in establishing the significance of research recently performed and currently underway there. The response underlines the public interest in maintaining and not harming the research activities of academic medical centers. However, the response does not clearly indicate that establishing a liver transplant program at SNGH would harm present or future research at MCVH.

For one thing, MCVH has been able to carry out the cited research while performing fewer than 40 transplants per year, but would—according to their projections—expect to perform considerably more than 40 transplants per year in the future, even if a program is established at SNGH. Then too, there is no evident reason why MCVH and SNGH could not conduct *joint research on a much larger combined pool of patients* than MCVH has ever had solely in house. Multi-center medical research seems to be quite common—virtually the norm for those studies that gain national prominence.

As with the issues surrounding medical training, discussed immediately above, it is difficult for DCOPN to evaluate all the ramifications of the issues surrounding liver transplant research. Nonetheless, on balance, DCOPN is not persuaded that establishment of a liver transplant program at SNGH would harm existing or future research at MCVH and might well enhance it.

Consideration of this issue provides no particular basis either for recommending approval or for recommending denial of this application.

**4.1.M. The special needs and circumstances of an applicant for a certificate, such as a medical school, hospital, multi-disciplinary clinic, specialty center or regional health service provider, if a substantial portion of the applicant's services or resources or both is provided to individuals not residing in the health planning region in which the project is to be located.**

The applicant is a regional health service provider, and a portion of the proposed services--but probably well under ten percent--would be provided to persons residing outside the health planning region, especially

residents of northeastern North Carolina. This is not judged to constitute a special need or circumstance that should materially influence evaluation of this application.

**4.1.N. The need and the availability in the health planning region for osteopathic and allopathic services and facilities and the impact on existing and proposed institutional training programs for doctors of osteopathy and medicine at the student, internship, and residency training levels.**

Considerations related to this review criterion are discussed under 4.1.L below.

**4.1.O. The special needs and circumstances of health maintenance organizations. When considering the special needs and circumstances of health maintenance organizations, the commissioner may grant a certificate for a project if the commissioner finds that the project is needed by the enrolled or reasonably anticipated new members of the health maintenance organization or the beds or services to be provided are not available from providers which are not health maintenance organizations or from other health maintenance organizations in a reasonable and cost effective manner.**

Although the parent organization of the applicant operates one or more health maintenance organizations, no special needs or circumstances of health maintenance organizations have been asserted or are evident in this case.

**4.1.P. The special needs and circumstances for biomedical and behavioral research projects which are designed to meet a national need and for which local conditions offer special advantages.**

This review criterion, as it is worded, does not appear relevant to this application. However, the potential effect of this project on research activities at MCVH is relevant and is discussed under 4.1.N above.

**4.1.Q. The costs and benefits of the construction associated with the proposed project.**

No construction is associated with this project. The projected capital costs of $61,900 consist entirely of equipment and professional fees.

**4.1.R. The probable impact of the project on the costs of and charges for providing health services by the applicant for a certificate and on the costs and charges to the public for providing health services by other persons in the area.**

These issues are discussed extensively under the SMFP "cost" standard, pages 12-20 above. In summary, that analysis finds that an estimated $165,000 of *new* costs, excluding new costs for physician services (which are outside the scope of the application and not readily estimated), would be placed into the health care system of Virginia as a result of this project.

The addition of this service to SNGH's present array of services would almost certainly *reduce* unit costs at SNGH, as a result of increasing units of service output with a relatively small increase in resources consumed. By the same token, the establishment of a liver transplant service at SNGH would almost certainly *increase* unit costs at MCVH, as a result of decreasing units of service output at MCVH while permitting only a much smaller decrease in resources consumed.

How these cost effects might influence charges is highly speculative. Hospital charges and (the more important) contractual agreements reflect management attitudes, competitive conditions, and the overall financial condition of the hospital. The addition of a new liver transplant service at a low-cost, low-charge hospital, such as SNGH, might well result in a reduction in average charges/average net revenue per liver transplant patient in Virginia. However, this is so speculative that it cannot reasonably be viewed as a factor favoring either approval or denial of this application.

**4.1.S. Improvements or innovations in the financing and delivery of health services which foster competition and serve to promote quality assurance and cost effectiveness.**

This project does not appear to encompass any improvements or innovations of the kind envisioned in this review criterion.

**4.1.T. In the case of health services or facilities proposed to be provided, the efficiency and appropriateness of the use of existing services and facilities in the area similar to those proposed.**

This is the ultimate criterion for this project review, and it will be used to summarize the findings and conclusions of the review. For this purpose, Table A from page 6 is reproduced and expanded here.

*Table Q*
**SUMMARY EVALUATION**
**OF PRINCIPAL POINTS IN SUPPORT OF AND IN OPPOSITION TO**
**ESTABLISHMENT OF A LIVER TRANSPLANT PROGRAM**
**AT SENTARA NORFOLK GENERAL HOSPITAL**

| SNGH Points in Support | DCOPN Evaluation | MCVH Points in Opposition | DCOPN Evaluatio |
|---|---|---|---|
| Travel from the SNGH area to MCVH is burdensome for liver transplant patients and families. For some parts of the SNGH service area, travel time to MCVH exceeds the SMFP standard of two hours. | Agree, but extent of burden does not seem large in most cases. | Access to MCVH from the SNGH service area is "easy". Patients have testified to the convenience and the quality of care at MCVH. | Generally dis- agree re. acce Agree re. qua |
| The number of liver transplant patients from the potential SNGH service area for liver transplantation constitutes an adequate caseload for a new program. | Agree. The number from the area is 25-30. Not all would go to SNGH, but at least 10-15 would. | MCVH has ample capacity to serve the existing and future caseload from the SNGH area. The possibility that SNGH would meet minimum volume standards is not a sufficient reason to establish a new liver transplant program. | Agree. |
| SNGH is a long-established provider of transplant services and has had excellent results with existing transplant programs. | Agree. | A new liver transplant program would have higher mortality and morbidity than MCVH's existing program. | Disagree. Assertion no substantiate |
| A liver transplant program at SNGH would eliminate the *medical risk* of transferring acutely ill patients from SNGH to MCVH. It would reduce problems of non-optimal communication and lapses in the continuum of care. | Agree, but benefit seems infrequent. | Dividing one larger caseload into two smaller ones diminishes the opportunity to manage the overall pool of patients for optimal outcomes. | Agree, but uncertain as extent of bec |
| SNGH is an established provider of transplant services for other organs. Establishment of this program would require few new resources and little new cost. | Agree, but *some* new *and duplicative* cost likely involved. | A new program will result in higher overall costs and higher cost per case for liver transplant services in Virginia. | Generally disagree. N additional c modest. |
| A liver transplant program at SNGH would eliminate the *cost* of transferring acutely ill patients from SNGH to MCVH. | Agree, but benefit seems infrequent. | | |
| A liver transplant program at SNGH would eliminate the costs associated with duplicate performance of services, tests, and procedures, which often occurs when patients begin their liver care under a Sentara physician and then enter the transplant program at MCVH. | Agree, but extent of benefit not determined. Judged to be modest. | | |
| | | Reduction in MCVH transplant volume would negatively affect transplant training at MCVH. | Agree but considerab uncertaint |
| | | Reduction in MCVH transplant volume would negatively affect transplant research at MCVH. | Disagree. Assertion substantia |

In final summary, DCOPN finds:

- The potential service area for an SNGH liver transplant program encompasses about 1.6 million persons. Establishment of a liver transplant program at SNGH would markedly improve geographical accessibility of liver transplant services for much of this population, even though

more than one-half of this population lives within two hours driving time of MCVH. While establishment of a liver transplant program at SNGH would substantially improve geographical accessibility of services, it does not appear that it is a huge burden for most persons to travel to Richmond for these services. This consideration favors approval of the application, but only modestly so.

- The question of SNGH achieving at least the standard of minimum annual liver transplant volume in a reasonable period of time is not a significant issue. SNGH is likely to perform at least 12 liver transplants per year within two to three years of establishing their program. SNGH has been able to achieve and maintain at least the standard of minimum annual *heart* transplant volume, even though heart transplantation is a substantially lower-volume and (at least in Virginia) more crowded field than liver transplantation.

- When the data is carefully examined, there is little to substantiate contentions that a liver transplant program operating at SNGH's likely volume would be expected to experience high mortality. The statistical link between transplant program volume and mortality is very weak, except historically for a few centers that performed only two or three transplants per year over a period of several years and a few centers that began operation and then soon terminated, suggesting that severe operational problems were encountered. Regression analyses performed by DCOPN found that, at most, only five percent of the variation in graft survival among transplant centers was statistically explained by transplant volume.

- The question of large costs being added to the health care system as a result of this project is not a significant issue. Some, but very modest net addition of costs is likely. About 90% of expenses shown in the SNGH pro forma are already present at SNGH.

- MCVH's contention that a single-facility waiting list permits better management of patients and better results than a two-facility waiting list is regarded as plausible and important. This consideration favors denial of the application.

- There appears to be a significant likelihood, but not certainty, that establishment of a liver transplant program at SNGH would cause MCVH to fall below the minimum annual volume of 50 transplants now required to maintain accreditation as a site for liver transplant fellowship training programs. This consideration is viewed as important and favors denial of the application.

- There is very little reason to believe that establishment of a liver transplant program at SNGH would harm research activities at MCVH. It might even complement them.

## Staff Recommendation

The Division of Certificate of Public Need recommends denial of this application for the following reasons:

1. No substantial need for the proposed new service has been demonstrated.

2. A single-facility waiting list, as now exists with only one liver transplant program in the organ procurement organization's area, permits better management of patients on the waiting list and decreases waiting-list mortality.

3. Establishment of a liver transplant program at SNGH has a considerable probability of reducing volume at MCVH to a level that would harm training programs now in operation at MCVH.

Attachments: Table 1, Statement of Projected Revenues and Expenses...SNGH
Table 2, Transplant Volume...Virginia Transplant Programs--1988-1995
Table 3, UNOS Center-Specific Results...Liver Transplants... (by volume of transplants)
Table 4, UNOS Center-Specific Results...Liver Transplants... (by probability-weighted difference between actual and expected survival)

**TABLE 1**
**Statement of Projected Revenue and Expenses**
**Proposed Liver Transplant Program**
**Sentara Norfolk General Hospital**

| | Year 1 | | | Year 2 | | | Percent Change | Pct. Chg. Per |
|---|---|---|---|---|---|---|---|---|
| | No. Patients | Total Amount | Per Patient | No. Patients | Total Amount | Per Patient | Yr. 1-Yr. 2 | Patient |
| *Revenue* | | | | | | | | |
| Gross patient charges: | | | | | | | | |
| Transplants performed | 6 | 912,738 | 152,123 | 12 | 1,916,748 | 159,729 | 110% | 5.0% |
| Patients listed | 48 | 410,784 | 8,558 | 96 | 862,656 | 8,986 | 110% | 5.0% |
| Patients evaluated | 96 | 101,568 | 1,058 | 192 | 213,312 | 1,111 | 110% | 5.0% |
| Total gross patient charges | | 1,425,090 | NMF | | 2,992,716 | NMF | 110% | |
| Contractual adjust. & bad debts | | (497,373) | | | (1,023,272) | | 106% | |
| Net revenue | | 927,717 | | | 1,969,444 | | 112% | |
| *Net revenue as % gross charges* | | *65.1%* | | | *65.8%* | | | |
| *Expenses* | | | | | | | | |
| Direct expenses: | | | | | | | | |
| Salaries | | 67,153 | | | 69,473 | | 3% | |
| Benefits | | 10,440 | | | 10,858 | | 4% | |
| Depreciation | | 9,480 | | | 9,480 | | 0% | |
| Other | | 172,500 | | | 105,000 | | -39% | |
| Patient care costs | | 622,781 | | | 1,245,562 | | 100% | |
| Total direct expenses | | 882,354 | | | 1,440,373 | | 63% | |
| Indirect expenses | | 305,506 | | | 500,812 | | 64% | |
| Total expenses | | 1,187,860 | | | 1,941,185 | | 63% | |
| Contribution margin (net rev. - dir. exp.) | | 45,363 | | | 529,071 | | 1066% | |
| *Contribution margin as % net revenue* | | *4.9%* | | | *26.9%* | | | |
| Net Income | | (260,143) | | | 28,259 | | NMF | |
| *Net income as % net revenue* | | *-28.0%* | | | *1.4%* | | | |

NOTES

1 Basic data from SNGH Liver Transplant Pro Forma Income Statement - Years 1 & 2, revised.

2 Subtotal and total amounts calculated by VDH/DCOPN These may differ immaterially from the source, due to rounding procedures.

3 Percentages calculated by VDH/DCOPN

4 "NMF" = no meaningful figure

**TABLE 2**
**Volume of Solid-Organ Transplants**
**Virginia Transplant Programs–1988-1995**

00704

| Hospital | 1988 | 1989 | 1990 | 1991 | 1992 | 1993 | 1994 | 1995 | Avg. Ann. Rate of Chg. 1991-92 to 1994-95* | Comment Re. Calc. of Rate of Chg. |
|---|---|---|---|---|---|---|---|---|---|---|
| ***Kidney Transplants:*** | | | | | | | | | | |
| Roanoke Memorial | 0 | 0 | 0 | 0 | 0 | 11 | 20 | 18 | NMF* | |
| Fairfax | 0 | 0 | 0 | 0 | 9 | 22 | 38 | 26 | NMF | |
| Univ. of Virginia & Child. Re. | 25 | 43 | 62 | 58 | 55 | 52 | 41 | 50 | -7.0% | |
| Henrico Doctors | 0 | 0 | 7 | 17 | 26 | 28 | 40 | 43 | 24.5% | |
| Med. Coll. of Virginia | 41 | 47 | 57 | 34 | 38 | 45 | 46 | 29 | 1.4% | |
| Sentara Norfolk Gen. | 50 | 53 | 78 | 52 | 47 | 42 | 47 | 35 | -6.1% | |
| Virginia Total | 116 | 143 | 204 | 161 | 175 | 200 | 232 | 201 | 8.8% | |
| Avg. Vol. (prog. w/activ.)* | 39 | 48 | 66 | 40 | 42 | 38 | 39 | 34 | -4.1% | |
| *Sentara NGH as % of Va. Total* | *43%* | *37%* | *38%* | *32%* | *27%* | *21%* | *20%* | *17%* | *-14.0%* | |
| U.S. Total Volume | 9,041 | 8,988 | 9,879 | 10,122 | 10,231 | 11,021 | 11,391 | NAV | 4.9% | to 1993-94 |
| *Va. as % of U.S. Total* | *1.3%* | *1.6%* | *2.1%* | *1.6%* | *1.7%* | *1.8%* | *2.0%* | *NAV* | *8.0%* | *to 1993-94* |
| ***Heart Transplants:*** | | | | | | | | | | |
| Fairfax | 9 | 11 | 12 | 10 | 12 | 19 | 22 | 12 | 15.6% | |
| Univ. of Virginia & Child. Re. | 0 | 3 | 20 | 25 | 25 | 22 | 27 | 22 | -0.7% | |
| Henrico Doctors | 0 | 1 | 10 | 11 | 17 | 12 | 9 | 8 | -15.3% | |
| McGuire VA Med. Ctr. | 27 | 11 | 12 | 10 | 7 | 6 | 12 | 12 | 12.2% | |
| Med. Coll. of Virginia | 46 | 18 | 20 | 25 | 15 | 8 | 4 | 2 | -46.9% | |
| Child. Hosp. Kings Daugh. | 0 | 0 | 7 | 3 | 3 | 1 | 3 | 3 | 0.0% | |
| Sentara Norfolk Gen. | 0 | 10 | 16 | 21 | 8 | 9 | 14 | 13 | -2.4% | |
| Virginia Total | 82 | 54 | 97 | 105 | 87 | 77 | 91 | 72 | -5.3% | |
| Avg. Vol. (prog. w/activ.)* | 27 | 13 | 14 | 15 | 12 | 11 | 13 | 10 | -5.3% | |
| *Sentara NGH as % of Va. Total* | *0%* | *19%* | *16%* | *20%* | *9%* | *12%* | *15%* | *18%* | *4.6%* | |
| U.S. Total Volume | 1,676 | 1,705 | 2,108 | 2,125 | 2,171 | 2,297 | 2,340 | NAV | 3.9% | to 1993-94 |
| *Va. as % of U.S. Total* | *4.9%* | *3.2%* | *4.6%* | *4.9%* | *4.0%* | *3.4%* | *3.9%* | *NAV* | *-10.0%* | *to 1993-94* |
| ***Lung Transplants:*** | | | | | | | | | | |
| Fairfax | 0 | 0 | 0 | 1 | 1 | 2 | 6 | 2 | 58.7% | |
| Univ. of Virginia & Child. Re. | 0 | 0 | 3 | 8 | 17 | 18 | 13 | 15 | 3.8% | |
| McGuire VA Med. Ctr. | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 3 | 26.0% | |
| Med. Coll. of Virginia | 0 | 0 | 0 | 3 | 4 | 5 | 0 | 4 | -17.0% | |
| Sentara Norfolk Gen. | 0 | 0 | 0 | 0 | 3 | 3 | 2 | 4 | 0.0% | since 1992 |
| Virginia Total | 0 | 0 | 3 | 13 | 26 | 29 | 22 | 28 | 8.6% | |
| Avg. Vol. (prog. w/activ.)* | NMF | NMF | 3 | 3 | 5 | 6 | 6 | 7 | 13.9% | |
| *Sentara NGH as % of Va. Total* | *NMF* | *NMF* | *0%* | *0%* | *12%* | *10%* | *9%* | *14%* | 3.4% | since 1992 |
| U.S. Total Volume | 33 | 93 | 203 | 405 | 535 | 666 | 722 | NAV | 21.5% | to 1993-94 |
| *Va. as % of U.S. Total* | *0.0%* | *0.0%* | *1.5%* | *3.2%* | *4.9%* | *4.4%* | *3.0%* | *NAV* | *-4.2%* | *to 1993-94* |
| ***Heart-Lung Transplants:*** | | | | | | | | | | |
| Univ. of Virginia & Child. Re. | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | NMF | |
| McGuire VA Med. Ctr. | 1 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | NMF | |
| Med. Coll. of Virginia | 1 | 0 | 1 | 2 | 1 | 1 | 0 | 0 | NMF | |
| Sentara Norfolk Gen. | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | NMF | |
| Virginia Total | 2 | 0 | 2 | 4 | 2 | 2 | 2 | 1 | NMF | |
| Avg. Vol. (prog. w/activ.)* | 1 | 0 | 1 | 2 | 1 | 1 | 1 | 1 | NMF | |
| *Sentara NGH as % of Va. Total* | *0%* | *NMF* | *0%* | *0%* | *0%* | *50%* | *50%* | *100%* | *NMF* | |
| U.S. Total Volume | 74 | 67 | 52 | 51 | 48 | 60 | 70 | NAV | 14.6% | to 1993-94 |
| *Va. as % of U.S. Total* | *2.7%* | *0.0%* | *3.8%* | *7.8%* | *4.2%* | *3.3%* | *2.9%* | *NAV* | *-28.2%* | *to 1993-94* |

## Volume of Solid-Organ Transplants
## Virginia Transplant Programs—1988-1995

00705

| Hospital | 1988 | 1989 | 1990 | 1991 | 1992 | 1993 | 1994 | 1995 | Avg. Ann. Rate of Chg. 1991-92 to 1994-95* | Comment Re. Calc. of Rate of Chg. |
|---|---|---|---|---|---|---|---|---|---|---|
| ***Pancreas Transplants:*** | | | | | | | | | | |
| Fairfax | 0 | 0 | 0 | 0 | 2 | 3 | 7 | 3 | NMF | |
| Univ. of Virginia & Child. Re. | 1 | 5 | 9 | 6 | 3 | 10 | 7 | 5 | 10.1% | |
| Med. Coll. of Virginia | 0 | 0 | 0 | 0 | 0 | 2 | 9 | 11 | NMF | |
| Virginia Total | 1 | 5 | 9 | 6 | 5 | 15 | 23 | 19 | 56.3% | |
| Avg. Vol. (prog. w/activ.)* | NMF | 5 | 9 | 6 | 3 | 7 | 8 | 6 | 18.1% | |
| *Sentara NGH as % of Va. Total* | *NAP** | *NAP* | *NAP* | *NAP* | *NAP* | *NAP* | *NAP* | *NAP* | *NAP* | |
| U.S. Total Volume | 249 | 417 | 528 | 531 | 557 | 774 | 842 | NAV | 21.9% | to 1993-94 |
| *Va. as % of U.S. Total* | *0.4%* | *1.2%* | *1.7%* | *1.1%* | *0.9%* | *1.9%* | *2.7%* | *NAV* | *51.8%* | *to 1993-94* |
| ***Liver Transplants:*** | | | | | | | | | | |
| Fairfax | 0 | 0 | 0 | 0 | 4 | 14 | 18 | 37 | NMF | |
| Univ. of Virginia & Child. Re. | 1 | 17 | 54 | 51 | 36 | 66 | 62 | 53 | 9.7% | |
| Henrico Doctors | 0 | 0 | 0 | 5 | 0 | 0 | 0 | 0 | NMF | |
| Med. Coll. of Virginia | 21 | 18 | 16 | 27 | 31 | 37 | 33 | 39 | 7.5% | |
| Virginia Total | 22 | 35 | 70 | 83 | 71 | 117 | 113 | 129 | 16.3% | |
| Avg. Vol. (prog. w/activ.)* | 21 | 18 | 35 | 28 | 34 | 39 | 38 | 43 | 9.7% | |
| *Sentara NGH as % of Va. Total* | *NAP** | *NAP* | *NAP* | *NAP* | *NAP* | *NAP* | *NAP* | *NAP* | *NAP* | |
| U.S. Total Volume | 1,713 | 2,201 | 2,690 | 2,954 | 3,064 | 3,440 | 3,652 | NAV | 8.6% | to 1993-94 |
| *Va. as % of U.S. Total* | *1.3%* | *1.6%* | *2.6%* | *2.8%* | *2.3%* | *3.4%* | *3.1%* | *NAV* | *12.6%* | *to 1993-94* |
| ***Total Above Transplants:*** | | | | | | | | | | |
| Roanoke Memorial | 0 | 0 | 0 | 0 | 0 | 11 | 20 | 18 | NMF | |
| Fairfax | 9 | 11 | 12 | 11 | 28 | 60 | 91 | 80 | 63.7% | |
| Univ. of Virginia & Child. Re. | 27 | 68 | 148 | 150 | 136 | 168 | 150 | 145 | 1.0% | |
| Henrico Doctors | 0 | 1 | 17 | 33 | 43 | 40 | 49 | 51 | 9.6% | |
| McGuire VA Med. Ctr. | 28 | 11 | 13 | 11 | 9 | 7 | 14 | 15 | 13.2% | |
| Med. Coll. of Virginia | 109 | 83 | 94 | 91 | 89 | 98 | 92 | 85 | -0.6% | |
| Child. Hosp. Kings Daugh. | 0 | 0 | 7 | 3 | 3 | 1 | 3 | 3 | 0.0% | |
| Sentara Norfolk Gen. | 50 | 63 | 94 | 73 | 58 | 55 | 64 | 53 | -3.7% | |
| Virginia Total | 223 | 237 | 385 | 372 | 366 | 440 | 483 | 450 | 8.1% | |
| Avg. Facil. Vol. (prog. w/activ.)* | 45 | 47 | 55 | 53 | 52 | 61 | 60 | 56 | 3.4% | |
| *Sentara NGH as % of Va. Total* | *22%* | *27%* | *24%* | *20%* | *16%* | *13%* | *13%* | *12%* | *-11.0%* | |
| U.S. Total Volume | 12,786 | 13,471 | 15,460 | 16,188 | 16,606 | 18,258 | 19,017 | NAV | 6.6% | to 1993-94 |
| *Va. as % of U.S. Total* | *1.7%* | *1.8%* | *2.5%* | *2.3%* | *2.2%* | *2.4%* | *2.5%* | *NAV* | *4.9%* | *to 1993-94* |

Sources: Data for 1988-1994 from 1995 Annual Report of the U.S. Scientific Registry of Transplant Recipients and the Organ Procurement and Transplantation Network, Transplant Data: 1988 - 1994, United Network for Organ Sharing, 1995. Data for 1995 from the Virginia Transplant Council, revised March 1996.

*Notes:

1. The average annual rate of change is calculated as the change between the *mean* of the data for 1991-92 (or 1992-93 if indicated) and the mean of the data for 1994-95 (or 1993-94 if indicated).
2. "NMF" = no meaningful figure. The numbers are too small or the data period too short to produce valid statistics.
3. "NAP" = not applicable. "NAV" = not available.
4. "Avg. Vol. (prog. w/activ.)" excludes programs with no transplants in that year and excludes a program's start-up year, which is usually less than a full year.

**TABLE 3**
**UNOS Center-Specific Results**
**One-Year Graft Survival**
**Liver Transplants 10/1/87-12/31/91**
(facilities arrayed by volume of transplants)

00706

| Hospital | No. of Transplants | Actual Pct. Surviv. | Expected Pct. Surviv. | Difference Act-Exp. | "p" Value | 1-"p" | Diff. x 1-"p" |
|---|---|---|---|---|---|---|---|
| Univ of Pittsburgh-Presby Hosp | 1705 | 66.8 | 64.4 | 2.4 | 0.01 | 0.99 | 2.4 |
| Univ of Calif-Los Angeles | 679 | 62.7 | 62.8 | -0.1 | 0.98 | 0.02 | 0.0 |
| Univ Nebraska, Univ Hosp | 532 | 71.6 | 65.4 | 6.2 | 0.00 | 1.00 | 6.2 |
| Baylor Univ Med Ctr | 494 | 72.0 | 69.2 | 2.8 | 0.14 | 0.86 | 2.4 |
| Univ of Chicago Med Ctr | 376 | 50.3 | 62.1 | -11.8 | 0.00 | 1.00 | -11.8 |
| Children's Hosp of Pittsburgh | 345 | 67.5 | 65.0 | 2.5 | 0.25 | 0.75 | 1.9 |
| Univ of Michigan Med Ctr | 319 | 66.5 | 68.2 | -1.7 | 0.49 | 0.51 | -0.9 |
| Univ of Calif-San Francisco | 318 | 80.2 | 69.4 | 10.8 | 0.00 | 1.00 | 10.8 |
| Mt Sinai Med Ctr | 313 | 69.0 | 67.8 | 1.2 | 0.62 | 0.38 | 0.5 |
| Calif Pacific Med Ctr | 286 | 80.4 | 68.2 | 12.2 | 0.00 | 1.00 | 12.2 |
| Univ of Wisconsin | 275 | 70.9 | 65.6 | 5.3 | 0.05 | 0.95 | 5.0 |
| Rochester Methodist Hosp | 221 | 78.7 | 70.0 | 8.7 | 0.00 | 1.00 | 8.7 |
| New England Deaconess | 188 | 62.8 | 66.3 | -3.5 | 0.28 | 0.72 | -2.5 |
| Rush-Presbyterian-St Luke's | 158 | 51.9 | 59.1 | -7.2 | 0.05 | 0.95 | -6.8 |
| Barnes Hosp/St Louis Child. Hosp | 144 | 59.0 | 66.2 | -7.2 | 0.05 | 0.95 | -6.8 |
| Johns Hopkins Hosp | 135 | 60.7 | 65.5 | -4.8 | 0.22 | 0.78 | -3.7 |
| Ochsner Transplant Ctr | 132 | 63.6 | 71.1 | -7.5 | 0.05 | 0.95 | -7.1 |
| Univ of Virginia Med Ctr | 122 | 67.2 | 67.7 | -0.5 | 0.91 | 0.09 | 0.0 |
| Indiana Univ Med Ctr | 121 | 61.2 | 68.3 | -7.1 | 0.08 | 0.92 | -6.5 |
| Univ of Minnesota Hosp | 117 | 75.9 | 72.1 | 3.8 | 0.34 | 0.66 | 2.5 |
| Emory Univ | 113 | 64.8 | 69.0 | -4.2 | 0.32 | 0.68 | -2.9 |
| New England Med Ctr | 111 | 67.6 | 66.4 | 1.2 | 0.79 | 0.21 | 0.3 |
| Univ of Colorado Hosp | 106 | 78.3 | 73.2 | 5.1 | 0.21 | 0.79 | 4.0 |
| Hosp of the Univ of Penn | 103 | 57.8 | 68.3 | -10.5 | 0.02 | 0.98 | -10.3 |
| Duke Univ Med Ctr | 101 | 53.5 | 69.4 | -15.9 | 0.00 | 1.00 | -15.9 |
| Children's Med Ctr of Dallas | 98 | 68.8 | 66.2 | 2.6 | 0.57 | 0.43 | 1.1 |
| Cedars-Sinai Med Ctr | 97 | 76.3 | 65.6 | 10.7 | 0.02 | 0.98 | 10.5 |
| Cleveland Clinic Found | 93 | 71.0 | 72.9 | -1.9 | 0.67 | 0.33 | -0.6 |
| Massachusetts Gen Hosp | 89 | 67.4 | 69.3 | -1.9 | 0.69 | 0.31 | -0.6 |
| Med Coll of Virginia | 84 | 63.1 | 70.9 | -7.8 | 0.11 | 0.89 | -6.9 |
| Thomas Jefferson Univ Hosp | 82 | 59.8 | 66.3 | -6.5 | 0.18 | 0.82 | -5.3 |
| Ohio State Univ Hosp | 79 | 70.9 | 70.3 | 0.6 | 0.90 | 0.10 | 0.1 |
| Univ of Washington Med Ctr | 78 | 73.1 | 72.3 | 0.8 | 0.87 | 0.13 | 0.1 |
| Froedtert Mem Lutheran Hosp | 72 | 56.9 | 64.7 | -7.8 | 0.14 | 0.86 | -6.7 |
| Univ of Miami-Jackson Mem | 70 | 47.1 | 63.0 | -15.9 | 0.00 | 1.00 | -15.9 |
| LDS Hosp-Salt Lake City | 67 | 62.7 | 70.8 | -8.1 | 0.12 | 0.88 | -7.1 |
| Children's Hosp-Cincinnati | 66 | 68.2 | 65.7 | 2.5 | 0.65 | 0.35 | 0.9 |
| Univ of Alabama-Birmingham | 59 | 79.7 | 73.5 | 6.2 | 0.27 | 0.73 | 4.5 |
| St Christopher's Hosp | 59 | 74.6 | 63.2 | 11.4 | 0.05 | 0.95 | 10 8 |
| VA Medical Center-Pittsburgh | 54 | 77.8 | 67.9 | 9.9 | 0.11 | 0.89 | 8.8 |
| Univ of Tenn, Wm F Bowld Hosp | 53 | 66.0 | 74.6 | -8.6 | 0.14 | 0.86 | -7.4 |
| Methodist Hosp of Indiana | 51 | 66.7 | 67.4 | -0.7 | 0.91 | 0.09 | -0.1 |
| Children's Hosp of Philadelphia | 49 | 42.9 | 58.9 | -16.0 | 0.01 | 0.99 | -15.8 |
| Univ Hosp-Newark | 46 | 60.0 | 69.0 | -9.0 | 0.18 | 0.82 | -7.4 |
| Good Samaritan Reg Med Ctr | 44 | 54.5 | 74.6 | -20.1 | 0.00 | 1.00 | -20.1 |
| St Louis Univ Med Ctr | 43 | 51.2 | 63.4 | -12.2 | 0.08 | 0.92 | -11.2 |
| Univ Hosps of Cleveland | 43 | 74.4 | 69.4 | 5.0 | 0.46 | 0.54 | 2.7 |
| Oregon Hlth Sci Univ/PVAMC | 41 | 70.7 | 69.0 | 1.7 | 0.80 | 0.20 | 0 3 |
| The Methodist Hospital-Houston | 40 | 45.0 | 67.5 | -22.5 | 0.00 | 1.00 | -22 5 |
| Children's Hosp-Boston | 35 | 71.4 | 62.8 | 8.6 | 0.25 | 0.75 | 6.5 |

**TABLE 3**
**UNOS Center-Specific Results**
**One-Year Graft Survival**
**Liver Transplants 10/1/87-12/31/91**
(facilities arrayed by volume of transplants)

00707

| Hospital | No. of Transplants | Actual Pct. Surviv. | Expected Pct. Surviv. | Difference Act-Exp. | "p" Value | 1-"p" | Diff. x 1-"p" |
|---|---|---|---|---|---|---|---|
| Univ of Kansas Hosp Med Ctr | 32 | 77.4 | 76.1 | 1.3 | 0.86 | 0.14 | 0.2 |
| Hartford Hosp | 30 | 60.0 | 69.2 | -9.2 | 0.26 | 0.74 | -6.8 |
| Univ of Iowa Hosp | 30 | 73.3 | 73.0 | 0.3 | 0.96 | 0.04 | 0.0 |
| Univ of Cincinnati Coll of Med | 29 | 75.9 | 70.2 | 5.7 | 0.49 | 0.51 | 2.9 |
| Shands Hosp-Univ of Florida | 28 | 71.4 | 73.2 | -1.8 | 0.83 | 0.17 | -0.3 |
| Univ of Texas-Hermann Hosp | 28 | 53.6 | 67.8 | -14.2 | 0.09 | 0.91 | -12.9 |
| Green Hosp of Scripps Clinic | 25 | 64.0 | 72.7 | -8.7 | 0.31 | 0.17 | -6.0 |
| Yale Univ Sch of Med | 24 | 37.5 | 66.9 | -29.4 | 0.00 | 1.00 | -29.4 |
| Wilford Hall USAF Med Ctr | 24 | 45.8 | 66.6 | -20.8 | 0.02 | 0.98 | -20.4 |
| St Louis Children's Hosp | 23 | 52.2 | 65.8 | -13.6 | 0.13 | 0.87 | -11.8 |
| VA Hospital-Portland OR | 23 | 60.9 | 63.2 | -2.3 | 0.80 | 0.20 | -0.5 |
| NYU Medical Center Univ Hosp | 21 | 81.0 | 69.2 | 11.8 | 0.22 | 0.78 | 9.2 |
| Univ of Illinois | 20 | 40.0 | 61.1 | -21.1 | 0.04 | 0.96 | -20.3 |
| Jewish Hosp | 18 | 66.7 | 66.9 | -0.2 | 0.98 | 0.02 | 0.0 |
| Children's Hosp of Wisconsin | 17 | 76.5 | 71.7 | 4.8 | 0.65 | 0.35 | 1.7 |
| Henry Ford Hosp | 16 | 68.8 | 71.3 | -2.5 | 0.81 | 0.19 | -0.5 |
| Med Univ of South Carolina | 16 | 81.3 | 73.7 | 7.6 | 0.48 | 0.52 | 4.0 |
| Texas Children's Hosp | 16 | 62.5 | 71.4 | -8.9 | 0.41 | 0.59 | -5.3 |
| Egleston Child. Hosp-Atlanta | 11 | 63.6 | 78.0 | -14.4 | 0.25 | 0.75 | -10.8 |
| LeBonheur Child.-Memphis | 11 | 72.7 | 70.3 | 2.4 | 0.86 | 0.14 | 0.3 |
| Vanderbilt Univ Med Ctr | 11 | 72.7 | 67.2 | 5.5 | 0.67 | 0.33 | 1.8 |
| The Children's Hosp-Denver | 10 | 80.0 | 74.5 | 5.5 | 0.68 | 0.32 | 1.8 |
| LSU-Willis Knighton Med Ctr | 9 | 77.8 | 76.5 | 1.3 | 0.93 | 0.07 | 0.1 |
| The Children's Hosp-Columbus | 8 | 75.0 | 71.9 | 3.1 | 0.84 | 0.16 | 0.5 |
| Columbia Presbytenan Med Ctr | 6 | 00.0 | 69.8 | -69.8 | 0.01 | 0.99 | -69.1 |
| Children's Hosp & Med Ctr-Seattle | 6 | 100.0 | 74.3 | 25.7 | 0.14 | 0.86 | 22.1 |
| Tampa Gen Hosp | 5 | 20.0 | 71.3 | -51.3 | 0.05 | 0.95 | -48.7 |
| Glennon Cardinal Mem Hosp | 5 | 80.0 | 69.8 | 10.2 | 1.00 | 0.00 | 0.0 |
| Hennco Doctors' Hosp | 5 | 20.0 | 77.0 | -57.0 | 0.02 | 0.98 | -55.9 |
| North Carolina Memorial Hosp | 4 | 75.0 | 64.8 | 10.2 | 1.00 | 0.00 | 0.0 |
| Howard Univ Hosp | 3 | 00.0 | 57.5 | -57.5 | 0.15 | 0.85 | -48.9 |
| Louisiana State Univ Hospital | 3 | 66.7 | 72.6 | -5.9 | 1.00 | 0.00 | 0.0 |
| St Luke's Hosp of Kansas City | 3 | 50.0 | 81.4 | -31.4 | 0.67 | 0.33 | -10.4 |
| Univ of Mississippi Med Ctr | 3 | 66.7 | 79.3 | -12.6 | 1.00 | 0.00 | 0.0 |
| Stanford Univ Med Ctr | 2 | 100.0 | 80.4 | 19.6 | 1.00 | 0.00 | 0.0 |
| Univ Hosp UCSD Med Ctr | 1 | 00.0 | 78.3 | -78.3 | 0.43 | 0.57 | -44.6 |
| Univ Hosp-Oklahoma City | 1 | 00.0 | 77.4 | -77.4 | 0.45 | 0.55 | -42.6 |
| Albert Einstein Med Ctr | 1 | 100.0 | 68.5 | 31.5 | 1.00 | 0.00 | 0.0 |
| *AVERAGES (unwgt.)* | *109* | *63.1* | *69.2* | *-6.1* | *0.39* | *0.60* | *-5.7* |
| *MEDIANS* | *45* | *66.8* | *69.1* | *-1.8* | *0.26* | *0.75* | *-0.1* |
| *TOTAL* | *9634* | | | | | | |
| *NO. CENTERS = 88* | | | | | | | |

| Hospital | No. of Transplants | Actual Pct. Surviv. | Expected Pct. Surviv. | Difference Act-Exp. | Diff. X 1-"p" |
|---|---|---|---|---|---|
| Univ of Pittsburgh-Presby Hosp | | | | | |
| Univ of Calif-Los Angeles | | | | | |
| Univ Nebraska, Univ Hosp | | | | | |
| Baylor Univ Med Ctr | | | | | |
| Univ of Chicago Med Ctr | | | | | |
| Children's Hosp of Pittsburgh | | | | | |
| Univ of Michigan Med Ctr | | | | | |
| Univ of Calif-San Francisco | | | | | |
| Mt Sinai Med Ctr | | | | | |
| Calif Pacific Med Ctr | | | | | |
| Univ of Wisconsin | Average for facil. from 221 to 1705 transplants (12 facil.): | | | | |
| Rochester Methodist Hosp | 489 | 69.7 | 66.5 | 3.2 | 3.1 |
| New England Deaconess | Median for facil. from 221 to 1705 transplants (12 facil.): | | | | |
| Rush-Presbytenan-St Luke's | 332 | 70.0 | 66.7 | 2.7 | 2.4 |
| Barnes Hosp/St Louis Child. Hosp | Total transplants this group: | | | | |
| Johns Hopkins Hosp | 5863 | | | | |
| Ochsner Transplant Ctr | | | | | |
| Univ of Virginia Med Ctr | | | | | |
| Indiana Univ Med Ctr | | | | | |
| Univ of Minnesota Hosp | | | | | |
| Emory Univ | | | | | |
| New England Med Ctr | | | | | |
| Univ of Colorado Hosp | | | | | |
| Hosp of the Univ of Penn | | | | | |
| Duke Univ Med Ctr | | | | | |
| Children's Med Ctr of Dallas | | | | | |
| Cedars-Sinai Med Ctr | | | | | |
| Cleveland Clinic Found | | | | | |
| Massachusetts Gen Hosp | Average for facil. from 84 to 188 transplants (18 facil.): | | | | |
| Med Coll of Virginia | 117 | 65.1 | 68.2 | -3.1 | -2.9 |
| Thomas Jefferson Univ Hosp | Median for facil. from 84 to 188 transplants (18 facil.): | | | | |
| Ohio State Univ Hosp | 112 | 64.2 | 68.3 | -3.9 | -2.7 |
| Univ of Washington Med Ctr | Total transplants this group: | | | | |
| Froedtert Mem Lutheran Hosp | 2112 | | | | |
| Univ of Miami-Jackson Mem | | | | | |
| LDS Hosp-Salt Lake City | | | | | |
| Children's Hosp-Cincinnati | | | | | |
| Univ of Alabama-Birmingham | | | | | |
| St Christopher's Hosp | | | | | |
| VA Medical Center-Pittsburgh | | | | | |
| Univ of Tenn, Wm F Bowld Hosp | | | | | |
| Methodist Hosp of Indiana | | | | | |
| Children's Hosp of Philadelphia | | | | | |
| Univ Hosp-Newark | | | | | |
| Good Samaritan Reg Med Ctr | Average for facil. from 41 to 82 transplants (18 facil.): | | | | |
| St Louis Univ Med Ctr | 59 | 64.3 | 68.0 | -3.7 | -3.8 |
| Univ Hosps of Cleveland | Median for facil. from 41 to 82 transplants (18 facil.): | | | | |
| Oregon Hlth Sci Univ/PVAMC | 57 | 66.4 | 68.5 | -3.6 | -2.7 |
| The Methodist Hospital-Houston | Total transplants this group: | | | | |
| Children's Hosp-Boston | 1056 | | | | |

| Hospital | No. of Transplants | Actual Pct. Surviv. | Expected Pct. Surviv. | Difference Act-Exp. | Diff. X 1-"p" |
|---|---|---|---|---|---|
| Univ of Kansas Hosp Med Ctr | | | | | |
| Hartford Hosp | | | | | |
| Univ of Iowa Hosp | | | | | |
| Univ of Cincinnati Coll of Med | | | | | |
| Shands Hosp-Univ of Florida | | | | | |
| Univ of Texas-Hermann Hosp | | | | | |
| Green Hosp of Scripps Clinic | | | | | |
| Yale Univ Sch of Med | | | | | |
| Wilford Hall USAF Med Ctr | | | | | |
| St Louis Children's Hosp | | | | | |
| VA Hospital-Portland OR | | | | | |
| NYU Medical Center Univ Hosp | | | | | |
| Univ of Illinois | | | | | |
| Jewish Hosp | | | | | |
| Children's Hosp of Wisconsin | | | | | |
| Henry Ford Hosp | | | | | |
| Med Univ of South Carolina | Average for facil. from 16 to 40 transplants (20 facil.): | | | | |
| Texas Children's Hosp | 25 | 63.3 | 69.0 | -5.8 | -5.6 |
| Egleston Child. Hosp-Atlanta | Median for facil. from 16 to 40 transplants (20 facil.): | | | | |
| LeBonheur Child.-Memphis | 24 | 65.4 | 69.2 | -2.4 | -0.5 |
| Vanderbilt Univ Med Ctr | Total transplants this group: | | | | |
| The Children's Hosp-Denver | 495 | | | | |
| LSU-Willis Knighton Med Ctr | | | | | |
| The Children's Hosp-Columbus | | | | | |
| Columbia Presbyterian Med Ctr | | | | | |
| Children's Hosp & Med Ctr-Seattle | | | | | |
| Tampa Gen Hosp | | | | | |
| Glennon Cardinal Mem Hosp | | | | | |
| Henrico Doctors' Hosp | | | | | |
| North Carolina Memorial Hosp | | | | | |
| Howard Univ Hosp | | | | | |
| Louisiana State Univ Hospital | | | | | |
| St Luke's Hosp of Kansas City | | | | | |
| Univ of Mississippi Med Ctr | Average for facil. from 1 to 11 transplants (20 facil.): | | | | |
| Stanford Univ Med Ctr | 5 | 56.0 | 73.0 | -17.0 | -15.2 |
| Univ Hosp UCSD Med Ctr | Median for facil. from 1 to 11 transplants (20 facil.): | | | | |
| Univ Hosp-Oklahoma City | 5 | 69.7 | 73.5 | -2.3 | 0.0 |
| Albert Einstein Med Ctr | Total transplants this group: | | | | |
| *AVERAGES (unwgt.)* | 108 | | | | |
| *MEDIANS* | Grand total transplants: | | | | |
| *TOTAL* | 9634 | | | | |
| *NO. CENTERS = 88* | | | | | |

Notes:

1. Data on number of transplants and statistics on survival and "p" values taken from Summary of 1994 Report of Center Specific Graft and Patient Survival Rates. Edwards, E.B., UNOS. 1995
2. Data table and average and median statistics prepared by VDH, Division of Certificate of Public Need
3. The column labeled "Diff. x 1-p" provides a *probability-weighted* measure of the difference between actual and expected survival of grafts performed at the facility.

**TABLE 4**

**UNOS Center-Specific Results**

**One-Year Graft Survival**

**Liver Transplants 10/1/87-12/31/91**

00710

(facilities arrayed by probability-weighted difference between actual and expected survival)

| Hospital | No. of Transplants | *Actual* Pct. Surviv. | *Expected* Pct. Surviv. | Difference Act. - Exp. | "p" Value | 1-"p" | Diff. X 1-"p" |
|---|---|---|---|---|---|---|---|
| Children's Hosp & Med Ctr-Seattle | 6 | 100.0 | 74.3 | 25.7 | 0.14 | 0.86 | 22.1 |
| Calif Pacific Med Ctr | 286 | 80.4 | 68.2 | 12.2 | 0.00 | 1.00 | 12.2 |
| St Christopher's Hosp | 59 | 74.6 | 63.2 | 11.4 | 0.05 | 0.95 | 10.8 |
| Univ of Calif-San Francisco | 318 | 80.2 | 69.4 | 10.8 | 0.00 | 1.00 | 10.8 |
| Cedars-Sinai Med Ctr | 97 | 76.3 | 65.6 | 10.7 | 0.02 | 0.98 | 10.5 |
| NYU Medical Center Univ Hosp | 21 | 81.0 | 69.2 | 11.8 | 0.22 | 0.78 | 9.2 |
| VA Medical Center-Pittsburgh | 54 | 77.8 | 67.9 | 9.9 | 0.11 | 0.89 | 8.8 |
| Rochester Methodist Hosp | 221 | 78.7 | 70.0 | 8.7 | 0.00 | 1.00 | 8.7 |
| Children's Hosp-Boston | 35 | 71.4 | 62.8 | 8.6 | 0.25 | 0.75 | 6.5 |
| Univ Nebraska, Univ Hosp | 532 | 71.6 | 65.4 | 6.2 | 0.00 | 1.00 | 6.2 |
| Univ of Wisconsin | 275 | 70.9 | 65.6 | 5.3 | 0.05 | 0.95 | 5.0 |
| Univ of Alabama-Birmingham | 59 | 79.7 | 73.5 | 6.2 | 0.27 | 0.73 | 4.5 |
| Univ of Colorado Hosp | 106 | 78.3 | 73.2 | 5.1 | 0.21 | 0.79 | 4.0 |
| Med Univ of South Carolina | 16 | 81.3 | 73.7 | 7.6 | 0.48 | 0.52 | 4.0 |
| Univ of Cincinnati Coll of Med | 29 | 75.9 | 70.2 | 5.7 | 0.49 | 0.51 | 2.9 |
| Univ Hosps of Cleveland | 43 | 74.4 | 69.4 | 5.0 | 0.46 | 0.54 | 2.7 |
| Univ of Minnesota Hosp | 117 | 75.9 | 72.1 | 3.8 | 0.34 | 0.66 | 2.5 |
| Baylor Univ Med Ctr | 494 | 72.0 | 69.2 | 2.8 | 0.14 | 0.86 | 2.4 |
| Univ of Pittsburgh-Presby Hosp | 1705 | 66.8 | 64.4 | 2.4 | 0.01 | 0.99 | 2.4 |
| Children's Hosp of Pittsburgh | 345 | 67.5 | 65.0 | 2.5 | 0.25 | 0.75 | 1.9 |
| Vanderbilt Univ Med Ctr | 11 | 72.7 | 67.2 | 5.5 | 0.67 | 0.33 | 1.8 |
| The Children's Hosp-Denver | 10 | 80.0 | 74.5 | 5.5 | 0.65 | 0.32 | 1.8 |
| Children's Hosp of Wisconsin | 17 | 76.5 | 71.7 | 4.8 | 0.65 | 0.35 | 1.7 |
| Children's Med Ctr of Dallas | 98 | 68.8 | 66.2 | 2.6 | 0.57 | 0.43 | 1.1 |
| Children's Hosp-Cincinnati | 66 | 68.2 | 65.7 | 2.5 | 0.65 | 0.35 | 0.9 |
| The Children's Hosp-Columbus | 8 | 75.0 | 71.9 | 3.1 | 0.84 | 0.16 | 0.5 |
| Mt Sinai Med Ctr | 313 | 69.0 | 67.8 | 1.2 | 0.62 | 0.38 | 0.5 |
| Oregon Hlth Sci Univ/PVAMC | 41 | 70.7 | 69.0 | 1.7 | 0.80 | 0.20 | 0.3 |
| LeBonheur Childrens-Memphis | 11 | 72.7 | 70.3 | 2.4 | 0.86 | 0.14 | 0.3 |
| New England Med Ctr | 111 | 67.6 | 66.4 | 1.2 | 0.79 | 0.21 | 0.3 |
| Univ of Kansas Hosp Med Ctr | 32 | 77.4 | 76.1 | 1.3 | 0.86 | 0.14 | 0.2 |
| Univ of Washington Med Ctr | 78 | 73.1 | 72.3 | 0.8 | 0.87 | 0.13 | 0.1 |
| LSU-Willis Knighton Med Ctr | 9 | 77.8 | 76.5 | 1.3 | 0.93 | 0.07 | 0.1 |
| Ohio State Univ Hosp | 79 | 70.9 | 70.3 | 0.6 | 0.90 | 0.10 | 0.1 |
| ***Median—Actual > Exp. Surv.*** | ***63*** | ***74.8*** | ***69.3*** | ***5.1*** | ***0.40*** | ***0.60*** | ***2.5*** |
| ***No. facilities act. > than exp. surv.*** | ***34*** | | | | | | |
| ***No. these facil. <= 25 transplants*** | ***9*** | | | | | | |
| Univ of Calif-Los Angeles | 679 | 62.7 | 62.8 | -0.1 | 0.98 | 0.02 | 0.0 |
| Univ of Virginia Med Ctr | 122 | 67.2 | 67.7 | -0.5 | 0.91 | 0.09 | 0.0 |
| Univ of Iowa Hosp | 30 | 73.3 | 73.0 | 0.3 | 0.96 | 0.04 | 0.0 |
| Jewish Hosp | 18 | 66.7 | 66.9 | -0.2 | 0.98 | 0.02 | 0.0 |
| Glennon Cardinal Memorial Hosp | 5 | 80.0 | 69.8 | 10.2 | 1.00 | 0.00 | 0.0 |
| North Carolina Memorial Hosp | 4 | 75.0 | 64.8 | 10.2 | 1.00 | 0.00 | 0.0 |
| Louisiana State Univ Hospital | 3 | 66.7 | 72.6 | -5.9 | 1.00 | 0.00 | 0.0 |
| Univ of Mississippi Med Ctr | 3 | 66.7 | 79.3 | -12.6 | 1.00 | 0.00 | 0.0 |
| Stanford Univ Med Ctr | 2 | 100.0 | 80.4 | 19.6 | 1.00 | 0.00 | 0.0 |
| Albert Einstein Med Ctr | 1 | 100.0 | 68.5 | 31.5 | 1.00 | 0.00 | 0.0 |
| ***Median—No Prob.-Wgt. Diff. in Surv.*** | ***5*** | ***70.3*** | ***69.2*** | ***0.1*** | ***1.00*** | ***0.00*** | ***0.0*** |
| ***No. facilities with no prob.-wgt. diff.*** | ***10*** | | | | | | |
| ***No. these facil. <= 25 transpl.*** | ***7*** | | | | | | |

**TABLE 4**
**UNOS Center-Specific Results**
**One-Year Graft Survival**
**Liver Transplants 10/1/87-12/31/91**
(facilities arrayed by probability-weighted difference between actual and expected survival)

| Hospital | No. of Transplants | *Actual* Pct. Surviv. | *Expected* Pct. Surviv. | Difference Act. - Exp. | "p" Value | 1-"p" | Diff. X 1-"p" |
|---|---|---|---|---|---|---|---|
| Methodist Hosp of Indiana | 51 | 66.7 | 67.4 | -0.7 | 0.91 | 0.09 | -0.1 |
| Shands Hosp-Univ of Florida | 28 | 71.4 | 73.2 | -1.8 | 0.83 | 0.17 | -0.3 |
| VA Hospital-Portland OR | 23 | 60.9 | 63.2 | -2.3 | 0.80 | 0.20 | -0.5 |
| Henry Ford Hosp | 16 | 68.8 | 71.3 | -2.5 | 0.81 | 0.19 | -0.5 |
| Massachusetts Gen Hosp | 89 | 67.4 | 69.3 | -1.9 | 0.69 | 0.31 | -0.6 |
| Cleveland Clinic Foundation | 93 | 71.0 | 72.9 | -1.9 | 0.67 | 0.33 | -0.6 |
| Univ of Michigan Med Ctr | 319 | 66.5 | 68.2 | -1.7 | 0.49 | 0.51 | -0.9 |
| New England Deaconess | 188 | 62.8 | 66.3 | -3.5 | 0.28 | 0.72 | -2.5 |
| Emory Univ | 113 | 64.8 | 69.0 | -4.2 | 0.32 | 0.68 | -2.9 |
| Johns Hopkins Hosp | 135 | 60.7 | 65.5 | -4.8 | 0.22 | 0.78 | -3.7 |
| Texas Children's Hosp | 16 | 62.5 | 71.4 | -8.9 | 0.41 | 0.59 | -5.3 |
| Thomas Jefferson Univ Hosp | 82 | 59.8 | 66.3 | -6.5 | 0.18 | 0.82 | -5.3 |
| Green Hosp of Scripps Clinic | 25 | 64.0 | 72.7 | -8.7 | 0.31 | 0.69 | -6.0 |
| Indiana Univ Med Ctr | 121 | 61.2 | 68.3 | -7.1 | 0.08 | 0.92 | -6.5 |
| Froedtert Mem Lutheran Hosp | 72 | 56.9 | 64.7 | -7.8 | 0.14 | 0.86 | -6.7 |
| Hartford Hosp | 30 | 60.0 | 69.2 | -9.2 | 0.26 | 0.74 | -6.8 |
| Rush-Presbyterian-St Luke's | 158 | 51.9 | 59.1 | -7.2 | 0.05 | 0.95 | -6.8 |
| Barnes Hosp/St Louis Children's Hosp | 144 | 59.0 | 66.2 | -7.2 | 0.05 | 0.95 | -6.8 |
| Med Coll of Virginia | 84 | 63.1 | 70.9 | -7.8 | 0.11 | 0.89 | -6.9 |
| Ochsner Transplant Ctr | 132 | 63.6 | 71.1 | -7.5 | 0.05 | 0.95 | -7.1 |
| LDS Hosp-Salt Lake City | 67 | 62.7 | 70.8 | -8.1 | 0.12 | 0.88 | -7.1 |
| Univ Hosp-Newark | 46 | 60.0 | 69.0 | -9.0 | 0.18 | 0.82 | -7.4 |
| Univ of Tenn, Wm F Bowld Hosp | 53 | 66.0 | 74.6 | -8.6 | 0.14 | 0.86 | -7.4 |
| Hosp of the Univ of Penn | 103 | 57.8 | 68.3 | -10.5 | 0.02 | 0.98 | -10.3 |
| St Luke's Hosp of Kansas City | 3 | 50.0 | 81.4 | -31.4 | 0.67 | 0.33 | -10.4 |
| Egleston Children's Hosp-Atlanta | 11 | 63.6 | 78.0 | -14.4 | 0.25 | 0.75 | -10.8 |
| St Louis Univ Med Ctr | 43 | 51.2 | 63.4 | -12.2 | 0.08 | 0.92 | -11.2 |
| Univ of Chicago Med Ctr | 376 | 50.3 | 62.1 | -11.8 | 0.00 | 1.00 | -11.8 |
| St Louis Children's Hosp | 23 | 52.2 | 65.8 | -13.6 | 0.13 | 0.87 | -11.8 |
| Univ of Texas-Hermann Hosp | 28 | 53.6 | 67.8 | -14.2 | 0.09 | 0.91 | -12.9 |
| Children's Hosp of Philadelphia | 49 | 42.9 | 58.9 | -16.0 | 0.01 | 0.99 | -15.8 |
| Univ of Miami-Jackson Memor | 70 | 47.1 | 63.0 | -15.9 | 0.00 | 1.00 | -15.9 |
| Duke Univ Med Ctr | 101 | 53.5 | 69.4 | -15.9 | 0.00 | 1.00 | -15.9 |
| Good Samaritan Reg Med Ctr | 44 | 54.5 | 74.6 | -20.1 | 0.00 | 1.00 | -20.1 |
| Univ of Illinois | 20 | 40.0 | 61.1 | -21.1 | 0.04 | 0.96 | -20.3 |
| Wilford Hall USAF Med Ctr | 24 | 45.8 | 66.6 | -20.8 | 0.02 | 0.98 | -20.4 |
| The Methodist Hospital-Houston | 40 | 45.0 | 67.5 | -22.5 | 0.00 | 1.00 | -22.5 |
| Yale Univ Sch of Med | 24 | 37.5 | 66.9 | -29.4 | 0.00 | 1.00 | -29.4 |
| Univ Hosp-Oklahoma City | 1 | 00.0 | 77.4 | -77.4 | 0.45 | 0.55 | -42.6 |
| Univ Hosp UCSD Med Ctr | 1 | 00.0 | 78.3 | -78.3 | 0.43 | 0.57 | -44.6 |
| Tampa Gen Hosp | 5 | 20.0 | 71.3 | -51.3 | 0.05 | 0.95 | -48.7 |
| Howard Univ Hosp | 3 | 00.0 | 57.5 | -57.5 | 0.15 | 0.85 | -48.9 |
| Hennco Doctors' Hosp | 5 | 20.0 | 77.0 | -57.0 | 0.02 | 0.98 | -55.9 |
| Columbia Presbyterian Med Ctr | 6 | 00.0 | 69.8 | -69.8 | 0.01 | 0.99 | -69.1 |
| ***Median–Actual < Than Exp. Surv.*** | ***45*** | ***58.4*** | ***68.7*** | ***-9.1*** | ***0.14*** | ***0.87*** | ***-7.4*** |
| ***No. facilities act. < than exp. surv.*** | ***44*** | | | | | | |
| ***No. these facil. <= 25 transplants*** | ***17*** | | | | | | |

Note: Please see notes at end of accompanying Table 3.

**SENTARA NORFOLK GENERAL HOSPITAL**

**COPN FOR LIVER TRANSPLANT**

***INFORMAL FACT-FINDING CONFERENCE***

***MAY 20, 1997***

## EXHIBIT LIST

00733

# Sentara Norfolk General Hospital
# Liver Transplant Program
# Statement of Consistency With Twenty Required Considerations

**A. The recommendation and reasons therefor of the appropriate regional health planning agency.**

The Board of Directors of the Eastern Virginia Health Systems Agency ("EVHSA") recommended approval of the project because it will improve the availability and geographic accessibility to liver transplant services for residents of P.D.20 and the addition of a liver transplant program would round out the complement of transplant services that are presently provided at Sentara Norfolk General Hospital.

**B. The relationship of the project to the applicable health plans of the regional health planning agency, the Virginia Health Planning Board, and the State Board of Health.**

The only plan applicable to this project is the State Medical Facilities Plan ("SMFP") for organ transplantation services. This project complies fully with all applicable provisions of the SMFP.

**2.1 Acceptability**

**Consumer participation - Providers of organ transplantation services should provide a program of patient and family education regarding the nature of the patient's organ disease and the treatment of the patient and family in the management of the organ pre- and post-transplantation.**

As an existing provider of organ transplant services, Sentara has already developed a program of patient and family education. Existing programs will be modified as needed to assure that patients and families are fully informed of the disease and treatment process. The application complies with this SMFP standard.

**2.2 Accessibility**

**A. Organ transplantation services, of any type, should be accessible within two hours driving time, under normal conditions, of 95% of Virginia's population.**

There is a substantial patient population that currently resides more than two hours from a liver transplant provider. When typical travel conditions such as tunnel congestion and traffic is factored in, the commute time for many residents

of the Tidewater region to a liver transplant provider is much greater than two hours. In addition, there are a significant number of patient from northeastern North Carolina and the Eastern Shore who would be served by the Sentara program. In short, the introduction of liver transplant services at Sentara would significantly improve access to a substantial number of Virginians, in compliance with this provision of the SMFP.

**B. Patient Access to Available Organs**

**Providers or organ transplantation services should demonstrate to the satisfaction of the Department that they have clearly defined patient/organ recipient policies based solely on medical criteria.**

As a participant in the donor network, Sentara already has such programs and policies in place for other organ systems. The GI Advisory Team of SNGH's Transplant Council is revising the policies to accommodate liver transplantation. Based on the information submitted with the application, the state staff has concluded that Sentara meets this standard.

**2.3 Availability**

**A. Regionalization of Services**

**There should be no more than one transplantation program for each organ system in health planning region.**

Currently, there are no providers of liver transplant services in HSA V. Upon initiation of this project, SNGH will operate the region's only liver transplant service. Currently SNGH provides the region's only heart, heart lung, kidney and lung transplant services. This project complies fully with this criteria.

**B. Conditional Approval**

**Approval of organ transplantation programs shall be conditioned upon a facility's meeting both minimum volume and survival standards. Failure to meet these standards within two years of initiation of the service may be cause for revocation of the certificate of public need.**

SNGH has a twenty-five year history of providing low-cost, high-quality transplant services. Based on its experience with its Transplant Center, SNGH fully expects to meet or exceed the minimum volume and survival standards set out in the SMFP.

**C. HCFA/Medicare Requirements**

**1. Proposals to establish new transplantation services should demonstrate compliance with all Medicare program coverage criteria within two years of the initiation of the program.**

SNGH, as an existing provider of transplant programs that are certified by HCFA, expects to meet certification criteria.

**2. Proposals to expand existing transplantation programs should demonstrate that existing organ transplantation services comply with all applicable federal Health Care Financing Administration criteria for Medicare program coverage.**

SNGH's heart and kidney transplant programs comply with all applicable criteria for Medicare program coverage. The lung transplant program has not yet achieved compliance because volumes are constrained due to limited organ availability.

## 2.4 Continuity of Care

**Discharge planning and follow-up care**

**A. Providers of organ transplantation services should have written procedures and policies for discharge planning and follow-up care for the patient and family which are part of the institution's overall discharge planning program.**

As an existing provider of organ transplant services, SNGH already has such policies and procedures in place. See Attachment IV.E.2.4.A to the COPN Application.

**B. Providers of organ transplantation services should have established protocols for referring physicians and the organ transplantation service to assure adequate post-operative diagnostic evaluation for transplant patients.**

As an existing provider of organ transplant service, SNGH already has such policies and procedures in place. Examples are included in the COPN Application at Attachment IV.E.2.4.B.

## 2.5 Cost

**Cost and charges - The total cost (direct and indirect) for providing all organ transplantation services should be comparable to other similar service providers in the health planning region and the state.**

Sentara facilities have a long tradition of providing high quality care on a low-cost basis. Statewide, Sentara system facilities have among the lowest charges. Since there are no other facilities within SNGH's planning district or region that offer organ transplant services, a comparison of costs and charges on this basis cannot be made.

When compared to other tertiary care providers that support teaching programs, SNGH's costs and charges are typically low. As the state staff analysis points out, overall, SNGH's costs are 77% of the average when compared to the other major tertiary hospitals in the Commonwealth (Fairfax, UVA, MCV and Roanoke Memorial). This is true even though SNGH's case mix index is on average 118 % of the group average. Similarly, as the state staff observed, SNGH's net revenue per admission was 86% of that collected by the group, on average. As the state staff concluded "SNGH is serving a slightly more demanding case mix of patients, but using less resources and receiving less revenue to do so, than the four other major tertiary hospitals, on the average." *State Staff Report at 12.*

## 2.6 Quality

### A. Minimum utilization

**1. Proposals to establish, expand, or replace organ transplantation services should demonstrate that a minimum number of transplants will be performed annually. The minimum number required by organ system is:**

**Liver 12**

Following a period of program start-up, SNGH projects that it will perform in excess of the minimum number of transplants required annually by the SMFP. Area hysicians that now refer liver transplant patients to other facilities outside of the health planning region estimate that approximately 25-30 such patients were referred out of the area last year. These physicians have expressed their commitment to the Sentara program and expect to refer their patients to the local program when it becomes available. Based on input from the physicians, SNGH conservatively projects six procedures in year one, twelve procedures in year two and fifteen procedures in year three.

Recent statistics from UNOS support SNGH's volume projections. These statistics show that an adequate number of liver transplant patients originate from SNGH's primary service area to support the volumes required under the SMFP. In 1994, eighteen patients from SNGH's primary service area received liver transplants. In 1995, twenty-one such patent received transplants and in 1996, twenty-eight patients from the SNGH service area received a liver transplant. See Exhibit F. If only half of the area's liver transplant patients go to SNGH, the program will still exceed the SMFP standard for minimum utilization. As the state staff found, SNGH should be able to meets its utilization projections.

2. **Successful transplantation programs are expected to perform substantially larger numbers of transplants annually. Performance of minimum transplantation volumes does not necessarily indicate a need for additional transplantation capacity or programs.**

There are three providers of liver transplant services in the Commonwealth: MCV, UVA and Fairfax Hospital. In 1996, all three providers had volumes well in excess of the SMFP minimum standard:

| Facility | Volume | % Over SMFP Standard |
|---|---|---|
| MCV | 66 | 550% |
| UVA | 37 | 308% |
| Fairfax | 53 | 441% |

As the state staff found, SNGH could easily meet its volume projections and "still leave the MCVH and UVAH programs with volume several times as great as the SMFP ( and Medicare) minimum annual volume standard of 12." *State Staff Report a p.44.*

3. **Preference will be given to expansion of successful existing services, either by enabling necessary increases in the number of organ systems being transplanted or by adding transplantation capability for additional organ systems, rather than developing other programs that could reduce average program volume.**

In perfect harmony with this provision, SNGH seeks to expand upon its existing successful transplant program to add the capability to perform liver transplant services. Sentara's transplant center has been in existence for twenty-five years. The Center currently performs kidney, lung, heart-lung and heart transplants. The survival rates of the Sentara transplant programs exceed SMFP standards and are among the best in the Commonwealth. Sentara proposes to build upon its successful organ transplantation program to make liver transplants, the second most commonly transplanted organ in the Commonwealth, more accessible to the Tidewater region's population. As indicated above, this expansion could be implemented to improve access to liver transplant services while maintaining the volume of existing providers of liver transplant services at levels well above the SMFP standard. Under this provision, the SNGH project is entitled to a preference.

**B. Minimum survival rates**

**1. Facilities should demonstrate that they will achieve and maintain minimum transplant survival rates. Minimum one-ear survival rates, listed by organ system, are**

| | |
|---|---|
| **Kidney** | **90-95%** |
| **Heart** | **70-80%** |
| **Heart/Lung** | **None set** |
| **Liver** | **50-60%** |
| **Pancreas** | **80-90%** |

All of the organ transplant programs operated by Sentara meet or exceed the one year survival rates set out in the SMFP:

| Organ | Number | Period | SNGH % | SMFP std. |
|---|---|---|---|---|
| Kidney | 291 | 1990-95 | 94% | 90-95% |
| Heart | 44 | 1992-95 | 95.4% | 70-80% |
| Lung | 15 | 1992-95 | 66% | none set |

As the state staff found, "SNGH's existing transplant programs more than meet the minimum one-year patient survival rates stated in the SMFP. . . . This experience offers reason to believe that SNGH would likely achieve *at least* the SMFP's minimum one-year liver transplant patient survival rate . . . if a liver transplant program is established at SNGH." *State Staff Report at p. 46-47.*

**2. Survival rates beyond one year should be consistent with the Health Care Financing Administration (HCFA) Medicare program requirements, or with applicable professional-society-recommended standards acceptable to the department where there are no HCFA criteria.**

The HCFA standard for liver transplant programs for two-year patient survival is 60%. Based on SNGH's compliance with all other applicable HCFA standards, SNGH expects to meet or exceed this standard:

| Organ | HCFA std. | SNGH % |
|---|---|---|
| Kidney | none set | 90% |
| Heart | 65% | 94.5% |
| Lung | 62% | 66% |

According to the state staff, SNGH's application is consistent with this standard.

**C. Service proficiency**

**Proposals to add additional organ transplantation services should demonstrate at least two years successful experience with all existing organ transplantation systems.**

SNGH has at least two years of successful experience with each of the organs systems currently transplanted at the hospital. As the statistics above indicate, SNGH meets or exceeds all applicable survival standards and with the exception of lung transplants, which are in very short supply, meets or exceeds all applicable volume standards. As the state staff recognizes, SNGH substantially complies with this standard.

**D. Staffing**

1. **All physicians that perform transplants should be board certified by the appropriate professional examining board, and should have a minimum of one year of formal training and two years experience in transplant surgery and post-operative care.**

Upon receipt of a COPN, the medical group serving the SNGH transplant program will recruit and hire a transplant surgeon that possess at least these qualifications. Dr. Colonna, who has talked with the group about developing a liver transplant program at SNGH meets these standards. See Exhibit T. As the state staff observes, SNGH complies or should be able to comply with this standard.

2. **Organ transplantation services should have a complete team of surgical, medical and other specialists, with at least two years experience in the proposed organ transplantation system.**

SNGH has surgical medical and other specialty physicians on staff with liver experience. Refresher training will be made available to update staff on recent advances in liver transplantation. SNGH will assure that all staff have the requisite experience to perform effectively. As the state staff observes, SNGH should be able to comply with this standard.

E. **Systems Operations**

1. **Providers of organ transplantation services should document that they participate in a regional and national organ donor network. The facility should have written policies and procedures governing organ and tissue procurement.**

SNGH's policies and procedures are included in the COPN application. As the state staff observes, SNGH complies fully with this criteria.

2. **Providers of organ transplantation services should have an ongoing approved medical education program.**

As a provider of transplant services, SNGH already has in place an approved medical education program. All physicians associated with SNGH's transplant programs participate in continuing medical education programs. As the state staff recognizes, SNGH's application meets this criteria.

3. **Providers of organ transplantation services should collect and submit to the Department transplantation program operating statistics, including patient and procedure volumes, mortality data, and program costs and charges.**

SNGH will collect and submit such data. As the state staff recognizes, the application meets this standard.

F. **Support Services**

**Providers of organ transplantation services should demonstrate that they have direct and immediate access to a histocompatibility testing laboratory that meets the American Society for Histocompatibility and Immunogenetics (ASHI) standards.**

SNGH operates a laboratory which is accredited by ASHI, meeting this standard.

C. **The relationship of the project to the long-range development plan, if any, of the person applying for a certificate.**

The introduction of liver transplant services at SNGH will round out the solid organ transplantation services currently available at SNGH, allowing residents of the service area to have their transplant needs met locally. Because a successful and cost effective transplant program is already in place at SNGH, liver transplantation services can be added with only minor increases in cost.

**D. The need that the population served or to be served by the project has for the project.**

Currently, there is no provider of liver transplant services in HSA V. If SNGH obtains approval of its COPN, it will be the only provider of liver transplant services in its region.

The region served by SNGH is the largest and fastest growing in the Commonwealth. It is the only area of its size in the State where a substantial number of residents do not have access to liver transplant services within a two hour drive time. The state staff estimates that approximately 400,000 people in SNGH's service area, 6% of the population of the Commonwealth, that are more than two hours from a liver transplant provider. *State Staff Report at 8.* The staff estimates that there are another 100,000 North Carolinians whose access to liver transplant services will improve substantially if this project is approved. *State Staff Report at 8.* Under the SMFP formula for availability, these numbers alone, demonstrate a statistical need for the project.

Currently, residents of the SNGH service area who need liver transplant services have to travel to providers outside the region for these services. Some go to UVA or Fairfax. Many go to MCV. The burden of traveling is exacerbated by the nature of liver disease and the long period of waiting for an organ. Patients awaiting transplant have to travel outside the region numerous times to be evaluated, travel repeatedly for periodic monitoring while they await the availability of an organ, travel for the procedure itself, and for follow-up post-operatively. Most patients have to rely on family members to take them, which means family members have to take time off of work, or even quit their jobs. The process is burdensome, expensive and time consuming. Much of this inconvenience, anxiety and expense can be eliminated if liver transplant services are made available locally.

Referring patients to other regions for care also presents problems with continuity and follow-up. Frequently, physicians who have referred patients to MCV do not get test results and are not kept informed of the status of the patient. In addition, many diagnostic tests that were performed prior to referral for transplant services have to be repeated at additional cost to patients and payors. Bringing liver transplant services to the area would eliminate all of these problems, as the referring physician would remain involved in the care of the patient, and diagnostic tests performed previously would be used for purposes of evaluation.

**E. The extent to which the project will be accessible to all residents of the area proposed to be served.**

The SNGH project will dramatically improve geographic access to liver transplant services for residents of the service area. As indicated above, currently there is no provider of liver transplant services in the region. Residents who need liver transplants must travel outside the region to obtain these services. A substantial number of

Tidewater resident reside more than two hours from providers of liver transplant services. In addition, there are a substantial number of North Carolinians whose geographic access to liver transplant services will improve if the SNGH project is approved.

From a financial perspective, the SNGH program will also improve financial access to services. Although existing providers of services provide liver transplants without regard to the ability to pay, SNGH affiliated physicians have been told that the next available slot for an indigent liver transplant case at MCV will be in 1999. If SNGH is able to offer these services, it will expand the base of providers from whom indigent patients can obtain services, providing enhanced access. SNGH has a long tradition of providing health services to patients in need whether or not they have the ability to pay. With respect to organ transplants in particular, Sentara has actively provided indigent services. Since the heart transplant program was initiated at SNGH, more than 200 patients have been evaluated for transplant and no indigent patient has been turned away because of an inability to pay. SNGH expects to continue this tradition with respect to liver transplant services.

**F. The area, population, topography, highway facilities and availability of the services to be provided by the project in the particular part of the health planning region in which the project is proposed.**

Currently, the population of the region is not served by an area liver transplant provider. Access to services is complicated by traffic, the congestion at tunnels in Hampton Roads, Norfolk and Newport News, and ongoing construction. If the project is approved, access to liver transplant services will be substantially improved for residents of the area. SNGH is conveniently located in downtown Norfolk and is accessible to all residents of its service area through a system of interstate highways and major roads. As the state staff found, "Relative to the distribution of population and considering the pattern of roadways and impediments to travel created by the waterways, this location provides a high level of geographic accessibility for the population of the health planning region." *State Staff Report at 57.*

**G. Less costly or more effective alternate methods of reasonably meeting identified health service needs.**

There are no less costly or more effective alternatives to meet the need of the area population for improved access to comprehensive chronic liver disease treatment including transplant services. Continuing to require area patients to seek services outside of the health planning region is costly, disruptive to continuity, and adversely impacts the efficiency and effectiveness of care. Setting up a local clinic may reduce some of the inconvenience and expense associated with repeated travel, but the continuity of care issues, patient confidence factors, and costly duplication of diagnostic services would not be eliminated. The Tidewater region has a population that is more

than adequately sized to support a quality liver transplant program. SNGH has the experience and ability to bring a quality program to the region without significant additional cost to the health care system. The total cost of the project, in terms of capital and incremental operating costs, is relatively low. There are no less costly or more effective alternatives to meet the need that has been identified.

**H. The immediate and long-term financial feasibility of the project.**

Based on SNGH's reasonable projection of transplant activity, the marginal cost of providing the liver transplant services will be offset by the additional income derived from the service. Even if there is a loss during the start-up period, SNGH is committed to assuring the viability of the project.

**I. The relationship of the project to the existing health care system *of the area* in which the project is proposed.**

As indicated previously, there are no providers of liver transplant services in the health planning region in which this project is proposed. The SMFP states in clear terms that tertiary services, such as liver transplant services, are to be planned and evaluated on a regional (i.e., HSA) basis. Since there are no other providers in the region, the project cannot, by definition, have any adverse impact on any other existing provider in the area. Rather, the only impact to be considered under this provision is the positive one that this project will have, introducing to a health planning region with a substantial population a service not presently available to its residents.

**J. The availability of resources for the project.**

Because the liver transplant service is an addition to an existing, otherwise comprehensive organ transplant program, very little additional resources will be required. SNGH already has in place the systems to operate the program and many staff members who are experienced in liver transplantation are already employed at the facility. SNGH anticipates no difficulty in obtaining the additional resources necessary to institute this service. As the state staff recognizes, SNGH should have no difficulty obtaining resources for this project.

**K. The organization relationship of the project to necessary ancillary and support services.**

As an existing provider of organ transplant services, the necessary ancillary and support services area already available at SNGH. As the state staff recognizes, SNGH meets this standard.

**L. The relationship of the project to the clinical needs of the health professional training programs *in the area* in which the project is proposed.**

Except for the Eastern Virginia Medical School ("EVMS") which uses SNGH as its primary training site, there are no health professional training *in the area* in which this project is proposed. The impact of this project on the EVMS program will be extremely positive, giving internists and GI trainees, the opportunity to observe and study liver transplantation as part of their medical training. There are no programs *in the area in which the project is proposed* that would be negatively impacted. Moreover, there is no credible risk that MCV's annual volumes will be reduced below appropriate levels as defined by the SMFP. In short, there is no evidence that a liver transplant program at SNGH will impact MCV in an inappropriate way.

The state staff discussed at length the potential negative impact upon MCV. SNGH respectfully observes that MCV is not *in the area in which the project is proposed.* Moreover, the true impact on MCV is speculative at best. As the state staff recognizes, even if SNGH is able to divert from MCV all of the cases it projects for its first few years of operation, MCV will still be doing many more cases than it has in any year from the initiation of the program until 1995. MCV is gaining a national reputation and increasingly is transplanting patients from outside the state (using Virginia organs) thus the MCV program is not likely to suffer substantial harm, even if that were an applicable consideration under this criterion.

**M. The special needs and circumstances of an applicant for a certificate, such as a medical school, hospital, multi-disciplinary clinic, specialty center or regional health service provider, if a substantial portion of the applicant's services or resources or both is provided to individuals not residing in the health planning region in which the project is to be located.**

SNGH, as a regional health service provider, provides health services to residents of the Tidewater region, the Eastern Shore and north-eastern North Carolina. To the extent liver transplant services will be made more accessible to resident of SNGH's health planning region, they will also be more accessible to residents of the other areas traditionally served by SNGH.

**N. The need and availability in *the health planning region* for osteopathic and allopathic services and facilities and the impact on existing and proposed institutional training programs for doctors of osteopathy and medicine at the student, internship and residency training levels.**

The availability of liver transplant services at SNGH will enhance medical training programs *in the health planning region* by giving students the opportunity to observe all stages of chronic liver disease treatment and management, equipping them to better

care for their patients in the future. Although MCV has claimed that the expansion of the organ transplant program at SNGH to include liver transplant will cause them to lose their accreditation to train liver transplant surgeons, the evidence is that numerous accredited programs continue to operate at levels below 50 transplants per year. See Exhibit V. There is no evidence that accredited organizations have had their accreditation revoked when volumes fall below 50 procedures. In fact, the accrediting standards were just changed to give facilities with lower volumes the flexibility to maintain their accreditation. Exhibit V. There is no reason to believe that even if the SNGH program caused MCV volumes to fall below 50 per year (and there is no evidence to support that it will) that MCV will lose its teaching accreditation. Rather, all indications are that MCV's teaching program will not be harmed in any way.

**O. The special needs and circumstances of health maintenance organizations. When considering the special needs and circumstances of health maintenance organizations, the Commissioner may grant a certificate for a project if the Commissioner finds that the project is needed by the enrolled or reasonably anticipated new members of the health maintenance organization or the beds or services to be provided are not available from providers which are not health maintenance organizations or from other health maintenance organizations in a reasonable and cost effective manner.**

Sentara operates health maintenance organizations which will be benefited through the introduction of liver transplant services at SNGH. SNGH will be able to better control the cost of the service, and thus reduce health maintenance organization expenditures for transplant recipients. In addition, because the duplicate testing now required will be eliminated, diagnostic and monitoring costs will be saved. Further, SNGH believes that by improving the continuity of patient care, and fostering a system where all care givers, including primary care physicians remain integrally involved in and informed about the care of the patient through the transplant process, patient outcomes will be improved.

**P. The special needs and circumstances for biomedical and behavioral research projects which are designed to meet a national need for which local conditions offer special advantages.**

Currently SNGH physicians participate in many research projects designed to meet such needs. In fact, Dr. Ryan is participating in one such cooperative effort now through the Mid-Atlantic Liver Team (MALT) project. See Exhibit J. Physicians from other regional facilities, including UVA, Fairfax, MCV and Johns Hopkins also participate in the group. There are numerous similar opportunities for facilities and physicians to conduct research on a cooperative basis. Contrary to the claims of MCV that its ability to participate in research projects will somehow be hampered if the SNGH program is expanded to include liver transplant services, there is ample opportunity to conduct research on a cooperative basis.

**Q. The costs and benefits of the construction associated with the proposed project.**

There is no construction associated with the project. As an existing provider of organ transplant services, SNGH already has the physical facilities for the provision of liver transplant services. Indeed, that is one of the major advantage of the project. Because the facilities are already in place, the capital costs of the project are minimal.

**R. The probable impact of the project on the costs of and charges for providing health services by the applicant for a certificate and on the costs and charges to the public for providing health services by other persons in the area.**

As indicated previously, the capital cost and the incremental operating costs associated with this project are relatively low. Since much of the cost involved in providing transplant services is variable, existing providers that are affected by small reductions in volume should be able to modify their operations to reduce costs, resulting in very little economic impact to the public or to the health care system overall. The benefit to the patients in terms of improved access to care, improved continuity of care, and reduced duplication of tests more than outweighs the minimal cost impact to the health care system.

In terms of cost impact to patients from the SNGH service area, the impact will be positive. Patients will eliminate burdensome travel costs and the expensive duplication of diagnostic tests. SNGH's proposed charges are consistent with those of existing liver transplant providers and SNGH's goal is to strive to provide the highest quality services at the lowest cost to the consumer. As indicated above, SNGH has been particularly successful in this regard, providing services to sicker patients at costs well below those incurred by other similarly situated providers. See ¶ *B.2.5, supra* at p. 4.

**S. Improvements or innovations in the financing and delivery of health services which foster competition and serve to promote quality assurance and cost effectiveness.**

The improvements in continuity and the level of coordination for the treatment of chronic liver disease will constitute a dramatic improvement in the delivery of care to liver transplant recipients from SNGH's service area. Currently, continuity is disrupted, patient follow-up is sporadic, the flow of information from the transplant team to primary care physicians is unreliable, and the overall treatment process is disjointed. The service at SNGH will present the opportunity for close coordination of care, will improve continuity, and should ultimately affect patient outcomes in a positive way.

**T. In the case of health services or facilities proposed to be provided, the efficiency and appropriateness of the use of existing services and facilities *in the area* similar to those proposed.**

There are no similar facilities and services *in the area* of the proposed project. Indeed, it is because of the access problems and the disruption in continuity of patient care that SNGH seeks to expand its existing transplant program to offer liver transplant services.

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# SENTARA NORFOLK GENERAL HOSPITAL

00751

## COMPARISON OF ORGAN TRANSPLANT PROJECTS BY MAJOR REVIEW FACTORS

| | SNGH Project VA -5969 | RMH Project VA - 5470 |
|---|---|---|
| Capital Cost | $61,900 | $61,172 |
| Existing Transplant Provider | Yes | No |
| Existing Provider within HSA? | No | No |
| # Transplants from area previous year | 28 | 32 |
| Min. Volume per SMFP | 12 | 25 |
| Impact to existing providers likely to reduce below minimum standards? | No | No |
| Survival rates at lower volume programs generally consistent with larger volume programs | Yes | Yes |
| Existing provider within 2 hours for most of population? | Yes * | Yes |
| Travel time significantly shortened for a high proportion of population | Yes | Yes |

Source: COPN Applications and State Staff Reports for VA-5969 and VA-5490

* The staff's assessment is that most of the population is within two hours; however, there is a substantial number of area residents more than two hours away from an existing liver transplant provider.

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# SENTARA NORFOLK GENERAL HOSPITAL

## ORGAN TRANSPLANT ANALYSIS: PRIOR STANDARD OF REVIEW

**On impact to existing providers:**

- *"the establishment of this new center should be possible without critically reducing transplant volume at UVA, the facility which will be most affected by this project." (p.4).*

- *"While the impact on the UVA (University of Virginia Hospital) program (kidney transplant program) may be noticeable, it does not appear to be likely to reduce volume below minimum state requirements." (p. 3).*

- *"It appears likely that this new program can be initiated in Roanoke, achieve a level of appropriate utilization and efficient operation, and not reduce the level of transplantation procedures at any existing center to an inappropriate level." (p 9).*

**On projected utilization:**

- *"There is a sufficient number of patients with end-stage renal disease (ESRD) in Southwest Virginia to support a kidney transplant program in Roanoke at a minimum transplantation procedure volume considered appropriate." (p. 5).*

**On access:**

- *"most of Southwest Virginia's population can probably reach an existing transplantation center within two hours, but the availability of this service in Roanoke will provide a significant improvement in access for a high proportion of the area's population, a major benefit for the post-transplant patient." (p. 5).*

**On cost-effectiveness:**

- *"Because of the reduced travel time for transplant patients in the Southwest part of Virginia, this project will represent a more cost-effective transplantation alternative for many of these patients relative to existing transplantation centers in Charlottesville, Richmond, or other states." (p. 9).*

Source: State Staff Report for Roanoke Memorial Hospital Kidney Transplant COPN NO. VA-5470

00753

# COMMONWEALTH of VIRGINIA

ROBERT B STROUBE M.D. M.P.H.
STATE HEALTH COMMISSIONER

*Department of Health*

January 6, 1993

Mr. A. Dale Byington
Director of Planning
Carilion Health System
Post Office Box 13727
Roanoke, Virginia 24036-3727

Dear Mr. Byington:

RE: COPN No. VA-03086
Roanoke Memorial Hospitals
Roanoke, Virginia
Establish Kidney Transplant Services at Carilion Transplant Center

In accordance with Chapter 4, Article 1:1 of Title 32.1 of the Code of Virginia of 1950, as amended, I reviewed the application and all supporting documents submitted by Roanoke Memorial Hospitals (RMH) to establish a kidney transplant program, to be known as the Carilion Transplant Center.

I am approving RMH's application and enclose COPN No. VA-03086 for the period of January 6, 1993 through January 6, 1994 based upon the acknowledgement and acceptance by RMH of the condition set forth in the Department of Health's December 23, 1992 staff report. Specifically, as indicated in the enclosed January 4, 1993 letter from you, RMH agrees that its COPN authorization for kidney transplant services will be formally reconsidered for renewal or revocation after two years of program operation based on a review of the program's success in meeting both minimum transplant procedure volume levels and transplant patient survival rates.

I am issuing this certificate based on the following findings:

- The proposal is generally consistent with the State Medical Facilities Plan.
- RMH has presented reasonable evidence that it can initiate and maintain a high quality kidney transplantation service without unduly reducing procedure volume at existing transplantation centers.

- A substantial proportion of kidney transplantation patients in southwest Virginia will have significantly improved geographic access to this service through the development of a program in Roanoke.

- RMH has a good track record in the harvesting of kidneys for transplantation and the delivery of service to end-stage renal disease patients.

- The Southwest Virginia Health Systems Agency has recommended approval of the project.

As required by Section 32.1-102.3B of the Code of Virginia, I have considered all factors which must be taken into account in making a determination of public need and have concluded that the approval of the request is warranted. Further, because there is no known opposition to the proposal, there was no need for an informal fact-finding conference prior to my decision.

Not later than 30 days before the expiration date of the certificate, please file two copies of the enclosed application for a certificate extension with the Department and one copy with the regional health planning agency. Part VI of the Rules and Regulations governing the Virginia Certificate of Public Need Program identifies the filing requirements and review procedure for certificate extension requests.

Sincerely,

Robert B. Stroube, M.D., M.P.H.
State Health Commissioner

Enclosures

pc: Carol S. Nance, Assistant Attorney General
Paul E. Parker, Director
Division of Resources Development
Joseph L. Holliday, M.D., M.P.H., Director
Community Health Operations - West
Donald R. Stern, M.D., M.P.H., Director
Roanoke City Health District
Blue Cross/Blue Shield of Virginia
Department of Medical Assistance Services
Office of Health Facilities Regulation

# COMMONWEALTH OF VIRGINIA
# DEPARTMENT OF HEALTH
# MEDICAL CARE FACILITIES CERTIFICATE OF PUBLIC NEED

THIS CERTIFIES THAT ROANOKE MEMORIAL HOSPITALS (RMH)

is authorized to initiate the proposal as described below

NAME OF FACILITY CARILION TRANSPLANT CENTER

LOCATION JEFFERSON AND BELLEVIEW STREETS; ROANOKE, VIRGINIA 24014

OWNERSHIP AND CONTROL VIRGINIA NON-PROFIT CORPORATION

SCOPE OF PROJECT ESTABLISH A KIDNEY TRANSPLANT PROGRAM. THE AUTHORIZED CAPITAL COST IS $61,172. THIS CERTIFICATE HAS BEEN ISSUED ON THE BASIS THAT RMH AGREES TO HAVE THE AUTHORIZATION FOR KIDNEY TRANSPLANT SERVICES FORMALLY RECONSIDERED FOR RENEWAL OR REVOCATION AFTER TWO YEARS OF PROGRAM OPERATION BASED ON A REVIEW OF THE PROGRAM'S SUCCESS IN MEETING

(OVER)

286


Pursuant to Chapter 4, Article 1:1 of Title 32.1, Sections 32.1-102.1 through 32.1-102.11, Code of Virginia (1950), as amended and the policies and procedures promulgated thereunder, this Medical Care Facilities Certificate of Public Need is issued contingent upon substantial and continuing progress towards implementation of the proposal within twelve (12) months from the date of issuance. A progress report shall be submitted to the State Health Commissioner within twelve (12) months from the date of issuance along with adequate assurance of completion within a reasonable time period. The Commissioner reserves the right not to renew this Certificate in the event the applicant fails to fulfill these conditions. This Certificate is non-transferable and is limited to the location, ownership, control and scope of the project shown herein.

00755

CERTIFICATE NUMBER VA-03086

JANUARY 6, 1993

Date of Issuance

JANUARY 6, 1994

State Health Commissioner

**CARILION**
*Health System*

Carilion Health System
Post Office Box 13727
Roanoke, Virginia 24036-3727
Telephone 703-981-7000

00756

January 4, 1993

Direct Number: 703-981-8064

Mr. Paul Parker, Director
Division of Resources Development
Virginia Department of Health
P.O. Box 2448
Richmond, Virginia 23218

RE: COPN REQUEST NO. VA-5470
ROANOKE MEMORIAL HOSPITALS
INTRODUCTION OF KIDNEY TRANSPLANT PROGRAM

Dear Paul:

In regards to your letter of December 23, 1992, Roanoke Memorial Hospitals does not wish to request an informal fact-finding conference concerning the above referenced project. Officials at Roanoke Memorial Hospitals have reviewed the Department of Health's Staff Report and would agree to the conditions as stated in the staff's recommendations.

Sincerely,

A. Dale Byington
Director of Planning

blg

cc: Kenneth G. Cook, Jr., Executive Director
Southwest Virginia Health Systems Agency (HSA III)

00757

**CARILION**
Health System

Carilion Health System
Post Office Box 13727
Roanoke, Virginia 24036-3727
Telephone 703-981-7347

TELEFAX MESSAGE

TELEFAX NUMBER (703) 344-5716
TROUBLE NUMBER (703) 981-7002

TO: PAUL PARKER

FROM: A. DALE BYINGTON

DATE: 1/4/93

NUMBER OF PAGES (INCLUDING THIS PAGE) 2

SPECIAL INSTRUCTIONS:

CARILION
Health System

Carilion Health System
Post Office Box 13727
Roanoke, Virginia 24036-3727
Telephone 703-981-7000

00758

January 4, 1993

Direct Number: 703-981-8064

Mr. Paul Parker, Director
Division of Resources Development
Virginia Department of Health
P.O. Box 2448
Richmond, Virginia 23218

RE: COPN REQUEST NO. VA-5470
ROANOKE MEMORIAL HOSPITALS
INTRODUCTION OF KIDNEY TRANSPLANT PROGRAM

Dear Paul:

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Sincerely,

A. Dale Byington
Director of Planning

blg

cc: Kenneth G. Cook, Jr., Executive Director
Southwest Virginia Health Systems Agency (HSA III)

00759

COMMONWEALTH of VIRGINIA

Department of Health

ROBERT B. STROUBE, M.D., M.P.H.
STATE HEALTH COMMISSIONER

December 23, 1992

RE: COPN Request No. VA-5470
Roanoke Memorial Hospital
Roanoke, Virginia
Introduction of a New Organ Transplantation Service

Mr. A. Dale Byington
Director of Planning
Carilion Health System
Post Office Box Box 13727
Roanoke, Virginia 24036-3727

Dear Mr. Byington:

For your consideration, I enclose the Department of Health staff report and the information transmitted to the Department by the Southwest Virginia Health Systems Agency on the request for a certificate of public need for the above-referenced project.

Because conditional approval of this proposal is being recommended, you may wish to request an informal fact-finding conference in accordance with the Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations and § 9-6.14:11 of the Code of Virginia. Please call me at (804) 786-7463 at your earliest convenience to indicate your desire with respect to the convening of such a conference.

Sincerely,

Paul E. Parker, Director
Division of Resources Development

elwj:1

Enclosure

pc: Robert B. Stroube, M.D., M.P.H., State Health Commissioner
Raymond O. Perry, M.P.H., Adjudication Officer
Carol S. Nance, Assistant Attorney General
Shelia I. Givens, Office Services Specialist
Blue Cross/Blue Shield of Virginia
Southwest Virginia Health Systems Agency
Office of Health Facilities Regulation

VDH VIRGINIA DEPARTMENT OF HEALTH

COPN Request No. VA-5470
Roanoke Memorial Hospitals
Roanoke, Virginia
Introduction of a New Organ
Transplantation Service

CO760

DEPARTMENT OF HEALTH

Staff Analysis

The Project:

Roanoke Memorial Hospitals (RMH), a private non-profit corporation proposes the development of a kidney transplantion program, to be known as the Carilion Transplant Center. The program will utilize the medical and surgical facilities of Roanoke Memorial Hospital in Roanoke, a 677 bed general hospital. This is the first organ transplantation program initiated by RMH and the first proposed for development in southwest Virginia (Health Planning Region III). The total estimated capital expenditure for this project is $61,172, primarily for office equipment and furnishings for the transplant surgeon and his staff.

Applicant's Justification:

The following excerpts from the application summarizes the justification offered by the applicant:

> The establishment of renal transplant services is a key objective emanating from RMH's strategic mission as a tertiary care center to provide comprehensive health care to residents of Southwest Virginia. In July 1990, RMH appointed a Transplant Advisory Committee to study the feasibility of and develop plans for renal transplant services. Consequently, RMH contracted exclusively with Joseph M. Hayes, MD for his medical direction of the proposed Center and to coordinate all preliminary program approvals and certifications required through national organizations, including the United Network for Organ Sharing ("UNOS") and the Health Care Financing Review to secure full Medicare participation. Dr. Hayes has over three years formal transplant training and greater than three years experience in transplant surgery and post-operative care, and he is American Board and UNOS certified .... In addition, RMH has in place additional staff to support this proposed project, including three other nephrologists to assist Dr. Hayes in the preoperative selection and postoperative care of transplant recipients, and two renal transplant coordinators, who will coordinate the collection and submission of data to UNOS and other registries.
>
> **Need for Transplant Services in HSA III**
>
> The number of individuals awaiting kidney transplants in Virginia increased by twenty-eight percent between 1990 and 1991. In 1991, 151 kidney transplants were performed, and 338 individuals with ESRD were

awaiting renal transplants.... Four facelities in Virginia offer renal transplant services; however, each is located outside HSA III and the closest facility to the Roanoke is located in Charlottesville, which is 120 miles away.

Based upon the patient origin of individuals with and the prevalence rates of ESRD, there is a need for renal transplant services in HSA III, In 1991, thirty-two individuals with ESRD and using dialysis units in HSA III received kidney transplants in facilities outside the region, and the number totalled forty-two in 1990...

However, these numbers do not reflect all the individuals in need because the availability of kidneys affects the number of renal transplants that can be performed. Newell Falkinburg, MD, a senior physician with Valley Nephrology Associates, Inc. the largest nephrologist group in the region, stated that, since 1990, his group referred 118 patients with ESRD for renal transplant services (46 in 1990, 38 in 1991, and 34 in 1992).... Nationally, the proportion of dialysis patients to the number of transplants performed has remained relatively constant, ranging from 7.5 percent to 10 percent between 1984 and 1991. consequently, nearly forty-nine potential kidney transplant recipients resided in HSA III in 1991, and the number totalled forty-six in 1990....

Similarly, the prevalence or the number of individuals with ESRD in HSA III indicated that there is a need for renal transplant services in the region. Between 1990 and 1991, the prevalence rate in Virginia incresed by twelve percent from 3,515 to 3,942 cases. Accordingly, approximately 697 individuals with ESRD lived in HSA III in 1991, and of those, fifty-two were potential kidney transplant recipients.

Currently, individuals awaiting kidney transplants ...[who] residents of HSA III must travel outside the region to obtain renal transplant services. Most of these facilities are more than two hours away from HSA III. The long travel distance also increases the difficulty of kidney recipients to obtain regular post-operative exams with their transplant surgeon, who would monitor results of patients with renal transplants.

The establishment of a renal transplant program at RMH fulfills both a logical progression of tertiary care service offerings and provides a much needed medical service in the HSA III region.

00762

## Staff Analysis

4.1 In determining whether a public need exists for a proposed project, the following factors shall be taken into account when applicable:

4.1.A. The recommendation and the reasons therefor of the appropriate regional health planning agency.

Staff Comment:
The Board of Directors of the Southwest Virginia Health Systems Agency, considered this proposal at a meeting on December 2, 1992, following a public hearing on the proposal. The Board voted to recommend approval of the application "conditional for two years to determine if the program is capable of meeting minimum volume and survival rates contained in the State Medical Facilities Plan." Its decision was based on the following considerations:

* Establishment of the program can be done at a low capital cost;

* Roanoke Memorial Hospitals has the financial resources to cover losses the program may suffer during the first two years of operation and beyond;

* As a tertiary care center, RMH has a wide range of medical and other support services available to support the transplant program. RMH routinely performs complicated surgery;

* RMH is a major harvester of organs in western Virginia and West Virginia. This should increase the probability of a match between a donor and a patient in southwest Virginia, thus improving the likelihood the proposed program will meet minimum volume criteria;

* While the impact on the UVA (University of Virginia Hospital) program (kidney transplant program) may be noticeable, it does not appear to be likely to reduce volume below minimum state requirements. If travel time is a key factor in a patient's decision to have a transplant, then it is unlikely that there will be a major impact on surrounding programs;

* Data indicates that while a small number of programs had actual 12-month patient outcomess lower than expected survival levels, in general survival rates at lower volume renal transplant programs are consistent with those at larger volume programs.

No opposition to the proposal was expressed at the public hearing or received in written correspondence by the HSA or the Department.

4.1.B. The relationship of the project to the applicable health plans of the regional health planning agency, the Virginia Health Planning Board and the Board.

Staff Comment:
This proposal is consistent, in most respects, with the 1992 State Medical Facilities Plan (SMFP). As noted in the SWVHSA staff report, a high proportion of the population of southwest Virginia is currently located within two hours driving time of a kidney transplantation facility, the accessibility standard of the SMFP. This project isn't needed in order to meet this accessibility standard. This standard reflects the specialized nature of this service. Obviously, travel time for kidney transplantation will be significantly shortened for a high proportion of this population through implementation of this project.

It is not anticipated that RMH will have any problem in providing a quality transplant team or adequate surgical and support facilities. There is a reasonable basis for believing that RMH can perform the minimum number of kidney transplant procedures recommended in the SMFP (25) and a reasonable basis for believing that appropriate outcomes, in terms of graft and patient survival, can be achieved.

While the critical problem in maximizing the potential health benefit of kidney transplantation at this time in Virginia appears to be increasing organ harvesting rather than developing new transplant centers, a case can be made that RMH has "earned" the right to establish a center in southwest Virginia through its efforts in harvesting kidneys, and the establishment of this new center should be possible without critically reducing transplant volume at UVA, the facility which will be most affected by this project.

4.1.C. The relationship of the project to the long-range development plan, if any, of the person applying for a certificate.

Staff Comment:
RMH has included this project in their long-range planning.

4.1.D. The need that the population served or to be served by the project has for the project.

Staff Comment:
There is a sufficient number of patients with end-stage renal disease (ESRD) in southwest Virginia to support a kidney transplant program in Roanoke at the minimum transplantation procedure volume considered appropriate, and this ESRD patient population is growing (See SWVHSA staff report, page 7).

4.1.E. The extent to which the project will be accessible to all residents of the area proposed to be served.

Staff Comment:
From a geographic standpoint, RMH is well positioned, in Roanoke, for access by the most heavily populated regions of southwest Virginia.

Almost all patients who will be candidates for kidney transplantation will have the cost of their transplant covered by the Medicare program.

4.1.F. The area, population, topography, highway facilities and availability of the services to be provided by the project in the particular part of the health planning region in which the project is proposed.

Staff Comment:
The topography of southwest Virginia, coupled with its size, presents the greatest problems in terms of travel difficulty and travel time among the Commonwealth's five health planning regions. As noted previously, most of southwest Virginia's population can probably reach an existing transplantation center within two hours but the availability of this service in Roanoke will provide a significant improvement in access for a high proportion of the area's population, a major benefit for the post-transplant patient.

4.1.G. Less costly or more effective alternate methods of reasonably meeting identified health service needs.

Staff Comment:
As noted by the SWVHSA, kidney transplantation is a more cost-effective approach for treating ESRD than dialysis. This is probably not the critical factor for consideration of less costly or more effective alternatives to this project. RMH is the only logical sponsor for a kidney transplantation center in southwest Virginia. The alternative to this project is to continue to provide kidney transplantation for southwest Virginians at the existing centers in Virginia, North Carolina, and West Virginia.

00765

RMH has presented a reasonable case for providing this service at a cost and level of effectiveness comparable to these existing centers at a location that will significantly improve geographic accessibility for southwest Virginia.

4.1.H. The immediate and long-term financial feasibility of the project.

Staff Comment:
RMH is a financially stable institution that can be reasonably expected to bear the potential losses which implementation of this project may entail. (A loss of approximately $72,000 is projected in the first year of operation.) A reasonable projection of revenues and expenses has been presented which indicates that breakeven for this program should be achieved at a procedural volume between 30 and 40 transplants, which RMH projects reaching in the second year of operation. This utilization projection is reasonable.

As noted previously, the capital costs of initiating this service are negligible.

4.1.I. The relationship of the project to the existing health care system of the area in which the project is proposed.

Staff Comment:
As noted previously, kidney transplantation is not currently available at any other hospitals in southwest Virginia. The closest existing centers to Roanoke are in Charlottesville and Richmond. RMH is the largest and most comprehensive hospital facility in southwest Virginia and is, thus, the logical candidate to initiate the first transplantation service in the area.

4.1.J. The availability of resources for the project.

Staff Comment:
RMH has the financial resources to undertake this project.

RMH has recruited a qualified surgeon and several other of the required personnel. No major problems are anticipated in recruiting the additional personnel needed and no adverse impact on existing facilities is anticipated.

RMH has the ancillary and support services necessary for successful implementation of this project. It will utilize the facilities of UVA's histocompatability lab for tissue typing.

4.1.K. The organizational relationship of the project to necessary ancillary and support services.

Staff Comment:
Because RMH is a full service general hospital, it currently has the necessary ancillary and support services to support the project. Dialysis services for ESRD patients have been in place for some time at RMH. Development of an appropriate organizational relationship of the transplantation center to necessary ancillary and support services should be easily achieved.

4.1.L. The relationship of the project to the clinical needs of health professional training programs in the area in which the project is proposed.

Staff Comment:
It does not appear that the development of the kidney transplantation program at RMH is important to meeting the clinical needs of health professional training programs in the area.

4.1.M. The special needs and circumstances of an applicant for a certificate, such as a medical school, hospital, multidisciplinary clinic, specialty center or regional health service provider, if a substantial portion of the applicant's services or resources or both is provided to individuals not residing in the health planning region in which the project is to be located.

Staff Comment:
The primary service area of RMH lies in southwest Virginia and it is likely that the bulk of patients served by the proposed transplantation center will originate in this health planning region (H.P.R. III). A region of southeast West Virginia may be served by the proposed transplantation center as well.

4.1.N. The need and the availability in the health service area for osteopathic and allopathic services and facilities and the impact on existing and proposed institutional training programs for doctors of osteopathy and medicine at the student, internship, and residency training levels.

Staff Comment:
It does not appear that the development of the proposed project is important to meeting the need for osteopathic and allopathic services and facilities.

4.1.O. The special needs and circumstances of health maintenance organizations. When considering the special needs and circumstances of health maintenance organizations, the commissioner may grant a certificate for a project if the commissioner finds that the project is needed by the enrolled or reasonably anticipated new members of the health maintenance organization or the beds or services to be provided are not available from providers which are not health maintenance organizations or from other health maintenance organizations in a reasonable and cost effective manner.

Staff Comment:
It does not appear that this project is needed by the enrolled or reasonably anticipated new members of a health maintenance organization. Kidney transplantation services are available in Virginia through providers which are not health maintenance organizations.

4.1.P. The special needs and circumstances for biomedical and behavioral research projects which are designed to meet a national need and for which local conditions offer special advantages.

Staff Comment:
It does not appear that development of the proposed project is relevant to meeting the need for any biomedical or behavioral research projects.

4.1.Q. The costs and benefits of the construction associated with proposed project.

Staff Comment:
There is no construction associated with this project.

4.1.R. The probable impact of the project on the costs of and charges for providing health services by the applicant for a certificate and on the costs and charges to the public for providing health services by other persons in the area.

Staff Comment:
This project is not anticipated to generate excess revenue until the second year of operation. RMH should be able to absorb the net loss projected during the initial buildup of services without increasing other charges to subsidize the transplantation program.

Cost savings will occur for transplant patients with reduced travel expenses due to the availability of kidney transplantation services in southwest Virginia.

This project is likely to reduce the volume of kidney transplantations at UVA, which is likely to have a negative impact on that facility's bottom line. Given the considerable transplantation waiting list, if some improvement in the levels of kidney harvesting can occur in Virginia, this impact should be short-term.

4.1.S. Improvements or innovations in the financing and delivery of health services which foster competition and serve to promote quality assurance and cost effectiveness.

Staff Comment:
The proposed project involves no improvements or innovations in financing. Most kidney transplantations will qualify for Medicare reimbursement. Because of the reduced travel time for transplant patients in the southwest part of Virginia, this project will represent a more cost-effective transplantation alternative for many of these patients relative to existing transplantation centers in Charlottesville, Richmond, or other states.

4.1.T. In the case of health services or facilities proposed to be provided, the efficiency and appropriateness of the use of existing services and facilities in the area similar to those proposed.

Staff Comment:
Three of the four existing kidney transplantation programs in Virginia have performed more than the minimum standard of 25 transplant procedures in each of the last three years. Henrico Doctors Hospital in Richmond initiated this service in 1990, when COPN authorization of this service was not required, and performed 17 procedures in FYE 9/30/91. As noted previously, the proposed project will be the first kidney transplantation program in southwest Virginia. UVA is the existing center which will be most affected by this project. It reported the highest number of kidney transplants in the state (58) in FYE 9/30/91.

It appears likely that this new program can be initiated in Roanoke, achieve a level of appropriate utilization and efficient operation, and not reduce the level of transplantation procedures at any existing center to an inappropriate level.

## Staff Recommendation

00769

The staff of the Division of Resources Development recommends to the State Health Commissioner that the proposal by RMH to introduce an organ transplantation service in Roanoke be conditionally approved. The condition is that the COPN authorization be formally reconsidered for renewal or revocation after two years of program operation based on a review of the program's success in meeting both minimum transplant procedure volume levels and transplant patient survival rates.

The basis for this recommendation is as follows:

* The proposal is generally consistent with the State Medical Facilities Plan.

* RMH has presented reasonable evidence that it can initiate and maintain a high quality kidney transplantation service without unduly reducing transplantation procedure volume at existing transplantation centers.

* A substantial proportion of kidney transplantation patients in southwest Virginia will have significantly improved geographic access to this service through the development of a program in Roanoke.

* RMH has a good track record in the harvesting of kidneys for transplantation and the delivery of service to ESRD patients.

* The Southwest Virginia Health Systems Agency has recommended approval of the project.

## SENTARA NORFOLK GENERAL HOSPITAL

00834

### GROWTH IN LIVER TRANSPLANT VOLUME
### COMMONWEALTH OF VIRGINIA 1992-1996

| | 92 | 93 | 94 | 95 | 96 |
|---|---|---|---|---|---|
| Fairfax | 4 | 14 | 18 | 36 | 53 |
| MCV | 31 | 37 | 33 | 39 | 66 |
| UVA | 36 | 66 | 62 | 54 | 37 |
| TOTAL | 71 | 117 | 113 | 129 | 156 |
| % Growth | | 65% | (3%) | 14% | 21% |

Average Annual Growth 30%

Source: United Network for Organ Sharing Research Department

J:\HOT\SENTARA NORFOLK\ORGAN 2\TRANS VOL

# SENTARA NORFOLK GENERAL HOSPITAL

## SERVICE AREA PATIENTS OBTAINING LIVER TRANSPLANTS

00836

| | 1994 | 1995 | 1996 |
|---|---|---|---|
| Region 2 | 0 | 4 | 2 |
| Region 4 | 0 | 7 | 2 |
| Region 11 | 18 | 10 | 24 |
| **Totals from Area** | **18** | **21** | **28** |

Source: UNOS Research Department

J:\HCT\SENTARA\NORFOLK\ORGAN 22\EXH5.DOC

# SENTARA NORFOLK GENERAL HOSPITAL

## PROJECTED HSA V LIVER TRANSPLANTS BASED ON STATEWIDE USE RATE

00838

| | |
|---|---|
| VA Liver Transplants 1996 | 156 |
| VA Population 1996 * | ÷ 6,612,877 |
| Transplant Incidence/1,000 | .0235 |

| | |
|---|---|
| HSA V Population 1998 * | 1,557,745 |
| Transplant Incidence/1,000 | x .0235 |
| Projected 1998 Area Liver Transplants | 37 |

* Extrapolated from Virginia Employment Commission State Population Projections 1990, 2000 & 2010.

Source for liver transplant data: United Network for Organ Sharing Research Department

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00895

Langley and McDonald, P.C.

Engineers
Surveyors
Planners
Landscape Architects
Environmental Consultants

GEORGE E. LANGLEY
Consultant
T. JOSEPH McDONALD
1906-1982

May 19, 1997

Ms. Sandra Miller
Sentara Norfolk General
6015 Poplar Hall Drive
Norfolk, VA 23502

RE: Travel Time Study for Liver Transplant Application
L&M Project No. 84158-17-61

Dear Ms. Miller:

As you requested the following is a breakdown of census tracts in South Hampton Roads located more than two hours from MCV in Richmond.

In order to determine the travel time from MCV to Hampton Roads, Langley and McDonald measured a base travel time from South Hampton Roads to MCV. The travel time was measured from the Interstate 64 and Route 44 interchange to MCV by two drivers who maintained the posted speed limit. The weather condition for both trips was fair, and no traffic congestion was encountered.

Using an average of the two travel times, the base time from the I-64/Route 44 interchange to MCV in Richmond is 1 hour and 40 minutes. Next, using the base travel time along with regional travel times developed by the Hampton Roads Planning District Commission in the *Hampton Roads Regional Travel Time Analysis*, estimated travel times were developed from MCV to census tracts in Chesapeake, Virginia Beach, Suffolk, the Eastern Shore, and Northeastern North Carolina. The areas are listed below with population by census tract. Population data is based on 1990 census data.

*Suffolk* - 80% of Total Population - 41,826

*Chesapeake*

| CENSUS TRACT | POPULATION |
|---|---|
| 208.04 | 2,764 |
| 210.03 | 8,508 |
| 210.04 | 3,339 |
| 211.01 | 4,144 |
| 211.02 | 4,637 |
| 212 | 4,616 |
| TOTAL | 28,008 |

MAIN OFFICE
5544 Greenwich Road
Virginia Beach, VA 23462
(757) 473-2000
FAX: (757) 497-7933

201 Packets Court
Williamsburg, VA 23185
(757) 253-2975
FAX: (757) 229-0049

*Eastern Shore*

| COUNTY | POPULATION |
|---|---|
| Northampton | 13,061 |
| Accomack | 31,703 |
| TOTAL | 44,764 |

*Virginia Beach*

| CENSUS TRACT | POPULATION |
|---|---|
| 420 | 3,476 |
| 422 | 8,534 |
| 430.01 | 5,715 |
| 430.02 | 3,359 |
| 432 | 1,184 |
| 434 | 2,082 |
| 436 | 1,675 |
| 438 | 3,728 |
| 440.01 | 6,655 |
| 440.02 | 7,381 |
| 442.01 | 6,322 |
| 444.01 | 3,896 |
| 444.02 | 5,625 |
| 446 | 3,645 |
| 448.04 | 9,296 |
| 448.05 | 3,461 |
| 448.06 | 5,226 |
| 450.85 | 4,395 |
| 452 | 5,166 |
| 454.06 | 4,790 |
| 454.07 | 3,357 |
| 454.08 | 6,213 |
| 454.09 | 8,592 |
| 454.10 | 2,543 |
| 454.11 | 14,260 |
| 454.12 | 1,396 |
| 460.08 | 8,750 |
| 464 | 3,174 |
| 466 | 966 |
| TOTAL | 144,862 |

*Northeastern North Carolina*

| COUNTY | POPULATION |
|---|---|
| Camden | 5,962 |
| Chowan | 13,506 |
| Currituck | 13,736 |
| Dare | 24,700 |
| Edenton | 5,268 |
| Elizabeth City | 14,292 |
| Pasquotank | 32,382 |
| Perquimans | 10,447 |
| TOTAL | 120,293 |

**GRAND TOTAL 379,753**

As indicated above, these travel times are based on ideal conditions. The Hampton Roads Bridge Tunnel however is a source of frequent and often prolonged delay. The Virginia Department of Transportation completed an incident survey for the month of September 1996 on the westbound lanes of the Hampton Roads Bridge Tunnel. There were a total of 101 incidents for a total duration of 25 hours and 17 minutes. The duration of each delay incident is from the time the incident occurs until the vehicles are cleared and the lane is open to traffic.

The impact of each incident on delay is much greater than the duration of the incident. Each incident usually causes a delay of from 15 to 30 minutes due to the vehicle queue, or traffic back-up. Using alternate routes to avoid the congestion would increase the base travel time. The population which is more than two hours travel time from Richmond would increase substantially if delays at the Hampton Roads Bridge Tunnel approach 15 min.

In summary, while we cannot compute a pr[illegible] delays exceeding 15 minutes, considering Hampton Roads Bridge Tunnel congestion is a necessity in traveling across Hampton Roads.

Please contact us if you have any questions or comments at (757) 473-2000.

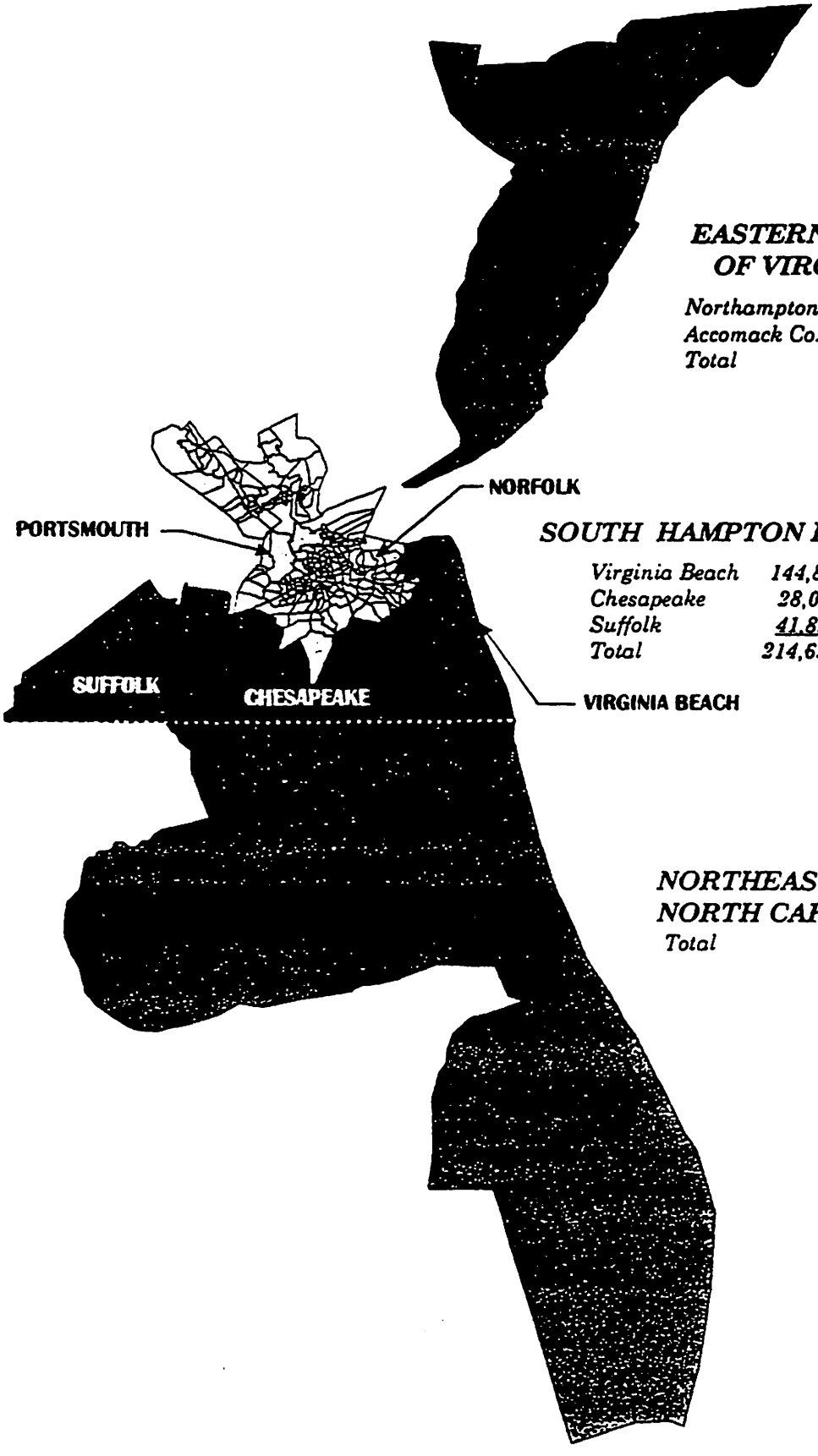
Very truly yours,

LANGLEY AND McDONALD, P.C.

William J Cashman, Jr.
Principal

# CENSUS TRACTS MORE THAN TWO HOURS TRAVEL TIME FROM RICHMOND, VIRGINIA
## (1990 CENSUS OF POPULATION)

00899



# SENTARA NORFOLK GENERAL HOSPITAL

## LIVER TRANSPLANT PROGRAMS* BY MSA DESIGNATION AND RANK

| MSA Rank | Metropolitan Area | Population (1990 Census) | # Liver Transplant Programs |
|---|---|---|---|
| 1 | New York, NY - NJ - CT - PA, CMSA | 19,549,649 | 6 |
| 2 | LA - Riverside - Orange, CA - CMSA | 14,531,529 | 5 |
| 3 | Chicago, IL - IN - WI, CMSA | 8,239,820 | 4 |
| 4 | DC - MD - VA - WVA, CMSA | 6,726,395 | 4 |
| 5 | San Francisco - Oakland - San Jose, CA - CMSA | 6,249,881 | 2 |
| 6 | Philadelphia, PA - NJ - DE - MD, CMSA | 5,893,019 | 5 |
| 7 | Boston, MA - NH - ME - CT, CMSA | 5,455,403 | 4 |
| 8 | Detroit - Ann Arbor, MI - CMSA | 5,187,171 | 2 |
| 9 | Dallas - Fort Worth, TX - CMSA | 4,037,282 | 2 |
| 10 | Houston - Galveston, TX - CMSA | 3,731,029 | 5 |
| 11 | Miami - Fort Lauderdale, FL - CMSA | 3,192,725 | 1 |
| 12 | Atlanta, GA - MSA | 2,959,500 | 2 |
| 13 | Seattle - Tacoma, WA - CMSA | 2,970,300 | 2 |
| 14 | Cleveland - Akron, OH - CMSA | 2,859,644 | 2 |
| 15 | Minneapolis - St. Paul, MN - MSA | 2,538,776 | 1 |
| 16 | San Diego, CA - MSA | 2,498,016 | 1 |
| 17 | St. Louis, MO - MSA | 2,492,348 | 4 |
| 18 | Pittsburg, PA - MSA | 2,394,811 | 2 |
| 19 | Phoenix - Mesa, AZ - MSA | 2,238,498 | 1 |

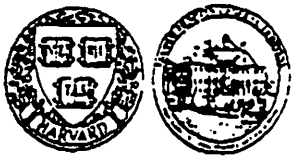
| MSA Rank | Metropolitan Area | Population (1990 Census) | # Liver Transplant Programs |
|---|---|---|---|
| 20 | Tampa - St. Petersburg, FL - MSA | 2,067,959 | 1 |
| 21 | Denver - Boulder, CO - CMSA | 1,980,140 | 3 |
| 22 | Cincinnati - Hamilton, OH - KY - IN, CMSA | 1,817,569 | 2 |
| 23 | Portland - Salem, OR - WA, CMSA | 1,793,476 | 2 |
| 24 | Milwaukee - Racine, WI, CMSA | 1,607,183 | 2 |
| 25 | Kansas City, MO - KS, MSA | 1,582,874 | 2 |
| 26 | Sacramento - Yolo, CA - CMSA | 1,587,898 | 1 |
| **27** | **Norfolk - Virginia Beach, VA - NC, MSA** | **1,444,710** | --- |
| 28 | Indianapolis, IN - MSA | 1,380,491 | 2 |
| 29 | San Antonio, TX - MSA | 1,324,749 | 1 |
| 30 | Columbus, OH - MSA | 1,345,450 | 2 |

* Source: Population Division - US Census Bureau, Department of Commerce and United Network for Organ Sharing

J:\HCT\SENTARA\NORFOLK\ORGAN 22\LIVERCHT MSA

HARVARD MEDICAL SCHOOL — MASSACHUSETTS GENERAL HOSPITAL

HUGH AUCHINCLOSS, JR., M.D.
Associate Professor of Surgery



TRANSPLANTATION UNIT
DEPARTMENT OF SURGERY
WHITE 5109
MASSACHUSETTS GENERAL HOSPITAL
BOSTON, MASSACHUSETTS 02114
(617) 726-6419
FAX (617) 726-3685
EMail Auchincloss@helix.mgh.harvard.edu

May 19, 1997

Ms. Laura Aaron
Attorney-at-Law
Mezzullo & McClandlish
1111 E. Main Street
Richmond, VA 23219

Dear Ms. Aaron:

This is to certify that at the American Society of Transplant Surgeons' meeting in Chicago during May 14-16, 1997, the Council of that Society decided to change the criteria for certification of transplant fellowship training programs. The new criteria specify that a transplant fellowship training program must have enough patients such that each fellow will have primary responsibility for 75 new patients during their fellowship training. To be certified as a liver transplant fellowship program, at least 45 of those patients must be liver transplantation patients.

Please contact me with any additional questions.

Sincerely,

2 year period

Hugh Auchincloss, Jr., M.D.
Chairman, Education Committee
American Society of Transplant Surgeons

HA/cms

# SENTARA NORFOLK GENERAL HOSPITAL

## ACCREDITED LIVER TRANSPLANT TRAINING PROGRAMS * ANNUAL VOLUMES BY PROGRAM

| Program | Annual Volumes | | |
|---|---|---|---|
| | 96 | 95 | 94 |
| University of California, San Francisco | 100 | 206 | 206 |
| University of Chicago | 129 | 132 | 125 |
| University of Cincinnati | 33 | 36 | 30 |
| Baylor University, Dallas | 118 | 140 | 145 |
| Deaconess Hospital, Boston | 45 | 30 | 45 |
| Duke University | 38 | 38 | 38 |
| University of Florida, Gainesville | 102 | 81 | 36 |
| Johns Hopkins, Baltimore | 45 | 51 | 61 |
| Massachusetts General, Boston | 34 | 22 | 25 |
| Mayo Clinic, Rochester Methodist Hospital | 89 | 91 | 76 |
| University of Miami | 179 | 194 | 116 |
| University of Michigan, Ann Arbor | 59 | 78 | 79 |
| University of Minnesota | 27 | 29 | 30 |
| Mt. Sinai, New York | 182 | 209 | 175 |
| University of Nebraska | 81 | 94 | 116 |
| New York University, New York | 59 | 50 | 37 |
| Ohio State University, Columbus | 28 | 35 | 32 |
| University of Pennsylvania | 64 | 47 | 19 |
| University of Pittsburg | 182 | 212 | 219 |
| Rush Presbyterian, Chicago | 63 | 65 | 77 |
| State University of New York | 0.00 | 0.00 | 1 |
| University of Texas, Houston, Hermann | 37 | 28 | 31 |

| Program | Annual Volumes | | |
|---|---|---|---|
| | 96 | 95 | 94 |
| MCV | 66 | 39 | 33 |
| UVA | 37 | 54 | 62 |
| University of Washington, Seattle | 67 | 53 | 56 |
| Washington University, Barnes | 57 | 50 | 59 |
| University of Wisconsin, Madison | 62 | 67 | 60 |

* Source: American Society of Transplant Surgeons, United Network for Organ Sharing

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HARVARD MEDICAL SCHOOL  MASSACHUSETTS GENERAL HOSPITAL

GH AUCHINCLOSS, JR., M.D.
Associate Professor of Surgery

01005

TRANSPLANTATION UNIT
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November 26, 1996

Marc P. Posner, M.D., F.A.C.S.
Professor and Chairman
Division of Transplantation Surgery
Director, MCV Transplant Program
Medical College of Virginia Transplant Program
P.O. Box 980057
Richmond, VA 23298

Dear Dr. Posner:

Your application for re-certification of your transplant fellowship training program was reviewed by the Education Committee and by the Council of the American Society of Transplant Surgeons. At the meeting in San Francisco in October, 1996 the following action was taken:

Your program was certified for: Kidney/Liver

Certification for your program will continue until December 31, 1999.

This certification process has evolved and been in flux for several years, generating considerable confusion. This is likely to continue, especially since the A.S.T.S. Council expressed an interest in revising the certification guidelines so that they are based on the number of transplants performed per fellow rather than the absolute number of transplants. The A.S.T.S. Education Committee will consider this issue and report back to the Council next spring. New guidelines may well make it possible for some programs which are not currently certified or which are on probation to gain Council approval. Thus, program directors should watch the CHIMERA next year for the outcome of these discussions. In addition, program directors should be aware that training too large a number of fellows relative to the volume on their service may jeopardize their chances for certification as a program in the future.

Sincerely,

Hugh Auchincloss, Jr., M.D.
Chairman, A.S.T.S. Education Committee

HA/cms

# REQUIREMENTS FOR ASTS ACCREDITATION OF TRANSPLANT SURGERY FELLOWSHIP TRAINING PROGRAMS

February 1995, the Council of the ASTS, upon recommendation by the Education Committee, agreed upon the .owing requirements for ASTS accreditation of transplantation surgery fellowship training programs.

## Duration of Training:

Regardless of the intensity of exposure to clinical transplantation, there is a consensus that transplant surgery training programs should be two years in duration.

## Content of Training:

The scope and depth of transplantation has changed dramatically in the recent years with heavy emphasis on multi-organ transplantation expertise. There is stronger emphasis for fellowship trainees to have experience in kidney, liver, pancreas transplantation, as well as multi-organ procurement. Although the following requirements are listed for each organ transplant individually, it is ideal that exposure to transplant surgery approaches all requirements.

Kidney Transplantation: A minimum of one year of clinical experience at an institution performing a minimum of 60 kidney transplants annually, during which the transplant surgery fellow participates in all activities of kidney transplantation (i.e. provision of vascular access, organ procurement, and at least 30 transplant operations as primary surgeon or co-surgeon over the two year fellowship) is mandatory.

Liver Transplantation: Clinical liver transplantation fellowship programs are encouraged in institutions having an adequate case load and opportunity for long-term follow-up. The Council of the ASTS judge that the institution should perform at least 50 liver transplants annually. Adequate transplant fellow experience over the two year fellowship is a minimum of 40 liver transplants either as primary surgeon or first assistant. The liver transplantation experience should include adequate training in multi-organ procurement (kidneys, livers, pancreases) with 25 procedures as primary or co-surgeon required during the two year fellowship duration.

Pancreas Transplantation: Clinical pancreas transplantation is sufficiently complex and unique that fellowship training is encouraged in institutions having an adequate case load. The Council of the ASTS judges that the fellowship training institution should perform at least 20 pancreas transplants annually. Adequate transplant surgery fellow experience over the two year fellowship is a minimum of 15 pancreas transplants, either as a primary surgeon or first assistant.

Multi-Organ Transplantation: Programs are encouraged to seek approval for training in kidney, liver, and pancreas transplantation, either as individual institutions or by amalgamating with another. Broad and intensive clinical exposure to kidney, liver, and pancreas transplantation, as well as multi-organ procurement is sought.

Multi-Organ Procurement: Training in multi-organ procurement is essential and transplant surgery fellow experience over the two year fellowship is a minimum of 25 multi-organ procurements, either as primary surgeon or first assistant.

## The Application Process:

If you have questions or added input, please contact Hugh Auchincloss, Jr., M.D., Chair, ASTS Education Committee, Department of Surgery/Transplantation, Massachusetts General Hospital, 32 Fruit Street, White 510-B, Boston, Massachusetts 02114. Upon receipt of the application form and after a preliminary review, a site visit will be scheduled. The site visit team will arrange an agenda with the transplant program to ascertain the strength of institutional support for the transplant program and to help optimize the transplant surgery fellowship potential at that center. Our intention is to be helpful and constructive.

Hugh Auchincloss, Jr., M.D.
Chair, Education Committee

# SPECIAL REQUIREMENTS FOR GRADUATE EDUCATION IN RENAL AND VISCERAL TRANSPLANT SURGERY

Objective:

The objective of a Transplant Surgery Fellowship Training Program is to develop proficiency in the surgical and medical management of patients with end-stage organ diseases amenable to transplantation. This objective can be achieved through a structured supplemental program for the study and treatment of these diseases in an accredited and properly supervised transplant surgery fellowship. Candidates for such training must have satisfactorily completed a residency which satisfies the educational requirements for certification by the American Board of Surgery or The American Board of Urology.

Structure of Program:

The objective of a Transplant Surgery Fellowship Training Program can best be achieved when it is based within an institution approved for graduate medical education in General Surgery or Urology and also in those other disciplines particularly related, such as Infectious Disease, Immunology, Radiology, Nephrology, Diabetology, Cardiology, Pulmonary, and Gastroenterology. To provide for an effective training program, the Transplant Surgery Section should be organized within the framework of a larger administrative unit, such as a Department of Surgery, General Surgery, or Urology. It is essential that the clinical component be centralized if a proper transplant surgery fellowship program is to be conducted. This can be best achieved by establishment of a unit to which all transplant cases are admitted. This should be under the direction of a qualified transplant surgeon with continuous responsibility for

teaching, quality of patient care, and research. The director of the program should be certified by the American Board of Surgery or the American Board of Urology. Other staff members should be experienced in transplant surgery, dedicated to teaching, willing to devote the necessary time and effort to the education program, and should be engaged in research activities as well.

Scope of Training:

The program must provide instruction in the clinical and basic sciences, encompassing anatomy, physiology, pathology, and immunology including histocompatibility testing, as they relate to the diagnosis and treatment of end-stage organ diseases. Case material in sufficient volume must be available for the development of skill in the management of patients requiring transplantation. Adequate facilities must also be available for instructing the trainee in the performance and interpretation of special diagnostic techniques and instrumentations necessary for the management of transplant patients. Most importantly, the candidate must be provided with an adequate volume of operative experience.

Surgical Content and Duration of Training:

The activity of the training program must be sufficient to insure adequate exposure to the surgical procedures applied to transplantation. For accreditation as a kidney transplant training program, the center must perform at least 60 kidney transplants annually. Accreditation as a liver and/or pancreas transplantation program requires performance of at least 50 liver transplants annually and 20 pancreas

annually. In addition, sufficient activity in multi-organ procurement is required such that the transplant center exists within organ procurement organization boundaries that can account for at least 25 multi-organ procurements annually. The program must also be of sufficient duration to allow the trainee to acquire skill in the pre- and postoperative management of transplant patients. The length of the fellowship period should be no less than 24 months. Programs offering training in kidney-only or liver-only transplantation should offer at least 12 months of clinical training with the balance of the two-year fellowship spent in additional clinical work or laboratory work. Programs offering training in both renal and extrarenal transplantation including multi-organ procurement should offer at least 18 months of clinical training, with the balance of the two-year fellowship spent in additional clinical work or laboratory experience.

Clinical Material:

The clinical experience must be obtained after completion of the candidate's residency requirements. It is essential for trainees to learn the management of end-stage organ disease and the specific indications and contraindications for organ transplantation. It is also important for the trainee to gain understanding of the function of the histocompatibility laboratory with respect to cross-matching techniques, PRA testing, and tissue typing. Actual time spent in the histocompatibility laboratory is considered desirable.

The trainee must obtain operative experience under the supervision of the Director of the Transplant Program or his/her deputy. An adequate volume of surgical

experience must include; living related and/or cadaver donor operations; transplantation procedures including re-operations as management of complications; and, for fellowships in kidney transplantation, vascular access procedures. The number of transplant operations performed by the candidate as primary surgeon or first assistant, over the 24-month fellowship, must be no less than 30 kidney transplants in a kidney transplant fellowship, 40 liver transplants in a liver transplant fellowship, and 15 pancreas transplants in a pancreas transplant fellowship.

It is essential that the trainee also have an intimate acquaintance with the laboratory and radiologic procedures used in the diagnosis of rejection, infection, and other problems. The trainee should also gain familiarity of pathology of rejection and must be fully conversant with the various techniques of immunosuppression and their complications. He/she must also have experience in the workup of living donors and in the procurement and preservation of organs obtained from cadaver donors. The trainee must also have continuity of experience in the postoperative and long-term follow-up of transplant recipients. Finally, opportunities for participation in basic science research or clinical research is strongly encouraged.

Approval of Programs:

It is not essential nor even desirable that all institutions adopt exactly the same content and structure of their programs, but it is necessary that all programs meet the essentials for approval and demonstrate that they can provide a high quality of education through the clinical experience provided the trainee.

*GASTROENTEROLOGY, LTD.*

01075

BERTON W. ASHMAN, M.D.
ALAN P. GANDERSON, M.D.
JAMES W. RAWLES, JR., M.D.
JAN A. JANSON, M.D.

1101 FIRST COLONIAL ROAD, SUITE 200
VIRGINIA BEACH, VIRGINIA 23454
PHONE (804) 481-4817
FAX (804) 481-7138

August 20, 1996

Dr. Richard L. Hurwitz
Virginia Vascular Associates
880 Kempsville Rd., #1000
Norfolk, VA 23502

Dear Rick:

Thank you for your letter regarding the tentative plan for establishing a liver transplant program in Hampton Roads. While initially this seemed to be an appealing idea (primarily for reasons of convenience), I subsequently have had some reservations.

The majority of our liver transplant patients currently go to MCV, where the service has been excellent. Fortunately, this institution is really not very far away and has a very well-established and successful liver transplant program. While I do not doubt that the surgical and technical aspects of the procedure can be mastered here in Tidewater, I am not at all confident that the current situation in Tidewater lends itself well to the establishment of the other components necessary for a successful liver transplant program.

The medical aspects of liver transplant evaluation and management would require a full-time dedicated hepatologist, preferably allied with a major academic institution. I do not think that community gastroenterologists can function effectively in this role.

We must also consider that the effectiveness and success of the liver transplant program depend to a great extent on the depth of its experience. I think that dilution of this experience by establishment of an additional liver transplant center in our region does not serve our patients well.

At the present time, the availability of liver transplants is limited primarily by the availability of transplantable livers. A second transplant program, with additional hospital beds, equipment & physicians, will do nothing to change the one limiting factor. In addition, it may diminish the overall quality and effectiveness of this procedure in our area.

-continued-

Dr. Richard Hurwitz
August 20, 1996
Continued - page 2

I would, therefore, recommend that the plans for a liver transplant program in Hampton Roads be shelved for the present time.

Sincerely,

James W. Rawles, Jr., M.D.

JWR/jr:js

cc: Dr. Mitchell Shiffman
Chief, Hepatology Section
Medical College of Virginia

*GASTROENTEROLOGY, LTD.*

01080

BERTON W. ASHMAN, M.D.
ALAN P. GANDERSON, M.D.
JAMES W. RAWLES, JR., M.D.
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PHONE (804) 481-4817
FAX (804) 481-7138

July 8, 1996

Dr. Richard Hurwitz
Virginia Vascular Associates
880 Kempsville Rd., #1000
Norfolk, VA 23502

Dear Rick:

Thanks for your letter of 6/27/96. Unfortunately, due to a heavy day after being on-call, I was unable to attend the meeting to discuss a possible liver transplant program at Sentara Norfolk General Hospital.

I have certain concerns that you should know about. I believe that there are at least three centers in Virginia which are already performing transplants. Forming a fourth center, I believe, would dilute our regional centers' experiences. To wit, I do not believe there is enough pathology to support a liver transplant center in Norfolk.

Thank you for your attention to this matter. Please don't hesitate to contact me if you wish any further discussion.

Sincerely,

Jan A. Janson, M.D.

JAJ:js

cc: Dr. Mitchell Shiffman, Medical College of Virginia
Dr. Michael Ryan

01085

**MEMORANDUM**

To: Mark S. Hedberg, Esquire
Hunton & Williams

From: Marc P. Posner, M.D., F.A.C.S.
Professor and Chairman
Division of Transplantation Surgery
Director, Medical College of Virginia
Transplant Program

Marc P. Posner MD

Date: June 13, 1997

**ASTS ACCREDITATION STANDARDS**

As we have discussed, the American Society of Transplant Surgeons recently amended their transplant fellowship accreditation standards. The new standards are summarized on the attached sheet. The new volume-based requirement for an accredited liver transplant fellowship program is that the liver transplant fellow perform at least 45 liver transplantation procedures as primary surgeon during his fellowship.

It is very difficult to predict how many procedures a liver transplant center must perform to permit a fellow to perform 45 procedures as primary surgeon. Fellows progress at different rates, and some will need to participate in more surgeries than others before they are ready to serve as primary surgeon. A loss of 10-15 liver transplant procedures per year to Sentara Norfolk General Hospital will make that process more difficult. It also will dilute the total pool of transplantation cases we have, hindering our ability to provide learning experiences for medical students, interns, residents and fellows.

Please let me know if you have any questions.

# ASTS Accreditation of Fellowship Programs

## Summary of Patient Volume Requirements for Fellowship Programs:

**75 transplant patients** must be available **for each transplant fellow** in the program to serve as primary surgeon over the course of their training

**In addition:**

To be certified as a **kidney** transplantation fellowship: **each fellow** must perform at least **30 kidney transplants** as primary surgeon

To be certified as a **liver** transplantation fellowship: **each fellow** must perform at least **45 liver transplants** as primary surgeon

To be certified as a **pancreas** transplantation fellowship: **each fellow** must perform at least **15 pancreas transplants** as primary surgeon

1

2 01098

3

4

5

6 INFORMAL FACT FINDING CONFERENCE IN RE:
UNIVERSITY HEALTH SERVICES, INC. AND THE MEDICAL
7 COLLEGE OF VIRGINIA HOSPITALS GOOD CAUSE PETITION

8 AND

9 COPN REQUEST NO. VA-5969
SENTARA NORFOLK GENERAL, HOSPITAL
10 NORFOLK, VIRGINIA
TO ADD A LIVER TRANSPLANT PROGRAM

11

12

13

14

15

16 3600 West Broad Street
Third Floor Conference Room
17 Richmond, Virginia

18

19 May 20, 1997
20 10:00 a.m.

21

22

23

24 CAPITOL REPORTING, INC.
P.O. Box 959
25 Mechanicsville, Virginia 23111
Tel. No. (804) 788-4917

1 of the transplant unit. That's about it.
2 Q Does MCV currently have a liver
3 transplant training program?
4 A Yes, it does.
5 Q And would you describe that for Mr.
6 Perry, please?
7 A This is called a transplant
8 fellowship, and MCV has had a transplant fellowship
9 since 1966. It's been accredited by the American
10 Society of Transplant Surgeons since 1974 which is the
11 year of inception of the American Society of Transplant
12 Surgeons for kidneys. We recently received
13 accreditation for livers as well.
14 Q I'm referring you to tab 5 in our
15 exhibit book. Was the accreditation granted in
16 November of 1996?
17 A Yes.
18 Q Were you -- I'm sorry, let me back
19 up. How many certified liver transplant fellowship
20 training programs are there in the country?
21 A There are 30.
22 Q And does a list of all the
23 accredited programs appear behind tab 6?
24 A Yes, it does.
25 Q Were you involved in the process of

1 getting the MCV liver transplant fellowship program
2 accredited?
3 A Yes, I was.
4 Q Can you describe that process for
5 Mr. Perry and how long it took?
6 A It took us four years or so because
7 the criteria for accreditation changed. The actual
8 volume of transplants necessary that a center performs
9 in order to have an accredited transplantation and
10 fellowship training in liver transplantation increased
11 each year from 1992 to 1995.
12 Q Where was it when it started?
13 A It started at 20.
14 Q Where is it now?
15 A Now it's at 50.
16 Q Behind tab 7 do the current
17 standards appear?
18 A Yes, they do.
19 Q If MCV loses part of its liver
20 transplant volume to Sentara's new program, what are
21 the implications of that volume loss to the fellowship
22 program's accredited status?
23 A As you can see from what's in tab
24 5, we are going to be revisited in 1999, so the
25 certification is good for three years. If you also

1 read the paragraph below that, there is some statement
2 to the effect that manpower issues may dictate
3 fellowship training numbers, and numbers of transplant
4 or transplant volume may reflect an interest in
5 decreasing the number of fellows trained.
6 The bottom line there is that if I
7 had to guess, I think that the volume requirement will
8 increase over time, and if we were to drop below that
9 then we would lose our certification.
10 Q Have you reviewed the staff reports
11 regarding the Sentara project issued by the Department
12 of Health and by the Eastern Virginia Health Systems
13 Agency?
14 A Yes, I have.
15 Q Does the staff report of the
16 Eastern Virginia Health Systems Agency take any of
17 these adverse training consequences into account?
18 A Well, I don't think they give it
19 enough weight.
20 Q Turning to the research issues for
21 a minute, Dr. Posner, are you familiar with the
22 suggestion in the Department of Health staff report
23 that MCV and Sentara could, quote, conduct joint
24 research on a much larger combined pool of patients
25 than MCV has ever had solely in house and the statement

1 transplant center at Dallas has also begun the
2 procedure.
3 Q So it's not a widely available
4 technique?
5 A No, it's not. And it's all being
6 directed through my laboratory and the Pittsburgh
7 laboratory.
8
9 MR. MCCANDLISH: Could I clarify
10 the time period in which these research
11 initiatives were first undertaken?
12 THE WITNESS: Yeah. These research
13 initiatives are all between '91 and '97.
14
15 BY MR. HEDBERG:
16 Q Ballpark estimate, how many
17 different research projects in that time span would you
18 say you have initiated with your colleagues?
19 A Well, it's, most are in the CV that
20 I have been the principal investigator on. It doesn't
21 reflect all of the co-investigations. Look at the CV,
22 I don't keep an open tab on how many I have projected.
23 Q In that time we are talking about
24 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15. 15
25 pages of titles of research programs?

1 A Yes. All the peer review
2 publications are from investigational approved either
3 human research or basic research that led to human
4 research.
5 Q So you all are fairly active in
6 research?
7 A Yes, sir, I think so.
8 Q Have you reviewed the staff reports
9 regarding the Sentara project that the Department of
10 Health and the Eastern Virginia Health Systems Agency
11 prepared?
12 A Yes, sir, I have.
13 Q Are you familiar with the
14 conclusion on page 64 the Department of Health staff
15 report that it is, quote, difficult for DCOPN to
16 evaluate all the ramifications of the issues
17 surrounding liver transplant research, nonetheless on
18 balance the COPN is not persuaded that establishment of
19 a liver transplant program at Sentara would harm
20 existing or future research at MCVH and might well
21 enhance it.
22 A I'm familiar with that statement.
23 Q Do you agree or disagree with that
24 conclusion?
25 A I disagree quite strongly.

1 McCandlish, to proceed.

2 MR. MCCANDLISH: All right. At the

3 outset I'd like to hand out our exhibit book

4 with Exhibits A through V and ask those be

5 accepted into the record.

6 MR. PERRY: Thank you, they are

7 accepted.

8 MR. MCCANDLISH: In this project

9 Sentara Norfolk General seeks to add liver

10 transplant services to the very successful

11 existing transplant program at Sentara

12 Norfolk General which currently provides

13 heart, lung, and kidney transplant services.

14 In those programs Sentara has demonstrated

15 its ability to operate high quality

16 transplant programs to meet the needs of area

17 residents.

18 Now in this proceeding, the key

19 issues we believe are the key issues that

20 appear in some form or another in most CON

21 proceedings. First of all is there a need

22 for the program in the area, is there a need

23 for the program that we propose to add.

24 And secondly, with respect to a

25 transplant program, obviously the question of

1 whether we can have a quality program is an
2 issue of concern as well which we have
3 addressed and I think have made a clear
4 showing on both the need and the quality
5 items.
6 MCV by its participation in the
7 process has attempted to introduce a third
8 issue of what will be the impact on MCV if
9 our program is established, and we recognize
10 that as a third issue that we need to deal
11 with, although we think much of what's been
12 put forward is really a smoke screen.
13 In our exhibit book, item A, and I
14 won't belabor it by repeating it here, is the
15 addressing of the 20 required considerations,
16 and we submit that for your consideration,
17 Mr. Perry.
18 With respect to the first issue of
19 need, I think it's always a challenge for you
20 as the hearing officer to decide how do you
21 view the need, how do you balance and look at
22 the need that is put forth with this type of
23 program, and of course we have the State
24 Medical Facilities Plan which is subject to
25 interpretation from time to time, and what we

1 have tried to do is to bring forward to you
2 some, and we'll bring forward to you today
3 some indicia of need coming from the
4 physicians and from the patients themselves.
5 I think one thing that stands out
6 that is uncontrovertible fact, and that is
7 the Tidewater area, the Tidewater, Norfolk,
8 Virginia Beach standard metropolitan
9 statistical area with approximately a million
10 and a half people is the 27th largest FMSA in
11 this country and it is the largest
12 metropolitan area in the United States that
13 does not have a liver transplant program.
14 With over 100 programs, the Norfolk, Virginia
15 Beach area is the largest that doesn't have
16 one, and that --
17 MR. PERRY: Excuse me, 100 liver
18 transplant programs?
19 MR. MCCANDLISH: More than 100.
20 MR. PERRY: And only 30 are
21 accredited, is that right?
22 A SPEAKER: 30 training programs.
23 MR. PERRY: 30 training programs,
24 all right.
25 MR. MCCANDLISH: When you are

1 looking at issues of travel time and distanc
2 and population with respect to transplant
3 services, there is a prior decision of the
4 commissioner with respect to implementation
5 of kidney transplant services at Roanoke
6 Memorial Hospital, and we believe in this
7 instance there are many distinctions between
8 Roanoke Memorial's kidney transplant
9 application and the Sentara Norfolk General
10 application, but all of those distinctions
11 strongly favor the Sentara Norfolk General
12 program.
13 We have done an outlying comparisor
14 at Exhibit B and we have provided some
15 quotations from the staff report requesting
16 or recommending approval, and we provided the
17 Certificate of Public Need itself.
18 And basically in terms of capital
19 cost, comparability, and in terms of a
20 variety of factors, comparability, the
21 factors that demonstrate strongly that this
22 program is a more justified, more appropriate
23 program, number one, hugely different
24 population to be served, much larger
25 population in this situation than was the

1 case in the Roanoke Memorial application, an
2 so the travel factors that lead the
3 commissioner to approve a transplant program
4 at Roanoke Memorial were somewhat similar or
5 really less compelling travel difference
6 between I'm going to Roanoke or going to
7 Charlottesville, are really much stronger in
8 this situation and affect many more people.
9 The second factor is that in terms
10 of the hurdle to come to establish the
11 program was much greater in the Roanoke
12 Memorial situation. They didn't have an
13 existing transplant program, and so they had
14 to develop all of the infrastructure
15 necessary for a successful transplant progran
16 which is a significant challenge that Sentara
17 does not have to overcome, and so the
18 decision to recognize the need in that case
19 despite the lack of an existing transplant
20 program is even more compelling.
21 And I think another factor just in
22 terms of the volume of the transplants that
23 came from that area before in relationship to
24 the minimum volume standard discussed in the
25 State Medical Facilities Plan gives an

1 indication also. In that matter there were
2 32 transplants from the area in the previous
3 year versus a minimum volume standard of 25,
4 so slightly more.
5 In this situation we have 28
6 transplants from our region in the last year
7 versus a minimum volume standard in the SMFP
8 of 12, so more than double the minimum volume
9 standard, and we would submit that when the
10 hearing officer is looking at the standard
11 for judging need, that the Roanoke Memorial
12 decision gives a base line that demonstrates
13 very clearly this project ought to be
14 approved.
15 With respect to the quality
16 program, I have already discussed that and I
17 won't belabor that.
18 With respect to the alleged impact
19 on MCV, we will have discussion on that, but
20 at the outset I would simply note that the
21 training and the research initiatives that
22 MCV has testified to were all undertaken and
23 predominantly operated in that time period
24 from 1991 to 1995 when the MCV program
25 operated successfully at volumes between 30

1 and 40 per year, and so they had their
2 program and operated it successfully at those
3 levels.
4 Well, in 1996 there are increasing
5 numbers of liver transplants. In 1996 they
6 went up to over 60 patients per year, and if
7 we were to hit the numbers that we have
8 suggested and MCV did not even increase its
9 rate of growth or did not even increase, it
10 continued to grow as it has in the past, but
11 simply stayed flat, we still would not reduce
12 MCV down even to something approximating the
13 level that it successfully operated at in the
14 past, so I think the comments that MCV has
15 made with respect to the training and
16 research issues need to be placed in that
17 context, and there will be some more direct
18 discussion of it.
19 With that background I'd like to
20 bring Dr. Ryan forward.
21
22
23
24
25

1 01184

2 MICHAEL J. RYAN, M.D., having

3 previously been duly sworn, testifies as follows:

4

5 BY MR. MCCANDLISH:

6 Q Dr. Ryan,'s curriculum vitae is at

7 tab C, but I'd like you to introduce yourself for the

8 record, Dr. Ryan, and give some of your educational and

9 work background.

10 A I'm a practicing gastroenterologist

11 and liver specialist in the Tidewater area. I trained

12 at Johns Hopkins first as a medical student and then

13 internal medicine residency for three years and then

14 went to Yale New Haven Hospital from 1982 through 1984

15 and have been practicing in the Tidewater area for 13

16 years.

17 Also our group, my partner is the

18 chief of gastroenterology at the medical school. We

19 are the predominant group at the medical school, and

20 I'm an associate professor at the school.

21 Q And your specialty is?

22 A Gastroenterology but particularly

23 liver disease. I do almost all the liver teaching for

24 the school.

25 Q And let's turn now to the question

1 of liver disease in Tidewater, growth, and incidence o
2 liver disease and how that relates to the need for
3 transplant services in Tidewater.
4 A Things have changed dramatically
5 since I left Yale. When I was at Yale, we tried to
6 start a liver transplant program, and at that point
7 there were less than 100 transplants being done per
8 year in the whole country. They were initially
9 unsuccessful for surgeons moving away and political
10 reasons, but obviously liver transplantation has grown
11 tremendously, and now over 4,000 liver transplants don
12 per year, and hopefully as a nation we can get to abou
13 5000 per year.
14 Back in the late '80's I would
15 occasionally send somebody out and sent many people
16 out, sent a few people to Pittsburgh at that time when
17 Medical College of Virginia's program wasn't as strong
18 as it is now, and I have sent many people to Universit
19 of Virginia, I have sent some people over to Hopkins
20 including Medical College of Virginia, but lately
21 predominantly Medical College of Virginia.
22 The numbers have steadily
23 increased. I had one week, two weeks ago I had five
24 new liver transplant candidates, and it has become
25 increasingly clear, and I have made the comment severa

1 times, we need a van, we need a bus to go back and
2 forth to the Medical College of Virginia now because we
3 have such a large volume of patients that require
4 transplant evaluation, they are going to require post
5 transplant care, in addition to some of the medical
6 aspects of the liver disease.
7 Because of this we have tried,
8 really made a concerted effort to get involved with the
9 research aspect, to provide the front line in medical
10 research for those liver patients now. Dr. Shiffman
11 and I are involved in a multi-center study together
12 right now with Hepatitis C patients. We visit a
13 tremendous number of those patients. We now know that
14 1 out of every 60 people in the country are infected
15 with Hepatitis C, so we are looking at 4 million
16 people, estimate that 20 percent of those end up with
17 cirrhosis and 20 percent of those may need a
18 transplant, so we are looking at tremendous volumes
19 just on hepatitis besides all the liver diseases that
20 are there.
21 They can't all be served up in
22 Richmond. We are trying to build up our liver center
23 in addition to providing transplantation which is just
24 one part of following that continuum of disease as
25 well.

1 So the numbers have steadily grown.
2 We are trying to build up the medical and in addition
3 to the surgical aspects.
4 And I can show you in one of these
5 exhibits we have just formed, and this is under U, we
6 just formed, I think it's under U, we just formed a
7 liver research group and multi-center study group --
8 Q Exhibit J.
9 A -- with Sentara, Medical College of
10 Virginia itself, University of Virginia, Johns Hopkins,
11 and Fairfax Hospital we are all in MALT.
12
13 MR. PERRY: MALT?
14 THE WITNESS: MALT, yes.
15
16 A We all formed this group so we are
17 all involved in it, medical group. Interesting name
18 for it. Not advertisement for the MALT liquor, but
19 MALT, and we are trying to embark on many different
20 studies, so we are trying to bring that research to the
21 Tidewater area, not just the surgical aspects.
22 Q At the present time you have noted
23 the growth of Hepatitis C and other factors that are
24 increasing the need for liver transplant, and there are
25 also some developments with respect to organ

1 availability that help to support the response to the
2 increase.
3 A Well, there are many different, I
4 mean we have been able to increase the number of organs
5 that are available, not as much as we would like.
6 There clearly have been improvements in surgical
7 techniques. Split livers are becoming more prominent
8 in surgical procedures.
9 I don't know where xeno
10 transplantation or animal transplantation is going.
11 That may be five or ten years down the road, but that
12 is coming, and we need to be ready for it. The number
13 of liver patients just continues to grow and grow and
14 grow.
15 Q Look at some historical utilization
16 at Exhibit E.
17 A If you look at Exhibit E, you can
18 see that the number of transplants in the State of
19 Virginia has steadily grown, and that's due to improved
20 procurement and public awareness. You can see that was
21 grown on average actually 30 percent per year. Medical
22 College of Virginia actually went up 70 percent between
23 1995 and 1996 which may be one of the reasons we are
24 here too. I think that's been difficult for them to
25 handle. I think that they have had increasing numbers

1 of patients. Dr. Sanyal himself has said that they are
2 almost overwhelmed. They have had so many patients it
3 is hard to keep up. I think they have seen that partly
4 because of the drop in University of Virginia, but they
5 have seen tremendous numbers going up at this point.
6 Q Look at Exhibit F, and that's
7 identified specifically our service area patients who
8 have obtained liver transplants, and as I understand it
9 the regions refer to the area where they actually
10 received their transplants?
11 A Region 11 is our OPO which consists
12 of Richmond and Virginia Beach and the Tidewater area,
13 and you can see out of that area there were 24 that
14 received -- the 28 people that received the liver
15 transplant out of our service area last year, 24 of
16 them got it at Medical College of Virginia. 2 of them
17 it appears got it out of Fairfax or that area, and 2
18 may have gone down to San Antonio down in Texas.
19 Q All right. Let's turn to what's
20 been marked as Exhibit G, and can you identify that as
21 a projection for liver transplant need for 1998 from
22 the Norfolk General service area using the statewide
23 use rate?
24 A This is, the source for this data
25 is also from UNOS, but the projected need for our

1 service area in 1998 would be that 37 people out of our
2 area would require a liver transplant.
3 Q And do you anticipate that that
4 number will continue to grow because of factors that
5 you have discussed?
6 A Well, the need will be higher than
7 that. The number of patients that get transplanted I
8 hope will grow too. Just a matter of how many organs
9 we can procure and what techniques we can come up with.
10 Q Let's turn to the question of how
11 the patients that come from the Norfolk General service
12 area currently interact with their care for liver
13 disease and ultimately with transplantation. Can you
14 explain to Mr. Perry the obstacles and problems that
15 they encounter?
16 A The patients are initially referred
17 from their primary care physician to a
18 gastroenterologist because of either abnormal liver
19 blood tests or finding they have Hepatitis C on a
20 routine blood donation or they have already had some
21 clinical manifestation of their liver disease, so at
22 that point they will encounter the gastroenterologist,
23 and you heard Dr. Shiffman say that these patients
24 develop end stage disease at different rates. Some of
25 them are fairly quick, and they may be a few months,

1 six months, or a year. Most of those diseases though
2 are years, and some of these bile duct diseases,
3 cholestatic diseases can take ten years or more.
4 These patients then usually develop
5 a fairly strong bond with their physicians. They know
6 that they are going to get into trouble at sometime
7 down the road. When it comes time to send them away,
8 all of a sudden I have said time to go away, meet all
9 these new physicians, and this is when you are going to
10 need a liver transplant. That's been pointed out to me
11 that's got to be difficult for somebody to leave an
12 established relationship where they have a lot of faith
13 and go to a whole new set of physicians.
14 And then at Medical College of
15 Virginia they may see several physicians in addition to
16 residents. Then they have to go through evaluation and
17 then they have got to get all the data back, and that
18 can often take quite a long time. We have had many
19 times two or three months that it will take a while,
20 and Dr. Shiffman alluded to that. We have had a few
21 tough times where we have had trouble getting that
22 done.
23 It requires them to come up here
24 for three days. They have to stay. We had one patient
25 say I'm going to lose my job. I can't keep working and

1 do that.

2 And then if they do get accepted

3 and they get listed, then they will come back anywhere

4 from one to every three months depending on the

5 situation. Most of the time every month or so to kind

6 of get reassessed where they are on the list. That is

7 difficult if they are going to try and work and try and

8 remain in the functioning population, they have a hard

9 time doing that.

10 Then when they come up here and

11 they get transplanted, you heard it's three to four

12 weeks in Richmond. If they are going to come up with

13 their family, the whole family is displaced, they are

14 not working either. If they have small children, they

15 are all coming up here, and that is a major

16 inconvenience. I know that the centers, whether it be

17 Fairfax, Medical College of Virginia, have tried to

18 provide places for these people, still not easy for

19 these families to do that.

20 You have heard post transplant

21 that's usually once a week and usually twice a week

22 that they have got to be seen at least that often, and

23 then many of these patients develop rejection or they

24 are going to develop some technical problems. The

25 surgeons will tell me that at least 50 percent of them

1 will require rehospitalization. C1193

2 We heard Mrs. Kelliher tell us that

3 even six years out she was seen five times in two

4 weeks, so these people come back a lot.

5

6 MR. PERRY: For kidney problem.

7 MS. KELLIHER: May I interrupt? I

8 know it is out of order.

9 MR. PERRY: No, ma'am, you may not.

10

11 A But these people come back very

12 frequently, and they frequently develop complications,

13 so they are back a lot.

14 Even if we were to have a clinic I

15 think in the Norfolk area, I'm not sure that's going to

16 address the complications that they develop who is

17 going to take care of them at nighttime which is a

18 problem. They get sick and they get sick quickly.

19 Q You talked about the interruption

20 in continuity of care. Do you believe that that has an

21 impact on patient outcomes as well?

22 A I think it does, I think the

23 patients can tell you that it does. We did a focus

24 group that's in your exhibit here. We did a focus

25 group, and we were asked, I was asked to submit names

1 of patients that are pre transplant as well as post
2 transplant, and they were asked many of these
3 questions.
4 Q Let's turn to what is marked as
5 Exhibit D. Can you just reflect to Mr. Perry what is
6 presented in that application?
7 A I did not participate, I did not
8 participate at all in this focus group nor did I make
9 up any of these questions. On page 5 in D there is an
10 executive summary here and then there is also the full
11 report.
12 But on question 5 you can see they
13 were asked had they experienced in their medical care
14 anything that could have been done better. And if we
15 go down three lines there, Medical College of Virginia
16 physicians were not aware of their medical conditions,
17 faxes sent from Dr. Ryan got lost.
18 Q Let me just, at the outset can you
19 confirm that this was done by market researchers and
20 analysts. You said you were not directly involved, an
21 independent research firm?
22 A A firm out of Richmond and Newport
23 News.
24 Q Okay.
25 A And subsequently that patients as

1 well preoperatively, they had many concerns. Patients
2 come back to me. If I sent them up here and they have
3 not heard from Medical College of Virginia or they feel
4 like information is not getting transmitted, I'll
5 obviously get complaints and get them back.
6 The patients who have already been
7 transplanted, you can see in that next paragraph
8 several felt the physicians here had not followed up
9 with them, that they had fallen through the crack, and
10 Dr. Shiffman and I work together, and I don't want
11 alienate us any more, but there has been one patient
12 that hasn't heard from Medical College of Virginia in
13 over two years. I don't know how they can report
14 whether she is alive or not. I did send Dr. Shiffman a
15 note that she hasn't seen them.
16 There have been patients that have
17 fallen through that haven't gotten their reports back,
18 and I think everybody has that problem, but these
19 patients are so sick they can't really afford that.
20 Clearly if it's local, if they are
21 nearby, they know how to get us, they know how to deal
22 with us. It's a lot more effective.
23 One of the problems we have had
24 with Medical College of Virginia is dealing with the
25 ancillary staff, with the cardiology and the pulmonary

1 staff. I know how to get Dr. Shiffman. I have
2 actually called him at home in the middle of a snow
3 storm to tell him I couldn't get results one night. He
4 will respond. But as far as the cardiology and the
5 pulmonary departments go, I don't know how to deal with
6 them, and that has been a major problem and a major
7 source of complaints.
8 Q Those should be cured by working
9 with the staff at Sentara Norfolk General where you do
10 know how to deal with them?
11 A Yeah, I sure know how to deal with
12 them.
13 Q Any other comments?
14 A I think if you read this, which may
15 take a while to read, the patients develop, I have been
16 impressed by reading this, the bond that they develop,
17 the faith that they develop in their physicians is
18 incredible that they develop over time, and I think
19 that's an important part of this whole process.
20 These patients really need careful
21 follow-up. They need feedback. They often don't get
22 it as quickly as they should. I'm fairly faithful with
23 trying to do that. I think just dotting the i's and
24 crossing the t's, you have to do it every day on every
25 patient, and I think it's tough sometimes in an

1 institution where there is a lot of rotating physicians
2 as well.
3
4 MR. MCCANDLISH: Mr. Perry, you
5 have the summary derived from material which
6 is in a form we thought would be most helpful
7 for you. We do have the original tapes you
8 can peruse through if you like. We are not
9 suggesting that we think that's necessary,
10 but we'd be happy to make them available if
11 you have any questions.
12 MR. PERRY: Thanks.
13 MR. MCCANDLISH: Would you like to
14 take them?
15 MR. PERRY: No thanks.
16 MR. HEDBERG: Mr. Perry, I'd like
17 to ask just one clarification point. The
18 sampling method in the report reflects that
19 Dr. Ryan contacted each patient who
20 participated by letter. I was wondering if
21 he might be able to describe how the patients
22 who participated in the study were selected.
23 THE WITNESS: We took any -- is it
24 okay if I answer the question? We took my
25 whole list of patients that were on the

1 transplant list and all the patients that had
2 been done. They were actually, the firm,
3 this firm made up a letter which I put my
4 signature to and said if you would like to
5 participate in a focus group regarding the
6 possibility of liver transplantation being
7 established in the Tidewater area, please
8 contact us. So they were left to contact us.
9 I never spoke to them about this. It was
10 just a letter from this focus group.
11 MR. MCCANDLISH: I believe that
12 protocol was described in the exhibit.
13 MR. PERRY: That's what he was
14 reading from. Go ahead. Proceed.
15
16 BY MR. MCCANDLISH:
17 Q Let's turn to what's been marked as
18 Exhibit H which is a letter from Dr. Klein, and you
19 want to comment on Dr. Klein's letter?
20 A Dr. Klein, Dr. Andrew Klein is the
21 chief of the transplantation division at the Johns
22 Hopkins Hospital. He's the director of the liver
23 transplant program as well. He's also the director of
24 the comprehensive transplant center.
25 He is in addition the UNOS liver

1 and intestine transplant committee chairman, and he has
2 written a letter in our behalf, and he said the concern
3 that initiation of a second program would dramatically
4 reduce our volume, and I can tell you how he came about
5 this proved to be unwarranted.
6 Several years ago the University of
7 Maryland opened up a program a few miles from Johns
8 Hopkins which was a major concern to them. Despite the
9 University of Maryland opening, it has not reduced the
10 volume at Johns Hopkins. And Dr. Klein goes on to say
11 it has actually improved quality because of the
12 competition.
13 In addition he goes on to say in
14 the next paragraph on the second page that, about the
15 clinical research that it has actually fostered, that
16 the research has improved.
17 I would hope if we have a
18 transplant center we certainly don't plan not to do
19 research, we'd like to continue to do multi-center
20 studies, and we can see we are trying to do that. My
21 CV states we are doing a great deal of research as
22 well. But the research has not been affected by
23 opening up a second program in only a few miles.
24 The next to last sentence there,
25 the paragraph here says Medical College of Virginia

1 would still exceed the requirements for fellowship
2 training by a substantial margin even if Sentara opened
3 up a program.
4 Q And would you turn to what's been
5 marked as Exhibit I which includes physician letters in
6 support of the project?
7 A You want me to go over this first
8 one?
9 Q If you just comment on that.
10 A Dr. Busuttil from UCLA has written
11 a letter in support as well, and mainly supporting the
12 transplant surgeon that we have started to talk to
13 who's interested in helping us start the program. I'll
14 leave that for you to look at.
15 We also have support letters from a
16 number of physicians throughout the community. All
17 these physicians have been involved, either
18 gastroenterologists have been involved in the
19 transplant program which includes the renal transplant
20 surgeons, the cardiac surgeons, the ones dealing with
21 the pulmonary or lung transplant program as well.
22 We have letters from the infectious
23 disease people and we have an infectious disease person
24 who is actually trained in the Medical College of
25 Virginia and did some research in transplantation.

1 In addition we have support from
2 the pathology department which has been made much
3 stronger in the last few years, and they are well
4 familiar with transplant. We have a dedicated
5 gastrointestinal liver pathologist as well, so I think
6 we have put everything in order. The infrastructure is
7 there.
8 Liver transplantation right now is
9 only second in volume to kidneys in this whole country.
10 Despite that we are doing hearts and heart lungs and
11 doing them successfully with a tremendous success rate.
12 I have never pushed for liver
13 transplant. I have been here for 13 years, but it's
14 become increasing clear that we need it, we have the
15 volume to support it. It's become a hardship on the
16 patients. It is particularly hard on the indigent
17 patients. Many of them have no transportation to get
18 back and forth. Out of those five people I saw two
19 weeks ago, two are indigent. One of the problems we
20 have right now, there are no slots in the State of
21 Virginia for indigent patients.
22 Q What do you mean by slots?
23 A The Medical College of Virginia has
24 allotted two slots per year for indigent patients to be
25 done. You can ask them, but it is my understanding

1 that those slots have already been taken through at
2 least this year and possibly 1998. We have budgeted
3 for at least one if not two for indigent patients to be
4 done per year, possibly more depending how the program
5 goes. So one of the major problems is the indigent
6 patients can't, they particularly can't get here.
7 Q Establishment of your program at
8 the Sentara Norfolk General will increase the
9 availability for indigents in part because of the
10 travel issue and in part because of the availability?
11 A Right, and also the medical care as
12 well, the whole continuum, the medical care for them as
13 well and the Hepatitis C as well.
14 Q Let's turn back to the question of
15 MCV, and is it, you indicated that you had received
16 some indication from persons associated with MCV of
17 challenges in handling the volume that they have
18 currently, that the program is quite busy currently?
19 A Well, they--
20 Q Explain that.
21 A Medical College of Virginia had
22 four hepatologists and they transiently fell down to
23 three and then they are back up to four, but the
24 numbers haven't increased. You can see that their
25 numbers, they have gone up 70 percent since 1995 to

1 1996, so they are handling all these patients. In
2 addition that means they are going to see a lot more
3 transplant evaluations as well.
4 And you saw Dr. Shiffman said that
5 40 percent of what he sees are transplant patients.
6 That's a lot to do. In addition they are trying to do
7 their research. Dr. Shiffman is away lecturing a lot,
8 involved with lot of national committees as well. It
9 is difficult for them to keep up. It is difficult
10 sometimes to get them in.
11 Now when I send somebody to the
12 Medical College of Virginia, as far as I'm concerned
13 they are pretty much evaluated. I have stopped
14 evaluating, I have stopped doing cardiac and pulmonary
15 workups because they'll get repeated if I send them up
16 there.
17 So, when I send them up there, they
18 are ready to go. The problem is when I'm ready to go,
19 it may take a few weeks, a month, sometimes longer to
20 get them in up here. Then it takes time for them to
21 get evaluated, so the process is drawn out right now.
22 They are having trouble handling
23 all the patients because there's that many. We have
24 all seen a tremendous growth in the number of liver
25 patients. Fifteen years ago we couldn't do anything

1 for the hepatitis patients. We can do a lot now.
2 Q You referred previously to the
3 willingness to continue in multi-facility research
4 efforts, but would you comment specifically on why
5 MCV's discussion about coming to DePaul and doing some
6 clinic work is inadequate to meet the need in
7 Tidewater?
8 A We need full time. I mean if we
9 are going to have somebody do transplant work, they
10 need to be down in the area full time. What we heard
11 is that a significant number of these patients develop
12 complications post procedure. They need to be, their
13 physicians need to be in the area to deal with them
14 when they get sick, and at least 50 percent of them are
15 going to be rehospitalized.
16 So even if they come down and set
17 up their clinic, it's half a day or one day a week, I
18 don't know how they are going to do that. I don't know
19 how they are going to drive back and forth to do that.
20 But if they do, they are going to have, they are still
21 not going to be able to handle them if when get sick in
22 the evenings. They are still not going to be able to
23 deal with when they need to be hospitalized. They are
24 still going to be coming back up 64 at this time.
25 There is no reason we can't work medically together.

1 The surgery, all these things need to be done in
2 Tidewater with the size of the population.
3 Q Can you comment on the timing of
4 MCV's overtures towards Sentara? Did they come after
5 Sentara indicated its intent to file for Certificate of
6 Need?
7 A Well, we filed the Certificate of
8 Need. I need these notes to help me here a little. we
9 filed the Certificate of Need in July. Then we
10 received letters asking us to meet with them, and we
11 met with Medical College of Virginia twice. We
12 actually asked them for a proposal, what do you have in
13 mind, how would you look to work with us. We never
14 received a letter. We never received a letter of how
15 would you like to work with us.
16 We heard, and these statistics were
17 good, survival was good, we provide you excellent care,
18 that was it. We didn't get a request for how we would
19 like to work with you.
20 We went, next thing we really heard
21 from Medical College of Virginia was in March that they
22 wanted to open up a clinic at Sentara. We then said we
23 are not sure that you really mean this, we have not
24 heard from you in months, but we are willing to talk,
25 we are willing to open up discussion. Actually that

1 letter was not sent to the gastroenterologist, it was
2 sent to the Sentara administration, maybe around to
3 gastroenterologists in the community but to the Sentara
4 administration.
5 We still had not heard, and next
6 thing we heard was this week that they are going to
7 open up a clinic at DePaul.
8 There has really not been an
9 attempt in any way to include the gastroenterologists,
10 liver specialists at all in the Tidewater area.
11 Q Do you have any further comments
12 for Mr. Perry on just the overall need as you see it?
13 A No. I just think it goes back to
14 we are seeing increasing numbers, and really the
15 concept of continuity of care. These patients see
16 their physicians for a long period of time, and all of
17 a sudden that umbilical cord is broken. They come up
18 here, and you can see in this focus group some of those
19 patients feel like they are numbers, not all, but some
20 feel like they are numbers.
21 There is no reason to break that
22 continuity, not when we have such a large population
23 that we can do this as well in the Tidewater area.
24 We are in addition trying to build
25 up the research aspect. We are doing a tremendous

1 amount of research on the cardiac transplant side, on
2 the kidney stuff as well. The infrastructure is all
3 there. There is no reason we can't do this as well.
4
5 MR. MCCANDLISH: Anything
6 questions?
7 MR. PERRY: Yeah. Why did you ask
8 MCV for a proposal as opposed to saying what
9 kinds of terms you would like to see them
10 provide you?
11 THE WITNESS: Well, we, I don't
12 know if we did not. We did talk. We had two
13 meetings, and those meetings went on for well
14 over an hour. I think we have all evolved
15 through this. I'm not, I'm not sure we
16 didn't do that though as well.
17 We never, the discussions never
18 went any further. They never came back and
19 said well look, what would you like, can we
20 do this together.
21 MR. PERRY: But they did offer to
22 extend their services down there in some
23 fashion at Sentara Norfolk General?
24 THE WITNESS: I can't speak to
25 that. I didn't get the letter, but they have

1 offered to open up a clinic. 01208

2 MR. PERRY: It's your understanding

3 that's what occurred though?

4 THE WITNESS: (Witness nods head)

5 MR. PERRY: And that was rejected

6 by the hospital or --

7 THE WITNESS: No, I don't think it

8 was outright rejected. It was we are open

9 for discussion, but we are not sure we

10 believe your sincerity since it took from

11 July to March to get that letter.

12 MR. PERRY: Okay. And that all

13 happened subsequent to the filing of the

14 application?

15 THE WITNESS: The application in

16 July of '96.

17 MR. PERRY: Okay, thank you.

18 MR. MCCANDLISH: Thank you, Dr.

19 Ryan. Chris Burge.

20

21

22

23

24

25

1

2 CHRIS BURGE, having previously been
3 duly sworn, testifies as follows:
4
5 BY MR. MCCANDLISH:
6 Q Could you introduce yourself for
7 Mr. Perry and the record and state your position at
8 Sentara? You can talk to Mr. Perry.
9 A All right. I'm Chris Burge,
10 B-u-r-g-e, and I'm some of the infrastructure to which
11 Dr. Ryan has referred. I'm employed with the Sentara
12 Health System. My responsibilities there are to manage
13 the solid organ transplant program as well as
14 responsibility for strategic planning and program
15 development for the cardiac, the vascular, and the
16 transplant program. And in addition I administer our
17 research programs for those same three areas.
18 Q Can you describe your involvement
19 in this project and how it's developed?
20 A I have been involved with this
21 project for a year now since its very inception, was
22 involved with the decision to file the Certificate of
23 Public Need, intimately involved in the actual
24 application process, and have continued to be involved
25 with every aspect of program development including the

1 recruitment of staff, physicians, et cetera.
2 Also I directed the financial
3 aspects, pro forma, et cetera, for the application
4 process.
5 Q Can you describe for Mr. Perry how
6 the project will relate to the existing infrastructure
7 and transplant program at Sentara?
8 A This program truly shows some of
9 the benefits of already having a transplant program.
10 For example, we just have me as the administrator and
11 will continue that. My support staff again will
12 support both programs.
13 On the professional side, things
14 like our immunology lab to which Dr. Fisher referred,
15 that's the same lab that's used for all programs. We
16 have the types of experts, quite frankly people that
17 have their doctorate in pharmacy are intimately
18 involved in immunosuppressant medications, an atrophic
19 support for the transplant patients, and those will be
20 one in the same people for liver transplants. Also
21 other people such as the pathology department and even
22 physicians such as our infectious disease physician who
23 is a specialist in treating transplant patients, so
24 that same team will also work with the liver program.
25 Q I know Mr. Perry is very familiar

1 with Sentara, but just for the record could you just
2 discuss a little bit about Sentara's overall role in
3 the health care delivery system in Tidewater?
4 A Sentara Health System is the
5 largest integrated health care system in the state. We
6 currently own four hospitals, are affiliated with the
7 fifth. I'm sure you are very familiar that we have a
8 proposal to merge with the Tidewater health care
9 system. We have an insurance division, mental health
10 facilities and programs, home health, long term care,
11 and also physician office practices, so we are truly an
12 integrated health care system. Our mission is to
13 provide for the wellness as well as managed illness for
14 the people in our community.
15 Q Can you comment on the indigent
16 care mission for Sentara?
17 A Sentara is a not for profit
18 organization, so by its very nature we take care of an
19 indigent population. We each year spend in excess in
20 the millions, somewhere this year as we just finished
21 our fiscal year, somewhere between 20 and $30 million
22 when you count all the indigent care that we give as a
23 system.
24 Q Can you comment on the role that
25 Sentara plays within teaching at the Eastern Virginia

1 Medical School?

2 A We are the primary teaching

3 facility for the Eastern Virginia Medical School. Many

4 of our physicians, Dr. Ryan already referenced it

5 today, are on the staff as professors at the medical

6 school, and then also educationally we provide all

7 kinds of nursing programs, et cetera, for the region.

8 Q Can you comment on the role that

9 Sentara Norfolk General plays as a tertiary care center

10 for the region?

11 A Sentara has been for many many

12 years and continues to be a tertiary care center for

13 the region that we serve.

14 Q Does that include, can you outline,

15 Tidewater, Virginia plus Eastern Shore?

16 A Yes. Really our primary service

17 area for Sentara is, as Mr. McCandlish said, the

18 Eastern Shore. We also go in, we consider 70 miles our

19 primary service area, so that does go as high as

20 Williamsburg, out to Suffolk, Franklin area, and it

21 does cut down into the eastern North Carolina area, so

22 that's why you see on any proposal we include that

23 because those people depend on us very much.

24 Q For that area including for the

25 east, northeast North Carolina, you are the closest

1 tertiary level facility?

2 A Yes, absolutely.

3 Q Let's turn to the exhibit book, and

4 starting with Exhibit K, if you'll just identify

5 briefly for Mr. Perry what's included there?

6 A Mr. Perry, these letters represent

7 the support that we have in the area from some of our

8 elected officials who are bound to support the

9 community. You'll see from the legislators as well as

10 the majors of Norfolk and Virginia Beach.

11 Q Now let's turn to what's been

12 marked as Exhibit L, and can you identify what is

13 included there?

14 A Yes. This is a very simple

15 breakdown of some of the costs of bringing up the

16 program as well as the fixed costs or the costs we

17 would continue to have with the program. As you can

18 see there, our total outlay in capital expenditure for

19 this project is, we have estimated to be just under

20 62,000. It's very very small. The reason we can do

21 that is because of all the tertiary care that we

22 currently do at Sentara Norfolk General.

23 Then I think it's real important to

24 take those numbers and start breaking them down per

25 patient per year so you can truly see the impact, what

1 we call the fixed costs, the costs that are going to be
2 there whether we do 1 or 20 transplants, and as you can
3 see, if you look at really every patient that we touch
4 or evaluate becomes very light.
5 Q And bottom line, the entire capital
6 costs or the fixed annual, fixed costs of the program
7 is exceeded substantially by the cost of one
8 transplant?
9 A Absolutely.
10 Q Okay. Let's turn to what's been
11 marked as Exhibit M. Can you identify what is included
12 there?
13 A Yes. These are, and its source
14 there is from the Virginia Health Services Cost Review
15 Council. One of the things that Sentara quite frankly
16 is known for is the provision of high quality services
17 at very low charges. And this is just a sketch of some
18 of those from this report. One I'd like to highlight
19 in particular is the cabbage procedure, the heart
20 procedure. We are tremendously --
21 Q That's coronary artery bypass?
22 A Yes, thank you. We are
23 tremendously low there in our charges and have superior
24 outcomes for that program. I think why that particular
25 line item is significant to this hearing is that one of

1 the physicians that you'll hear from today, Dr. Glenn
2 Barnhart who is the medical director of our heart
3 transplant program, this is his heart program, and I
4 have every expectation that with his leadership, the
5 liver program will have some of the same benefits.
6
7 MR. MCCANDLISH: Mr. Perry, without
8 belaboring the issue, obviously, in many
9 Certificate of Need applications we are
10 talking about costs and charges as a
11 significant part, and our point here very
12 simply is that we think it should be readily
13 accepted Sentara has established a record of
14 being a high quality low cost provider, and
15 it should be clear from that record that the
16 impact of having Sentara with these
17 transplant services will be to help lower the
18 cost of all these services.
19
20 Q Let's turn to what's been marked as
21 Exhibit N, and can you identify for Mr. Perry that?
22 A Yes. This is a professional travel
23 study. We have heard many comments today on the travel
24 and how far people go and how long it takes. This was
25 provided by the Langley and McDonald Company. There's

1 a couple things I'd like to highlight in there.
2 What we had, the part of this study
3 was the obvious I think, you have people who simply
4 drive from Norfolk to Richmond or the Virginia Beach
5 area to see how far it takes. They have documented in
6 there if you drive from the interchange of 64, 44 up to
7 Richmond, no tunnel traffic, no backups, yes, you can
8 get there in an hour and 40 minutes, but then they
9 additionally mention that in a one month period there
10 were --
11 Q Before we get to that complication,
12 there are a large number of census tracts --
13 A Yes.
14 Q -- which, because of the additional
15 travel time to those census tracts, even in normal
16 periods, are more than two hours from MCV?
17 A Yes. If you look at the last page,
18 what they did was actually totaled the numbers of
19 people that are more than two hours from the transplant
20 center, and it's total there is 379,753.
21 Q Then you were referring --
22 A There's a map.
23
24 MR. PERRY: These are people from
25 Carolina?

1 THE WITNESS: Yeah, there's Suffolk
2 and Chesapeake, Eastern Shore, and then
3 behind this there is a map that gives you the
4 specific areas.
5 MR. MCCANDLISH: We would submit,
6 Mr. Perry, that even though they are not
7 Virginians, they deserve some access to
8 services.
9
10 A But the issue besides the number of
11 people is that for example if you yourself have ever
12 tried to get from Richmond to Virginia Beach in the
13 summertime during the day, you are very hard pressed to
14 get there in under two hours, so that's a point they
15 make is that's not a very dependable estimate.
16 Q There was more, in a one month
17 period it refers to more than a hundred incidents of
18 travel interruption which would add --
19 A 15 to 30 minutes easily to your
20 travel time.
21
22 MR. PERRY: Is there a two hour
23 travel standard, is that what the story is,
24 there's a two hour travel standard?
25 MR. MCCANDLISH: There was a two

1 hour travel standard which was interpreted in
2 the Roanoke situation.
3 MR. PERRY: Oh, okay. Let's move
4 on.
5 MR. MCCANDLISH: We believe the two
6 hour standard is satisfied. Even if you
7 concluded it were not, we still believe the
8 project should be approved.
9 MR. PERRY: I drive home frequently
10 enough to know that it takes approximately
11 two hours.
12 MR. MCCANDLISH: When you are
13 lucky.
14 MR. PERRY: No, regardless.
15 MR. MCCANDLISH: You have been
16 speeding a little bit.
17 MR. PERRY: No.
18
19 A One additional thing that I'd like
20 to point out when we talked about our costs, our
21 charges, et cetera, the Department of Health staff
22 report did make some mention that perhaps our
23 evaluation listing, et cetera, numbers were high. We
24 still believe those are accurate because we'd be
25 bringing up a new program. There may be patients that

1 would be double listed patients. Some of it simply is
2 when you say the evaluation process starts, so we still
3 stand by those numbers.
4 Q Do you have any other final
5 comments for Mr. Perry?
6 A Yes. One thing that I think it's
7 important for you to understand that with the Sentara
8 Health System, and we talked about bringing liver
9 transplantation into our repertoire, is that saying we
10 are going to have a high quality low cost program
11 doesn't apply just to the transplant program. This is
12 the very aim of Sentara's mission in their value.
13 This project has the full support
14 not only of the administrative staff but the full
15 support of our board of directors who are very
16 committed also to making this a very successful
17 program.
18
19 MR. MCCANDLISH: Thank you. Any
20 other questions?
21 MR. PERRY: I don't think I do.
22 Thank you very much.
23 MR. MCCANDLISH: Dr. Barnhart's CV
24 is included at Exhibit O.
25

1 01220

2 GLENN REID BARNHART, having

3 previously been duly sworn, testifies as follows:

4

5 BY MR. MCCANDLISH:

6 Q Dr. Barnhart, perhaps you can just

7 briefly outline your educational background and work

8 experience?

9 A Right. I went to college at

10 Bridgewater College, went to medical school at the

11 Medical College of Virginia and did most of my training

12 there. General surgery and cardiac surgery, two years

13 of that was interrupted by going to the National

14 Institutes of Health doing cardiovascular research and

15 six months on the end at Boston Children's because of

16 my additional interest in congenital heart surgery, and

17 then came back on the staff at MCV for about a year and

18 eight months, and then at that time I went to Sentara

19 in '89 where I have been since that time.

20 Q And you serve currently in what

21 capacity at Sentara?

22 A I am a heart surgeon and the

23 director of the heart transplant program at Sentara

24 Norfolk General and the chairperson of the Transplant

25 Leadership Council.

1 Q In that capacity can you comment on
2 the ability of Sentara Norfolk General to bring this
3 liver transplant service within the transplant program?
4 A Well, I think one would need to
5 restep back if you allow me for a few moments to share
6 with you the history there. The kidney transplant
7 program was initiated in early 1970's, and that has
8 really grown and prospered and done well with the
9 various phases of leadership. It really was the
10 foundation upon which allowed us to come in and very
11 easily start the heart transplant program.
12 Heart transplantation is obviously
13 very closely connected with cardiac surgery but also
14 requires the support mechanisms and the infrastructure
15 and culture, if you will, to be able to be able to
16 succeed, and we started that in 1989.
17 Since then we have done 120 heart
18 transplants, we have done an additional 20 children's
19 heart transplants at the physically adjoined Children's
20 Hospital, and there have been also 22 heart lung and
21 lung transplants performed. That program was started
22 about 1991 by one of my partners that we recruited from
23 Stanford.
24 We also have started an LVAS
25 program which stands for left ventricular assist

1 systems. We are one of 20 centers in the country using
2 this particular system called the Novacor left
3 ventricular assist system which allows us to support
4 patients who are critically ill who can no longer wait
5 for a heart transplant on medical treatment, and that
6 program likewise has been very successful and has
7 substantially reduced the number of deaths while
8 waiting for heart transplantation.
9 So I think if you look at the whole
10 program, it has evolved and it has grown because of
11 sort of constant nurturing by everybody involved there
12 wanting to see successful results in clinical
13 transplantation.
14 The other thing that has been added
15 since we have been there because of the increasing need
16 was our local immunologist. The hospital has been very
17 supportive in that regard, and so our immunology lab is
18 very vibrant and productive, and the clinical
19 immunologist who we have participates weekly in all of
20 our conferences, and we have him involved in the
21 clinical issues that arise constantly.
22 Q And can you talk about the cost
23 efficiencies of using your existing structure and
24 systems for this program?
25 A Well, what we have found over the

1 last, it's probably just become evident I guess over
2 the last several years is that with the advent of
3 recognizing that we really aren't just a kidney
4 transplant program and a heart transplant program,
5 especially with the inception of the lung and the heart
6 lung program, we took a much more comprehensive look at
7 the programmatic issues, so we created the solid or the
8 transplant unit of which the Transplant Leadership
9 Council oversees, and that has allowed us to look at
10 issues that cross all of those disciplines such as
11 immunology, such as transplant coordinators, research
12 efforts, and has formulated into the transplant center
13 which has been supported overwhelmingly by the Sentara
14 administration, and we now have an administrative
15 structure which Ms. Burge has outlined, so I think that
16 really has allowed us to be very cost effective.
17 The other issues that we are able
18 to provide or the other problems that we are able to
19 solve with this type of cross fertilization, if you
20 will, is that we have recently been introducing a trend
21 in medical care is the issue of clinical pathways or
22 critical pathways in trying to be much more objective
23 about the care we do render to patients, and we have
24 championed some of that in cardiac surgical services
25 and adapted it to cardiac transplantation and we are

1 doing the same in the other form of organ
2 transplantation and will plan to do that with liver
3 transplantation because it clearly impacts and reduces
4 the cost of care plus simultaneously it allows one to
5 study performance indicators, to look at clinical
6 outcomes, and if they are substandard or not what you
7 want them to be, then you can scientifically and
8 objectively change them, modify what you are doing, and
9 move on.
10 Q I take it that you have concluded
11 that Sentara can and will, if given permission,
12 establish a high quality liver transplant program?
13 A There is no question in my mind. I
14 think all of us want to see that succeed. I have to
15 comment when Dr. Klein came for his site visit, one of
16 his comments initially was that, and this is Dr. Klein,
17 the letter that was written.
18 Q From Johns Hopkins?
19 A From Johns Hopkins, commented if
20 the cardiac surgeons are supportive of this, half the
21 battle is over. I say that in jest, but in seriousness
22 also, because quite often cardiac surgery is resistant
23 to a huge program like this potentially coming in, huge
24 in terms of capital resources and that type of thing,
25 taking over some of their terrain so to speak, but we

1 as a group discussed it early on. We had some
2 controversy in our group, but we have elected to
3 support it, and the reason being is because we want to
4 see our own specific interest being cardiac
5 transplantation, lung and heart lung transplantation
6 flourish, but we realize that is not going to happen
7 unless we continue to foster an environment of solid
8 organ transplantation.
9 The hospital clearly has supported
10 that over the past, since I have been there, since
11 1989, and it is clear to me that they will go all out
12 to do a first rate job regardless of the specific organ
13 that is involved.
14 Q All right. Let's turn to what's
15 been marked as Exhibit P. Can you comment to Mr. Perry
16 on what that is?
17 A Exhibit P demonstrates the results
18 of solid organ transplantation at Sentara Norfolk
19 General. I would point out to you under the kidney
20 column that these are one year survival rates, graft of
21 kidneys, 94 percent, and the SMFP standard is 90 to 95
22 percent. Under heart, and again these are specific
23 time periods, the time period that was studied there is
24 '90 to '95. One year survival rate was 95 percent.
25 Our overall one year survival rate in a heart

1 transplant program is actually about 90 percent. The
2 SMFP is 70 to 80 percent. We don't have a standard to,
3 benchmark to judge the SMFP but we do have a HCFA
4 standard for the lung transplant program is 62 percent.
5 Lung transplantation at Norfolk General is 66 percent.
6 Lung transplantation is still in a phase of evolution
7 and is clearly a few years behind heart transplantation
8 and kidney transplantation.
9 Q You have heard some comment on
10 numbers and quality and how those relate, and I wonder
11 if you could turn to Exhibit Q and just make comments,
12 Q and R, and address any comments you'd like to make
13 about transplant volume and quality.
14 A Well, let me preface the documents
15 by saying that, you know, with a heart transplant
16 program that was concern initially that we had, and we
17 have been, in the scheme of things, a relatively small
18 volume heart transplant program but it certainly has
19 not affected our results. One year we did eight heart
20 transplants, and we primarily do about 12 to 15. This
21 year we are a little bit busier, but it comes and goes.
22 If you look at one year survivals, it is pretty
23 standard across the board.
24 Exhibit Q demonstrates that there
25 are programs that do relatively small to what I would

1 consider very small number of transplants, 6, 8, 9 and
2 10 in terms of liver transplants in which their
3 survival rates are actually very good. How does one
4 explain this? Well, I think that a tremendous amount
5 of effort has to be put into the acquiring of skilled
6 surgical care and medical care. I think that the
7 personnel issues are key. They are of fundamental
8 importance to make the success of the program
9 initially, but more importantly initially I think long
10 term. It's the long term maintenance of the program
11 that is particularly important. It has to be
12 constantly cultivated over time.
13 Q And a similar analysis from Exhibit
14 R?
15 A Exhibit R really looks at the same
16 question from a different way. There are different
17 metropolitan areas that have been sampled, and if one
18 looks at those metropolitan areas, it doesn't
19 necessarily mean that a bigger program is better. You
20 can see that we have chosen ones here that obviously
21 take our position, but it is just that point, that
22 there can be programs that are large but don't
23 necessarily have the same survival rates as programs
24 that are small and serving the same metropolitan area.
25 Q Can you discuss with Mr. Perry, you

1 have heard some concern from MCV that there would be a
2 negative impact on MCV in one way or another. Would
3 you comment on those assertions?
4 A I guess I really don't sense that
5 to be the case. I can understand their concern,
6 honestly, but I believe that that concern could and
7 shall be offset by a continuing effort for a regional
8 approach to all the issues that have been discussed
9 here. Clinical care and research I think are foremost.
10 We can't lose focus of what the issue is here. The
11 issue is patient care, and research is important to
12 advance the cause of patient care, but the first
13 fundamental issue is patient care. And I think because
14 of the issues that we have proposed in terms of access
15 and availability, I think that that is the most
16 important issue that can't sway our decisions.
17 I believe that the, there will be a
18 transient period where there will be some diminution in
19 volume at MCV. I don't think it will be significant, I
20 don't think it will be sudden.
21 In fact there were, I must say that
22 there were similar concerns an analogy can be drawn
23 with us opening a heart surgery program with Virginia
24 Beach General several years ago and the impact upon the
25 Sentara program. In fact what happened was there was a

1 transient period of a loss of a small amount of volume
2 and there was a dip and then both programs have just
3 grown right along, so I would think that the situation
4 would be pretty analogous to that.
5 Q There was some discussion about the
6 benefit of having only one provider with the ability to
7 manage the waiting list. Can you comment on that?
8 A I'm going to defer most of that
9 discussion to Dr. Colonna because he is an expert in
10 that area. I'm not a liver transplant surgeon but I do
11 know that there are a couple of areas in which UNOS
12 right now is looking to change the criteria, the
13 uniform status to address some of the issues that Dr.
14 Shiffman has made, some of the issues and concerns that
15 he has raised.
16 There is one area I would like to
17 clarify. I want to make sure that everyone is clear on
18 this, that the, when a patient is transferred from one
19 center to the other, let's say that this does come
20 about and we open on that day, the patient's waiting
21 time is transferred with that patient, and I just want
22 to make that point, that the patient doesn't lose
23 anything in that. Again it focuses on the patient.
24 It's not like that those patients have to go back to
25 ground zero, but most of that discussion I think Dr.

1 Colonna will be able to handle. 01230

2 Q Do you have any other comments for

3 Mr. Perry?

4 A I do. I have three areas that I

5 would like to address. First is there's been a lot

6 said here today about research. I don't want to lose

7 sight of the fact the Sentara program has really placed

8 a lot of emphasis on clinical research. We are not

9 basic science researchers but we are interested in

10 clinical research and advancing the issues that arise

11 in our observations of patient care and participating

12 in those.

13 The cardiovascular and transplant

14 center as it is organized administratively and

15 clinically has a nine member staff, and this is just

16 for research. They have seven advanced practice nurse

17 coordinators, they have one research analyst, and one

18 secretary. And what those individuals do with the over

19 25 research projects that are just in cardiovascular

20 and transplant, they provide a cooperative effort, a

21 comprehensive effort to go out into the community and

22 address some of the issues obviously that Dr. Fisher

23 has raised about follow-up. We take a very pro active

24 stance on that, and that's why in many of our studies

25 with the cardiac surgery under this program our

1 follow-up rates are in excess of 98 to 99 percent
2 because this is all these individuals do is that they
3 participate in the research aspects of the program.
4 That is a program that is supported
5 by the hospital but the attempts are made to keep that
6 revenue neutral so that those individuals through
7 research funding support themselves, and to date so far
8 that has worked successfully.
9 The second issue I'd like to raise
10 is the issue of indigence because in my mind I think
11 that is a very important issue. The heart, when we
12 started the heart transplant program in 1989 we felt
13 very strongly about the issue of indigent care, and we
14 made the statement and the position, took the position
15 that we really didn't want to have a program that had
16 any sort of limitations and restrictions at that time,
17 and it still remains true today that many programs have
18 an entry fee of say 30 to $50,000 up front to be able
19 to open the program, to be able to be listed.
20 There are other ways to handle that
21 such as you have heard today at MCV and UVA which they
22 have two indigent patients per year. I'm proud to say
23 that in the heart transplant program to date we have
24 not had to turn away a patient because of purely
25 financial reasons. We have not done that.

1 My administrators always get
2 nervous when I state that, but it is something that we
3 work very hard at. We exhaust all possibilities, and
4 so far we have not had to do that.
5 That means that we, the program
6 basically runs off of a revenue neutral position, and
7 we have been successful today. We know we can't break
8 the bank if we are constantly reassessing that, but we
9 are still trying to keep that position.
10 Finally one issue I think is very
11 important in all of this is, I don't think of us should
12 lose sight of, is long term follow-up is becoming more
13 and more important, the maintenance of a program,
14 seeing patients back on a yearly basis. It has become
15 clear to all of us that any organ is a precious
16 national resource that can't be reproduced anywhere,
17 and that is one of the reasons that we are here with
18 this issue because there are only a limited number to
19 go around. How those organs and therefore those
20 patients are cared for years 5, 6, 7 and 8 become
21 increasingly more important so that we can get more
22 mileage, if you will, out of those organs.
23 And I think local access,
24 availability to care locally for a very committed firm
25 serious program is of fundamental importance to

1 accomplish that goal.

2 Q Thank you.

3

4 MR. MCCANDLISH: Mr. Perry, do you

5 have other questions?

6 MR. PERRY: Thank you very much.

7 MR. MCCANDLISH: Dr. Hurwitz. Dr.

8 Hurwitz's CV is at Exhibit S.

9

10

11

12 RICHARD L. HURWITZ, M.D. having

13 previously been duly sworn, testifies as follows:

14

15 BY MR. MCCANDLISH:

16 Q Dr. Hurwitz, would you just briefly

17 outline for Mr. Perry your background and experience

18 and current position?

19 A I'm Richard Hurwitz. I'm a

20 vascular and kidney transplant surgeon, an associate

21 professor of surgery at Eastern Virginia Medical

22 School.

23 I guess I'm here wearing three

24 hats. One hat is as director of the kidney transplant

25 program. The other hat is medical director and

1 chairman of the board of Life Net which you have heard
2 is the organ procurement organization for both Richmond
3 and Tidewater. And the third hat is president of the
4 private practice group who will be recruiting the liver
5 transplant surgeon to our community.
6 With regard to the kidney
7 transplant program, I took over its direction in 1976,
8 and we recently did our 1,000 kidney transplant. Up
9 until 1991 when UNOS changed the rules of allocation,
10 the program at Norfolk General did more than UVA and
11 MCV combined in terms of number of kidney transplants
12 per year, but that has changed since 1991 because of
13 allocation.
14 We are currently participating in
15 two national multi-center studies for our kidney
16 transplant patients and one regional study. We have a
17 transplant clinic in the hospital where many hundreds
18 of patients who have been transplanted are followed,
19 and patients are evaluated to go on the kidney
20 transplant list.
21 Q Okay. There's been some discussion
22 about organ availability, allocation, and waiting
23 lists. Can you comment from your myriad of
24 prospectives on that issue as it affects this
25 application?

1 A As Mr. Perry knows, I'm sure, that
2 one of the most critical issues in organ
3 transplantation is organ availability. Life Net serves
4 the transplant centers in Richmond and in Norfolk, and
5 for the most part one organ procurement agency serving
6 more than one transplant center, there is a requirement
7 to have a common list so that all patients are listed
8 on one list, and that indeed would be the case if
9 Sentara Norfolk General started a liver transplant
10 program.
11 I'm proud to say that Life Net is
12 an OPO, performs in most categories in the top third of
13 OPO's around the country, and there's various ways to
14 gauge that in terms of donors per million and number of
15 organs retrieved per donor, et cetera.
16 Last year Life Net procured 62
17 donors, and from those 62 donors, 57 livers, most of
18 which were, 49 were transplantable, and most of those
19 were transplanted at the Medical College of Virginia.
20 More than 20 of those donors were procured at Sentara
21 Hospitals who continued to work closely with Life Net
22 to give strong support for organ procurement.
23 Fortunately less than 50 percent of the time when
24 organs can be procured is permission obtained, and
25 that's a national average. We have actually been above

1 the national average, but that is part of the crisis
2 that we have and part of the need to have a strong
3 hospital community and strong programs in the organ
4 procurement organization.
5 With regard to allocation, if for
6 example MCV had 75 patients waiting on their list
7 currently and if 25 of those were from Tidewater, if we
8 opened a program, if those patients chose, they could
9 come down to Tidewater, get on the list at Norfolk
10 General Hospital, and carry with them the time that
11 they have accrued waiting.
12 If there is no change in their
13 status, if they do not qualify to be moved to a sicker
14 status, then there would really be no difference in
15 their ability to be transplanted with Life Net organs,
16 and there would be no difference in waiting list
17 mortality, but it is a patient's right to transfer to
18 any program that they want.
19 Q Can you comment briefly just on the
20 future prospects for increasing the availability of
21 organs through, and especially in the liver through
22 split liver and stuff like that?
23 A The, I may leave that to our liver
24 transplant surgeon, but Life Net continues to develop
25 very aggressive hospital development programs, and the

1 62 donors that we had in 1996 were up considerably from
2 the year before which saw less than 50 donors. It's a
3 bit of fluctuation, but nationally the way, the rate of
4 increase of organ donors is only about 4 percent a
5 year, and it's hard to break that number, but
6 aggressive policies and an active OPO are certainly
7 required to do that.
8 Q Can you discuss with Mr. Perry your
9 efforts toward recruitment of a liver transplant
10 surgeon?
11 A Yes. I must say that we haven't
12 had to go out and beat the bushes. As soon as the word
13 got out that we were considering opening a program, we
14 had inquiries from many people, and we have been very
15 pleased to attract the attention of a very qualified
16 person who is quite interested and ready to commit if
17 we should get a program in the Norfolk area.
18 And I would like to introduce him
19 if that's appropriate.
20 Q Yeah, I think that is. Dr. --
21
22 MR. HEDBERG: Before we get to
23 that, I have got one point of clarification
24 on Dr. Hurwitz's testimony about the waiting
25 list. His testimony seemed to suggest that

1 the allocation of organs might not be based
2 solely on wait list time even when patients
3 from MCV transferred to Norfolk if they
4 choose to do that.
5 MR. PERRY: I don't think he said
6 that. I think he said they would not lose
7 their wait, their initial wait date, in other
8 words they would transfer but they would have
9 the same date that they had been placed on
10 the waiting list.
11 MR. HEDBERG: But he also testified
12 there would be no impact on the waiting list
13 mortality and that suggests some flexibility
14 that Dr. Shiffman testified would be
15 eliminated, and that's what I'm seeking
16 clarification of.
17
18 A I'm glad you brought that up. I
19 would like to comment that unless a patient gets sick
20 enough to move to a more critical status, that you are
21 not suppose to shift who gets a liver. If you do, if
22 there is a need to do that, then a letter needs to be
23 written to UNOS to explain why you bypassed one patient
24 within that category to go to another, and sometimes
25 that's necessary.

1 Historically I understand that that
2 is rarely done, rarely has been done in Life Net, that
3 there has not often been a need to do that. The way to
4 move somebody up the list is to establish that they
5 qualify to be in a sicker category.
6
7 MR. PERRY: Because they are more
8 critically ill?
9 THE WITNESS: More critically ill.
10
11 BY MR. MCCANDLISH:
12 Q And that would apply across the
13 board?
14 A Yes, and the point I was trying to
15 make is that although having one list at MCV is not
16 different than having two lists if the same patients
17 are included because there is a common list that
18 encompasses those two centers.
19 Q Let's turn to what's been marked as
20 Exhibit T which is Dr. Colonna's curriculum vitae and
21 if we may proceed to introduce him.
22 A As I mentioned, we have been
23 fortunate to attract the attention of Dr. Colonna who,
24 although not born in Virginia went to high school here,
25 went to college, and went to medical school at the

1 Medical College of Virginia. As you can see he did the
2 rest of his surgery training in California and was a
3 fellow in liver transplantation at a program in 1990 to
4 '92. At that time the program was the second largest
5 volume liver transplant program in the country, and now
6 I understand this is the most active program in the
7 country.
8 John is currently the director of
9 organ transplantation at Walter Reed and finishing up a
10 stint for the U.S. Army. He has been to the Norfolk
11 area to look at the transplant situation, to evaluate
12 the potential of joining our private practice group.
13 There are five of us currently
14 doing vascular and transplant surgery. My group is the
15 only group that performs kidney transplant, so he would
16 fit in will as a member of an organ transplant team,
17 abdominal organ transplant team.
18
19 MR. MCCANDLISH: And Mr. Perry, I
20 would note for you there is a letter that was
21 previously introduced with exhibit --
22 MR. PERRY: I remember seeing that.
23 MR. MCCANDLISH: All right, from
24 Dr. Busuttil who was a part of the
25 postoperative training program for Dr.

1 Colonna.

2

3 A I would like to add we just haven't

4 produced him for this meeting. We checked references.

5 He's had a couple visits and we have gotten to know

6 each other pretty well.

7 Q Any other comments you'd like to

8 direct to Mr. Perry?

9 A Just answer questions.

10

11 MR. PERRY: Thank you.

12

13

14

15 JOHN OWEN COLONNA, M.D., having

16 previously been duly sworn, testifies as follows:

17

18 BY MR. MCCANDLISH:

19 Q Dr. Colonna, you have already been

20 somewhat introduced for the record. Is there anything

21 you want to add about your background and experience

22 and perhaps also experience at the Fairfax Hospital?

23 A Well, as I said, I was not born in

24 Virginia but 10 of the other 11 generations of Colonnas

25 were. I did attend high school in Northern Virginia at

1 Lee High School and then went to Virginia Military
2 Institute for my biology degree, then had the pleasure
3 of attending Medical College of Virginia from '79 to
4 '83. At that point I was accepted for general surgery
5 residence training at UCLA, during that time did spend
6 two years in Dr. Busuttil's research lab on liver
7 transplantation, and then upon completion of my general
8 surgery residency was allowed by the Army to do a
9 clinical fellowship in liver transplantation prior to
10 coming to Walter Reed Army Medical Center where we do
11 kidney and pancreas transplants, and through a
12 cooperative agreement we have with both Fairfax
13 Hospital and Howard University Hospital, we do the
14 liver transplants with them at that facility.
15 I was asked to mention some of my
16 experience in Fairfax. In April of 1995 their liver
17 transplant surgeon took a job in Philadelphia and they
18 were suddenly left without a transplant surgeon. We
19 were interested in Walter Reed in continuing our
20 program while they were busy recruiting a new surgeon
21 and were allowed by the Army to continue our program
22 there and basically took over their program in the
23 interim, and between April of '95 until December when
24 my partner, Dr. Shaver, got out of the Army, went over
25 there full time, then through April of '96 when he

1 became qualified to be a UNOS certified liver
2 transplant surgeon, we performed 48 liver transplants,
3 and the one year survival on those 48 patients is 93
4 percent and the coming up on two year survival now is
5 88 percent.
6 Q So you have been personally
7 involved in a Virginia program and responsible for high
8 survival rates at that program?
9 A Yes, sir. I was the program
10 director listed with UNOS during that time.
11 Q And the Fairfax program started up
12 what year? 1992?
13 A '92.
14 Q Okay. And during the period
15 from -- when did you first become involved with that
16 program?
17 A Well, our agreement with Fairfax
18 Hospital began in '94, so I was working with Dr.
19 Mansobeitia (phonetic) in summer of '94 until April of
20 '95 when he left.
21 Q Let's talk directly about the issue
22 of quality and what factors are important toward
23 developing a quality program. Can you tell Mr. Perry,
24 please, why you believe you can conduct a quality
25 program at Sentara Norfolk General?

1 A Well, there are several things that
2 are important in having a successful liver transplant
3 program. As we see from the data that was presented
4 early, it is not at all uncommon for a new program to
5 start and initially have difficulty with their results,
6 and much of that is due to how do you start your
7 program? Do you just decide I'm going to do livers,
8 let's hire somebody and go, or is there a disciplined
9 and concerted effort to develop a good program.
10 It certainly helps that at Sentara
11 they have a well established kidney transplant program
12 and a very successful heart transplant program, so a
13 great deal of the infrastructure necessary to have a
14 transplant program is already there. They have
15 subspecialists who will consult on these patients who
16 know about the differences in transplant patients from
17 the general population, have an existing
18 histocompatibility laboratory and quite a long history
19 of support for developing and maintaining a successful
20 program.
21 Another thing which is a difference
22 that you will see in some of the newer data as it comes
23 out as a new program starts is who's starting these
24 programs. In the past programs were often started by
25 people coming right out of their fellowship. There

1 weren't that many people who were trained in liver
2 transplant. If a place wanted to start a program, they
3 usually get someone who is coming right out of
4 Pittsburgh or where ever to start a program. They were
5 often people who hadn't really been away from the
6 mother ship, if you will, for any period of time and
7 were starting off on their own. What you are seeing
8 more and more now is when people come to start or
9 rejuvenate a program, they are people who have had
10 experience, have a track record, who have had the
11 experience of starting a new program or running a new
12 program, and that's why I think you can expect to see a
13 program started by someone with experience, they are
14 going to do much better than those started by a very
15 inexperienced person.
16 Q Let's turn to what has been marked
17 as Exhibit U in the book. Can you comment on your
18 understanding of the existing and future need for a
19 program in a metropolitan area like Norfolk, Virginia
20 Beach?
21 A Well, it certainly, as you
22 mentioned earlier, it stands out that 27th largest
23 metropolitan area does not have its own liver
24 transplant program, and when you compare it to others,
25 there are actually some centers have more than are

1 listed here. The Los Angeles area now has six, San
2 Diego has two, San Antonio has two. But as the college
3 at MCV pointed out, you need to have a certain volume
4 to run a really good program, and that requires a
5 certain population base, and certainly the Tidewater
6 area meets that requirement.
7 Q Can you talk about -- you heard Dr.
8 Ryan discuss some of the need for continuity and local
9 availability of surgical and medical teams working
10 together. Can you comment to Mr. Perry?
11 A People who can be followed at the
12 transplant center in conjunction with the local doctors
13 who think they are at an advantage to those who have to
14 seek their care far away, and even if they are far
15 away, because some people have insurance plans that say
16 we send everybody to bam, bam, whatever, if they then
17 come back to the community that has a liver transplant
18 program, they are at an advantage, and in the military
19 at Walter Reed, we do that, have people transplanted at
20 Pittsburgh, all over the place.
21 In addition to those transplanted
22 on our own since we started, it allows patients access
23 to someone with a great deal of expertise who is
24 familiar with the complications and how insidious their
25 onset can be and allows those complications to be

1 picked up early when they are much easier to manage.
2 If you wait until the complication is really set in and
3 advanced, it is much more difficult to get these
4 patients through, and they can be quite fragile. Some
5 things aren't day to day and there are some things that
6 are. The patient can really rapidly deteriorate, and
7 if it is missed, they are in trouble.
8 Q There was a discussion earlier of
9 follow-up care, how often a patient would have to come
10 back to the hospital and a question about projection
11 rates and how that would influence the intensity of
12 follow-up care. Can you discuss that?
13 A As Dr. Shiffman alluded, the
14 average uncomplicated patient isn't that big of a deal,
15 but the average uncomplicated uncomplicated liver
16 transplant patient isn't the average liver transplant
17 patient. In most large series, it's anywhere from 40
18 to 60 percent of patients have episodes of rejections
19 which requires daily treatment, usually daily
20 monitoring of the response to the treatment at least
21 initially. After the first five, seven days, they
22 don't have to be checked every day.
23 Other complications, people who
24 have strictures in their bile ducts, et cetera, need to
25 often go back to the transplant center for a repeat

1 interventional radiology, et cetera.

2 So it can be, for individual

3 patients, quite a commitment to being in the area of

4 the university hospital or the transplant center, and

5 for, in this case, many of those patients would have

6 access to that level of care right where they live and

7 not have to make the frequent trips.

8 Q Okay. There's also been some

9 discussion of the effect of opening this program on

10 MCV. Can you discuss that from both a volume and

11 quality standpoint and from an accreditation for

12 fellowship program?

13 A Sure. As Dr. Barnhart said, I

14 think one could anticipate that perhaps eventually

15 there could be a small decline in numbers, and if you

16 look at the history of their program through the years,

17 when UVA opened up, they decreased for a couple

18 transplants. When Henrico Doctors' opened up, they had

19 a year where they may be a little bit down but they

20 continued to grow, and Fairfax opening up didn't make a

21 big difference, they just went ahead and broke their

22 record. So as their program continues to provide the

23 excellent care it does, they'll continue to grow.

24 As we have noted earlier and one of

25 the things, the annual number of transplants in

1 Virginia continues to grow and grow and grow, and
2 Virginia is a very fortunate state to have the quality
3 of liver transplant care it has. Many states would be
4 envious at this level of care.
5 Q With respect to the accreditation
6 fellowship program?
7 A We just had the American Society of
8 Transplant Surgeons meeting in Chicago this past week,
9 and that is always an interesting area to discuss
10 what's happening to fellows, and they actually invited
11 Dr. Dixon Kaufman (phonetic) who is at Northwestern to
12 find out what is happening to transplant fellows in
13 this country because everyone is kind of aware we may
14 be over saturating this market.
15 Q Meaning that there may be more
16 fellows than needed?
17 A I would, when you say there's more
18 fellows, there's not a shortage of liver transplant
19 surgeons in the country. And what he did was look over
20 the years as what's happening to transplant fellows.
21 In 1995, every transplant fellow who was U.S. Canadian
22 trained, if you will, had a job in transplantation. In
23 1996 there were 43 transplant fellows trained in the
24 country. Of those 14 were foreign medical graduates,
25 if you will, who had visas that said you leave in a

1 year, and none of them obviously stayed in the U.S. Of
2 the 29 U.S. Canadian trained, 27 had jobs. It was the
3 first time anyone had not gotten a job. In 1997, the
4 coming year, fully one quarter U.S. Canadian trained
5 transplant fellows don't have a transplant job next
6 year.
7 Some have gone back to their
8 primary specialty, general surgery, urology, or some
9 have elected to stay on, do a year of research to try
10 to make them more attractive to a transplant center.
11 About half of the people who do train and get a job,
12 it's where they train. The transplant center either
13 has a position or rather than send that guy off to
14 nowhere, keep them around, hopefully they'll be able to
15 get a job.
16 The percentage of foreign medical
17 graduates doing a fellowship increased to 50 percent
18 last year. In the discussion they had invited comments
19 by Dr. John Ajarien (phonetic) who's the chairman at
20 Minnesota and has trained many many transplant surgeons
21 in the country. His remarks were, back in the '70's
22 and early '80's, when he had a fellow, they had 12 jobs
23 to choose from, you take your pick. Nowadays he says
24 he's happy if they have one or two to choose from.
25 That doesn't account for the desirability of those

1 jobs.

2 They also had Dr. Barker from the

3 University of Pennsylvania, and both of them felt that

4 in terms of what's going to happen to transplantation

5 fellowships is that it will be largely market driven.

6 As people find there are not jobs, they are not going

7 to do the fellowship, much as what has happened in

8 anesthesia around the country.

9 And that the other thing, I think

10 there still will be a need for fellows, but the bulk of

11 that will be made up by foreign medical graduates.

12 In terms of the numbers required

13 for adequate training, that has undergone a number of

14 changes as Dr. Fisher noted in terms of what

15 constitutes adequate training for liver

16 transplantation.

17 Q Dr. Fisher I believe was referring

18 to a standard of 50 procedures for year for a program

19 for accreditation, and the concern that after 1999 if

20 their program is below 50 per year that that might

21 constitute a problem. Could you comment on that?

22 A I spoke to Dr. Kaufman specifically

23 on that issue and then actually Dr. Auchincloss who is

24 the head of transplantation at Massachusetts General.

25 The 50 number was due to go in effect for UNOS later

1 this summer like in June. Apparently they have
2 actually reconsidered and are changing their numbers,
3 that the American Society of Transplant Surgeons,
4 realizing that many traditionally strong transplant
5 programs aren't doing 50. Johns Hopkins didn't do 50
6 last year.
7 And what their -- the number 50 is
8 one item in their required criteria for certification
9 for liver transplantation. If a new program wants to
10 become certified, they will have to meet those
11 standards. Those that are existing when they are
12 recertified or up for recertification, they'll look at
13 the whole program and see, 50 is the number they like
14 to see, but if the fellows are meeting their surgical
15 case experience, which right now is they have to be
16 primary or assistant surgeon on 45 cases in two years,
17 which certainly MCV won't have any problem doing,
18 that's a plus. If the other things that are going on
19 in that fellowship may continue to put out a high
20 quality transplant surgeon, that will also count.
21 Q Can you turn to what's been marked
22 as Exhibit V, and perhaps you can discuss what's
23 included there from that perspective?
24 A This is Dr. Hugh Auchincloss who is
25 the transplant surgeon at Massachusetts General and

1 also the chairman of the education committee at the
2 American Society of Transplant Surgeons. These are the
3 people who make those numbers.
4 Just to show you what he has
5 required is that the patient -- the transplant fellow
6 during his transplant fellowship must take primary
7 responsibility for 75 new patients. That can be
8 kidney, kidney pancreas or liver. To be liver
9 certified, 45 of those new patients must be liver.
10 That's over a two year period, not a per year period,
11 so I think there's been the realization that maybe that
12 ladder was set a little high, the bar was set a little
13 high for many centers who continue to put out good
14 quality transplant surgeons despite not having the
15 absolute number of 50 per year.
16 Q Can you identify the next two pages
17 of that exhibit as the annual volumes for accredited
18 training programs in liver transplant?
19 A This is just showing the 30 ASTS
20 Committee approved liver transplant programs which are
21 certified in liver transplantation.
22 Q And a number of those are below 50?
23 A Correct, including UVA.
24 Q All right. There's been some
25 discussion of research and multi-facility research. Can

1 you comment on that and your willingness to participate
2 in research protocol?
3 A I think it's very exciting to hear
4 that Dr. Fisher and his team at MCV are interested in
5 collaborating with other centers since he's as far as
6 Nebraska and Baylor, et cetera, and certainly there is
7 no reason that couldn't be done with Sentara. In fact
8 I think it is much easier doing multi-center stuff if
9 the centers are close by. It's much easier for us to
10 decide on what type of therapy we are going to agree on
11 and how to follow the patients, if they are as close as
12 a call or a drive away, then to met and review the
13 results, et cetera.
14 I would be very excited about the
15 opportunity to collaborate with them. Obviously as an
16 alumnus of MCV, I have an affection for that
17 institution, and it would be an honor to work with them
18 on any program.
19 During my fellowship at UCLA, we
20 were part of many multi-center studies, and even though
21 we were this hugh center that was doing 250 transplants
22 a year, we still participated in multi-center studies,
23 we didn't take the attitude well, we can do it
24 ourselves, we don't need anybody else's help.
25 Q Can you also comment on the

1 question of organ procurement and the management of the
2 wait list?
3 A Well, the management of the wait
4 list as Dr. Shiffman described is certainly something I
5 think certainly in principle is potentially an
6 advantage and one that at times during my career we
7 have been able to take advantage of that as well.
8 Where that causes concern or where
9 it's actually going to lose its ability is UNOS is now
10 instituting a mandatory minimum listing criteria, and
11 that basically a person has to be a certain degree of
12 ill to warrant being put on the waiting list, and this
13 has been done because there is a lot of concern among
14 different centers saying whatever allocation scheme you
15 are going to arrive at, we'll talk about that in a
16 little bit, we'd like to know that the playing field is
17 level.
18 Our patients are waiting X amount
19 of time and other patients are getting transplanted
20 quicker, they want to know that our patients aren't
21 being punished because they are here, that everybody
22 has the same degree of sick patients.
23 And there is the backup in the UNOS
24 system that as you get sicker, you move up in the
25 priority of allocation. So most of the list management

1 occurs on the Status 3 patients where there is the
2 greatest variability in how sick people are, and the
3 hope is that with this uniform listing criteria, that
4 difference is going to shrink.
5 The other thing, that does not mean
6 that things can't be done, and we have done this in
7 D.C., we did it in Los Angeles when an individual case
8 arrives or where there's a patient who may be further
9 down the waiting list but really needs to be done,
10 that's a phone call. We have done it at Fairfax with
11 Howard University where we had a patient who wasn't
12 doing well and their patient was up, they were already
13 out procuring a liver for one of their patients and we
14 had a patient who wasn't doing well, and we are not in
15 this to build empires despite what 60 Minutes would
16 say. We are here to take care of patients with end
17 stage liver disease.
18 Even arch rival programs like UCLA
19 and Cedars of Sinai use to be, when it's the bottom
20 line and if somebody is dying, the liver goes to them.
21 I would hope, particularly if there are two programs
22 that were collaborating on research, that is all going
23 to enhance that ability.
24 Right now MCV has a pediatric
25 program, and Dr. Fisher spoke to their success, and

1 that really lends itself very well to the new split
2 liver technology. They have a surgeon trained in
3 University of Chicago where they have pioneered much of
4 that, and that allows even more sharing so that one
5 center isn't hit with two simultaneous transplants. It
6 is easier if they are doing one and we are doing one,
7 as close as the two centers are, it's not like doing
8 one here and then sending one 6 hours on the plane.
9 So I think the relationship really
10 lends itself to those that can increase liver donation.
11 We spoke about Hopkins and
12 University of Maryland. They have recently been doing
13 that, splitting the livers, and these are two centers
14 that were all over the Baltimore Sun about how terrible
15 it was they were starving and vise versa, so when the
16 dust all settles, everyone is back trying to take care
17 of patients and those things work out.
18 Q Okay. Do you have any other
19 comments?
20 A The other thing on the list
21 management is it does sometimes give a bad taste to
22 people when someone finds out the patient who was
23 passed over, they are rarely called and said we are
24 passing you on a list. They are usually told when they
25 are evaluated that this is how the allocation scheme

1 works, and they have that expectation that's how it's
2 going to work.
3 Now most of them understand if you
4 tell them, but occasionally or most of the time they
5 don't know that and they hear about people who waited
6 two months and I have waited eight months, why is that.
7 Those kind of things wind up on the news or in the
8 newspaper, they hurt organ allocation. People think
9 there is gamesmanship going on in transplantation, and
10 it makes it less likely that people are going to donate
11 organs.
12 We have all seen, at least in D.C.,
13 a great slowing on our organ donation since the recent
14 60 minute thing on non heartbeat donors.
15 Another thing that may affect
16 ability to manage your waiting list is changes in organ
17 allocation which has now been sent to the Federal
18 Government, that we have had the hearings for DOT, and
19 they are going to come out with some statement.
20 At transplant meeting last Friday
21 we had a big seminar on that, and the conclusion of the
22 person who spoke about his impressions of the
23 government, the government didn't send a
24 representative, is that some change is going to be
25 made, and much of that change is expected to be

1 increased regional sharing, particularly for the status
2 one and status two patients, so I would imagine with
3 the uniform listing criteria, your need to manage your
4 list is going to be less, and with changes in organ
5 allocation, whatever comes down the road, probably your
6 ability to do it if you wanted to is going to be less.
7 And then with the backup, the two
8 centers that are working together, the sick person is
9 going to get the liver.
10
11 MR. MCCANDLISH: Unless you have
12 questions, we'll reserve further comments for
13 our written submission.
14 MR. PERRY: No questions.
15 MR. MCCANDLISH: Thank you.
16 MR. PERRY: Is that is?
17 MR. MCCANDLISH: Yes. We'll
18 reserve comment for our written submission.
19 MR. PERRY: Mr. Boynton?
20 MR. BOYNTON: Thank you very much.
21 A For a change, Mr. Perry, for these
22 kinds of hearings I'll be relatively brief. As perhaps
23 you know, even though the EVHSA staff had recommended
24 denial of this project, our board of directors on
25 November 12, 1996 recommended approval of the project

1 on a 6 to 3 vote after a wide ranging and in depth
2 discussion of many of the issues surrounding the
3 project.
4 As I advised Mr. Packer in my
5 November 13, 1996 letter which is also in the record,
6 the board recommended approval of this project because
7 it would improve the availability and geographical
8 accessibility to liver transplant services for P.D. 20
9 residents and because the project would also round out
10 the complement of transplant services that are
11 presently being provided at Sentara Norfolk General
12 Hospital.
13 Both our board and staff hold
14 Norfolk, Sentara Norfolk General and its present
15 transplant programs and staff in very high regard, and
16 the board felt that because of the quality of Norfolk
17 General's existing transplant programs is quite high,
18 the quality of its proposed liver transplant program
19 would also be quite high even though it would have low
20 transplant volumes in its initial years of operation.
21 As for the record, I'd like to take
22 this opportunity to submit our only exhibit for today
23 which is our Exhibit A. Our Exhibit A is the minutes
24 of the November 12, 1996 board meeting at which this
25 project was recommended for approval. I think it will

1 give you a sense of how detailed and comprehensive the
2 discussion of this project was by our board.
3 Thank you for this opportunity to
4 comment, and I will be pleased to attempt to answer any
5 questions you may have. I have already given copies to
6 Mr. Perry.
7
8 MR. PERRY: Anything else, Mr.
9 Boynton?
10 MR. BOYNTON: No.
11 MR. PERRY: Mr. Clement.
12 MR. CLEMENT: Thank you.
13 A This application was a very
14 difficult application for us to review. It presented a
15 number of difficult and complex issues which have been
16 spoken to today and issues that go well beyond the type
17 of issues that the COPN program normally deals with,
18 and certainly this application challenged the ability
19 of the COPN division staff to deal with the issues that
20 were presented.
21 My hope in preparing the staff
22 report was not to provide the final word on what should
23 be done with this application, although obviously we
24 did have to reach a conclusion and we did reach a
25 conclusion, but my primary hope was to provide a good

1 basis for the next step in this process, and we are of
2 course at that next step now, and I think the staff
3 report did provide that good basis for the next step,
4 but certainly we were not able to explore as fully as I
5 would have hoped and one might hope all of the issues
6 that this application presented.
7 The issues were presented not only
8 by the application of course but also by the opposition
9 to the application from MCV, and because of the
10 complexity and breadth of these issues, I was eager to
11 seek the advice of MCV and to seek their input, and I
12 raised a number of questions with them, and all that
13 material is in the record, I would just like to note my
14 appreciation to Brian Letourneau who was my point of
15 contact for providing responses to those fairly
16 numerous questions, and that was very helpful in our
17 review.
18 I think that simply to present our
19 report which of course is in writing and is very
20 lengthy obviously, I would just like to review the
21 points that were raised in the application and the
22 points in opposition and then offer our summary
23 findings and conclusions and recommendations on those
24 points.
25 The points in support of the

1 application, the first point offered by the applicant
2 was the travel from the Sentara Norfolk General area to
3 MCVH is burdensome for liver transplant patients and
4 families for some parts of the Sentara Norfolk General
5 service area, travel time to MCV exceeds the SMFP
6 standard of two hours.
7 In opposition to that, MCV Hospital
8 said that access is easy and that patients have
9 testified to the convenience and the quality of care at
10 MCV.
11 The second point in support of the
12 application by the applicant, the number of liver
13 transplant patients from the potential Sentara Norfolk
14 General service area for liver transplantation
15 constitutes an adequate case load for a new program.
16 In opposition to that, MCV Hospital said that they have
17 ample capacity to serve the existing and future case
18 load from the Sentara Norfolk General area, and the
19 possibility that Sentara Norfolk General would meet
20 minimum volume standards is not a sufficient reason to
21 establish a new liver transplant program.
22 The third point in support of the
23 application is that Sentara Norfolk General is a long
24 established provider of transplant services and has had
25 excellent results with existing transplant programs.

1 In opposition to that, MCV stated a new liver
2 transplant program would have higher mortality and
3 morbidity than MCV's existing program.
4 The fourth point in support of the
5 application was that a liver transplant program at
6 Sentara Norfolk General would eliminate the medical
7 risk of transferring acutely ill patients from Sentara
8 Norfolk General to MCV. It would reduce problems of
9 non optimal communication and lapses in the continuum
10 of care.
11 In opposition to that point, MCV
12 said that dividing one larger case load into two
13 smaller ones diminishes the opportunity to manage the
14 overall pool of patients for optimal outcomes.
15 The fifth point in support of the
16 application, Sentara Norfolk General is an established
17 provider of transplant services for other organs.
18 Establishment of this program would require few new
19 resources and little new costs.
20 Along with that, Sentara Norfolk
21 General said that a liver transplant program there
22 would eliminate the cost of transferring acutely ill
23 patients from Sentara to MCV and also that the liver
24 transplant program at Sentara would eliminate the costs
25 associated with duplicate performance of services,

1 tests, and procedures which often occurs when patients
2 begin their liver care under a Sentara physician and
3 then enter the transplant program at MCV.
4 In opposition to those three just
5 stated points, MCV said that a new program would result
6 in higher overall costs and higher costs per case for
7 liver transplant services in Virginia.
8 And then MCV also offered as
9 additional points in opposition that reduction in the
10 MCV transplant volume would negatively affect
11 transplant training at MCV, and further that reduction
12 in the MCV transplant volume would negatively affect
13 transplant research at MCV.
14 Of course all those points have
15 been dealt with here, and I think this discussion has
16 advanced our collective state of knowledge of these
17 points.
18 But based on the material that we
19 had in the application and that we subsequently got in
20 follow-up contact with the applicant and in subsequent
21 considerable communication with MCV, we reached these
22 ultimate findings:
23 The potential service area for an
24 SNGH liver transplant program encompasses about 1.6
25 million persons. Establishment of a liver transplant

1 program at Sentara Norfolk General would markedly
2 improve geographical accessibility of liver transplant
3 services for much of this population, even though more
4 than half of this population lives within two hours
5 driving time of MCV.
6 While establishment of a liver
7 transplant program at Sentara would substantially
8 improve geographical accessibility of services, it does
9 not appear that it is a huge burden for most persons to
10 travel to Richmond for these services. This
11 consideration favors approval of the application but
12 only modestly so.
13 Secondly, the question of Sentara
14 Norfolk General achieving at least the standard of
15 minimum annual liver transplant volume in a reasonable
16 period of time is not a significant issue. Sentara is
17 likely to perform at least 12 liver transplants per
18 year within two to three years of establishing that
19 program.
20 Sentara has been able to achieve
21 and maintain at least the minimum annual heart
22 transplant volume even though heart transplantation is
23 a substantially lower volume and at least in Virginia a
24 more crowded field than liver field than liver
25 transplantation.

1 Third, when data is carefully
2 examined, there is little to substantial the contention
3 that a liver transplant program operating at Sentara
4 Norfolk General's likely volume would be expected to
5 experience high mortality. The statistical link
6 between transplant program volume and mortality is very
7 weak except historically for a few centers that
8 performed only two or three transplants per year over a
9 period of several years and a few centers that began
10 operation and then soon terminated, suggesting that
11 severe operational problems were encountered.
12 Regression analysis performed by
13 the Division of Certificate of Public Need found that
14 at most only 5 percent of the variation in graft
15 survival among transplant centers was explained by
16 transplant volume.
17 The question of large costs being
18 added to the health care system as a result of this
19 project is not a significant issue. Some, but a very
20 modest net addition of cost is likely. About 90
21 percent of expenses shown in the Sentara Norfolk
22 General pro forma are already present at Sentara
23 Norfolk General.
24 MCV's contention that a single
25 facility waiting list permits better management of

1 patients and better results than a two facility waiting
2 list is regarded as plausible and important. This
3 consideration favors denial of the application. There
4 appears to be a significant likelihood but not
5 certainty that establishment of a liver transplant
6 program at Sentara Norfolk General would cause MCV to
7 fall below the minimum annual volume of 50 transplants
8 now required to maintain accreditation as a site for
9 liver transplant fellowship training programs. This
10 consideration is viewed as important and favors denial
11 of the application.
12 Finally, our conclusion, there is
13 little reason to believe that establishment of a liver
14 transplant program at Sentara Norfolk General would
15 harm research activities at MCV. It might even
16 compliment them. Those were our findings.
17 Our recommendation: First, we
18 recommend denial of the application for the following
19 reasons:
20 No substantial need for the
21 proposed new service has been demonstrated.
22 Two, a single facility waiting list
23 as now exists with only one liver transplant program in
24 the organ procurement organization's area permits
25 better management of patients on the waiting list and

1 decreases waiting list mortality.

2 Third, establishment of liver

3 transplant program at Sentara Norfolk General Hospital

4 has a considerable probability of reducing volume at

5 MCV to a level that would harm training programs now in

6 operation at MCV.

7 And that is the staff report, and I

8 would just say that had we had at the time of the staff

9 report and had we had the ability and the time to

10 digest all the information presented here today, we

11 might have taken a different tact, we might have taken

12 a slightly different view. I certainly cannot say that

13 because this was a collective decision.

14 This was a very difficult

15 application for us to evaluate and it did receive a

16 great deal of thought, and we do stand by the

17 recommendation that we made. Thank you.

18

19 MR. PERRY: Okay. Thank you very

20 much. Let's talk about closing this record.

21 The transcript will be available on June 3rd.

22 Will we need the transcript to offer up

23 proposed findings and conclusions?

24 MR. HEDBERG: I think we'd like to

25 have it.

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# COMMONWEALTH of VIRGINIA

*Department of Health*

RANDOLPH L. GORDON, M.D., M.P.H.
COMMISSIONER

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June 13, 1997

MEMORANDUM

TO: Raymond O. Perry, M.P.H., Adjudication Officer

FROM: Samuel A. Clement, Project Review Analyst,
Division of Certificate of Public Need

SUBJECT: Closing Argument: COPN Request No. VA-5969,
Addition of Liver Transplant Services, Sentara Norfolk General Hospital

## SUMMARY DESCRIPTION OF PROJECT, BACKGROUND INFORMATION, AND PRINCIPAL ISSUES

**Summary Description of Project.** Sentara Norfolk General Hospital ("SNGH"), one of the state's principal tertiary-care hospitals and an established provider of transplant services, wishes to add liver transplantation to their existing programs of kidney, heart, lung, and heart-lung transplantation. SNGH proposes to do this without significant capital costs--new equipment estimated at $54,400, plus legal fees. SNGH believes also that they can constrain the amount of new operating costs associated with the proposed new service, because they will rely substantially on existing personnel associated with their transplant center to serve the liver transplant patients. SNGH believes, and Division of Certificate of Public Need ("DCOPN") agrees, that within two or three years of program establishment, SNGH would have a minimally adequate number of liver transplant procedures per year, at least 10-15.

**Background Information.** Three hospitals in Virginia now perform liver transplants: Fairfax Hospital, University of Virginia Hospitals ("UVAH"), and Medical College of Virginia Hospitals ("MCVH"). MCVH began their liver transplant program in the mid-1980s. It was one of the first such programs in the country. UVAH began their program in 1988, at which time MCVH was performing approximately 20 liver transplants per year. Fairfax Hospital began their liver transplant program in 1992, at which time the two previously established programs were each performing 30-50 transplants per year.

Henrico Doctors Hospital performed five liver transplants in 1991, but none before or since. No new liver transplant programs have been established in Virginia since 1992. The three existing providers are now each performing 35-70 liver transplants per year, or about three to six times the minimum volume standard of twelve established in the State Medical Facilities Plan ("SMFP") and also by the Medicare program.

As the liver transplant program closest to SNGH, MCVH now provides more than one-half of the 25-30 liver transplantations per year on patients who reside in SNGH's tertiary-care service area. It appears that the MCVH program would be most affected by establishment of one at SNGH. MCVH expressed extensive opposition to this application, through a number of substantive written communications and through testimony at the Eastern Virginia Health Systems Agency ("EVHSA") public hearing. UVAH also submitted a brief letter of opposition to the SNGH application.

**Principal Issues.** The DCOPN staff report dealt with the following principal issues in evaluating this application:

1. The burdens, costs, and effects on patients of having to travel from the SNGH service area to MCVH for liver transplant services, including the pre-operative, operative, and post-operative services.

2. The number of liver transplant patients from the SNGH service area, the proportion that might use a program at SNGH, and whether this would be an adequate caseload to support a new program.

3. The quality issues associated with a new liver transplant program at SNGH, considering SNGH's experience in transplantation and the extent of statistical association between program volume and patient/graft survival.

4. Problems of continuity of care and acceptability of care related to SNGH-area patients beginning care in the SNGH area and then being transferred to MCVH care.

5. The comparative costs and the net additional costs associated with establishing a new liver transplant program at SNGH.

6. The effect on MCVH training programs of a new liver transplant program at SNGH.

7. The effect on MCVH research of a new liver transplant program at SNGH.

8. The effect of a new liver transplant program at SNGH on MCVH's management of their waiting list for optimum patient outcomes.

DCOPN's findings and conclusions with respect to these issues are summarized on pages 67-68 of the staff report. After extensive analysis of the issues, DCOPN recommended denial of this application. Only four of these issues were significant in the recommendation. DCOPN's reasons for recommending denial were:

1. No substantial need for the proposed new service has been demonstrated. The burdens, costs, and effects on SNGH-area patients of having to travel to MCVH were not judged to be substantial, although they exist. Similarly, lessened continuity of care and lessened acceptability of care related to SNGH-area patients beginning care in the SNGH area and then being transferred to MCVH care were not judged to be substantial negative factors for patients, although they exist.

2. A single-facility waiting list, as now exists with only one liver transplant program in the organ procurement organization's area, permits better management of patients on the waiting list and decreases waiting-list mortality.

3. Establishment of a liver transplant program at SNGH has a considerable probability of reducing volume at MCVH to a level that would harm training programs now in operation at MCVH.

ASSESSMENT OF MATERIAL PRESENTED AT THE IFFC RELATIVE TO DCOPN'S RECOMMENDATION OF DENIAL

No Substantial Need. At the informal fact-finding conference ("IFFC"), MCVH presented material asserting that the DCOPN staff report very substantially overstated the frequency and duration of required travel to MCVH for liver transplant pre-operative and post-operative services. In developing the description of required travel (Table P, p. 55, and related text of staff report), DCOPN relied on oral and written communications from SNGH, in part supplementary to the actual application. DCOPN may have misinterpreted the information supplied, and SNGH may have given incorrect information. It must be assumed that MCVH knows more accurately what is required of patients in their program. DCOPN has no basis for disputing the testimony of MCVH on this point.

Furthermore, at the IFFC MCVH announced plans to establish a clinic at DePaul Hospital in Norfolk to provide many of the pre-operative and post-operative services required by liver transplant patients. Although this clinic would be staffed by MCVH physicians, visiting only occasionally, it would materially reduce the extent of travel to MCVH. It is not clear that it would materially improve the continuity and acceptability of care.

Somewhat offsetting this showing that the burden of travel to MCVH is not so great as portrayed in the staff report, and will become even less, was material presented by SNGH regarding patient views of the acceptability and continuity of care under the present arrangements. Interviews with patients, conducted by a marketing firm retained by SNGH, provided more credible evidence of patient dissatisfaction with the present arrangements than could reasonably be inferred from material previously presented by the applicant and by MCVH.

In addition, testimony at the IFFC, especially by Dr. Ryan, regarding problems of communication and continuity of care was much more detailed and persuasive than information previously provided. However, it was essentially anecdotal and not a comprehensive and conclusive assessment of continuity problems.

In summary of this point, issues of geographical accessibility appear to be less significant than previously thought, while issues of continuity and acceptability of care may be more significant than originally thought. DCOPN judges the net effect of these opposite factors to constitute a modest net gain in favor of the application. Still, there is no showing that patient well-being is measurably diminished by the continuity and acceptability issues that may exist.

On balance, DCOPN believes that no substantial need has yet been demonstrated for the proposed new service. DCOPN maintains the original conclusion on this point and reason for denial.

**Single-Facility Waiting List Permits Better Management of Patients and Improves Patient Outcomes.** Among the points affecting DCOPN's recommendation of denial, this was the most important, but also the point least addressed and least able to be addressed by DCOPN. The staff report stated (pp. 59-60):

> The principal lesson of the MCVH experience with waiting-list mortality seems to be that personnel recruitment and organization, rather than volume of cases, are key to good results.
>
> Yet, the above observations do not detract from the plausibility of MCVH's contention that a single-program waiting list in an organ procurement organization's area permits more effective management of the patients than would be possible with a two-program waiting list. Although DCOPN does not understand all the nuances of waiting-list management and organ-recipient matching, DCOPN nonetheless judges this factor to be a material point favoring denial of this application.

At the IFFC, Dr. Shiffman of MCVH explained that about 90% of liver transplant patients are in "status 3" or least urgent classification. The organ procurement organization ("OPO") allocates an available liver to a hospital according to the patient with the longest waiting time in the highest status category, which is usually status 3, least urgent. However, the hospital reportedly has the possibility of using the liver for a patient (in the same status category) who is sicker than the patient with the longest waiting time.

If all patients in the OPO are under the care of one hospital, then the opportunity for judgment is maximized. However, if patients are divided among two or more hospitals, the opportunity for overall patient-care management is sub-optimized by being limited to the pool of status 3 patients under the care of that hospital which is to receive the liver.

Dr. Shiffman testified (p. 64 of IFFC transcript) that MCVH waiting-list mortality is about 5.1% (generally consistent with levels cited in the DCOPN staff report), while the current national average is 14% (as compared to less than ten percent cited in the staff report). Dr. Shiffman said, "We attribute that [favorable difference] to being the only transplant center in our OPO."

This is a very clear statement, and, if accurate, it means that about nine percent of MCVH's waiting list are *not* dying who *would be* dying under typical circumstances nationwide. Making assumptions about the size and rate of turnover of the waiting list, DCOPN assumes this means five to ten MCVH liver patients per year are *surviving* who would *not survive* under typical waiting-list circumstances. This is certainly a dramatic patient-care effect. If it is to be assumed that establishment of a liver transplant program at SNGH would cause waiting-list mortality in this OPO area to revert to the national average, then that consideration, by itself, would be ample reason to deny this application.

Dr. Shiffman did *not* say that establishment of a liver transplant program at SNGH would cause waiting-list mortality in this OPO area to revert to the national average, and this does not seem plausible to DCOPN. However, Dr. Shiffman did specifically affirm (p. 64 of transcript) that "the wait list mortality at both centers would be higher than the wait list mortality at MCV currently."

Subsequent testimony by Dr. Colonna (pp. 158-159 of IFFC transcript) cast some doubt on the actual (rather than theoretical) latitude--especially in the future--for managing liver allocations among patients in the same status category, on the frequency with which this is done, and on the propriety of doing so. However, Dr. Colonna's statements did not directly refute the very specific assertions made by Dr.

Shiffman. Accordingly, DCOPN believes that the net effect of IFFC testimony on this point is to strengthen this reason for DCOPN's recommendation of denial for the application.

At the same time, it must be observed that applying judgment to liver allocations so as to best serve *all* the patients in an OPO area, when there is more than one transplant facility, is a matter of cooperation among physicians and institutions and a matter of establishing and enforcing agreed-upon procedures. Agreement and disciplined cooperation among just two entities in the same state, and only 100 miles apart, ought not to be out of the question. Nonetheless, DCOPN continues to believe that better management of the waiting list with only one liver transplant facility in the OPO area is a credible and sufficient reason to recommend denial of the application.

Effect of a Liver Transplant Program at SNGH on Training Programs at MCVH. Based on information supplied by MCVH (cited on pp. 62-63 of the DCOPN staff report), the staff report stated:

> In a subsequent telephone conversation, MCVH explained that prior to 1996 the ASTS volume requirement [for accreditation of liver transplant training programs] was only 25, which permitted MCVH to be accredited in past years. Thus, if MCVH liver transplant volume were now to fall below 50 per year, which a new program at SNGH might well cause to happen, MCVH would lose accreditations and fellowship training opportunities which MCVH has had for a number of years. These accreditations apply to training of both liver transplant surgeons (ASTS) and transplant hepatologists (ASTP).

The staff report went on to say "there is a significant public interest in [MCVH] maintaining accreditation and fellowship opportunities in liver transplantation." This became a third reason for recommending denial of the application.

However, a fuller and up-to-date understanding of this matter, which was made possible by the IFFC testimony and exhibits, reveals that it is not nearly so clear-cut as DCOPN originally thought. Based on the prior information provided by MCVH, DCOPN thought that the performance of 50 liver transplants per year was an *absolute requirement* for accreditation. It is no longer, if it ever was.

A letter of May 19, 1997, from Dr. Hugh Auchincloss, Chairman, Education Committee, American Society of Transplant Surgeons ("ASTS"), Exhibit V submitted at the IFFC by SNGH, stated:

> [At their meeting May 14-16, 1997], the Council [of the ASTS] decided to change the criteria for certification of transplant fellowship training programs. The new criteria specify that a transplant fellowship training program must have enough patients such that each fellow will have primary responsibility for 75 new patients during their fellowship training. To be certified as a liver transplant fellowship program, at least 45 of those patients must be liver transplantation patients.

Thus, the accreditation standard is no longer the volume of transplant *procedures per facility* but the volume of *new patients per fellow*. This allows the facility to manage its accreditation circumstances to some degree by altering the number of fellows there. MCVH's liver transplant training program is accredited until December 31, 1999. This allows time for them to adjust to the new volume standard, if any adjustment is necessary.

Furthermore, MCVH's liver transplant volume is higher than that of several prominent institutions now accredited, including Duke, Johns-Hopkins, and Massachusetts General. It seems unlikely that accreditation would be removed from such facilities simply on the basis of a minor shortfall of volume. Even the former volume standard for *liver* transplant accreditation seemed to imply some latitude for

judgment. This was in contrast to the much firmer language on procedure volume for *kidney* transplant accreditation (which MCVH did not come close to meeting in 1996, but was accredited for kidney transplantation nonetheless).

Based on more complete and up-to-date information regarding the volume standard for accreditation of liver transplant training programs, DCOPN no longer believes that establishment of a liver transplant program at SNGH would be likely to reduce volume at MCVH such that MCVH's liver transplant training program would lose its accreditation. DCOPN no longer regards this matter as a reason to recommend denial of the application.

SUMMARY STATEMENT

The testimony and exhibits at the IFFC removed one of DCOPN's reasons (possible loss of accreditation of MCVH's liver transplant training program) for recommending denial of this application. The IFFC also weakened slightly another of DCOPN's reasons (no substantial need demonstrated) for recommending denial. However, the IFFC strengthened DCOPN's most important reason for recommending denial--that better management of the waiting list and better patient outcomes are possible when there is only one liver transplant facility in the OPO area.

DCOPN urges you to sustain DCOPN's recommendation of denial for SNGH's application to add liver transplant services.

c: Sandra J. Miller, Sentara Health System
Laura G. Aaron, Esq., Mezzullo & McCandlish
Mark S. Hedberg, Esq., Hunton & Williams
David L. Ross, Esq., VCU/MCVH
Brian E. Letourneau, Service Line Admin., MCVH
Paul M. Boynton, Executive Director, EVHSA
Paul E. Parker, Director, Division of COPN

01387

# COMMONWEALTH of VIRGINIA

RANDOLPH L. GORDON, M.D., M.P.H.
COMMISSIONER

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June 20, 1997

MEMORANDUM

TO: Raymond O. Perry, M.P.H., Adjudication Officer

FROM: Samuel A. Clement, Project Review Analyst
Division of Certificate of Public Need

SUBJECT: Rebuttal: COPN Request No. VA-5969,
Addition of Liver Transplant Services, Sentara Norfolk General Hospital

As described in the DCOPN staff report and as reaffirmed and amplified in our closing argument of June 13, 1997, there is one overriding consideration that most strongly compels DCOPN's recommendation for denial of this application: that a single-facility waiting list, as now exists with only one liver transplant program in the organ procurement organization's ("OPO") area, permits better management of patients and improves patient outcomes.

Although the applicant's presentation at the IFFC and the applicant's closing argument addressed effectively several of the concerns raised about this application, the applicant has not convincingly addressed this most important question of how waiting-list mortality might be adversely affected by having a second liver transplant program in the OPO area.

The applicant's closing argument states:

> Finally, there is no evidence that that MCV's ability to manage its waiting list will be impaired if SNGH develops a liver transplant program....The alleged inability to manage the waiting list is not a factor that weighs against approval of this project.

But, in fact, testimony was given at the IFFC by Dr. Shiffman that the large favorable difference in waiting-list mortality experienced at Medical College of Virginia Hospitals ("MCVH") could be attributed to being the *only* liver transplant center in this OPO area. Dr. Shiffman supported this assertion by explanation of how patients are classified on the waiting list and how decisions are made regarding allocation of organs. In short, the statistical evidence says MCVH is doing a distinctly superior job--relative to the national average--of managing their liver-transplant waiting list, and Dr. Shiffman gave a specific and convincing explanation of how this is accomplished.

The applicant's witness, Dr. Colonna, did not directly and specifically refute Dr. Shiffman's contentions or offer any alternative explanation for MCVH's very favorable experience with waiting-list mortality.

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In fact, Dr. Colonna acknowledged the potential advantages of being the only program in an OPO area and noted that he had personally seen this advantage in his own experience as a liver transplant surgeon.

DCOPN continues to find MCVH's contentions on this point persuasive and overriding. We further note that the applicant had nearly three months from the time of issuance of the staff report until the IFFC to research this matter and prepare counterarguments. That no really strong and focused counterarguments were offered strengthens our conviction that important gains in patient well-being--the probability of survival--result from having only a single liver transplant program in the OPO area.

It is conceivable, as the applicant suggests, that the advantages which now seem to accrue to a single-facility waiting list *might* be overcome by new procedures which *might* in the future be adopted by the OPO and/or by transplant facilities. However, the future occurrence of these developments and their effects are matters of speculation, while present advantages to patients of a single-facility waiting list seem to have been convincingly demonstrated and explained.

DCOPN urges you to sustain our recommendation for denial of SNGH's application to add liver transplant services.

c: Sandra J. Miller, Sentara Health System
Laura G. Aaron, Esq., Mezzullo & McCandlish
Mark S. Hedberg, Esq., Hunton & Williams
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Paul E. Parker, Director, Division of COPN

Richmond Times-Dispatch

Friday, June 27, 1997 B3

01389

# New liver transplant system devised

## *Donor organ rules come under fire*

THE ASSOCIATED PRESS

Under fire from the federal government and from advocates for organ transplant patients over its rules for allocating donor organs, the United Network for Organ Sharing has created a new priority system for people who need liver transplants.

The UNOS board voted yesterday to establish a new priority category for people in dire need of a liver transplant.

The new category, for people with chronic liver disease who suddenly become critically ill, ranks higher in priority than chronic liver patients who are stable. But it ranks lower than patients with sudden new cases of liver failure, such as those whose livers shut down as a result of having eaten a poison mushroom or having a toxic reaction to a drug.

The new system is better than one UNOS proposed late last year which would have lumped all chronic liver disease patients together, whether they were desperately ill or not, said Dr. John J. Fung, director of transplant surgery at the University of Pittsburgh Medical Center.

The board is also creating a standardized system for defining the medical condition of potential liver recipients, said UNOS president James Burdick. That could minimize disparities in waiting-list times around the country which result in part from subjective decisions about who is most in need.

Once standards are in place, UNOS may move to a system of sharing livers nationwide instead of primarily within local regions, as is now the case, Burdick said.

Some patients and large transplant centers that stand to gain from a national system of organ sharing had long advocated such a change.

The board, in the first of two days of meetings in Arlington, also approved a new system for matching kidney donors and recipients. It is designed to make those organs more available to minorities and will run on a trial basis.

Thousands of people die each year because of a shortage of donor organs, and the government and transplant patients' groups have been demanding UNOS improve the system.

Richmond-based UNOS operates under contract to the federal Department of Health and Human Services, which is already rewriting the rules under which UNOS operates.

UNOS has angered HHS officials in recent months by refusing to reveal to the agency how many times various transplant centers were offered organs but refused to accept them — without the knowledge of patients who needed them — for such nonmedical reasons as lack of a surgeon on duty. In such cases, the organ goes elsewhere, and the passed-over patient may die waiting for the next good match.

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August 11, 1997

01390

The Honorable Randolph Lee Gordon, M.D., M.P.H.
State Health Commissioner
Virginia Department of Health
Main Street Station, Suite 214
1500 East Main Street
Richmond, VA 23219

**RE: COPN Request No. VA-5969**
**Sentara Norfolk General Hospital**
**Norfolk, Virginia**
**Establish Liver Transplant Service**

Dear Commissioner Gordon:

This letter is submitted for your consideration on behalf of the Medical College of Virginia Hospitals, an entity affected by the captioned project, pursuant to 12 VAC 5-220-240. I write in response to the submission, on June 30, 1997, by Sentara Norfolk General Hospital of a June 27, 1997 *Richmond Times-Dispatch* article regarding the creation of a "new" liver transplant system by the United Network for Organ Sharing ("UNOS").

The changes in Status categories approved by UNOS in June and briefly discussed in the article have not become effective to date. If these changes do go into effect, Status 1 (which currently includes all patients in liver failure and facing imminent death within 7 days) would be split into two categories: Status 1 (limited only to patients with acute fulminant hepatic failure, patients in need of retransplantation for primary graft non-function or hepatic artery thrombosis, and children with inborn errors of metabolism) and a new Status 2a (made up of patients with chronic liver disease whose condition has deteriorated to the point that they are now on life support and in imminent danger of death within 7 days). Although approved by UNOS board, we at MCV believe this is not a good policy change because it would give priority to those patients with the poorest chance for long term survival (Status 2a), over patients with the best chance for long term survival (current Status 2, which would be redesignated Status 2B). We continue to believe that the best way in which to minimize pre-transplant mortality and maximize post-transplant survival is to perform hepatic transplantation on patients prior to their reaching these critical stages of liver failure. Of course, if the new designations ever do become effective, we will abide by them.

This recategorization of liver transplant patients will have no adverse affect on the flexibility we currently enjoy in managing our liver transplant waiting list; it will merely change the categories within which such management takes place. As the record in this matter clearly reflects, if the SNGH project is approved this flexibility at MCVH will be lost, resulting in an increased liver transplant waiting list mortality rate at MCVH.

The article submitted by Sentara also notes that UNOS is creating a "standardized system for defining the medical condition of potential liver recipients." This aspect of organ allocation is a component of the status categories noted above. These criteria have evolved continuously over the past several years in response to a continuing trend of increases in pre-transplant waiting time and increases in pre-transplant, or waiting list mortality. The current attempt by UNOS to divide the Status 1 category into Status 1 and Status 2a is simply another "band-aid" at trying to make an intolerable system work as best as possible. The fact remains that there are simply insufficient organs within nearly every region across the United States, including Central and Eastern Virginia, to offer transplantation to all patients in need within a reasonable amount of time. As more liver transplant programs have opened during the past 5 years the situation has only worsened, not improved. Today, there are approximately 104 liver transplant programs in the United States and pre-transplant mortality is at its highest rate ever, approximately 14 percent nationwide in 1995. In fact, those regions with the largest numbers of programs have the highest pre-transplant mortality approaching 25% to 30%. In contrast, it is well known in the transplant community that those programs and citizens lucky enough to be listed by the sole program within an OPO or region enjoy the lowest pre-transplant mortality and the highest post-transplant survival among programs nationwide. As was already described during hearings regarding this matter, a single liver transplant program within an OPO allows the program flexibility to transplant those patients **within any given status** who are in greatest need of the transplant, regardless of waiting time. This flexibility is lost when another program enters the equation and organs are prioritized **within a status** solely by waiting time. For example, during the past 12 months at MCV, 12 patients were selected for transplantation based upon **severity of illness** and given priority ahead of patients with longer waiting times, but with more stable liver function. This accounted for 33% of all liver transplants performed at MCV during calendar year 1996. Such flexibility would have been impossible if MCV would have had to share organs with another program and organs were allotted within a given status based upon waiting time alone. I estimate that at least 4-6 of these patients would have already died under such a system. The remaining patients would still be awaiting hepatic transplantation today, their situation would be more critical and their chance for long term survival even if they received an organ would be significantly reduced.

I would appreciate your taking this information into account as you render your decision regarding the SNGH project.

Sincerely yours,

Mitchell L. Shiffman, M.D.
Chief, Hepatology Section
Medical Director, Liver Transplant Program

MLS/dmh

cc: Mr. Raymond O. Perry
Mr. Paul E. Parker
Mr. Samuel L. Clement
Mr. Paul M. Boynton
Laura G. Aaron, Esquire
Mark S. Hedberg, Esquire

## ASSIGNMENTS OF ERROR

1. The Court of Appeals erred when it concluded that the Commissioner exceeded his statutory authority when he determined that Sentara's application was inconsistent with the State Medical Facilities Plan (SMFP).

2. The Court of Appeals erred when it concluded that the Commissioner considered evidence not in the record on the issue of the availability of donor livers and gave no deference to the Commissioner's specialized competence and experience.

3. The Court of Appeals erred when it failed to conclude that even if the Commissioner considered evidence that was not in the record such action was harmless error.

4. The Court of Appeals erred when it concluded that the Commissioner's mistake of fact regarding liver transplant accreditation standards was not harmless error.