Andrew N. Pollak, MD
CHAIRMAN

STATE OF MARYLAND

Ben Steffen
EXECUTIVE DIRECTOR

MARYLAND HEALTH CARE COMMISSION

4160 PATTERSON AVENUE – BALTIMORE, MARYLAND 21215
TELEPHONE: 410-764-3460 FAX: 410-358-1236

MEMORANDUM

TO: Commissioners

Suburban Hospital
MedStar Georgetown University Hospital

FROM: Martha G. Rymer
Commissioner/Reviewer

RE: Recommended Decision

DATE: September 25, 2020

Enclosed is my Recommended Decision in my review of the Certificate of Need (CON) application by Suburban Hospital to establish a liver transplant service in Bethesda. The proposed transplant center would be part of the Johns Hopkins Medicine's Comprehensive Transplant Center (CTC) and would utilize existing surgical capacity at Suburban while drawing on CTC resources for staff and protocols. The projected annual cost for operating this service at full implementation (the fifth year of operation in which the applicant projects the performance of 46 liver transplantations) is $11.6 million.

I have considered the entire record in this review and recommend that the Maryland Health Care Commission **DENY** Suburban Hospital's application for a Certificate of Need to establish a liver transplant service. The proposed service fails to comply with the Need, Access, and Cost Effectiveness standards in COMAR 10.24.15.04B, the Organ Transplant Services Chapter of the State Health Plan. It also fails to meet the Need and Availability of More Cost-Effective Alternatives CON review criteria in COMAR 10.24.01.08G(3). My attached Recommended Decision details my analysis and findings regarding applicable standards and criteria.

Background

In its Organ Transplant Services Chapter, the Commission determined that organ transplantation is a specialized tertiary-level service that requires clinical expertise and a hospital setting with the most advanced diagnostic, surgical, and monitoring equipment. A specialized service like organ transplantation is intended to be available to a substantial regional population base in a limited number of general hospitals to promote both high quality care and an efficient

scale of operation. The Chapter maintains the long-standing three-hour, one-way drive time standard for reasonable geographic access to this service.

There are currently two liver transplant centers in Maryland, both located in Baltimore – at Johns Hopkins Hospital and the University of Maryland Medical Center. There is also a liver transplant center in the District of Columbia at MedStar Georgetown University Hospital (Georgetown). I recognized Georgetown, which provides liver transplantation services in the planning region, as an interested party in this review.

The most recent data on liver transplant volumes in the Maryland Region and Washington Region Donation Service Areas (DSAs) that cover Maryland is shown immediately below.

Number of Liver Transplants in the Maryland Region and Washington Region DSAs CY 2015- 2019

Transplant Center	2015	2016	2017	2018	2019
Johns Hopkins	100	126	103	120	120
UMMC	147	169	161	113	94
Maryland	**247**	**295**	**264**	**233**	**214**
Georgetown	81	117	125	110	124
Washington Region	**81**	**117**	**125**	**110**	**124**
Total Combined	**328**	**412**	**389**	**343**	**338**

The Organ Transplant Services Chapter of the State Health Plan is unique. Need for an organ transplant cannot be addressed solely by building or improving infrastructure. A patient in need of an organ transplant is placed on a waiting list and must wait for a compatible organ donation from a living or deceased donor. Thus, the Need standard, at COMAR 10.24.15.04B(1)(a), prescribes that an applicant demonstrate need for a new transplant service by addressing its proposed program's ability "to *increase the supply or use* of donor organs …." (emphasis added). Additionally, for this tertiary specialized service, the Access standard, at COMAR 10.24.15.04B(3)(c) dictates that "travel to an organ transplant center… is not, in and of itself, considered a barrier to access, if the drive time in less than three hours one-way."

Project Description

The proposed transplant center would be part of the Johns Hopkins Comprehensive Transplant Center (CTC). The proposed transplantation service would utilize existing surgical capacity at Suburban Hospital in Montgomery County in order to provide the Washington Region with an additional location for organ transplant services, while drawing on CTC resources such as staff and protocols.

There are no capital costs associated with the proposed liver transplantation service. The projected annual cost for operating this service at full implementation (the fifth year of operation in which the applicant projects the performance of 46 liver transplantations) is $11.6 million. At full implementation, Suburban Hospital projects a positive margin of $1.56 million for the program.

Recommendation

As I stated earlier, I recommend that the Maryland Health Care Commission **DENY** Suburban Hospital's application for a Certificate of Need to establish a liver transplant service because the applicant did not satisfy all applicable State Health Plan standards and CON review criteria adopted by the Commission Specifically, the application did not meet the requirements of Need, Access, and Cost Effectiveness standards in COMAR 10.24.15.04B, and the Need and Availability of More Cost-Effective Alternatives criteria in COMAR 10.24.01.08G (3).

Suburban Hospital failed to demonstrate that its proposed program is necessary to increase the supply or use of donor livers, or that there is a barrier to access that its liver transplantation service would remedy. Suburban projects to transplant 46 cases annually at maturity – 29 of which would not be new volume but cases that would be shifted from one of the three existing programs – at an annual cost of $11.6 million. Suburban's proposed liver transplant service is simply not needed because there are currently three high-performing existing liver transplantation services within geographic accessibility to the population. The applicant projects to grow the market by 10 liver transplant cases per year, if its application were approved. This additional volume could be absorbed by existing providers and does not justify creating an entire new liver transplant center at an annual expense of $11.6 million.

Further Proceedings

This matter will be placed on the agenda for the meeting of the Maryland Health Care Commission on October 15, 2020 which begins at 1:00 p.m. at 4160 Patterson Avenue in Baltimore. The Commission will issue a final decision based on the record of the proceeding.

As provided in COMAR 10.24.01.09B, an applicant or interested party may submit written exceptions to the enclosed Recommended Decision. Written exceptions must identify specifically those findings or conclusions to which exception is taken, citing the portions of the record on which each exception is based. Copies of exceptions and responses to exceptions must be emailed to all parties by the due date and time, but because of the current state of emergency, filing of paper copies with the Commission is not required.

Oral argument during the exceptions hearing before the Commission will be limited to 10 minutes for the interested party and 15 minutes for the applicant, unless extended by Vice-Chair Randolph Sergent, who is the Chair's designated presiding officer. The schedule for the submission of exceptions and any response to exceptions is as follows:

Submission of exceptions:	October 5, no later than 10:00 a.m.
Submission of responses:	October 9, no later than 3:00 p.m.
Exceptions hearing:	October 15, 2020, 1:00 p.m.

IN THE MATTER OF	*	**BEFORE THE**
	*	
SUBURBAN HOSPITAL	*	**MARYLAND HEALTH**
	*	
DOCKET NO. 17-15-2400	*	**CARE COMMISSION**
	*	

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Reviewer's Recommended Decision

October 15, 2020

(released September 25, 2020)

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I. BACKGROUND

Liver transplantation is the process of surgically transferring a donated liver into a patient with end-stage organ failure. It is often the only treatment for end-stage liver failure and is provided to segments of the population that are the most severely ill and at the highest risk for poor outcomes.

The National Organ Transplant Act (NOTA) of 1984 provided for the establishment of the national Organ Procurement and Transplantation Network (OPTN) in response to the growing need for donor organs and for a more centralized national organ donation registry. The OPTN links hospitals, health care professionals, and other organizations involved in the organ donation and transplantation system, with the primary goals of increasing organ sharing effectiveness and efficiency and improving equity in organ allocation. While OPTN is responsible for developing organ transplantation policy, the Scientific Registry of Transplant Recipients (SRTR) provides evaluation and data analysis. NOTA requires the OPTN network to be operated by a private non-profit organization under a federal contract. The Department of Health and Human Services awarded the OPTN contract to the United Network for Organ Sharing (UNOS), which develops, monitors, and enforces the rules governing allocation, procurement, and transplantation of organs as approved by HHS. UNOS manages the waiting list for organ transplants in the U.S. and matches donors to recipients.

In order to efficiently and equitably distribute organs to those who need an organ transplant, UNOS employs a computer matching system that generates a rank-order list of candidates to be offered each organ based on medical and logistical factors. Because the maximum organ preservation time for a liver is between 8 to 12 hours,[1] geography is an important factor.

For procurement, UNOS divides the U.S. into 11 regions. Maryland falls within Region 2, which includes Delaware, the District of Columbia, New Jersey, Pennsylvania, West Virginia, and Northern Virginia. Within regions, Organ Procurement Organizations (OPOs) are designated by the Centers for Medicare & Medicaid Services (CMS) to facilitate local organ procurement at local hospitals, with only one OPO designated to each Donation Service Area (DSA). Maryland jurisdictions are divided between two OPOs as described below:

- The Living Legacy Foundation of Maryland (LLF) serves western and central Maryland, the Eastern Shore, Calvert, and St. Mary's Counties in southern Maryland.

- The Washington Regional Transplant Community (WRTC) serves: the District of Columbia; Montgomery, Prince George's, and Charles Counties in Maryland; Arlington, Clarke, Fairfax, Fauquier, Loudoun, King George, Prince William, and Spotsylvania Counties in northern Virginia; and the cities of Alexandria, Fairfax, Falls Church, Manassas, and Manassas Park in Virginia.

There are currently two liver transplant centers in Maryland, both located in Baltimore, at Johns Hopkins Hospital (Johns Hopkins) and the University of Maryland Medical Center (UMMC), both falling within the jurisdictional boundaries of the LLF OPO (Maryland Region DSA). There is also a liver transplant center in the District of Columbia at MedStar Georgetown University Hospital

[1] https://unos.org/transplant/how-we-match-organs/

(Georgetown), which falls within the jurisdictional boundaries of the WRTC OPO (Washington Region DSA).

For transplant centers, CMS regulations governing participation in the Medicare and Medicaid programs serve to promote the provision of high-quality patient care for transplant recipients. All organ transplant programs must be located in a hospital that has a Medicare provider agreement. A transplant program must meet the transplant Conditions of Participation, as well as comply with the hospital Conditions of Participation. In Maryland, organ transplantation is considered a specialized tertiary-level service that requires clinical expertise and a hospital setting with the most advanced diagnostic, surgical, and monitoring equipment. A specialized service like organ transplantation is intended to be available to a substantial regional population base in a limited number of general hospitals to promote both high quality care and an efficient scale of operation.

Distribution policies for procured livers have evolved over the years. In 2002, OPTN/UNOS developed an objective scoring system to rank candidates based on routine laboratory results. Adult liver transplant candidates are ranked using the Model for End-Stage Liver Disease (MELD)[2] which assigns on a periodic basis[3] each patient a number based on how urgently s/he needs a liver transplant in the next three months. The candidates with the highest ranking are those who most urgently need an organ transplant and who have the best chance of survival following an organ transplant.

In 2013, CMS adopted a policy known as "Share 35" which increased regional priority for patients with a MELD score of 35 or greater and for sicker patients labeled Status 1 with acute (sudden and severe) liver failure. In 2017, an additional change in the national policy for liver allocation extended the "Share 35" program to apply to patients with a MELD score of 32.

Prior to February 2020,[4] OPO service areas factored into liver allocation, in that first priority was given to patients on waitlists within an OPO. Under these prior allocation policies, organs recovered from an OPO were most often allocated to patients at transplant centers within that OPO's DSA. However, under a new policy implemented in February 2020, called the "Acuity Circles Policy," OPO boundaries no longer play a role in liver distribution after recovery.[5] Instead, the new system expands priority for the sickest Status 1 patients on the waitlist within 500 nautical miles of the donor hospital. Then, candidates are prioritized based on patient severity within 150, 250, and 500 nautical miles from the donor hospital.[6] Modeling predicts most livers will be allocated within

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[2] The Model for End-Stage Liver Disease, or MELD, is a scoring system for assessing the severity of chronic liver disease. It was initially developed to predict mortality within three months of surgery in patients who had undergone a transjugular intrahepatic portosystemic shunt procedure, and was subsequently found to be useful in determining prognosis and prioritizing for receipt of a liver transplant. This score is now used by the United Network for Organ Sharing and Eurotransplant for prioritizing allocation of liver transplants instead of the older Child-Pugh score.

[3] UNOS. Questions & Answers for Transplant Candidates about PELD and MELD. https://www.unos.org/wp-content/uploads/unos/MELD_PELD.pdf

[4] With the exception of "Share 35."

[5] At the time this application was submitted, individuals on local wait lists within the OPO's DSA were given local priority over those listed in other DSAs or other regions and organs were more commonly transplanted at a center within the same DSA.

[6] UNOS. System notice: Liver and intestinal organ distribution based on acuity circles implemented Feb

150 miles of the donor hospital, as explained by the OPO serving the Maryland Region DSA. (DI #40, pp. 1-2).

The health planning regions for review of a Certificate of Need (CON) application to establish an organ transplant service are consistent with the OPO designations. This application is for the establishment of a liver transplant program in Montgomery County, which falls in the DSA served by the WRTC OPO.

II. INTRODUCTION

A. The Applicant

The applicant, Suburban Hospital (Suburban), is a 236-bed general hospital located at 8600 Old Georgetown Road in Bethesda (Montgomery County) that was established in 1943. It provides acute inpatient services for medical/surgical, pediatric, and acute psychiatric patients and is one of ten hospitals in Maryland offering cardiac surgery, having initiated this service in 2005. It is a designated Level II Trauma Center, annually treating between 1,500 and 1,600 trauma patients. Suburban became a member of Johns Hopkins Medicine in 2009, and has strategic partnerships with local and national health care organizations, including the National Institutes of Health, which is located adjacent to Suburban Hospital across Old Georgetown Road.

B. The Project

Suburban proposes to establish a liver transplant service at its Montgomery County location. The proposed transplant center would be part of the Johns Hopkins Medicine's Comprehensive Transplant Center (CTC). The CTC was created in 1996 by combining The Johns Hopkins Hospital's existing transplant programs into a single center, which includes four solid-organ transplant programs: liver; kidney/pancreas; lung; and heart. The proposed project would utilize existing surgical capacity at Suburban while drawing on CTC resources such as staff and protocols. (DI #3, p. 69; DI # 13, Exh. CQ2).

There are no capital costs associated with the proposed the proposed introduction of liver transplantation services at Suburban. (DI #13, pp. 3, 5 & Exh. CQ2). The projected annual cost for operating this new service at Suburban at full implementation (the fifth year of operation in which the applicant projects the performance of 46 liver transplantations) is $11.6 million. Projected operating expenses for the proposed project are shown in Table II-1. (DI #3, p. 135).

4. https://unos.org/policy/liver-distribution/.

Table II-1: Total Estimated Operating Expenses

	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries & Wages (including benefits)	$1,487,858	$2,926,907	$3,404,042	$3,895,623	$4,293,791
Contractual Services	$1,657,322	$1,927,093	$1,998,499	$2,366,299	$2,452,284
Supplies & Drugs	$78,310	$1,367,174	$1,594,672	$1,828,509	$2,020,755
Other Expenses*	$890,934	$1,953,179	$2,254,507	$2,557,425	$2,805,117
Total Operating Expenses	**$4,754,424**	**$8,174,353**	**$9,251,720**	**$10,647,857**	**$11,571,946**

Source: DI #3, p. 135.
*includes contingency allowance, outpatient diagnosis and treatment services, and organ acquisition.

Table II-2, below, shows the number of liver transplants that took place in the Maryland and D.C. transplant centers over the past ten years, which peaked in 2016 at programs in Maryland and in 2017 at the program in the District of Columbia.

Table II-2: Number of Liver Transplants in the Maryland and Washington Regions, CY 2010-2019

Transplant Center	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Johns Hopkins	39	36	48	82	86	100	126	103	120	120
UMMC	55	78	86	90	115	147	169	161	113	94
Maryland	**94**	**114**	**134**	**172**	**201**	**247**	**295**	**264**	**233**	**214**
Georgetown	84	100	116	91	102	81	117	125	110	124
Washington Region	**84**	**100**	**116**	**91**	**102**	**81**	**117**	**125**	**110**	**124**
Total Combined	**178**	**214**	**250**	**263**	**303**	**328**	**412**	**389**	**343**	**338**

Source: OPTN State Data Reports, https://optn.transplant.hrsa.gov/data/view-data-reports/.

The need for organ transplants continues to exceed the supply of organs, and the shortage of organs causes most patients to wait for a transplant, according to the OPTN. A patient may list at more than one transplant program and is counted as multiple registrations, if the patient lists with more than one transplant program. The candidate waiting lists for livers as of June 30, 2019, as reported in bi-annual reports from SRTR were:

- 355 at Johns Hopkins
- 388 at UMMC
- 263 at Georgetown

As of September 10, waiting list registrations for liver transplants at these centers were:

- 358 at Johns Hopkins
- 309 at UMMC
- 251 at Georgetown

C. Reviewer's Recommendation

I recommend that the Maryland Health Care Commission deny Suburban Hospital's application for a Certificate of Need to establish a liver transplant service because it fails to comply with three State Health Plan standards and with two CON review criteria:

(1) The Need standard, COMAR 10.24.15.04B(1);

(2) The Access standard, COMAR 10.24.15.04B(3);

(3) The Cost Effectiveness standard, COMAR 10.24.15.04B(4);

(4) The Need criterion, COMAR 10.24.01.08G(3)(b); and

(5) The Availability of More Cost-Effective Alternatives criterion, COMAR 10.24.01.08G(3)(c).

In this Recommended Decision, I analyze Suburban Hospital's compliance with all applicable standards and review criteria.

III. PROCEDURAL HISTORY

A. Record of the Review.

Please see Appendix 1, Record of the Review.

B. Interested Party

I recognized MedStar Georgetown University Hospital (Georgetown) as an interested party in this review. Georgetown is authorized to provide the same service as the applicant, in the same planning region used for purposes of determining need under the State Health Plan, and states that it would be adversely affected by the proposed project. The interested party opposes Suburban's application, arguing that the Commission should deny the application because the applicant fails to demonstrate a need for the program or that barriers to access exist. (DI #21, pp. 1-2).

C. Local Government Review and Comment

Uma S Ahluwalia, then-Director of the Montgomery County Department of Health and Human Services, provided a letter of support for the proposed project. This letter of support states that the proposed project will address the need for increased organ supply and the unmet demand for transplant services in Montgomery County. (DI #3, Exh. 17).

D. Community Support

The CON application also included letters of support for this project from the following:

- Kimberly D. Russo, Chief Executive Officer, George Washington University Hospital;
- Kirti Shetty, Director of Hepatology, and Jacqueline Laurin, Assistant Professor of Medicine and Transplant Hepatologist, Sibley Memorial Hospital;
- State Senator Susan C Lee;
- State Delegate C. William Frick;
- State Delegate Ariana Kelly;
- State Delegate Marc Korman;
- Montgomery County Executive Isiah Leggett;
- Marty Maren, President, TRIO (Transplant Recipients International Organization, Inc.)

Maryland; and

- Ivory Allison, Executive Director, American Liver Foundation, Mid-Atlantic Division.

(DI #3; Exh. 17).

IV. REVIEW AND ANALYSIS

The Commission is required to make its decisions in accordance with the general CON review criteria at COMAR 10.24.01.08G(3)(a) through (f). The first of these six general criteria requires the Commission to consider and evaluate this application according to applicable State Health Plan standards and policies.

A. STATE HEALTH PLAN

COMAR 10.24.01.08G(3)(a) State Health Plan.
An application for a Certificate of Need shall be evaluated according to all relevant State Health Plan standards, policies, and criteria.

The relevant chapter of the State Health Plan for Facilities and Services is the Specialized Health Care Services–Organ Transplant Services, COMAR10.24.15 (Organ Transplant Services Chapter). Pursuant to COMAR 10.24.15.04A(1), "an applicant for a Certificate of Need to establish an organ transplantation service shall address and meet the general standards in COMAR 10.24.10.04A."

COMAR 10.24.10 Acute Inpatient Services

A. General Standards.

(1) Information Regarding Charges. Information regarding hospital charges shall be available to the public. After July 1, 2010, each hospital shall have a written policy for the provision of information to the public concerning charges for its services. At a minimum, this policy shall include:

(a) Maintenance of a Representative List of Services and Charges that is readily available to the public in written form at the hospital and on the hospital's internet web site;

(b) Procedures for promptly responding to individual requests for current charges for specific services/procedures; and

(c) Requirements for staff training to ensure that inquiries regarding charges for its services are appropriately handled.

Applicant's Response

The applicant provided a copy of its policy for providing information about charges, which includes a written procedure requiring it to develop a hospital charge list on a quarterly basis and post the list on its website. In response to individual requests for charge information, either prior to service or after discharge, patients are directed to the website, or to the Financial Counseling Office or Billing Office, and receive a direct response to their requests. The Director of Patient Access is responsible for training staff in appropriately responding to requests for information regarding

charges. (DI #3, Exh. 11). The applicant posts a list of charges and fees for Johns Hopkins Medicine affiliates at https://www.hopkinsmedicine.org/suburban_hospital/planning_your_visit/financial_information/

Reviewer's Analysis and Findings

The applicant provides written policies that include how and when it updates a list of services and charges that is readily available to the public upon request and on the hospital's website. It has procedures designating responsibility for promptly responding to individual requests for current charges for specific services/procedures. It requires staff training to ensure that inquiries regarding charges for its services are appropriately handled. I verified that the list or charges and fees is located on the website at the link listed above.

I find that the applicant's policy complies with this standard.

(2) Charity Care Policy. Each hospital shall have a written policy for the provision of charity care for indigent patients to ensure access to services regardless of an individual's ability to pay.

(a) The policy shall provide:

(i) Determination of Probable Eligibility. Within two business days following a patient's request for charity care services, application for medical assistance, or both, the hospital must make a determination of probable eligibility.

(ii) Minimum Required Notice of Charity Care Policy.

1. Public notice of information regarding the hospital's charity care policy shall be distributed through methods designed to best reach the target population and in a format understandable by the target population on an annual basis;

2. Notices regarding the hospital's charity care policy shall be posted in the admissions office, business office, and emergency department areas within the hospital; and

3. Individual notice regarding the hospital's charity care policy shall be provided at the time of preadmission or admission to each person who seeks services in the hospital.

Applicant's Response

Suburban states that it provides quality care to all patients regardless of their ability to pay and has provided its financial assistance policy. (DI #3, Exh. 12). In its application, Suburban includes a copy of the Johns Hopkins Health System Policy and Procedure, Financial Assistance, Policy Number FIN034H, which became effective in 2016.[7] Citations included in the policy language related to each part of this standard are listed below. (DI #3, Exh. 12; DI #13, p. 6).

Regarding Subparagraph (i), the requirement to complete a Determination of Probable

[7] I note that, as detailed in the Staff Report regarding the application of Johns Hopkins Bayview Medical Center (Docket No. 18-24-2430) to add 16 special hospital-rehabilitation beds, Johns Hopkins has revised its charity care and financial assistance policy. The revised policy may be accessed at: https://www.hopkinsmedicine.org/patient_care/patients-visitors/billing-insurance/_docs/pfs035-2020/PFS035-effective-020120.pdf.

Eligibility within two business days, Suburban states:

- Page 3: "All hospital applications will be processed within two business days and a determination will be made as to probable eligibility. To facilitate this process each applicant must provide information about family size and income, as defined by Medicaid regulations;"
- Page 11, Appendix A-1: "There are instances when a patient may appear eligible for financial assistance, but there is no financial assistance form on file. Often there is adequate information provided by the patient or through other sources, which could provide sufficient evidence to provide the patient with financial assistance." The policy lists a number of ways that Presumptive Financial Assistance Eligibility may be determined on the basis of individual life circumstances without an application;
- Page 6: "Responsibilities" of "Financial Counselor (Pre-admission/Admission/In-House/ Outpatient), Customer Service Collector, Admissions Coordinator, Any Finance representative designated to accept applications for Financial Assistance" include, among other responsibilities, "Identify prospective patients; initiate application process when required. As necessary assist patient in completing application or program specific form;" and
- Page 8: "2. A preliminary application stating family size and family income (as defined by Medicaid regulations) will be accepted and a determination of probable eligibility will be made within two business days of receipt."

Regarding Subparagraph (ii), Notice of Charity Care Policy:

- Page 21: "Purpose," third paragraph: "JHHS hospitals will publish the availability of Financial Assistance on a yearly basis in their local newspapers, and will post notices of availability at patient registration sites, Admissions/Business Office, the Billing Office, and at the emergency department within each facility. Notice of availability will be posted on each hospital website, will be mentioned during oral communications, and will also be sent to patients on patient bills. A Patient Billing and Financial Assistance Information Sheet will be provided to inpatients before discharge and will be available to all patients upon request."

Johns Hopkins' charity care and financial assistance policy, which has since been revised to meet the Commission's requirements, may be accessed at https://www.hopkinsmedicine.org/patient_care/patients-visitors/billing-insurance/_docs/pfs035-2020/PFS035-effective-020120.pdf and is available upon request. (DI #13, p. 6). It also publishes the notice in the *Washington Post* on an annual basis and provided a copy of a classified advertisement published on December 23, 2016, the publication closest to its application filing date. (DI #3, Exh. 13). Additionally, Suburban states that it provides each patient registered for emergency care, same day care, or inpatient care information about financial assistance and how to apply. The applicant provided photographs of posted notifications in English and Spanish explaining the availability of financial assistance and contact information in the Emergency Department Lobby, within both the Emergency Department and the Pediatric Emergency Department, as well as at the Front Registration Desk and the Cardiac Catheterization Laboratory waiting area. (DI #3, Exh. 14).

Approval for financial assistance is based on submission of a financial assistance application. The financial assistance application is given to every self-pay patient with instructions on how to apply and contact information. The same information is provided to all other patients upon request, and is also available in Spanish. (DI #3, p. 86, Exh. 12).

In addition, Suburban points out that its financial counselors and social workers are trained to answer patient questions regarding financial assistance and link patients to other community assistance resources prior to discharge. Registration staff are trained to answer questions regarding financial assistance and direct patients for answers to billing questions or other financial questions. Patient Financial Services staff are also trained to answer questions and provide information to patients regarding financial assistance and billing. Suburban Hospital uses contractors who assist patients in applying for Maryland Medical Assistance, as well as interview all self-pay patients upon admission and provide them with information and referral for financial assistance. Patients interested in applying for financial assistance are instructed to submit their application and supporting documentation to the JHHS Patient Financial Services central business office for processing. Contact information for the Financial Assistance Unit is provided in the application instructions. Suburban's policy states that patients will be given a determination of probable eligibility within two business days of their inquiry, but the applicant notes that this determination usually is made on the same day as the request. (DI #3, p. 86).

Reviewer's Analysis and Findings

Suburban provides written policies that have the required provisions and meets the public notification requirements. I find the applicant's policies (and as revised in 2020) comply with Paragraph (a) of the standard.

> **(b) A hospital with a level of charity care, defined as the percentage of total operating expenses that falls within the bottom quartile of all hospitals, as reported in the most recent Health Service Cost Review Commission Community Benefit Report, shall demonstrate that its level of charity care is appropriate to the needs of its service area population.**

Applicant's Response

The FY 2015 Health Services Cost Review Commission (HSCRC) Community Benefit Report, the most recent published report at the time the application was prepared, identified the value of the charity care provided by Suburban Hospital as equal to 1.55% percent of total operating expenses. Suburban ranked 33rd out of 53 Maryland non-profit hospitals tracked for this level of charity care measure, placing Suburban in the third quartile of all Maryland hospitals. (DI #3, p. 87).

Reviewer's Analysis and Findings

The most recently published HSCRC Community Benefit Report, for FY 2018, indicates that the average level of charity care provided by general hospitals in 2018 was 2.2 percent (i.e., a value of charity care equivalent to 2.2 percent of total operating expenses). The bottom quartile of Maryland general hospitals in this year consisted of hospitals with a level of charity care of 1.1 percent or less. Suburban Hospital's level of charity care in FY 2018 was 1.5 percent, ranking it as

33rd out of the 51 hospitals for which a level of charity care was reported. Its performance places Suburban in the third quartile for this measure. Thus, the applicant has no further requirements under Paragraph (b) of this standard.

(3) Quality of Care. An acute care hospital shall provide high quality care.

(a) Each hospital shall document that it is:

(i) Licensed, in good standing, by the Maryland Department of Health and Mental Hygiene;

(ii) Accredited by the Joint Commission; and

(iii) In compliance with the conditions of participation of the Medicare and Medicaid programs.

Applicant's Response

Suburban states that it complies with all applicable federal, State, and local health and safety regulations. (DI #3, p. 88). Suburban provided a letter from the Office of Health Care Quality dated August 17, 2017 stating that Suburban is licensed and in good standing, is accredited by the Joint Commission, and is certified for Medicare by CMS. (DI #13, p. 7, Exh. CQ6).

Reviewer's Analysis and Findings

I find the applicant complies with Paragraph (a) of the standard. Suburban is licensed in good standing by the Maryland Department of Health, accredited by the Joint Commission, and in compliance with the conditions of participation of the Medicare and Medicaid programs.

(b) A hospital with a measure value for a Quality Measure included in the most recent update of the Maryland Hospital Performance Evaluation Guide that falls within the bottom quartile of all hospitals' reported performance measured for that Quality Measure and also falls below a 90% level of compliance with the Quality Measure, shall document each action it is taking to improve performance for that Quality Measure.

Applicant's Response

Suburban states that it provides high quality patient care with historical performance on most "core measures" at or above 96 percent. The data reported in the most recent Maryland Hospital Performance Evaluation Guide (HPEG) at the time of the application (January – December 2015) shows the Clostridium difficile infection (C diff) rate to be higher than average. Suburban states that its Infection Control team, Housekeeping Department, and staff worked diligently and collaboratively to improve on this measure. According to the applicant, focus of efforts has been on basic room cleaning procedures, use of ultraviolet light post cleaning of intensive care unit (ICU) rooms and C diff rooms, a review and revision of testing procedures, hand hygiene monitoring, and establishment of an antibiotic stewardship. Suburban states that infection rates are monitored closely and reported to appropriate committees including the Medical Quality Committee of the Board of Trustees on a regular basis. (DI #3, p. 88).

In response to staff's request, Suburban provided a report on Hospital Quality Measures &

Action Plan Summary for "below average" metrics. Suburban was rated below average on six out of the total 73 measures. Listed below are the metrics for which Suburban was rated below average, and the applicant's responses regarding action taken to improve performance and results of that action.

Metric: **Communication: Were patients always given information about what to do during their recovery at home?**

Action: Over the past 3 years we have worked with our new EMR (electronic medical record) system to improve the discharge instructions and our process for communicating with patients about post d/c instructions.

Result: Updated Hospital Compare data shows an improvement in Suburban's performance related to discharge information. We expect additional improvement as a result of the changes implemented since February 2017 (the educational video concerning discharge), near the end of the last data collection period for which measures are available, and other changes that occurred during the last data collection period, the effect of which was not fully reflected in the measure for the period. We will continue to assess the impact of the most recent changes and identify effective communication strategies for our patients.

Metric: **Wait Times: How long patients spent in the emergency department after the doctor decided the patient would stay in the hospital before leaving for their hospital room.**

Action: The Hospital has instituted a Clinical Decision Unit to ensure that patients are placed in a location where they will receive the appropriate level of care.

Result: Since implementation, the ED (emergency department) length of stay has been reduced by half.

Metric: **Results of Care: Dying within 30-days after getting care in the hospital for heart failure**

Action: Suburban's performance is reflective of our elderly population. Patients with heart failure often have comorbid conditions. Suburban has introduced the following initiatives to improve Heart Failure (HF) 30-day mortality:

To optimize treatment, Suburban screens HF patients during hospitalization for impaired Left Ventricular Ejection Fraction. We have instituted multidisciplinary rounds to better focus their care and ensure communication of the care plan among all team members, the patient and their family. Our EPIC EMR has a hard stop in the Discharge Order Set for HF patients requiring the evaluation of ACE1/ARB[8] at time of discharge. In addition, Case Managers assess these patients during admission for the need for assistance at discharge from Suburban's Transition Guide RNs (registered nurses). Post-discharge, HF patients are remotely monitored for blood pressure, weight, and pulse oximetry. They are also followed by HF Transition Guides and post-discharge phone calls to ensure they are taking medications, monitoring weight and have scheduled their follow-up appointments.

Result: Suburban will continue to seek the most effective ways to address the needs of HF patients during their admission and after discharge.

Metric: **Practice Patterns: Contrast material (dye) used during abdominal CT (computed tomography) scan**

Action: Exams completed in Medical Imaging reflect what is requested on the physician order. Suburban offers CT examinations using a 64-slice scanner, which in some cases eliminates the need for contrast in order to achieve the level of detailed imaging required.

Result: None requested by Staff

Metric: **Practice Patterns: Patients who came to the hospital for a scan of their brain and also got a scan of their sinuses.**

[8] Angiotensin converting enzyme inhibitors and angiotensin-receptor blockers are used to treat high blood pressure and congestive heart failure.

Action: During this reporting period we had a surgeon who performed a significant number of CT-guided surgeries. His patients received pre-operative scans of the brain and sinuses to use during those procedures. These pre-operative scans would not be captured in the data used here. Suburban Hospital has instituted new guidelines for the utilization of I-lead and Sinus CT evaluation of patients with headache to provide better instruction to our ordering physicians.

Result: On the most recently published Hospital Compare results, there was a significant decrease, from 7.0% to 2.3%, which is less than the Maryland state average.

Metric: **Results of Care: Complications: Patients who developed a blood clot while in the hospital and did not get treatment that could have prevented it.**

Action: We have incorporated anticoagulation therapy into order sets where appropriate and have not observed any unusual trends in our hospitalized patients.

Suburban converted to Computerized Physician Order Entry in July of 2014. Every Suburban admission order set contains venous thromboembolism (VTE) orders for chemical and mechanical prophylaxis. The provider "Admission Navigator" contains decision support for medical and surgical patients with risk factors and contraindications to therapy. If the provider does not complete this assessment, the software challenges the provider to complete it before selecting VTE prophylaxis. VTE prophylaxis spans both pharmacological and mechanical components, and both are hard stops. These steps must be completed in order to sign the orders. To assess VTE risk from immobility, in the "Nursing Achnission Navigator" patients are screened for difficulty walking and climbing stairs. This is required documentation in the Epic EMR platform. In the "Daily Care/Safety" template, patients are assessed daily via the nurse mobility assessment, documentation of AM-PAC[9] daily functional activities score, and Highest Level of Mobility, including level of assistance needed.

Result: The most recent data from Hospital Compare shows a 0% Potentially Preventable VTE rate for Suburban from the time period between 03/31/2016 and 04/01/2017.

(DI# 13, Exh. CQ8; DI #15, pp. 1-4).

Reviewer's Analysis and Findings

Paragraph (b) of this standard reflects the former HPEG, as it existed when this standard was first established. HPEG has been greatly expanded since that time.[10] There is still an HPEG in the hospital consumer guide component and a set of quality measures is included as a component of that guide. However, the Commission now focuses on two priority areas: (1) patient experience, as reported by CMS in its Hospital Consumer Assessment of Healthcare Providers and Systems survey; and (2) healthcare associated infections, as tracked by the Center for Disease Control's National Healthcare Safety Network. Suburban identified measures for which it was rated "below average" and discussed actions taken to improve its level of performance.

The applicant appropriately addressed quality measures for which it was rated below average and has provided sufficient detail regarding remediation and evidence of its commitment to improve performance. Thus, I find the applicant meets complies with this standard.

[9] The Activity Measure for Post Acute Care (AM-PAC) is an activity limitations instrument designed to be used across patient diagnosis, conditions, and settings where post acute care is provided.

[10] Staff will recommend amendments to the Acute Care Hospital Services chapter of the State Health Plan to reflect these changes when that chapter is updated.

COMAR 10.24.15, Organ Transplant Services

10.24.15.04 A.General Standards

(1) An applicant for a Certificate of Need to establish an organ transplantation service shall address and meet the general standards in COMAR 10.24.10.04A.

See discussion in the immediately preceding review of compliance with the general standards.[11]

(2) Each Maryland transplant program shall agree to comply and maintain compliance with all requirements of CMS and UNOS certification and, if applicable, accreditation by the Foundation for the Accreditation of Cellular Therapy.

(a) Each organ transplant service shall be certified by UNOS within the first year of operation.

(b) Each hematopoietic stem cell bone marrow transplant service shall be accredited by the Foundation for the Accreditation of Cellular Therapy within the first two years of operation.

Applicant's Response

Suburban states that it agrees to comply and maintain compliance with all requirements of CMS and UNOS certification for its proposed liver transplant program and to be certified by UNOS within the first year of operation. (DI #3, p. 90).

Reviewer's Analysis and Findings

I find that the applicant complies with Paragraph (a) of this standard and that Paragraph (b) is not applicable.

10.24.15.04 B. Project Review Standards

(1) Need.

An applicant shall demonstrate that a new or relocated organ transplant center is needed. Closure of an existing service, in and of itself, is not sufficient to demonstrate the need to establish a new organ transplant center.

In responding to the Need standard, and throughout its application, Suburban states that there is a disparity between liver transplantation services in the Washington Region DSA and the Maryland Region DSA. Specifically, it contends that residents in the Washington Region DSA have lower levels of availability and access to liver transplantation when compared to the experience of residents in the Maryland Region DSA. Suburban states that it will address this disparity by establishing a second liver transplant center in the region, which it maintains will result in more

[11] COMAR 10.24.10.04A, *supra,* pp. 6-12.

residents of the Washington Region DSA receiving liver transplants closer to home. (DI #3, pp. 23-53; 91-102).[12,13]

Current Liver Supply and Utilization

Suburban draws conclusions from the data presented in Table IV-1, on the next page, regarding the relative performance between the two DSAs in acquiring livers as well as delivering liver transplants.

[12] In Suburban's application (DI #3, pp. 23-53), Suburban gave information in an introductory section about how it demonstrates need for a new transplant service at Suburban which did not appear under its response to the Need standard. I include information from this section within Suburban's response to the Need standard.

[13] Georgetown offers a different perspective on Suburban's choice of presentation and interpretation of the data. See the interested party's comments on the Need standard, *infra*, pp. 26-34.

Table IV-1: Suburban: Data and Metrics Comparing Liver Transplantation in the Two DSAs

		Maryland Region						Washington Region					
	2015 Population	3,900,632						5,464,786					
		2011	2012	2013	2014	2015	2016	2011	2012	2013	2014	2015	2016
1	Livers Procured			102	119	121	174			92	97	89	101
2	Livers Exported			5	23	24	22			18	38	53	35
3	Livers Imported			41	85	126	124			30	41	33	45
4	Total Supply			138	181	223	276			104	100	69	111
5	Volume of Liver Transplants in DSA	114	134	172	201	247	295	100	116	91	102	81	117
6	Live Donor Transplants	0	6	14	20	24	19	4	1	2	2	12	6
7	# of DSA Residents who Received Liver Transplants					173						134	
8	# of Residents who Received Liver Transplant within Home DSA					161						62	
9	# of DSA Residents who Received Deceased Donor Liver Transplants	83	74	88	109	117	152	106	126	121	136	111	127
10	# of DSA Residents who Received Deceased Donor Liver Transplant within Home DSA	61	63	73	101	108	138	55	79	57	66	29	56
11	# of Liver Transplants Per Million Adults	34.2	35.2	41.9	46.0	54.3		26.5	30.3	25.4	32.0	25.9	
12	Liver Transplants Per Million Adults Received Within Home DSA	19.6	22.9	27.9	31.9	41.3		14.1	15.4	12.0	14.6	11.3	
13	Deceased Donor Liver Transplants Per Million Adults	28.1	24.8	29.3	36.1	38.5	49.9	26.8	31.3	29.5	32.8	26.4	30.1
14	Deceased Donor Liver Transplants Per Million Adults who Received Within Home DSA	20.6	21.1	24.3	33.4	35.5	45.3	13.9	19.6	13.9	15.9	6.9	13.3
15	Median MELD score	24	28	29	32	31		22	22	24	26	25	
16	# of Center Transplants with MELD ≥ 35					75	75					7	8
17	Waitlist Candidates	197	321	436	536	453	422	140	160	171	194	141	209
18	Waitlist Candidates as of March 1, 2017						853						276

Source: DI #3, pp. 24-27, 30, 39, 47, 48, 91-95, 101; DI #13, pp. 17, 18, 24; DI #15, p. 120.
Note: In this Table IV-1, I compiled various sets of comparative data provided by the applicant in response to the Need standard and the Access standard.

Supply of Livers

The applicant observes that the Washington Region DSA, with a single liver transplant center at Georgetown, "produces less than one-third the supply of livers" as the Maryland Region DSA,

based on the latest data available at the time the application was submitted,[14] despite having a considerably larger population (5.4 million compared to 3.9 million). (Table IV-1, above, Row 4). The applicant states that the data indicates that there were more livers recovered, more livers imported, and fewer livers exported per year between FY 2013 and FY 2015 in the Maryland Region DSA when compared to the Washington Region DSA. (Table IV-1, above, Rows 1-3). (DI #3, p. 5; DI #3, pp. 91-95).

The applicant interprets this data to mean that liver transplant candidates who reside in the Washington Region DSA have historically had access to fewer livers from the procurement of livers and transplant services than liver transplant candidates who reside in the Maryland Region DSA. To exemplify this, Suburban notes that in FY 2013, prior to implementation of the "Share 35" allocation policy, the LLF OPO exported five out of 102 livers procured (five percent), compared to the WRTC which exported 18 out of 92 livers procured (20 percent). In FY 2014, after the implementation of "Share 35", which was expected to result in an increase in organ exports out of the local DSA, the LLF OPO exported 23 out of 119 livers procured (19 percent), compared to 38 out of 97 (39 percent) exported by the WRTC. (DI #3, pp. 92). Based on this, the applicant concludes that "Share 35" did not have the intended beneficial impact for sicker patients in the Washington Region DSA. (DI #15, pp. 6, 7).

Liver Transplant Center Volume

Suburban presents data comparing the number of transplants performed in each DSA. It observes that the two centers in the Maryland Region DSA performed more than twice as many liver transplants as the Washington Region DSA's single center in 2016, and that the gap widened between 2012 and 2016. (DI #3, pp. 24, 25; Table IV-1, above, Row 5). Suburban states that the total number of liver transplants performed at the two liver transplant centers in the Maryland Region DSA has increased every year and more than doubled from 2011 to 2016, from 114 to 295, while the total transplants at the single center in the Washington Region DSA remained fairly constant at approximately 100 per year with minor fluctuations for the same six-year period. The applicant presents this within the context of the population of the Washington Region DSA of 5.5 million, 40 percent greater than the population of the Maryland Region DSA at 3.9 million. (DI #3, pp. 105, 106).

Resident Transplant Rates

The applicant also asserts that patient access should be measured by comparing a patient's DSA of residency to where that patient received a transplant. The following Table IV-2 presents data submitted by the applicant showing this comparison for 2015. (DI #3, p. 107).

[14] The applicant bases statements on data through 2015. Suburban provided comparable data for 2016 upon request by Commission staff during the completeness review. I include this updated data in the table above.

Table IV-2: Suburban: Liver Transplants Received by Maryland Region and Washington Region Residents and Center (CY 2015)

Donation Service Area of Residence	Location of Transplant				Total DSA Residents Transplanted	Transplanted in home DSA	
	Johns Hopkins	UMMS	MGUH	Other		#	%
Maryland Region	57	104	7	5	173	161	93%
Washington Region	22	25	62	25	134	62	46%

Source: DI #3, p. 107.

Suburban states that the data shows that 93 percent of the 173 Maryland Region DSA residents who received a liver transplant in 2015 received the transplant at one of the two Maryland Region DSA centers, while only 46 percent of the 2015 transplant recipients from the Washington Region DSA received their transplant at the center in their DSA, while 54 percent went to transplant centers outside the region. (DI #3, pp. 108-09). Suburban converted this information to a *transplants per million adults* metric, showing the Maryland Region DSA exceeding the Washington Region DSA with 54 liver transplants per million adults compared to 26 liver transplants per million adults.[15] (DI #3, p. 27, 107).

Patient Migration Patterns

The applicant states that residents in the Washington Region DSA disproportionately have to leave their DSA of residence to receive liver transplant services compared to residents in the Maryland Region DSA. Suburban points to the transplant rates per million for residents who receive a transplant within their "home" DSA as an indication of need related to a disparity in access to liver transplantation. For Maryland Region DSA residents, 41 liver transplants per million took place within the Maryland Region DSA, compared to 11 liver transplants per million for residents of the Washington Region DSA.[16] (DI #3, p. 28). From 2011 to 2015, between 38 and 54 percent of patients traveled from the Washington Region DSA to receive liver transplants each year, compared to between seven and 29 percent of patients who traveled from the Maryland Region DSA for transplants over the same period. (DI #3, p. 27, 107).

Referring to the data displayed in Table IV-2, above, Suburban points out that in 2015, 47 Washington Region DSA residents were transplanted in the Maryland Region DSA and only seven Maryland Region DSA residents were transplanted in the Washington Region DSA. The applicant states that this has a disproportionate impact on patients of a lower socioeconomic status. (DI #3, p. 35, 129).[17] It argues that liver transplant candidates and recipients migrating from their DSA of residence are by definition those with the means to do so, supported by a 2013 study by Dzebisashvili which found an association between higher socioeconomic status and the ability to travel to alternative DSAs, and the impact of that travel on patient survival.[18] The applicant states that the article's findings include that the ability to travel led to dramatic differences in

[15] Table IV-1, *supra*, p. 15, Row 11.
[16] Table IV-1, *supra*, p. 15, Row 12.
[17] In its response to the Access standard (Suburban's application, DI #3, pp. 113-30), Suburban gave information about its plans to increase the supply or use of livers for transplantation. I include that information within Suburban's response to the Need standard.
[18] Dzebisashvili, Nino, et al. "Following the organ supply: assessing the benefit of inter-DSA travel in liver transplantation." Transplantation 95.2 (2013): 361-371.

transplantation and survival. The applicant submits this study as evidence that lower income individuals in one DSA do not readily travel to another DSA in order to improve their chances of getting transplanted. (DI #3, p. 129-130).

Suburban asserts that the disparity in migration rates between the Maryland Region DSA and the Washington Region DSA suggests that Washington Region DSA residents migrate out of necessity and the addition of a second center in the Washington Region DSA will reduce this disparity and make liver transplant a possibility for more patients without the means to travel. (DI #3, p. 130).

Patient Acuity

Suburban states that the Washington Region DSA transplant center performs transplants on patients with lower acuity, or lower MELD, scores. Transplant candidates with higher MELD scores are given higher priority for available livers, so more livers are exported by the WRTC compared to the LLF. Using median MELD scores to compare the relative acuity of transplant patients, the applicant submits that the Washington Region DSA transplant center has consistently transplanted fewer sicker patients compared to the Maryland Region DSA. (DI #3, p. 120)[19] Suburban points out that the MELD scores in the Maryland-only Region DSA were five or six points higher than the MELD scores in the Washington Region DSA in 2013, 2014, and 2015.

The applicant also submits that the Washington Region DSA transplant center has consistently transplanted fewer sick patients as compared to the transplant centers in the five Region II DSAs. See Table IV-3.

Table IV-3: Suburban: Region 2 Median MELD Score by DSA, 2011-2015

DSA OPO Code	States	2011	2012	2013	2014	2015
LLF	MD	24	28	29	32	31
PADV	PA, DE, NJ	29	29	30	31	30
PADTF	PA, WV, NY	28	29	31	28	29
NJTO	NJ	24	25	27	29	27
WRTC	DC, MD, VA	22	22	24	26	25

Source: DI #3, p. 39, 120.

The applicant correlates this with the Washington Region DSA being the only single-center DSA of the five DSAs in the region, and points out that in each year shown "the WRTC had the lowest median MELD score of the five DSAs … mean[ing] that the single WRTC center consistently performs transplants on less sick adult patients …. Of note, the WRTC is the only single-center DSA of the five." (DI #3, p. 120). It also points out that patients with lower MELD scores have lower priority on the waitlist and, thus, less ability to "pull" (or import) donor organs from other DSAs, resulting in less case volume overall. (DI #3, p. 94).

Presenting more data on transplants for higher-acuity patients, Suburban shows that in 2015 and 2016 combined, the number of transplanted patients with MELD scores ≥ 35 totaled 150 in the Maryland Region DSA and just 15 in the Washington Region DSA. (Table IV-1, Row 16).

[19] Table IV-1, *supra*, p. 15, Row 15.

To further illustrate what it characterizes as liver-use disparity, the applicant notes that between 2014 and 2016, 21 livers were exported from the Washington Region DSA and transplanted in the Maryland Region DSA. Of these, six were exported as a result of "Share 35," but the other 15 were exported after being rejected by Georgetown, but were accepted and transplanted at Johns Hopkins, providing evidence that usable livers were rejected by the Washington Region DSA's transplant center. (DI #13, p. 33-34; DI #15, p. 7).

Number of Candidates on the Waitlist

The applicant compares the waitlists of the centers in the Washington Region and Maryland Region DSAs, as of March 1, 2017, and notes that the liver transplant waitlist at Georgetown had one-third the number of patients as the liver transplant waitlists in the Maryland DSA, and has lagged behind since 2012.[20] According to Suburban, over the previous four years, between 213 and 342 more patients were added to the waitlist in the Maryland Region DSA transplant centers each year than were added to the Washington Region DSA center's waitlist. (DI #3, p. 47-48).

An applicant shall address:

(a) The ability of the general hospital to increase the supply or use of donor organs for patients served in Maryland through technology innovations, living donation initiatives, and other efforts.

Applicant's Response

How Suburban Proposes to Increase the Supply or Use of Donor Organs

Suburban argues that its proposed project would result in an increased supply and use of organs to candidates in the Washington Region DSA.[21] The applicant suggests that its association with Johns Hopkins Medicine demonstrates how it could help increase awareness of the importance and benefits of liver donation and transplantation and utilization of available organs in the Washington Region DSA through:

- Education and outreach aimed at increasing organ donation;
- Increasing the volume of transplants performed on higher acuity patients by using livers that are not used by the existing liver transplant center;
- Outreach to live donors in the Washington Region (which would still be performed at Johns Hopkins), "freeing up" deceased donor livers for others;
- Johns Hopkins' offering human immunodeficiency virus (HIV)-positive donor transplants;
- Increasing the region's capacity to evaluate patients for candidacy; and

[20] Table IV-1, *supra*, p. 15, Rows 17-18.

[21] In its introductory sections and in response to the Access standard (Suburban's application, DI #3, pp. 23-72; pp. 113-30), Suburban gave information about how its proposed program would increase the supply and use of donor livers. I summarize information within Suburban's response to the Need standard, which specifically provides that an applicant, in demonstrating need, address its ability to increase the supply or use of donor organs.

- Increasing the region's capacity to perform more liver transplants.

(DI #3, pp. 96-102; DI #13, p. 21).

Suburban also references literature and case studies that it claims support the benefits of increased competition in the single-center Washington Region DSA. (DI #3, pp. 49-52).

Increasing the Supply of Livers through Education and Outreach

The applicant highlights the following education, outreach, and research programs in which the Johns Hopkins CTC and/or Johns Hopkins are engaged:

- Partnering with the American Liver Foundation, The American Transplant Foundation, and Donate Life America, the Living Legacy Foundation, National Kidney Foundation of Maryland, Organ Donation and Transplantation Alliance, and Transplant Recipients International Organization, Inc; (DI #3, p. 96).

- Participating in "Lobby days" at dialysis centers where staff members educate dialysis patients on the option of kidney transplantation, the option to double wait list, and answer any questions they may have about the transplantation process; (DI #3, p. 96).

- Arranging physician-to-physician meetings at which CTC physicians discuss advances in transplantation and novel therapies with community physicians; (DI #3, p. 96).

- Sponsoring webinars for both patients and providers in which CTC physicians discuss transplantation issues; (DI #3, p. 96).

- Presenting transplant-related community events that feature CTC physicians and staff; (DI #3, p. 96).

- Collaborating with the Minority Organ Tissue Transplant Education Program to provide outreach, education, and support for end stage liver failure and donor education. (DI #3, p. 149);

- Reaching out to Howard University, United Medical Center, the National Institutes of Health, U.S. military hospitals, and social and support agencies to identify minority and indigent patients in need of care in the community; (DI #3, p. 64);

- Creating a 2012 Facebook campaign that allowed users to specify their organ donor status in their profiles and provided links to educational materials and state registries to facilitate becoming a registered organ donor which resulted in more than 13,000 new donor registrations across the United States on its first day. (DI #3, p. 60, 97);

- Making significant scientific contributions, through the Johns Hopkins' Epidemiology Research Group in Organ Transplantation (ERGOT), in the areas of living donor recruitment and outcomes, development of transplantation models, and development of a

transplant-focused multidisciplinary team composed of more than 13 Hopkins faculty members and 70 staff in total;

ERGOT partners with the Scientific Registry of Transplant Recipients, the Johns Hopkins Welch Center for Prevention, Epidemiology and Clinical Research, the Center for Surgical Trials and Outcomes Research, and Facebook to increase organ donation. It is involved in numerous studies with the National Institutes of Health and others, in areas such as including frailty and End Stage Renal Disease, HIV Organ Policy Equity, incompatible organ transplantation, Live Donor Champion Program, and Wellness and Health Outcomes of Live Donors Study; (DI #3, pp. 60, 97);

- Partnering with LLF, sharing costs and coordinating efforts. The applicant claims that, in collaboration with LLF, the CTC developed an Organ Donation Culture, which facilitates effective, caring and compassionate solicitation and procurement of deceased organs. The applicant states that it hopes to establish a similar partnership with the WRTC if the project is approved; (DI #3, p. 100; DI #13, p. 76).

  CTC staff members work with ICU and other hospital staff in communicating with and delivering supportive end of life care for families. As part of this effort Johns Hopkins and LLF share employment of a Donor Advocate to manage donor education and management. The applicant claims that having a Donor Advocate as a part of the team has been critical to building a healthy and informed organ donation culture at Johns Hopkins, and is an example of the collaboration between CTC and the local OPO. (DI #3, p. 100); and

- Engaging in population health initiatives, through Suburban's Community Health and Wellness Division, with the goal of improving the health of the community. The applicant states that it currently targets five health priorities, including diabetes, obesity, and substance use disorders, all of which are risk factors for liver disease. (DI #13, p. 76).

Explaining that Johns Hopkins Medicine currently engages in outreach efforts in the Washington Region DSA through the hepatology practices at Sibley Memorial Hospital and Suburban, Suburban states that patients expect to be treated locally. Suburban suggests that it would leverage this experience to deploy efforts similar to those currently executed by the CTC at Johns Hopkins listed above in order to increase the number of registered organ donors and the supply of donated organs. (DI #3, pp. 59-66, 98-102; DI #13, pp. 39-40). It maintains that a second liver transplant program in the Washington Region DSA would allow CTC to double the scope of its outreach efforts by consolidating Suburban's and Johns Hopkins' communities to reach more potential donors. (DI #13, p. 25). The applicant also states it would engage in outreach to all regional hospitals to educate staff about approaching the families of potential deceased donors. (DI #13, p. 21).

Increasing the Use of Livers by Performing Transplants on Patients with Higher Acuity

The applicant presents data showing that the Washington Region DSA transplant center served a lower-MELD patient population relative to the centers in the Maryland Region. It concludes

that this leads to livers that are exported from the Washington Region DSA for use by patients in other regions to the detriment of Washington Region DSA liver transplant candidates. (DI #3, p. 20) Suburban states that the addition of a second center in the Washington Region DSA would maximize utilization of less desirable livers than Georgetown has historically used. It also points out that patients with lower MELD scores have lower priority on the waitlist and, thus, less ability to "pull" (or import) donor organs from other DSAs, resulting in less case volume overall. (DI #3, p. 93, 94). Based on a continued pattern of lower MELD scores through 2015, the applicant concludes that "Share 35" (implemented in June 2013) has not have the intended beneficial impact for sicker patients in the Washington Region DSA. Thus, it states that it should not be assumed that a new allocation policy will increase transplants for sicker patients in that region. Suburban claims that "intra-DSA competition will relieve this disparity and result in a greater number of transplants of sicker patients in the WRTC DSA." (DI #13, p. 43).

Suburban further states that allocation policies do not address the other issues that may be contributing to insufficient access in the Washington Region DSA, such as ICU bed availability, evaluation capacity, and waitlist additions. (DI #15, p. 7). Suburban reiterates that the proposed project would double the number of available ICU beds at transplant center hospitals within the Washington Region DSA, and that this is important because

> the availability of intensive care unit (ICU) beds is necessary for a transplant center. Patients with high MELD scores routinely require ICU care, and so the ability to perform liver transplants on those patients depends on ICU bed availability. On occasion, a transplant center may be unable to perform a liver transplant because an ICU bed is not available. That is less likely to occur in a hospital with a higher number of ICU beds. It is also less likely to occur in a DSA with more than one center.
> (DI #15, p. 4).

Thus, the applicant asserts that establishing a liver transplant program at Suburban with its additional 42 ICU beds would alleviate any access restriction that a shortage of ICU beds might impose on transplant patients with high MELD scores. (DI #13, p. 40; DI #15, p. 5).

Increasing the Supply and Use of Living Donors and HIV-positive Donations

In addition to increasing awareness through the outreach and education initiatives noted above, the applicant highlights Johns Hopkins Medicine's track record of performing both living donor and HIV-positive transplants. Suburban points out that living organ donation can help to address the critical shortage in available organs. It observes that, since 2011, 54 more live donor liver transplants have been performed in the Maryland Region DSA than the Washington Region DSA[22] (DI #3, pp. 98-99). Although Suburban is not proposing to perform live donor liver procedures (these procedures would continue to be performed at The Johns Hopkins Hospital in Baltimore with pre- and post-operative care at Suburban), it asserts that its presence as a liver transplant center in the Washington Region DSA will lead to an increase in support for education, identification, and recruitment of live donors in the Washington Region DSA. (DI #3, pp. 98-99, 101-02; DI #13, p. 31).

[22] Table IV-1, *supra*, p. 15, Row 6.

Suburban states that Congress' enactment in 2013 of the HIV Organ Policy Equity (HOPE) Act, which reversed the ban on organ donations from HIV-positive donors, led to an increased supply of organs that could be used for HIV-positive transplant recipients. It notes that Johns Hopkins performed the world's first HIV positive liver and kidney transplants in 2016 and estimates that an additional 500 to 600 HIV-positive patients could be transplanted annually in the U.S. (DI #3, pp. 100-01).

Increasing the Use of Livers by Adding a Transplant Center with More Capacity

Suburban states that the biggest factor driving the lower transplant rate in the Washington Region DSA is capacity. (DI #13, p. 15). It contends that an additional liver transplant center is needed in the Washington Region DSA to address the liver transplant needs of the 5.5 million residents in the area. According to Suburban, a liver transplant requires an evaluation process that is complex, iterative, and time consuming, with multiple consultations, laboratory tests, procedures, and other diagnostic tests, depending on the patient's clinical situation and co-morbidities. (DI #13, p. 44).

The applicant notes that the waitlists in the Maryland Region DSA centers are more than three times the size of the Washington Region DSA center's waitlist.[23] Suburban offers evidence that the age-adjusted death rate due to chronic liver disease is roughly equal for residents of the jurisdictions comprising the two DSAs (though slightly higher for residents of D.C. and Virginia than Maryland), again contrasting these facts with the much longer Maryland Region DSA waitlists. While there is no benchmark for waitlist length or the rate at which patients are added to the waitlist, the applicant suggests that the disparity between the waitlists at the center in the Washington Region DSA and the centers in the Maryland Region DSA may result from the single center in the Washington Region DSA lacking capacity to conduct a sufficient number of candidate evaluations. (DI #13, pp. 48-49; DI #15, p. 5).

According to Suburban, the decision to list a patient is ultimately at the discretion of the center's multidisciplinary team. It notes that the listing policies of UMMC and Georgetown are not publicly available. The applicant states that variations in policy may be found in: age; HIV status; certain disease states such as hypercoagulable disorders; alcohol abstinence; tobacco use; social support; pre-existing conditions such as cardiac disease; or re-transplants. An evaluation also requires demonstration of adequate insurance for transplant, transportation, and a capable adult caregiver to assist the potential recipient in the evaluation process and through the transplant process. Suburban states that patients lacking these resources experience an access barrier to transplantation, especially minority patients, low-income patients, and patients without an adequate social support system. (DI #13, p. 44)

Suburban claims that the difference in the number of transplants between the two regions is evidence that a two-center DSA operates more effectively. (DI #3, pp. 95-96). It suggests that the single transplant center within the Washington Region DSA lags behind in identifying, evaluating, and listing transplant-eligible patients. (DI #13, p. 44; DI #15, p. 5). Suburban states that its proposed center intends to increase the number of transplant evaluations performed and patients

[23] Table IV-1, *supra*, p. 15, Row 18.

added to the waitlist every year. According to the applicant, its proposed project will be able to evaluate and double-list additional patients in a cost-effective way, and may have different acceptance policies that could increase patient options. (DI #3, pp. 119-22; DI #13, p. 38).

Increasing the Use of Livers by Adding Capacity to Perform Liver Transplants

Suburban suggests that the Washington Region DSA could have realized an additional 108 liver transplants performed, if the same ratio of transplantations per population were achieved as in the Maryland Region DSA. (DI #3, p. 32). It suggests that an additional liver transplant center is needed to address this disparity. (DI #3, p. 28). The proposed project would increase the number of ICU beds available to liver transplant patients in the Washington Region DSA from approximately 57 to approximately 99. (DI #13, p. 21). Suburban states that the availability of ICU beds is especially necessary for patients with high MELD scores who routinely require ICU care. The applicant states that, on occasion, a transplant center may be unable to perform a liver transplant because an ICU bed is not available, and that is less likely to occur in a hospital with a higher number of ICU beds or to occur in a DSA with more than one center.

The applicant offers a comparison of UMMC, which has 266 ICU beds and performed 53 transplants on patients with MELD scores of 35 and above in 2016, and Georgetown, which has 57 ICU beds and performed eight transplants on patients with MELD scores of 35 and above, without noting a specific reference for this data. Suburban believes there is a correlation, but states that it cannot know for certain whether the lack of an available ICU bed contributed to Georgetown's lower number. According to Suburban, the proposed project will add a liver transplant program to a general hospital with 42 ICU beds, better accommodating patients with advanced liver disease in the Washington Region DSA. (DI #15, pp 4-5).

Research and Evidence on the Increased Use of Livers Due to Competition

Citing literature, as well as experience and anecdotal evidence, Suburban asserts that the lack of competition in the Washington Region DSA has led to disparities in the number of liver transplant candidates on the waitlist, number of transplants performed, the number performed locally, and the number of livers procured. Suburban provided summaries of research articles that it believes support this view:

- Halldorson (2013).[24] Examined the impact of having more than one transplant center within a DSA on post-transplant outcomes and variation in patients waitlisted. Observations include the following:
  1. When a DSA has more than one center, patients listed at the individual centers are ultimately combined into a single DSA list. Centers within a DSA compete to be the center where patients want to be waitlisted and ultimately transplanted;
  2. In the presence of competition, centers are more likely to transplant sicker patients (increasing access) and transplant recipients were more likely to be Status 1;[25] have a

[24] Halldorson, Jeffrey B., *et al*. "Center competition and outcomes following liver transplantation." *Liver Transplantation* 19.1 (2013): 96-104.

[25] Status 1A patients have acute (sudden and severe onset) liver failure and are not likely to live more than a few days without a transplant. Status 1B is reserved for very sick, chronically ill patients younger than 18

MELD score greater than 20; be on dialysis in the week before transplantation; have received a previous transplant; have been on life support; and have had a functional status requiring total assistance;
3. Competition led to the utilization of higher risk organs (increasing supply), with more frequent donors who have a donor risk index in the upper quartile; and
4. DSAs without competition had significantly fewer listings per million population;

- Adler (2015).[26] Analyzed and assessed how intra-DSA competition and liver transplantation center density are associated with liver transplantation volume within individual DSAs. Observations included the following:
  1. DSAs with more liver transplant centers were associated with more liver transplants, more listings, more donors, and higher Liver Donor Risk Index; and
  2. Transplant center density was associated with market competition, more listings for transplant, and higher MELD at transplant;

  Adler (2016).[27] Examined the impact of transplant market characteristics on OPO performance and found that competition within DSAs was strongly associated with OPO performance. For liver transplant, more competitive DSAs were associated with:
  1. Higher number of donors per million;
  2. Higher conversion rate;
  3. More livers transplanted per donor;
  4. Higher percent of liver donation after cardiac death;
  5. Higher mean Liver Donor Risk Index;
  6. Higher local Liver Donor Risk Index;
  7. Higher imported Liver Donor Risk Index;
  8. Longer waiting time;
  9. Higher MELD score;
  10. More new listings per 100,000;
  11. Higher percentage of transplants with MELD greater than 30; and
  12. Fewer livers recovered per donor, suggesting a more aggressive pursuit of marginal donors that yielded only kidneys.

(DI #3, pp. 49-50, 123).

Suburban asserts that these studies provide evidence that centers with no competition may be more selective about using organs other centers might consider too "high risk" and about transplanting organs in sicker recipients. It surmises that if a single center is more selective with potential recipients and donors, patients seek out other out-of-area centers with a higher risk tolerance. Patients in more urgent need of a transplant residing in a non-competitive DSA may either

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years old. Less than one percent of liver transplant candidates are Status 1A and 1B at any one time. Source: "Liver allocation questions and answers," Organ Procurement and Transplantation Network https://optn.transplant.hrsa.gov/data/organ-datasource/liver/liver-allocation-questions-and-nswers/#:~:text=Status%201A%20patients%20have%20acute,1B%20at%20any%20one%20time.

[26] Adler, Joel T., *et al*. "Market competition and density in liver transplantation: relationship to volume and outcomes." *Journal of the American College of Surgeons* 221.2 (2015): 524-531.

[27] Adler, Joel T., *et al*. "Is Donor Service Area Market Competition Associated With Organ Procurement Organization Performance?" *Transplantation* 100.6 (2016): 1349-1355.

be bypassed (and die), or seek services other DSAs to list and be transplanted, if they have the resources. Citing the research summarized above, Suburban points out that, compared to the less competitive Washington Region DSA, the more competitive Maryland Region DSA performs more transplants per year, has a higher median MELD score, has a higher organ supply utilization rate, lists more patients and has more new patient listings, and has a larger number of donors. (DI #3, p. 50-51).

Suburban concludes that the solution to resolving described disparities is to introduce an additional liver transplant center within the Washington Region DSA, and that Suburban Hospital, an affiliate of the Johns Hopkins Comprehensive Transplant Center, is the best way to increase competition and, thus, improve access. The applicant asserts that this is because of Johns Hopkins CTC's experience and expertise, Suburban's capabilities (as evidenced by its Level II Trauma Center and cardiac surgery program), the ability to minimize start-up costs by leveraging resources already available at the Johns Hopkins CTC, and the fact that Suburban is a lower cost setting than the existing providers, which are all academic medical centers. The applicant also states that competition will improve access and reduce migration across DSA borders and offer the ability to list with one health system in both the Washington Region and Maryland Region DSAs. (DI #3, p. 123-25).

Further extolling the merits of competition, the applicant adds that competition in the Maryland Region DSA has influenced the policies and practices of Johns Hopkins and UMMC, claiming that these two programs have experienced steady growth since 2010, transplant sicker patients, and make use of marginal organs, all while maintaining excellent outcomes and reducing outmigration from the Maryland Region DSA. (DI #13, p. 41). Suburban states that the following factors led to a reduction in out-migration from the Maryland Region between 2011 and 2015:

- Increased access afforded by two competing services within the Maryland Region DSA reduced the need for Maryland Region DSA residents to seek transplants outside the DSA;
- Intra-DSA competition encouraged more patient outreach and more robust referral practices, resulting in greater retention of Maryland Region DSA transplant patients;
- Intra-DSA competition led to an increase in the number of donors in the Maryland Region, thus making more organs available;
- The establishment of Share 35[28] by CMS, which allowed the Maryland Region DSA to use organs from outside the DSA; and
- Enhanced experience, outcomes, and reputations of the two Maryland Region DSA centers.

(DI #13, p. 41).

Finally, Suburban presents recent experience with kidney transplantation services in the Washington Region. In 2015, a new kidney transplant program was added in the Region at George

[28] In 2013, CMS adopted a policy known as "Share 35" which increased regional priority for patients with a MELD score of 35 or greater, or sicker patients labeled Status 1 with acute (sudden and severe) liver failure. In 2017, an additional change in the national policy for liver allocation extended the Share 35 program to apply to patients with a MELD score of 32. In February 2020, the "Acuity Circles" policy replaced Share 35.

Washington University Hospital. The applicant states that this led to additional kidney transplant volume in the DSA, and also resulted in Georgetown increasing its transplant volume by more than 30 percent. (DI #3, p. 125).

Interested Party Comments

Georgetown states that Suburban's case for the need for a new liver transplant program is neither objective nor valid. It argues that the data does not support the claim that a new program is needed in the Washington Region DSA and that the scientific literature and actual experience do not support the claim that increased competition leads to increased numbers of transplants and improved patient survival. It also states that the methodologies supporting the applicant's arguments regarding migration of patients and import/export of organs are inappropriate. (DI #21, cover letter, p. 2).

In its comments that address Suburban's compliance with the Need standard, Georgetown rejects Suburban's arguments that its proposed liver transplant service will increase both the supply of organs and the use of organs in the Washington Region DSA. The interested party rejects Suburban's assumption that the number of available organs and the volume of transplants that take place within each DSA should be compared to demonstrate the level of liver transplant services that are available to the population, particularly when, as here, the DSAs are contiguous. (DI #21, p. 2). Georgetown also disagrees with Suburban's contention that differences in organ supply metrics such as procurement, exports, and imports are markers for the adequacy of a program's operations. Georgetown further notes that it considers the data presented by Suburban on patient acuity levels outdated. It notes that the distribution of high-MELD patients changes over time and that the differences presented by Suburban are not statistically significant. (DI #21, p. 6).

Along with offering its own perspective on the applicant's data summarized in Table IV-1,[29] Georgetown draws conclusions from data presented in that table regarding the relative performance of the two DSAs in acquiring livers as well as delivering liver transplants.

[29] Table IV-1, *supra*, p. 15.

Table IV-4: Georgetown: Data and Metrics Comparing Liver Transplantation in the Two DSAs

		Maryland Region	Washington Region
		As of Oct. 2017	As of Oct. 2017
1	Deaths within DSA	34,829	30,639
2	Rank for Total # of Deaths	35/58	36/58
3	Death rate per 1,000 Population	8.93	5.61
4	Death Rate Rank	21/58	57/58
5	Eligible Deaths		163
6	Deceased Donors Meeting Eligible Criteria		108
6	Observed Donation Rate per 100 Eligible Deaths		66.3
7	Expected Donation Rate per 100 Eligible Deaths		64.4
8	Standardized Donation Rate Ratio		1.03
9	# of Locally Procured Livers Transplanted by Local DSAs	133	69
10	# of Locally Procured Livers Transplanted Outside of DSA	26	33

Source: DI #21, pp. 10, 11; SRTR OPO Reports for the LLF and WRTC released Jan. 2018.
Note: In this Table IV-4, I compiled various sets of comparative data provided by the interested party.

Supply of Livers

Georgetown states that liver procurement is a function of the number of deaths in a DSA, not simply the size of the population. It notes that, according to SRTR reports, despite the Washington Region DSA's larger population, that region has fewer annual deaths than the Maryland Region DSA. (Table IV-4, above, Rows 1, 2). Thus, the Maryland Region DSA transplant centers have access to more total organs than the Washington Region DSA transplant center, despite the smaller population. The interested party contends that the addition of a transplant center will have no impact on the number of deaths or the death rate within a DSA. (DI #21, pp. 9-12).

According to Georgetown, the centers in the Maryland Region DSA simply have had access to a larger supply of organs. It notes that, in the then-latest-available SRTR *OPO-Specific Report* released on January 5, 2018 (covering data through October 2017), , the Washington Region DSA had over 4,000 fewer deaths than the Maryland Region DSA despite having a slightly larger population. In the preceding year, the Washington Region DSA had 30,639 deaths compared to the Maryland Region DSA's 34,829. Converted to a population-based death rate, the Washington Region DSA ranked 57 out of 58 DSAs, with a death rate of 5.61 per 1,000; the Maryland Region DSA ranked 21 out of 58 DSAs, with a death rate of 8.93 per 1,000. (Table IV-4, above, Rows 1-4). The WRTC actually performed somewhat better than its expected donation rate per 100 eligible deaths, achieving 66.3 donated organs per 100 eligible deaths compared to an expected donation rate of 64.4/100, (DI #21, p. 12). (Table IV-4, above, Rows 6, 7).

Georgetown characterizes the applicant's discussion of liver imports and exports as a "self-created import-export equation methodology" that does not demonstrate that a new center would

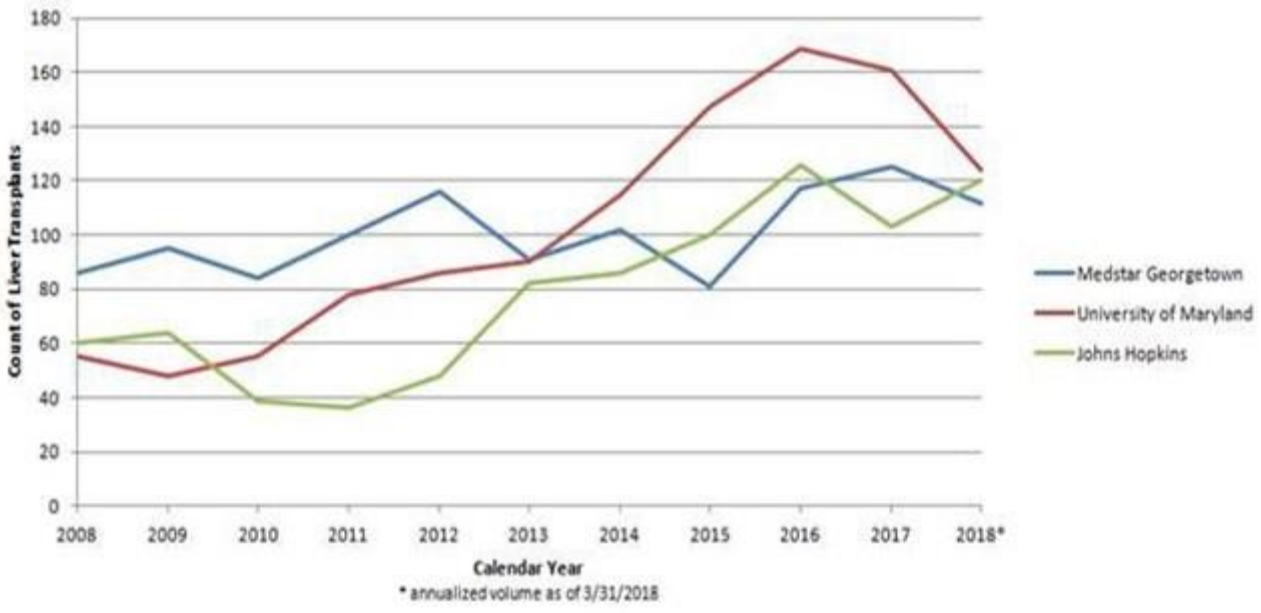
increase the supply of organs in the Washington Region DSA. Citing data from the SRTR database, Georgetown notes that there is "little difference in organs exported directly to one region over another" between the WRTC and LLF. Instead, Georgetown asserts that "[o]rgans travelling between centers do so because the allocation rules mandated by CMS require it." (DI #21, p. 12).

To illustrate the point, Georgetown notes that, in FY 2017, 33 WRTC livers were exported with five going to Johns Hopkins and seven to UMMC; the rest were exported to other programs. (Table IV-4, above, Row 10). The interested party draws the conclusion that variations represented in the Suburban application reflect evolving UNOS policy, which is intended to improve access for the highest acuity patients. Georgetown states that UNOS has determined that increased organ sharing, rather than more transplant centers, is the proper mechanism through which to address differences in OPO performance characteristics – and to provide greater access to organs for the most severely compromised patients. (DI #21, pp. 13-15).

Liver Transplant Center Volume

Addressing Suburban's statements regarding historical center volume, Georgetown illustrated volume trends as shown in Figure IV-A below, accompanied by several observations.

Figure IV-A: Georgetown: Liver Transplant Volume by Center, 2008-2018



Source: DI# 21, p. 3.

Georgetown contends that center volume fluctuations reflect evolving UNOS policy. It insists that increased organ sharing, rather than the number of transplant centers, is the proper mechanism through which to address differences in DSA characteristics and provide greater access to organs for the most severely compromised patients. (DI #21, p. 15). The interested party refers back to the import/export comparison between the Washington Region DSA and the Maryland Region DSA in the most recent SRTR data that it says shows little difference in organs exported

directly to one region over another.[30] (DI #21, pp. 12-13). Georgetown states that organs travel among centers because it is required by the allocation rules mandated by CMS. (DI #21, p. 12).

The interested party points out that volumes have also fluctuated over time for a variety of other reasons at times. It recounts that CMS sanctioned the Johns Hopkins liver transplant program for poor outcomes several years ago, which resulted in the program adopting more conservative organ acceptance practices and lower volumes. Since then, Hopkins' volumes have rebounded. As another example of volume fluctuation, Georgetown points out that UMMC experienced an increase in volume associated with new surgical leadership of its program during 2014 to 2016, but that this growth has contracted recently. (DI #21, p. 2). Georgetown acknowledges its own volume fluctuations, but characterizes them as less variable than others "due to stable programmatic and institutional leadership and outcomes," and also points out that "volume gaps are narrowing among all centers," as shown in Figure IV-A, above. (DI #21, pp. 2, 3).

The interested party further states that the Johns Hopkins CTC operates two sites in the Washington Region DSA at which liver transplant evaluations are performed, which creates a potential for "artificially created need," as those evaluation centers refer candidates to Johns Hopkins for transplantation despite the proximity of the transplant program at Georgetown. Thus, Georgetown asserts that the "livers are not leaving the Washington Region DSA due to a lack of access," but instead "follow[ing] high acuity patients for which sharing is mandated under UNOS allocation policy." (DI #21, pp. 12-15).

Disparities in DSA Transplant Rates, Migration, and Waitlists

The interested party disputes Suburban's argument that a new program will lead to increased transplant rates. According to Georgetown, overall "transplant volume cannot be tied specifically to population density, but rather to many variables" that include: the time that a program has been in operation; physician referral patterns that fluctuate over time; patient and donor selection criteria that evolve over time; the availability of organs which is determined by a variety of factors; and allocation policy governed by CMS/UNOS. Georgetown points to the data in Figure IV-A,[31] showing that case volume at the three programs in Maryland and D.C. has fluctuated over the decade as a consequence of internal programmatic developments. (DI #21, p. 2).

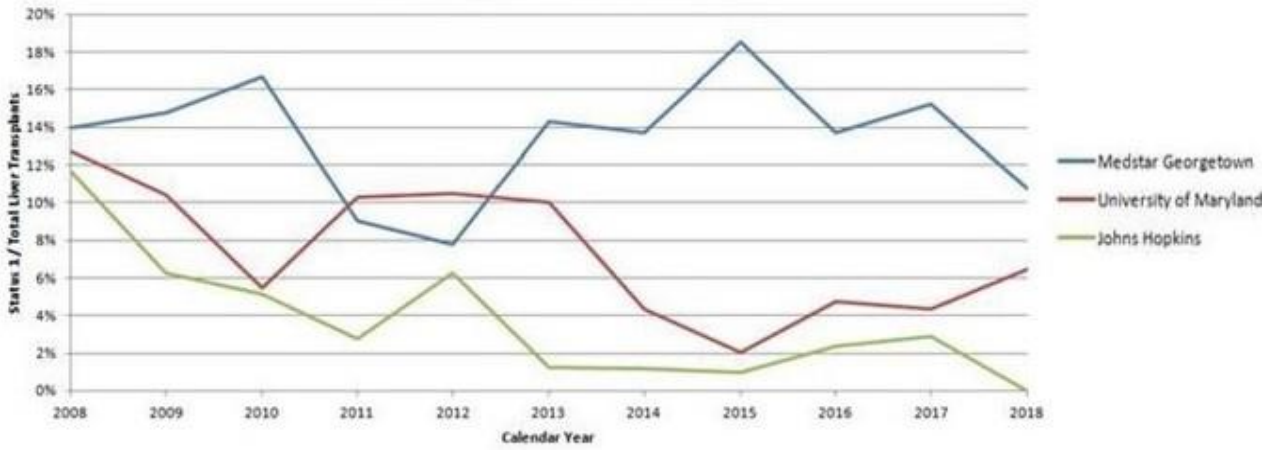
Georgetown attempts to debunk the idea that patient "migration" is an indicator of need or access, stressing that – especially in areas of close geographic proximity – there "should not be an expectation that residents of a DSA with arbitrary borders should be transplanted within that same DSA …." (DI #21, p. 4). It maintains that, "[i]n light of the liver organ allocation policy mandated by CMS, 'migration' based on 'access' simply does not occur, and thus should be ignored." (DI #21, p. 4). Instead, Georgetown states that wait-listing for transplant at one program or another is typically motivated by individual preference, referring physician recommendation, family support, perceived reputations of individual centers, and many other variables that may change over time. (DI #21, p. 4).

[30] Table IV-4, s*upra*, p. 28, Row 9-10.
[31] Figure IV-A, *supra*, p. 29.

Patient Acuity

The interested party takes issue with Suburban's contention that Georgetown's patient acuity is lower than patients at Maryland Region DSA transplant centers, stating that the applicant presents outdated data and draws conclusions based on just one SRTR reporting period. Georgetown contends that more recent data demonstrates that the distribution of high MELD score patients as a proportion of transplants changes over time and that the applicant did not present data that would show statistically significant differences. (DI #21, p. 6). As shown in Figure IV-B, Georgetown points out that it performs many more transplants on the most seriously ill "Status 1" patients, who will survive only hours without a liver transplant.

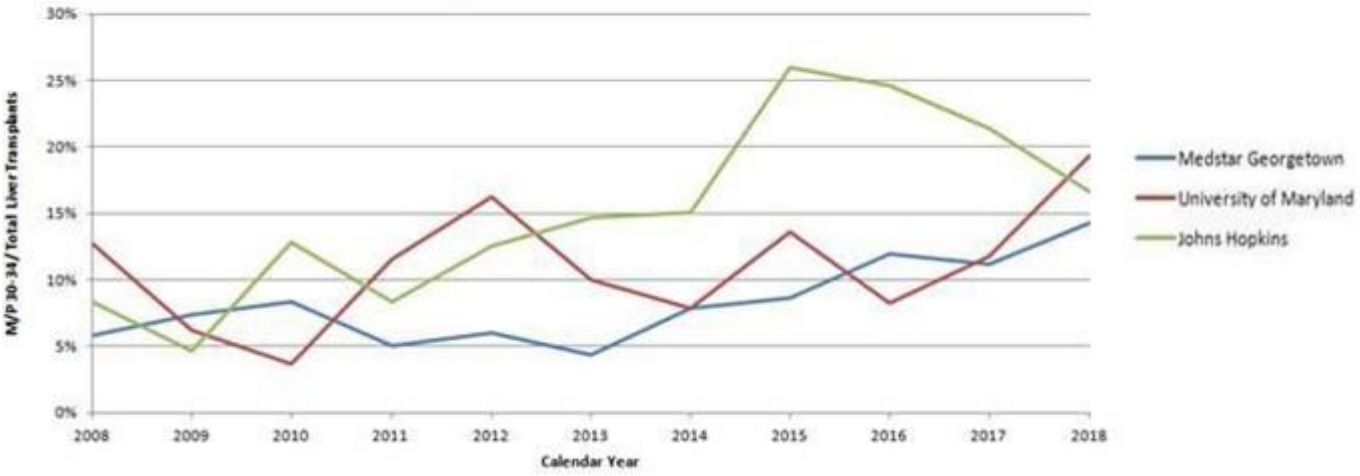
Figure IV-B: Georgetown: Percentage of Status 1 Transplants by Center, 2008-2018



Source: DI #21, p. 8.

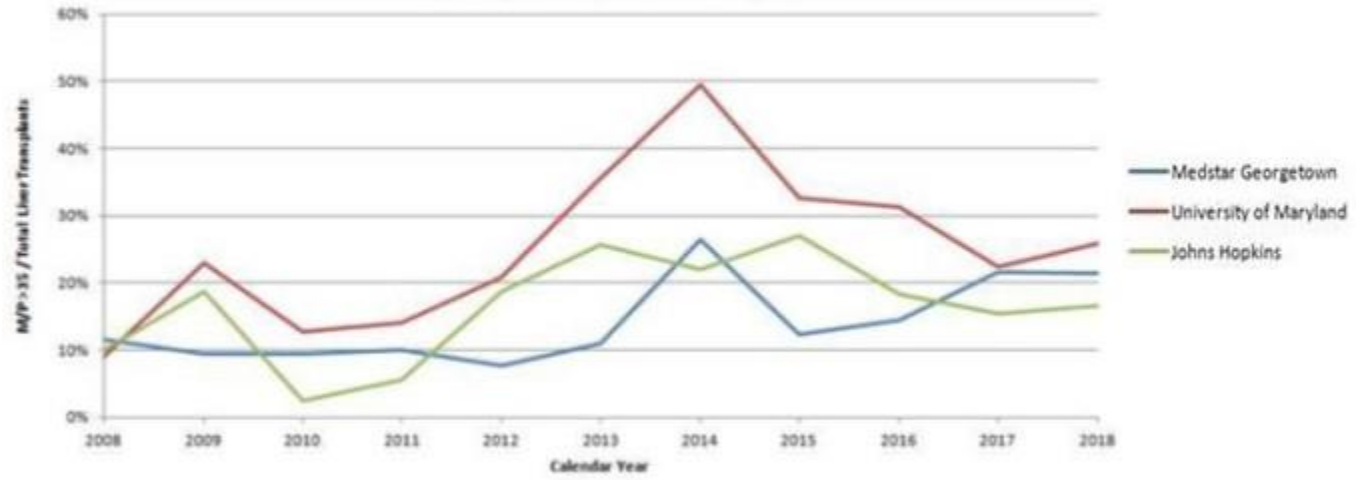
Georgetown states that, when the Status 1 group is combined with other high MELD score categories, they represent a higher proportion of acutely ill patients than that reported in the Suburban application. The interested party contends that the applicant selectively chose a limited cohort of patients to support its argument. Georgetown also states that the proportion of high acuity patients has fluctuated randomly over time as a consequence of changes in allocation policy and OPO performance. Figures IV-C and IV-D below show this variability that Georgetown states does not reflect divergent medical practices at one center and is not indicative of the need for an additional program. (DI #21, pp. 6-9).

Figure IV-C: Georgetown: Percentage of Transplants with MELD 30-34 by Center, 2008-2018



Source: DI #21, p. 9.

Figure IV-D: Georgetown: Percentage of Transplants with MELD Greater than 35 by Center, 2008-2018



Source: DI #21, p. 9.

Georgetown also references a 2018 publication[32] as a counterpoint to the literature cited by the applicant. The interested party's summary of this study states that MELD profile differences exist at all levels of allocation, including within a single DSA and that MELD, as a measure of acuity, is not in itself an appraisal of access to transplantation. It reports that this study found that transplant centers that aggressively utilize higher-risk organs often demonstrate a broader range of MELD scores than more conservative centers. In Georgetown's interpretation, this means that, as more donors are accepted under more expansive criteria, it is more likely that those organs will be utilized in patients with relatively lower MELD scores because the allocation system matches the

[32] Croome, *et al*. "Intraregional Model for End-Stage Liver Disease Score Variation in Liver Transplantation: Disparity in Our Own Backyard." Liver Transplantation 24, no. 4 (2018).

presumed highest functioning organs to the highest acuity recipients. Thus, a center that accepts less-than-ideal grafts for its relatively lower MELD patients, in whom those grafts are expected to be successful, effectively drives down its median MELD score. Georgetown states that this is its standard practice, which it says reflects an efficient strategy that increases patients' overall access to transplants and would explain its lower MELD scores. (DI #21, p. 6-7).

Attributes of the Washington Region's Existing Liver Transplant Services

The interested party contends that Suburban's proposal to establish a liver transplantation service is unnecessary because Georgetown has both the capacity and capability to meet the existing needs of the population. Georgetown contrasts the presence of Johns Hopkins Medicine, which has two hospital-centric sites (Suburban and Sibley) to serve liver disease patients to MedStar Health, which already has seven established and functioning evaluation centers distributed in the Baltimore-Washington area which are staffed with nurse coordinators and social workers and with other staff available via telemedicine. Georgetown maintains that it serves patients closer to their communities and that patients from the Johns Hopkins sites at Sibley and Suburban do not have to travel outside the Washington Region since they already have access to liver transplant services at Georgetown. (DI #21, p. 5).

Georgetown also disputes the applicant's general assertion that a DSA with only one center is more vulnerable to disruptions such as unexpected loss of personnel or other operational issues than a DSA with multiple centers. The interested party states that is not a realistic concern, as Georgetown has sufficient staff and bed capacity. Georgetown notes that, at its transplant center, physician staffing is never an issue with six full-time liver transplant surgeons and seven full-time hepatologists, and that it has ample beds available with the capacity to expand when necessary, including critical care beds. It points out that it recently opened 12 intermediate beds earmarked for advanced liver disease patients and is building a new pavilion that will house a variety of surgical services and new state of the art operating rooms. (DI #21, p. 4, 5).

Further, Georgetown states that its transplant program has never experienced an operational problem that precluded patient access. Rather, Georgetown points out that when Johns Hopkins was sanctioned by CMS due to poor outcomes, it was mandated to offer its patients wait-listing at other nearby programs, and patients were sent letters offering them Georgetown as an alternative. Georgetown also notes that its program has never been sanctioned. (DI #21, p. 5).

Comments on Research Regarding Competition

Georgetown rebuts Suburban's claims that increased competition results in an increased number of liver transplants or improved patient survival and cites what it describes as "specific limitations" of the Adler and Halldorson studies. Regarding the Adler study, the interested party states:

- The data used in the study pre-dates the implementation of Share 35, which increased regional sharing thus significantly reducing the effect that population density in a DSA has on the number of transplants. Future changes intended to reduce geographic disparities in access to liver transplantation will reduce this effect further;
- The most significant variable in increasing liver transplants is the number of donors and the paper does not discuss this factor;

- Data is generalized from multiple DSAs and may not be specifically applicable to areas where access to liver transplant is not geographically restricted;
- The methodology of Adler's analysis is questionable because novel measures of "competition" are used and multi-variate analysis is conducted using variables which were not significant when subjected to univariate analysis;
- Competition was associated with increased graft failure though not with patient mortality, suggesting that competition within a DSA may lead to use of higher risk organs and increased costs related to performing repeat transplants in a single patient;
- The authors acknowledge that this paper looks at "clustering and dispersion, but it is sensitive to the area of a DSA, rather than the actual population served or the demand for liver transplantation. The DSA might not be perfectly representative of a market…;'" and
- This study cannot account for major determinants of liver transplant case volumes, such as OPO performance, center performance, center listing practices, and center acceptance of donor organs.

The interested party states that the Halldorson study is not applicable to current liver transplantation as the data presented (before 2009) preceded changes in organ allocation which resulted in increased regional sharing; however, Georgetown also points out that the Halldorson study highlights that:

- Increased competition is associated with increased risk of graft failure;
- Increased competition is associated with increased risk of patient death after liver transplantation; and
- Increased competition is associated with increased costs associated with transplantation. (DI #21, pp. 16-18).

To further illustrate its point, Georgetown presents data that it claims shows that competition has no effect on OPO performance in the area of liver procurement for transplant by contrasting the performance of two OPOs that operate in highly competitive DSAs and are located in the mid-Atlantic region of the U.S. with similar large urban populations. The Philadelphia area has eight competitive transplant programs and Georgetown describes its OPO, the Gift of Life Donor Program (OPO Code: PADV), as the highest performing OPO in the country, in terms of livers procured for transplant. The New York City metro area's OPO, LiveOnNY (OPO Code: NYRT) has seven competing programs and is one of the nation's lowest, in terms of livers procured for transplantation. See Table IV-5, below.

Table IV-5: Georgetown: Comparative Organ Procurement, PADV and NYRT

			National		
Measures	**PADV**	**NYRT**	**Minimum**	**Average**	**Maximum**
Eligible Deaths	570	433	43	195.2	570
Deceased Donors	567	290	35	175.9	567
Deceased Donors Meeting Eligibility Criteria	428	231	29	137.7	428
Observed Donation Rate Per 100 Eligible Deaths	75.1	53.3	53.3	70.6	88.9
Expected Donation Rate Per 100 Eligible Deaths	72.0	65.6	--	--	--
Standardized Donation Rate Ratio	1.04	0.81	--	--	--

Source: DI #21, pp. 18-20.

Georgetown maintains that this data showing that two OPOs located in highly competitive mid-Atlantic markets had markedly different performance in acquiring livers for transplant, undercuts the applicant's theoretical argument for the benefits of competition, which is not reflected in the actual programmatic experience. (DI #21, p. 18-20).

The interested party adds that, in the past, the Washington Region DSA did have competing liver transplant programs, with programs at Howard University Hospital in the District of Columbia and Inova Fairfax Hospital, in Fairfax County, Virginia, in addition to Georgetown. The applicant states that the result of this more "competitive" landscape was lower total transplant volumes and, eventually, the failure of the programs at Howard and Inova, "a phenomenon," states Georgetown, "that has reversed under a single center with stable leadership." Georgetown suggests that this experience does not advance the theory that competition improves OPO performance. (DI #21, p.20).

Regarding the comparison that Suburban draws to kidney volume increases after a program was added in the Washington Region DSA at George Washington University Hospital, the interested party attributes that increase to the change in kidney allocation policy rather than the addition of a new program, and presents data that shows volume at the new program has not been sustained and is declining after peaking in 2016. (DI #21, pp. 21-23).

Applicant's Response to Interested Party's Comments

Suburban reiterates its position that there are disparities between the two DSAs and asserts that competition will help better meet the needs of residents in the Washington Region DSA. (DI #22, p. 2). The applicant repeats its point that the larger population of the Washington Region DSA (5.5 million) is served by a single liver transplant center while the two centers in the Maryland Region DSA serve a population of 3.9 million. It notes again that the single-center Washington Region DSA had fewer transplants performed despite being more-heavily-populated. (DI #22, p. 4-6).

The applicant repeats its contention that patients in the Maryland Region DSA are nearly twice as likely to obtain liver transplant and five times as likely to obtain one in their home DSA. It suggests that an additional liver transplant program at Suburban would particularly serve patients who do not have the resources to travel outside of their DSA for these services, stating that 66 percent of patients residing in the Washington Region DSA obtained a liver transplant in the Maryland Region DSA in 2015, compared to six percent that traveled to the Washington Region DSA from the Maryland Region DSA. (DI #22, p. 7).

Suburban reasserts that the Washington Region DSA exports more livers than the Maryland Region DSA and imports fewer, resulting in a supply imbalance. Suburban contends it will better use available organs within the Washington Region DSA. Further, it again states that an additional program will lead to an increase in outreach efforts to potential donors to increase the number of livers procured. (DI # 22, p. 12).

The applicant contends that competition is a key to decreasing apparent disparities. (DI #22, p. 2). The applicant suggests that the interested party attempts to distract from the problems in the Washington Region DSA with alternative data that the applicant characterizes as not relevant. (DI #22, p. 3). Suburban presents the following facts to reinforce its argument that there are disparities

between the DSAs that demonstrate need and a lack of access.

- There are consistently fewer transplants in the Washington Region DSA, even with its greater population, as shown in the table below. (DI #22, p. 3).

Table IV-6: Suburban: Adult Liver Transplants in Maryland and District of Columbia Hospitals, 2012-2017

DSA	2012	2013	2014	2015	2016	2017
Maryland Region	127	169	199	241	291	260
Washington Region	98	76	79	49	84	97

Source: DI #22, p. 4.

- The case volume gaps are not narrowing among centers. Suburban submits that in 2017, Georgetown performed 97 adult liver transplants, Johns Hopkins performed 99, and UMMS performed 161, which translates to 260 in the Maryland Region DSA and 97 in the Washington Region DSA. The applicant states that the latter regional comparison is the comparison that matters most. It points to Georgetown's comparative data for the first three-months of 2018 as unreliable, because complete data for the three centers would have been available at the time Georgetown obtained the data. (DI #22, p. 5-6);

- The use rate for residents of the Maryland Region DSA is nearly twice that of the Washington Region DSA;

- Sixty six percent of adult patients who resided in the Washington Region DSA out-migrated to another DSA to receive a liver transplant in 2015. The applicant contends that migration levels, in and out of a region, should be more comparable, if patients have similar levels of access to transplantation. If patients are required to migrate out of their DSA to receive services, those that do not have resources to migrate are at a disadvantage and may forego transplantation altogether. (DI #22, p. 7);

- Suburban reiterates its criticism that the interested party is not adequately serving relatively sicker patients, citing its lower median MELD scores from 2011 to 2015. (DI #22, p. 8). Suburban finds fault in Georgetown's "standard practice" to use marginal organs in less sick patients, thereby driving down its MELD scores. The applicant suggests this is not proper use of organs and a second center will incentivize more competitive use of available organs. (DI #22, p. 18);

  Suburban takes issue with the interested party's conflation of Status 1 patients with those patients with higher MELD scores, contending that Status 1 patients are irrelevant because they do not have chronic liver disease nor have they been on waiting lists. Instead the applicant describes them as having "experienced sudden liver failure from a cause other than liver disease, and their life expectancy is less than seven days …[they] are generally in much better overall health than patients with high MELD scores, and although their need is urgent, they do not pose the same challenges as transplants to high MELD score patients, whose health has badly deteriorated." Further, Suburban states that the two centers in the Maryland Region DSA combined served more Status 1A (adult) patients than the one center in the Washington Region DSA in the 2011 to 2015 period. Finally, Suburban criticizes the interested party for reporting figures as a percentage of

the whole rather than reporting absolute numbers, maintaining such an approach masks the fact that the percentages relate to "vastly different numbers," proffering the example of the 2015 data, which showed 241 adults were transplanted in the LLF DSA as compared to only 49 in the WRTC DSA. (DI #22, p .9-10);

- Suburban stresses that the centers in the Maryland Region DSA performed transplants on 75 adult patients whose MELD scores were 35 and above, while Georgetown performed only 8 in 2016. In 2017, the two centers in Baltimore performed 51 transplants on this population, compared to Georgetown's 21 in 2017. (DI #22, p. 10);

- Suburban states that the liver matching policies at Georgetown are "concerning," because, as the single center in the DSA operating without competition. it has a unilateral ability to declare that a liver is not suitable for patients with higher MELD scores and accept it for a patient with a lower MELD score. Suburban claims that in a single-center environment, Georgetown's incentive is to make conservative use of each liver, since it is not at risk of losing the liver to a competing center within the DSA.[33] (DI #22, p. 10);

- The applicant states that although it expects that it will increase the supply of livers by increasing outreach efforts in the Washington Region DSA, its principal contention for why it should be granted a CON for a liver transplant center is that "it will help increase supply because competition will lead to better use of available organs, as well as increased liver imports." (DI #22, p. 12);

- The applicant counters Georgetown's position that the lesser supply of livers acquired in the Washington Region DSA is explained by its lower death rate by arguing that the lower death rate does not explain the differences in import and export rates. Reiterating that a greater proportion of organs was exported from the Washington Region DSA than from the Maryland Region DSA, and a greater number of livers imported into the Maryland Region DSA than into the Washington Region DSA, Suburban claims that in a DSA with competing centers, livers that Georgetown is now allowing to be exported would more often be used within the DSA. It also claims that a competing center at Suburban would also increase the number of imported livers, as it claims occurs in the Maryland Region DSA. (DI #22, pp. 12-13); and

- Suburban points out that the waitlist in the Maryland Region DSA is more than double that of the Washington Region DSA, and asserts that wait list additions "reflect the degree to which the centers in a DSA are identifying, evaluating, and listing transplant-eligible patients ... the single transplant center in the WRTC DSA lags far behind the centers in the LLF DSA," and claims that a second center is the best remedy to narrow

[33] As a contrasting example of how such a scenario might play out in a DSA with more than one center, Suburban wrote that "[i]n the LLF DSA, however, if Hopkins has the highest MELD score patient to match with an available liver, the organ is offered to Hopkins. If Hopkins doesn't accept the organ offer, and the patient with the next highest MELD score to match is listed at UMMS, the liver is then offered to UMMS. In short, as long as there is no competing center in the same DSA, a center may choose to pass over higher acuity patients in favor of "patients with relatively lower MELD scores." (DI #22, p. 10).

the gap. (DI #22, pp. 12-13).

Suburban disputes Georgetown's contention that competition in the Washington Region DSA will have no effect on the productivity of the OPO because OPOs work closely with the transplant programs in a DSA, but contending that the primary benefits will be based on the added program competition. (DI #22, p. 19). Suburban contends that its proposed project would lead to additional outreach efforts to potential donors and, thus, an increase in the number of donors and livers procured. Additionally, Suburban could pick up slack if another program faces operational disruptions. (DI #22, p. 8-16).

Suburban dismisses Georgetown's comments about having competitors in its DSA in the past and the failure of that competition to produce the results predicted by Suburban and the eventual failure of the other transplant centers. It notes that this competition was a long time ago. Howard University Hospital last performed a liver transplant in 1997 and Inova Fairfax Hospital in 2006. (DI #22, p. 20).

Finally, the applicant notes that an affiliate of the interested party, MedStar Franklin Square Medical Center, submitted CON applications to the Commission to establish both kidney and liver transplant programs at MedStar Franklin Square Medical Center in Baltimore. The rationale for those applications was that a new liver program at Franklin Square will increase access for MedStar patients, despite the fact that each transplant program, if approved, would be the third kidney and liver transplant program in the Maryland Region DSA.

Suburban points out what it sees as contradictory positions being taken by MedStar in the current organ transplant review cycles. As an applicant, MedStar Franklin Square Medical Center maintains that the distance from Baltimore to Georgetown is a "geographic challenge for many," and contends that there are benefits related to having a transplant program closer to patients' homes. However, as an interested party opposing Suburban's application, MedStar does not seem to recognize such benefits for patients in the Washington Region DSA. Suburban claims this inconsistency undermines the interested party's comments regarding its application. (DI #22, p. 21).

(b) Projected volume shifts from programs in the two OPOs that serve Maryland residents, detailing the underlying assumptions upon which each projection is based.

Applicant's Response

The applicant projects that Suburban's liver transplant volume will be comprised of market shifts from existing transplant programs and market growth and creation of a larger demand for transplantation. Suburban presents two projection scenarios: (1) a "Status Quo Projection" which projects future volume at existing centers without a new center being added to the mix; and (2) an "Adjusted Projection" reflecting future volume with the addition of the proposed Suburban project. (DI #3, p. 103). Suburban's Status Quo Projection forecasts that each center would increase its volume by ten transplants per year, a forecast based on its assessment of the historical growth rate in

the Maryland Region DSA and Washington Region DSA combined between 2010 and 2015 (Table IV-7).[34]

Table IV-7: Suburban: Status Quo Projection

Transplant Center	2016	2017	2018	2019	2020	2021	2022
Johns Hopkins	110	120	130	140	150	160	170
Georgetown	91	101	111	121	131	141	151
UMMC	157	167	177	187	197	207	217
Total	**358**	**388**	**418**	**448**	**478**	**508**	**538**

Source: DI #3, p. 103.

The applicant's adjusted projection in Table IV-8, below, adds the proposed Suburban program to the mix, and forecasts its volumes as a combination of cases shifted from the other three centers and additional volume resulting from competition being introduced to the Washington Region DSA. The applicant assumes that there will be a ramp-up period in Year 1 as it initiates operations and conducts outreach.

Table IV-8: Suburban: Adjusted Projection

Transplant Center	2016	2017	Year 1	Year 2	Year 3	Year 4	Year 5
Johns Hopkins	110	120	126	135	144	153	161
Georgetown	91	101	105	114	123	132	141
UMMC	157	167	172	181	189	198	207
Suburban	-	-	17	32	37	42	46
Total	**358**	**388**	**420**	**461**	**493**	**524**	**555**

Source: DI #3, p. 103.

The applicant maintains that none of the existing centers will experience a significant loss of case volume if Suburban establishes a liver transplantation service. It projects a shift of 29 cases from the three existing centers in the fifth year of operation, a decline of four to seven percent from its projected status quo volume in 2022. Despite the projected declines, Suburban concludes that existing centers would remain well above the minimum case volume threshold. Suburban even surmises that "[i]t is quite possible that Georgetown will see an increase in its total volume as a result of the Suburban program being established, just as occurred when George Washington University [Hospital] started a new kidney transplant program in competition with the Georgetown kidney program." The applicant states that it hopes that volumes at all the centers will continue to grow through increased education, outreach, recruitment of donors, and use of more organs, and also as a result of the increased level of competition in the region. (DI #3, pp. 103, 104).

Interested Party's Comments

Georgetown critiques the applicant's projections of future liver transplants by combining the performance of two programs in the Maryland Region DSA, Johns Hopkins and UMMC, to project future performance for the proposed program in the Washington Region DSA. It states that

> [t]he impact of a new program can only be extrapolated from its current level of activity. By combining its data with that of a separate, unrelated entity (UMMS),

[34] Numbers in Table IV-7 reflect the applicant's projections, which may not correspond with the numbers shown previously in Table IV-1, which reflect actual utilization presented in Suburban's application.

> JHH's basic assumptions regarding a new program - as well as the projections for its future performance - are not realistic…. [M]any variables [affect transplant volume] including the time that a program has been in operation, physician referral patterns (that fluctuate over time), patient and donor selection (that evolve over time), availability of organs (determined by a variety of factors), and allocation policy (governed by CMS/UNOS).
> (DI #21, Att., pp. 1-3).

Applicant's Response to Interested Party's Comments

The applicant defends its comparison of the DSA volumes, instead of center volumes, by reiterating that DSA volumes point to the need for another program in the single-center Washington Region DSA. It states that the consistent pattern shows that the DSA with a single center performs fewer transplants than the two centers in the Maryland Region DSA.[35]

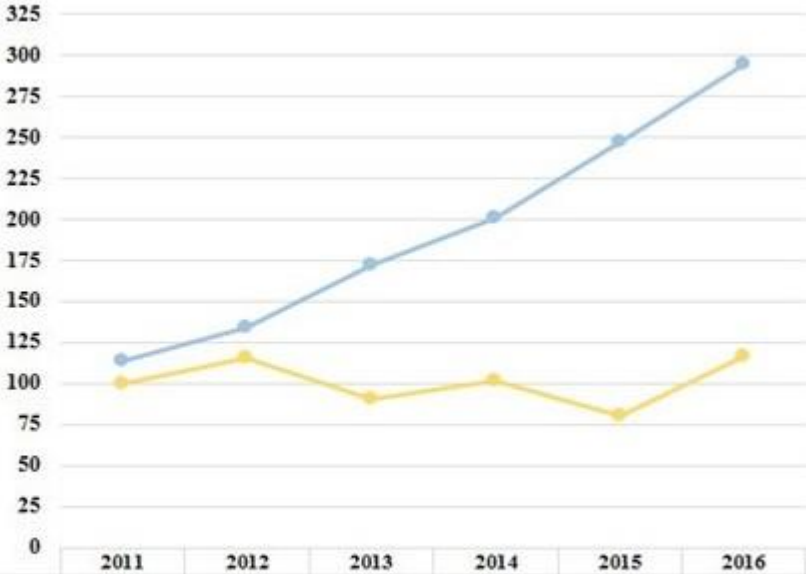
(c) The utilization trends for the health planning region in which the proposed organ transplant service will be located and the jurisdictions in which the population to be served resides. If the proposed service will be located in a jurisdiction that shares a border with another health planning region, then the utilization trends in each health planning region shall be addressed.

Applicant's Response

The applicant notes that liver transplant utilization has grown in the Maryland Region DSA from 2011 through 2015. In contrast, utilization in the Washington Region DSA is lower and was flat or trended downward for the same period, as shown in the figure below.

[35] Table IV-6, *supra*, p. 36; DI #22, p . 4.

Figure IV-E: Suburban: Liver Transplant Volume by DSA, CY 2011-2016



	2011	2012	2013	2014	2015	2016
LLF DSA Centers	114	134	172	201	247	295
WRTC DSA Center	100	116	91	102	81	117

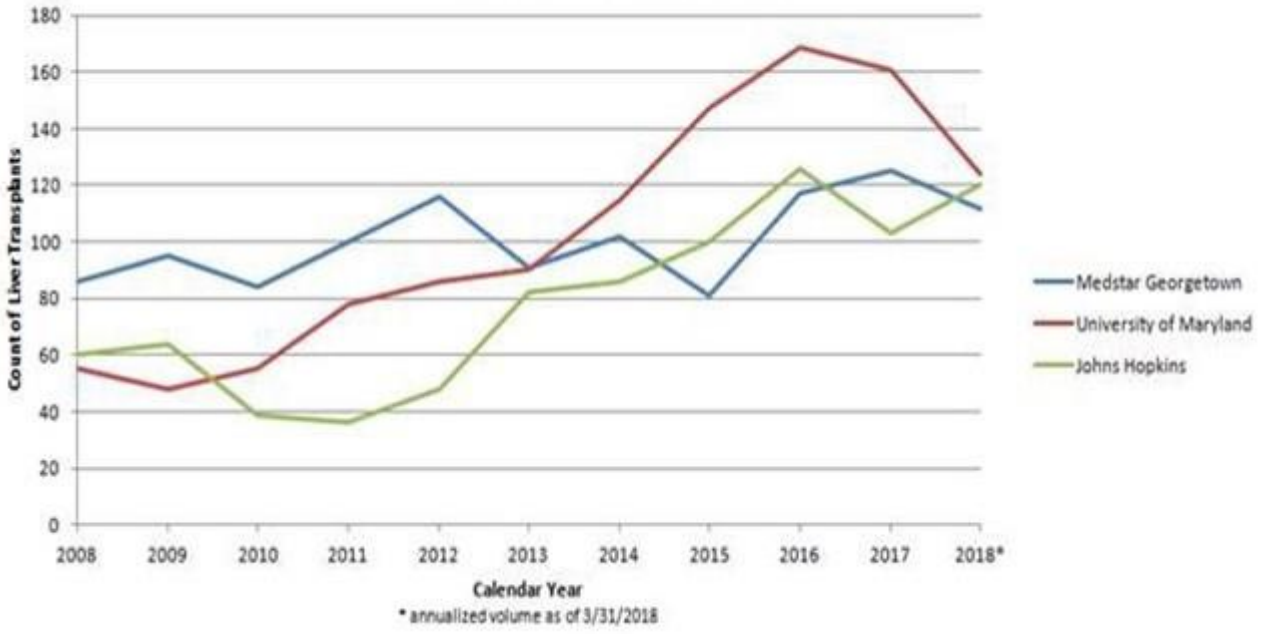
Source: DI #3, p. 105.

The applicant points out that the total number of liver transplants performed at the two Maryland Region DSA centers has increased every year and more than doubled from 2011 to 2016, while the number of total transplants at the single Washington Region DSA facility has hovered around 100 per year (six-year average of 101) for six years. (DI #3, p. 105-06). Suburban also expressed the differential between the two areas by calculating a transplants per million-person ratio, noting that the Maryland Region DSA had 44.4 per million, while the Washington Region DSA came in at 24.5 per million. (DI #3, pp. 105-09).

Interested Party's Comments

Addressing the applicant's observations regarding historical center volume, Georgetown illustrated volume trends as shown in Figure IV-F below, accompanied by several observations.

Figure IV-F: Liver Transplant Volume by Center, 2008-2018



Source: DI #21, p. 3.

Georgetown points out that:

- Volume at each of the three programs varied over the previous 10-year period as a result of internal programmatic developments. Decreases in volume at individual centers are due to programs taking a more conservative position in terms of recipient and donor selection, in order to improve patient/graft outcomes, which Georgetown states is a well-known phenomenon among programs;

- The Johns Hopkins program historically performed a lower volume of transplants than the Georgetown program until CY 2015. According to the interested party, a decrease in Johns Hopkins volume occurred when it entered into a systems improvement agreement with CMS for poor outcomes, during which time the program temporarily adopted more conservative organ acceptance practices. This phase ended with the release of the program from CMS scrutiny, creating a reversal in activity over time;

- UMMC demonstrated a significant increase in volume associated with new surgical leadership of its program between 2014 to 2016, but volume has contracted more recently;

- Georgetown attributes its smaller fluctuations to "stable programmatic and institutional leadership and outcomes;" and

- Volume gaps are narrowing among all centers.

(DI #21, p. 2-6).

Applicant's Response to Interested Party's Comments

Suburban emphasizes that case volume gaps are not narrowing among centers. Suburban submits that in 2017, Georgetown performed 97 adult liver transplants, Johns Hopkins performed 99, and UMMC performed 161, which translates to 260 liver transplants in the Maryland Region DSA and 97 in the Washington Region DSA. (DI #22, p. 5).

Reviewer's Analysis and Findings

The Need standard in the Organ Transplant Services Chapter is unique. Because need cannot be addressed solely by building or improving infrastructure, the Need standard, at COMAR 10.24.15.04B(1)(a), requires an applicant to demonstrate need for a new transplant service by addressing its proposed program's ability "to *increase the supply or use* of donor organs …." (emphasis added).

Suburban claims that a comparison of metrics and outcome data available from OPTN and SRTR show that residents in the Washington Region DSA are underserved by existing liver transplantation services, compared to the residents of the Maryland Region DSA. Suburban argues that program competition is beneficial, and that the lack of competition in the Washington Region DSA puts those in need of transplantation at a disadvantage because the region has only one liver transplant program.

My review of the application, the interested party comments, and the applicant's response to those comments, does not convince me that Suburban's proposed liver transplantation service will increase the supply or use of donor livers or that residents of the Maryland and D.C. Regions are disadvantaged by access to three liver transplantation programs. The following discussion details the bases for my conclusion that the application does not meet the requirements of the Need standard.

Supply of Livers

Suburban compares the volumes of procured livers, exported livers, and imported livers to show a greater supply in the Maryland Region DSA, which it characterizes as evidence that the Washington Region DSA could be better served by an additional program. Based on my review of the record, I do not agree that the procurement of livers is dependent on the number of transplant centers in a DSA. The primary source of supply, the procurement of livers is carried out by the OPO in the DSA.[36] OPOs work with all *donor* hospitals within its DSA to recover as many organs as possible.

In this matter, I reviewed data to determine whether Maryland residents in the two DSAs are actually provided with disparate levels of liver transplantation services through their OPOs. I reviewed recent SRTR OPO-specific reports. Table IV-9, below, shows selected data for the most recent bi-annual reports.

[36] See description in the Background section, *supra*, pp. 1-3.

Table IV-9: OPO-specific Report Data for OPOs covering Maryland Jurisdictions, FY 2019

Metric	LLF	WRTC
Population	3,919,340	5,593,845
Deaths	36,697	34,115
Death rate per 1,000	9.36	6.1
Liver transplant eligible deaths	197	155
Liver donations per 100 eligible deaths	62.4	63.9
Expected rate	64.3	58.3
Standardized donation rate ratio	0.97	1.10

Source: SRTR OPO Specific Reports, released January 7, 2020.

Data in the SRTR reports highlights factors that contribute to differences in the organ supply. The most noteworthy fact may be that, despite the population of the Washington Region DSA being 43 percent larger than that of the Maryland Region DSA, the death rate in the Washington Region DSA is much lower – just 65 percent of the death rate of the Maryland Region DSA. In fact, according to SRTR, the Washington Region DSA has the second lowest death rate among all 58 DSAs. As shown in Table IV-9, above, the Washington Region DSA had fewer total deaths than the Maryland Region DSA in FY 2019, but achieved a higher donation rate per eligible death (63.9 percent compared to 62.4 percent), even though the Washington Region DSA's expected rate of donation based on the distribution of age, sex, race, and cause of death among eligible deaths is considerably lower.

While the potential supply of deceased donors is determined by the eligible death rate, the OPO (*not* the transplant centers) is responsible for the procurement of organs. I observe that the Standardized Donation Rate Ratio shown in Table IV-9 (effectively a measure of the observed-to-expected donation rate) shows that the WRTC OPO outperformed the expected rate based on national experience in FY 2019, while the Maryland Region DSA underperformed slightly. In recent years, the WRTC has consistently outpaced the expected donation rate, with a standardized donation rate ratio higher than 1.0 in FY 2016 (1.10), FY 2017 (1.03), and FY 2018 (1.03).[37]

To review this matter comprehensively, I sought expert opinions on issues in liver transplantation from the designated OPO in each DSA covering Maryland. According to a letter provided to me from the WRTC, dated February 28, 2020 (see Appendix 2), currently 63.8 percent of people in the District of Columbia are registered donors, 62 percent in Maryland, and 65.8 percent in Virginia. Nationally, 58 percent of people are registered donors. Also included in the letter is a fact that WRTC DSA donor hospitals have a 99 percent compliance rate on contacting WRTC on all deaths or when donation triggers are met. (DI #41, pp. 4-5).

A similar letter from the Living Legacy Foundation of Maryland states that, "[n]otably, … donation rates at hospital transplant centers often underperform those of non-transplant hospitals." (See Appendix 2). Thus, I find that the presence or number of transplant hospitals that will ultimately receive a liver has limited impact on procurement.

While I agree that liver transplant candidates would benefit from an increase in the number of donors per capita, the SRTR reports show that the WRTC OPO is performing above expected rates

[37] SRTR OPO-Specific Reports released on January 7, 2019, January, 25, 2018, and January 5, 2017.

in terms of liver donation in its DSA and registered donor rates in the D.C. and Virginia exceed that of Maryland. Beyond successful procurement of livers by a designated OPO within its DSA, UNOS allocation policies also guide where procured livers will be offered based on the individual characteristics of patients on each center's waitlist.

I find that the Washington Region DSA is well served in terms of donor liver recovery, and that adding a liver transplant program would not alleviate any claimed disparity related to this. I also find that Suburban did not demonstrate that its proposed liver transplantation service is necessary to increase the supply of liver donations through the outreach proposed.

Liver Transplant Center Volume

As noted above, I do not agree with the applicant that an increase in the number of liver transplant centers in a DSA will necessarily result in increased supply of donor organs. I also do not agree that the number of liver exports or imports tells us anything meaningful about the level of access for liver transplantation experienced by patients in an area where three transplant centers are within 45 miles of each other. I note that DSA boundaries designate OPOs to work with donor hospitals within a geographic area, while the recovered livers are now allocated based on nautical miles from the recovery location. While DSA boundaries played a role in the allocation of livers at the time the application was submitted, the situation changed with the implementation of the new liver allocation policy in February 2020.

The applicant interprets the fact that the transplant centers in Baltimore performed 93 percent of the liver transplants received by residents in the Maryland Region DSA in 2015, while Georgetown performed just 46 percent of the liver transplants received by residents of the Washington Region DSA (62 transplants of the 134 received by residents) as evidence of inferior access for residents of the Washington Region DSA. (Table IV-10 below).

Table IV-10: Liver Transplant Recipients by Residence and Location of Transplant Center CY 2015

DSA	DSA State	Johns Hopkins	George-town	UMMC	Other Centers	Total	Out-migrants	% of Out-migrants
MD Region	Maryland	**57**	**7**	**104**	**5**	**173**	**12**	**7%**
Washington Region	D.C.	1	6	1	7	15	9	60%
	Maryland	11	24	20	8	63	39	62%
	Virginia	10	32	4	10	56	24	43%
	Total	**22**	**62**	**25**	**25**	**134**	**72**	**54%**
Total Marylanders in Both Regions		68	31	124	13	236	-	-

Source: DI #3, p. 34.

I view the data in Table IV-10 regarding liver transplants for Maryland residents by hospital location with a different perspective and emphasis than the applicant. In CY 2015, 236 Maryland residents received a liver transplant at any center. 192 of those residents received their transplant at either Johns Hopkins or UMMC, and an additional 31 of those Maryland residents received their transplant at Georgetown. That equates to 94.5 percent of total Maryland resident liver transplants performed at the transplant hospitals located in Maryland or D.C. and the transplant hospitals located

in the two DSAs that include Maryland jurisdictions.

Transplant Rates

The applicant presents what it characterizes as disparities in resident transplant rates in a number of ways to show a lower rate in the Washington DSA compared to the Maryland Region DSA. During the completeness review, Commission staff requested additional data that reflects the adult transplant rate per million population in both regions for deceased organ transplants only, as Suburban proposed to service adults who receive a deceased donor organ.[38] (DI #13, pp. 17-18).

In its application and as presented in Table IV-1,[39] Suburban highlights that the adult transplant rate for the Washington Region DSA was 25.9 per million adults, compared to 54.3 per million adults in the Maryland Region DSA (DI #3, p. 30). However, upon review of the additional data submitted during the completeness review, the disparity in the rate for adults who received a deceased donor liver was found to be less. The rate of liver transplants per million adults who received a deceased donor liver (the type of transplant that Suburban proposes it will perform) was 30.1 per million adults in the Washington Region DSA in 2016, compared to 49.9 per million adults in in the Maryland Region DSA. While this difference is less than originally presented by the applicant, I agree that there is a disparity. I find that lower liver transplant rates in the greater Washington Region DSA may be influenced by other factors including a lower death rate or migration of organs in accordance with UNOS policy.

As I previously noted, Marylanders have access to three liver transplant centers within 45 miles of each other and 94.5 percent of residents of Maryland who received a liver transplant in 2015 received them in Maryland or D.C. I find that adding another transplant center will not result in increased transplant rates, particularly for the Marylanders in the Washington Region DSA who are conveniently located in close geographic proximity to all three centers.

Patient Migration

I find the applicant's assertion that residents should be expected to be transplanted in their DSA to be baseless, particularly in this case, with three centers that are all located within a relatively short travel time of each other. For example, residents of Charles, Montgomery, and Prince George's Counties, who reside in the Washington Region DSA, are, respectively, 40, 22, and 20 miles away from the District of Columbia transplant center (measured by the designated center of the counties used by Google Maps). The transplant centers in Baltimore are only about 20 to 30 miles farther away for these Washington Region DSA residents.

As I stated under my findings regarding liver transplant center volume, above, the overwhelming majority of residents in either of these DSAs receive transplants in one or the other DSA. For Marylanders, 94.5 percent of patients who received a liver transplant in 2015 received it in Maryland or D.C. I do not see that as a problem.

[38] See Table IV-1, *supra*, p. 15, Rows 9-14.
[39] Table IV-1, *supra*, p. 15.

Existing Program Performance and Capacity

I reviewed recent SRTR program-specific reports for the existing liver transplant centers in the Washington Region and Maryland Region DSAs in my consideration of the Suburban's suggestion that the Washington Region DSA transplant center may underutilize locally-procured livers. Table IV-11 below includes my compilation of pertinent metrics.

Table IV-11: Liver Transplant Program-Specific Metrics for Review, FY 2019

Metric	Johns Hopkins	UMMC	Georgetown
Waiting list volume at FY start	383	454	263
Waiting list volume at FY end	355	388	255
Number of liver offers	2,559	2,525	3,176
Number of acceptances	93	83	97
Expected acceptances	62.7	72.1	89.4
Offer acceptance ratio	1.47	1.15	1.08
One-year graft failures	19	47	7
Expected graft failures	17.46	29.87	17.28
Patient deaths	16	40	7
Expected patient deaths	13.27	22.49	12.56
Adjusted probability for 1-Year survival with graft for transplants between 7/1/16-12/31/18	92.32%	90.12%	91.19%

Source: SRTR Program Specific Reports, released January 7, 2020.

Based on program performance metrics, as presented by SRTR, I do not agree with the applicant that Georgetown underperforms. At the start of FY 2019, the number of liver transplant candidates on waitlists differed among the programs, from fewer than 300 at Georgetown to more than 450 at UMMC. While this indicates that more patients are accepted onto the waitlists at certain programs, this does not offer insight into the residence of patients on those waitlists. Patients who are treated and evaluated at the Sibley Memorial and Suburban hepatology clinics who live in the Washington Region DSA are referred to Johns Hopkins for waitlist evaluation. Those patients would simply move from the Johns Hopkins waitlist to the Suburban waitlist, if the proposed project were implemented. Further, since CMS has no benchmark for an expected waitlist volume, I find that program waitlist length comparisons are not a good indication of disparity. The patient population of the Washington Region DSA may choose among the three programs within an accessible distance for a variety of reasons beyond location of residence, including individual preference, physician referral, family support, insurance networks, and perceived reputation or experience of individual centers.

I find that double-listing at Johns Hopkins and the proposed center, in different DSAs, is not as beneficial as Suburban suggests. The benefits the applicant ascribed to listing as a liver transplant candidate in the two contiguous DSAs that serve Maryland jurisdictions are outdated. The new UNOS allocation policy that went into effect in February 2020 changes the allocation system from one based around prioritizing allocation within a DSA to creating a system of priority for liver transplant patients within a specified distance of the donor hospital. Prior to this policy, organs recovered for transplant were prioritized to patients within the DSA of origin. Under the new national liver allocation policy implemented in February 2020, DSA boundaries no longer play a role in allocation. Instead, patients on waitlists are eligible for donor livers based on their distance from the location of organ recovery. This means that, for any liver procured by either the LLF or the

WRTC, all patients on waitlists at hospitals in Maryland or the District of Columbia would be eligible, consistent with national policies regardless of the DSA in which the patients reside.

Listing at multiple centers could still benefit a patient by expanding the patient's radius of eligibility, but that benefit becomes more marginal as the distance between transplant center hospitals at which the patient is wait listed becomes relatively short. For instance, since Suburban and Johns Hopkins are 40 miles from each other, a patient could extend his/her radius of eligibility by 40 miles by being registered at both centers (assuming that Suburban were a transplant center). However, this benefit is minimized as the distance between transplant hospitals at which a patient is waitlisted gets shorter. I find that this small mileage factor is not significant enough to justify creating an entirely new liver transplantation program.

Regarding the offer-to-acceptance ratio, all three programs are performing higher than the expected rate in terms of CMS benchmarks, as shown in Table IV-11 above. I note that Georgetown performed much better than national benchmarks in terms of one-year graft failures and patient deaths in FY 2019.

Suburban also states that its establishment of a liver transplant service will add to the supply of ICU beds available to liver transplant patients in the region. I find that such a benefit is, at best, very marginal, and would provide a solution to a problem that does not appear to exist for liver transplant recipients. The applicant presented no evidence that existing ICU capacity was insufficient to meet the current need or foreseeable future growth. Similarly, I am unconvinced about the risk of potential program disruptions to the single Washington Region DSA liver transplant center. Posing hypotheticals about potential program disruptions at a center that has been operating for more than 20 years without such disruption is not a reasonable basis for finding a need for the proposed project, especially when there are two other transplant programs within 45 miles of the existing transplant center.

Regarding the applicant's suggestion that an additional transplant program in the Washington Region DSA would address migration and travel barriers for "minority patients, low-income patients, and patients without a social support system," I find that Suburban failed to present convincing evidence that these populations are currently underserved in the Washington Region DSA, and if they are, it has not put forth a specific plan to better serve them at Suburban, beyond generic efforts to increase outreach.

To support its statements, the applicant referenced a 2013 study by Dzebisashvili et al., which compared outcomes for the patients with the lowest socioeconomic status on the liver transplant waitlists to those with the highest socioeconomic status. Essentially, the study found that patients on the liver transplant waitlist with the highest socioeconomic status (SES) had better outcomes. However, this study appears to have limited applicability in this matter since the article describes high SES patients as realizing the benefits of being "more likely to move to areas where access to the donor pool was improved." As I stated previously, the new UNOS allocation policy is projected to move more livers across greater distance to help ensure increased access for patients. I agree with the interested party that this research is outdated.

All of the liver transplant options are located within a reasonable travel time for this specialty service, particularly when routine pre- and post-transplant services are available in other more

proximate settings such as the hepatology clinics already within the Johns Hopkins CTC at Sibley and Suburban.[40] And the very presence of the hepatology clinics at Sibley and Suburban undoubtedly is a major factor in directing residents from the Washington Region DSA to the Maryland Region DSA for liver transplantation.

Patient Acuity

The applicant suggests that adding a liver transplant program at Suburban will result in sicker patients in the Washington Region DSA gaining improved access to a transplant. I find that the applicant's presentation, which combined data for all liver transplant centers in order to compare DSAs, may have resulted in a misleading comparison.

The applicant and interested party discuss MELD scores as indicators of program performance but have different perspectives on what the data reveals. Suburban claims that patients in the Maryland Region DSA have higher MELD scores and, therefore, sicker patients are better served in the Maryland Region DSA and underserved in the Washington Region DSA. I reviewed the MELD score category percentages in the recent SRTR program-specific reports, which are shown in the following table.

Table IV-12: Distribution of Medical Urgency Status (as %) for Selected Liver Transplant Programs, FY 2019

	Johns Hopkins	UMMC	Georgetown
Waiting list candidates			
MELD 6-10	51.5	44.3	32.9
MELD 11-14	25.6	28.0	33.7
MELD 15-20	16.1	14.9	11.4
MELD 21-30	3.1	6.7	8.6
MELD 31-40	0.6	0.5	1.2
Transplants, deceased donor livers			
Status 1A	4.8	2.2	12.1
MELD 6-10	22.1	15.2	18.1
MELD 11-14	19.2	12.0	7.8
MELD 15-20	15.4	3.3	13.8
MELD 21-30	17.3	22.8	11.2
MELD 31-40	18.3	44.6	19.8

Source: SRTR Program Specific Reports, released January 7, 2020.

These reports show that in FY 2019, the transplant patients at UMMC skewed much more

[40] The Multidisciplinary Clinic for Liver Transplantation and Liver Tumors at Sibley Memorial Hospital's website at https://www.hopkinsmedicine.org/sibley-memorial-hospital/patient-care/specialty/gastroenterology-hepatology/hepatology-multidisciplinary-center.html notes that, among other benefits, patients at this hospital receive:

- Specialized evaluation by transplant surgeons, hepatologists, social workers and nurse coordinators who are certified experts in the area of organ transplantation;
- Comprehensive assessment, including clinical evaluation, laboratory work and review of all pathologic and radiologic studies;
- Clearly defined expectations and conditions which must be met in order to be placed on a liver transplant waiting list; and
- Ongoing follow up with a transplant hepatologist and transplant coordinator.

toward the higher MELD score of 31-40 than the patients at either of the other two programs. In FY2019, Georgetown performed a higher percentage of transplants on both Status 1 patients and patients with MELD scores between 31-40 than Johns Hopkins. This FY 2019 data does not provide evidence to support Suburban's argument that Georgetown serves lower acuity patients than a Hopkins-affiliated hospital would. Even so, I acknowledge, as both the applicant and the interested party expressed, that there is more to MELD scores than meets the eye, including debates about the benefits of performing more transplants on sicker patients with higher MELD or using less-than-ideal organs for less acutely ill patients with lower MELD scores.

In its other arguments regarding what it views at liver-use disparity, Suburban notes that between 2014 and 2016, 21 livers were exported from the Washington Region DSA and transplanted in the Maryland Region DSA. Of these, six were exported as a result of "Share 35," but the other 15 were exported after being rejected by Georgetown, but were accepted and transplanted at Johns Hopkins. (DI #113, p. 33-34; DI #15, p. 7). The applicant sees this as evidence that usable livers are rejected in the Washington Region DSA; however, I see this as evidence that those livers do get used between the two DSA.

Regardless, the applicant suggests that adding a liver transplant program at Suburban will result in sicker patients in the Washington Region DSA gaining improved access to a transplant. I find that the latest SRTR program reports do not provide evidence to substantiate this claim. In FY 2019, Georgetown performed liver transplants on a higher percentage of their patients with MELD 31-40 than Johns Hopkins and it appears that UMMC focuses on serving this population to an even greater degree than the other programs, so Suburban's presentation, which combined all centers within the DSA, may have resulted in a misleading comparison. I find that each of the programs is performing as expected. I also note here that the applicant proposes that transplants on patients with MELD scores higher than 35 still be performed at Johns Hopkins (DI #3, p. 164), so little will change for these patients, as a result of the proposed project.

Suburban posits that the Johns Hopkins CTC program is more successful than its counterparts in its utilization of organs, with a 91.7 percent probability of survival rate in what it describes as sicker patients and patients who receive high-risk organs. I reviewed the SRTR program reports for the time periods the applicant and interested party discuss, as well as later updates. I found that the probable 91.7 percent one-year survival rate the applicant presented is the unadjusted rate. Adjusted for patient and donor characteristics, the Johns Hopkins facility posted a 90.6 percent probability of survival rate, compared to the UMMC rate of 85.5 percent, and the Georgetown rate of 87.4 percent. Table IV-13, below, displays the latest one-year survival rates of the existing centers for the four most recently available reports. In short, the table shows that, because of continual improvement at each program over the last four reports for rolling 12-month periods, the differences in survival rates have narrowed. (Table IV-13).

Table IV-13: Expected Probability of Surviving with a Functioning Graft at One Year (Adjusted for Patient and Donor Characteristics), Liver Transplant Programs in Maryland and the District of Columbia

	July 1, 2013-Dec. 31, 2015	July 1, 2014-Dec. 31, 2016	July 1, 2015-Dec. 31, 2017	July 1, 2016-Dec. 31, 2018
Johns Hopkins	90.6%	91.2%	92.0%	92.3%
Georgetown	87.4%	90.4%	90.6%	91.2%
UMMC	85.5%	88.9%	89.7%	90.1%

Source: SRTR Program-Specific Reports, January 2017-January 2020, Table C6.

I note that CMS monitors graft outcomes a year after liver transplants and uses them as a basis for intervening when it deems necessary. In 2009, Johns Hopkins entered into a systems improvement agreement with CMS due to lower-than-expected outcomes. This caused John Hopkins to review its policies and procedures and decrease the number of liver transplants in order to improve outcomes.[41] Since that time, CMS has not determined that the outcomes from any of these liver transplant programs cause concerns that need to be addressed. And while neither Program-specific nor OPO-specific reports point to problems at any of the programs, if indeed Johns Hopkins does utilize livers "better," Maryland residents of either region can choose to go there without a significant geographic barrier preventing them from doing so.

Education and Outreach

Suburban claims that its establishment of a liver transplant center, as part of the Johns Hopkins CTC, would increase the supply of organs through outreach and education efforts. While I find its programming commendable, it is not contingent or dependent on establishing a new organ transplant center in the Washington Region DSA. The establishment of a liver transplant program is not a precursor to hospitals' engaging in organ donation campaigns or outreach. For example, the highly successful Facebook campaign conducted by Johns Hopkins highlighted its existing ability to engage in promotion with national reach. Since Johns Hopkins currently operates two clinics for liver disease patients at Suburban and Sibley Memorial, one would expect that it would already be active in local outreach activities in the Washington Region DSA. The applicant fails to discuss any such efforts in the application materials.

When I was looking to learn more about OPOs that serve Maryland residents, I saw information suggesting that the WRTC and Suburban Hospital work together within the Montgomery County Latino Donation Awareness Community Taskforce to meet with various community and private organizations to discuss how to increase donation awareness in Montgomery County's Latino community and identify strategies for awareness and action.[42] I also noticed that, in March 2020, the WRTC's Facebook page listed Sibley Memorial, Johns Hopkins Medicine, and Suburban Hospital among 20 new donation champions that attended the WRTC's Donation Resource Specialist Program.[43]

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[41] "Transplant centers pull back to avoid sanctions." *The Bulletin*. (April 24, 2014). https://www.bendbulletin.com/lifestyle/health/transplant-centers-pull-back-to-avoid-sanctions/article_aa3ef7af-586c-5976-ae9a-f6ee82da62fb.html. See also, DI #21, p. 2.

[42] http://archive.constantcontact.com/fs090/1102584055218/archive/1102712545711.html

[43] https://m.facebook.com/beadonor/posts/10157742228273381

These facts point out that a relationship between the WRTC and Johns Hopkins Medicine exists without the Hopkins CTC operating a liver transplant center in the DSA. I find that adding a liver transplant center at Suburban is not necessary to increase CTC's donor outreach activities in the DSA. Yet in response to a completeness question from Commission staff, the applicant states that Suburban physicians do not currently interact with the CTC, except to refer patients as needed for transplant or other specialized care at Johns Hopkins, nor do residents of the Washington Region DSA connect with the resources available through the CTC, except for those residents who receive their transplant at Johns Hopkins. (DI #13, p. 30). Thus, there appears to be an existing opportunity for the CTC to more aggressively engage physicians and patients in the Washington Region DSA independent of whether a liver transplantation program is established at Suburban.

The applicant does not suggest that there is a need to fill a gap in outreach that is not already pursued within the region and, in fact, already partners with the WRTC to engage in community outreach. It repeatedly notes the opportunity for this growth based on what it characterizes as a disparity in the per capita donor rate, which I determined to be an oversimplification of the issue of relative difference in potential liver supply since the Washington Region DSA has a much lower death rate and fewer potential livers to procure. In fact, the liver donation rate is higher for the WRTC OPO than the LLF OPO, as shown in Table IV-9.[44]

Especially now, with the latest changes to UNOS allocation policies that expand the radius eligibility for an organ, donor outreach activities in either DSA should benefit patients listed at any of the three liver transplant centers. According to the LLF, there is no correlation between the number of transplant centers and the size of the donor pool. (DI #40, p. 2). Upon review of SRTR reports, I also found it interesting that Johns Hopkins Hospital had the third lowest observed donation rate of the 25 donor hospitals listed in the LLF's SRTR OPO-Specific Report in FY 2019, suggesting that having a liver transplant program does not correlate with a hospital's ability to secure more donations.

Live Donor Organs and HIV-positive Donor Transplants

Suburban notes that its affiliated Johns Hopkins program has performed more live donor liver transplants than Georgetown, and that a transplant program at Suburban would allow for expanded outreach and education efforts resulting in more live donors. Live donor liver transplants would still take place at Johns Hopkins "initially"[45] and not at Suburban if the proposed Suburban program is established, but the increased supply of live donors would free up deceased donor livers for more patients. The applicant also notes that Johns Hopkins performed the first HIV-positive liver transplant in 2016, and the applicant estimates that additional HIV-positive patients could be transplanted and saved each year.

Increasing the number of donor livers from live donors would certainly benefit liver transplant candidates. However, as I stated with regard to outreach and education, I find that the

[44] Table IV-9, *supra*, p. 44.

[45] Suburban used the word "initially" at times in its application but did not offer any timeline as to when live donor transplants would take place at the hospital if its application were approved. The applicant says numerous times that live donor transplants would be referred to Johns Hopkins. (DI #3, pp. 45, 62, 98-99, 101-02, 164; DI #13, p. 31, 39).

establishment of another transplant center is not required to conduct the outreach and education programs needed to increase live donor participation, especially given the Hopkins CTC presence at Sibley Memorial and Suburban Hospital. The applicant does not segment the projected volume for its proposed project into living and deceased donor transplants, and the volume of current live donor transplants does not suggest that a new liver transplant program is necessary to meet the demand in the two DSAs even if it were to increase slightly, as shown in the table below.

Table IV-14: Live Donor Liver Transplants at Maryland and District of Columbia Liver Transplant Programs, CY 2015-2019

Center	2015	2016	2017	2018	2019
Johns Hopkins	12	7	6	14	17
Georgetown	12	6	2	1	9
UMMC	12	12	10	15	15

Source: OPTN, https://optn.transplant.hrsa.gov/data/view-data-reports/.

As mentioned, Suburban would schedule live donor liver transplant cases at Johns Hopkins in the Maryland Region DSA, so the proposed project will not add a new location for live donor liver transplants. If an increase in live donor livers in the Washington Region DSA were to free up deceased liver donations for more patients, the patients at any of the three existing liver transplant programs would be eligible for any liver recovered in the Washington Region DSA with the new liver allocation policy, so it would be of equal benefit for both DSAs.

I share the excitement of the HIV-positive community regarding increased transplant options. According to UNOS, between 2016 and 2018, 31 HIV-positive liver transplants took place in the United States.[46] While this is innovative, I do not find that a case volume level of 31 HIV-positive liver transplants *in the U.S.* over three years warrants the establishment of a new liver transplant center in the Washington Region DSA. Maryland residents who need this specialized transplantation service currently may access the service at Johns Hopkins.

Overall, Suburban projects growth in the total volume of transplants across both DSAs by an additional ten cases per year. In Year 5, the applicant projects to shift 29 cases from existing centers, of the total projected 46 cases. (DI #3, p. 179). This means that most of the proposed project's volume (over 60%) is projected to shift from other centers, cases that would have taken place anyway. I find that the two specific categories of transplants that the applicant hopes to grow, live donor and HIV-positive donor transplants performed at Johns Hopkins, are donor populations to which the applicant can already reach out, using its existing resources at Sibley Memorial and Suburban. For reasons discussed in my analysis regarding the Need standard and in the Access standard,[47] I find that Suburban failed to show that its proposed liver transplant service will increase the supply or use of livers for Maryland patients to an extent that would justify the establishment of a new liver transplantation service.

Literature on the Benefits of Competition

Finally, Suburban submitted research by Adler and Halldorson that states that patient access

[46] https://unos.org/news/100-people-transplanted-thanks-to-hope-act/

[47] See my findings regarding *Live Donor and HIV-Positive Transplants* under the Access standard, *infra*, pp. 71-78.

to a liver transplant improves when inter-DSA competition increases. These studies pre-date 2020 changes in the organ allocation policy, which is projected to increase liver sharing. Considering the new allocation policy, the existing centers in both regions essentially "compete" for the same livers. The Adler studies point to a finding that more transplants centers in a DSA lead to more transplants and donors within a DSA. However, the increase in transplant volume that the applicant projects will take place in the Washington Region DSA would largely be a result of a shift in cases that would have taken place in the Maryland DSA anyway. In the article titled *Is Donor Service Area Market Competition Associated With Organ Procurement Organization Performance?*, Adler concludes that, "proposals to increase district size to increase competition among transplant programs could result in improved organ utilization over time by incentivizing the use of marginal donor organs and increasing access to transplantation." The new organ allocation policy aims to do just that.

Summary

Suburban Hospital has not demonstrated that liver transplant candidates who reside in Maryland need an alternative to the existing transplant centers already available in Baltimore and the District of Columbia in order to have their need for liver transplantation services met. Suburban has not shown that its proposed new program is justified on the basis that the proposal will result an increase in the supply or use of donor organs through technology innovations or other activity. The donor outreach programming it discusses can be accomplished by the existing complement of transplant centers and liver disease clinics in the Washington Region DSA and in the Maryland Region DSA. Suburban failed to demonstrate that it will better serve patients with higher acuity than the existing transplant centers. Live donor and HIV-positive liver transplantation will still be available at Johns Hopkins, to which Suburban currently sends patients.

I find that Suburban failed to demonstrate that its proposed liver transplantation service will increase the supply or use of donor organs, thereby failing to meet the Need standard.

(2) Minimum Volume Requirements.

(a) An applicant shall demonstrate that a proposed organ transplantation service can generate the minimum annual case volume required by this Chapter within the first three years of operation and will likely maintain at least the minimum annual case volume in subsequent years.

(b) An applicant shall acknowledge that, if its application for a Certificate of Need is approved, any approval is conditioned on the applicant's agreement to close its organ transplant service under the following circumstances:

(i) A service that meets the minimal annual case volume required for a new service is unable to sustain the minimum annual case volume for any two consecutive years, and is unable:

1. to provide an explanation acceptable to the Commission as to why it failed to maintain the minimum annual case volume; and

2. to develop a credible plan for achieving the minimum annual threshold case volume that is approved by the Commission; or

(ii) The program fails to achieve the minimum annual case volume by a deadline established by the Commission as a result of the program's failure to achieve the minimum annual case volume requirements.

Table 2: Minimum Annual Case Volume Requirements by Organ Type

Organ Type	**Minimum Annual Case Volume**
Kidney Adult Pediatric	 30 10
Liver	12
Pancreas, Heart/Lung, Intestine (small bowel)	No Volume Requirement
Heart	12
Lung	12
Hematopoietic Stem Cell: Autologous Allogeneic	 10 10
Other Transplantable Cells Islet Cells Hepatocytes	No Volume Requirement
Vascular Allograft	No Volume Requirement

Applicant's Response

The year three minimum annual case volume for liver transplant programs is 12 cases per year. By the third year over operation of its proposed transplant program, Suburban estimates it will perform 37 cases annually, well in excess of the minimum requirement. (DI #3, p. 111).

Suburban Hospital acknowledges that if its application for a Certificate of Need is approved, the approval is conditioned on Suburban's agreement to close its liver transplant service under the circumstances outlined in COMAR 10.24.15.05B(2)(b). (DI #3, p. 112).

Reviewer's Analysis and Findings

I find the applicant's projected case volume is likely to be achievable and that the project complies with this standard.

(3) Access.

(a) Each type of organ transplant service should be accessible within a three-hour one-way drive time for at least 95 percent of Maryland residents.

(b) An applicant that seeks to justify the need for additional organ transplantation services on the basis of barriers to access shall:

(i) Present evidence to demonstrate that barriers to access exist, based on studies or validated sources of information, and

Applicant's Response

Regarding Paragraph (a) of the standard, the applicant states that there are two liver transplant centers currently operating in Baltimore, making liver transplant accessible within a three-hour one-way drive time for at least 95 percent of Maryland residents. (DI #3, p. 113).

In its response to Paragraph (b) of the Access standard, the applicant states that barriers faced by residents in the Washington Region DSA result from: lack of capacity at the single liver transplant center to serve the population; lack of capacity to evaluate transplant candidates and add them to the waitlist; lack of sufficient ICU beds; potentially restrictive policies for candidates to be included on the waitlist; differences in patient acuity; and vulnerability to disruptions with only one center; insufficient supply of livers; and travel burdens. (DI #13, p. 38).

To demonstrate these barriers to access, Suburban compares metrics and studies which are interrelated to issues presented earlier in this report under the Need standard. They include comparisons of center volume and capacity, transplant rates among residents in each region, migration of residents from the Washington Region DSA to the Maryland Region DSA, waitlist policies, acuity of patients across DSAs, strategies to increase patient and donor education, and research on the benefits of center competition within a DSA.[48] (DI #3, p. 114).

The applicant's presentation of evidence of the barriers to access it describes is summarized below.

Liver Transplant Center Volume and Capacity

As discussed under the Need standard,[49] Suburban states that the Maryland Region DSA transplant centers performed more than twice as many liver transplants in 2016, and the gap widened between 2012 and 2016. It notes that the total number of liver transplants performed at the two liver transplant centers in the Maryland Region DSA doubled from 2011 to 2016, while the total transplants at the single center in the Washington Region DSA hovered at 100 per year annually for the same six-year period. The applicant points out that the population of the Washington Region DSA, at 5.5 million, is 40 percent greater than the population of the Maryland Region DSA at 3.9 million, which it concludes proves its hypothesis that residents in the Washington Region DSA are

[48] See Suburban's response related to these issues in the Need standard, *supra*, pp. 14-18.
[49] See Suburban's response regarding Table IV-1, *supra*, p. 15, Row 5 and *Liver Transplant Center Volume, supra,* p. 16.

underserved. (DI #3, pp. 114-15). The applicant contends that an additional liver transplant center is needed in the Washington Region DSA to sufficiently address the need of the population of 5.5 million residents in the area. Suburban states that the biggest factor driving the lower transplant rate in the Washington Region DSA, summarized in detail in the Need standard[50] is insufficient capacity. (DI #3, p. 46).

Suburban states that one measure of the capacity to conduct candidate evaluations in a DSA is the number of patients who are added to the waitlist, suggesting that, while there is no benchmark for waitlist length or the rate at which patients are added to the waitlist, the disparity between the waitlist at the center in the Washington Region DSA and the centers in the Maryland Region DSA may result because the single center in the Washington Region DSA lacks the capacity to conduct a sufficient number of candidate evaluations. In the Maryland Region DSA there are "twice as many" transplant centers and "more access to beds and options for transplant" than in the Washington Region DSA with its single transplant center. (DI #13, p. 15). Suburban states that the waitlist is three times as long in the Maryland Region DSA (853 candidates) as in the Washington Region DSA (276 candidates), despite a larger population in the Washington Region DSA. (DI #13, p. 49). Between 2013 and 2016, between 213 and 342 more patients were added to the waitlist in the Maryland Region DSA transplant centers each year than were added to the Washington Region DSA center's waitlist. Suburban believes that this disparity is even more striking given that the Washington Region DSA includes a population that is 40 percent greater than the Maryland Region DSA. Thus, it concludes that the single transplant center within the Washington Region DSA lags behind in identifying, evaluating, and listing transplant-eligible patients. (DI #3, pp. 119-22; DI #13, p. 38; DI #13, p. 44 and DI #15, p. 5).

Suburban also states that the availability of ICU beds is especially necessary for patients with high MELD scores who routinely require ICU care. It notes that the Maryland Region DSA has 382 ICU beds available for patients with MELD scores of 35 or higher, compared to 57 beds in the Washington Region DSA. (DI #13, p. 15). The applicant states that, on occasion, a transplant center may be unable to perform a liver transplant because an ICU bed is not available, and that is less likely to occur in a hospital with a higher number of ICU beds or to occur in a DSA with more than one center. (DI #15, p. 4). The applicant cites current capacity across all liver transplant programs in the two DSAs and compares the acuity of patients, stating that UMMC has 266 ICU beds and performed 53 transplants on patients with MELD scores of 35 and above in 2016. Georgetown has 57 ICU beds and performed eight transplants on patients with MELD scores of 35 and above, without noting a specific reference for this data. (DI #15, p. 5). Suburban suggests these are related, but states that it cannot know for sure if Georgetown's lower number was due to the lack of available ICU beds. (DI #15, p. 5).

Finally, the applicant points out that patients would be vulnerable in the event that the single liver transplant center in the Washington Region DSA were to be disrupted by a loss of surgeons or staff or the imposition of oversight restrictions and that an alternative transplant center in the DSA would protect against such an eventuality limiting access. (DI #13, pp. 28, 29).

[50] See the applicant's response regarding *Increasing the Use of Livers by a Transplant Center with More Capacity*, *supra*, p. 23.

Resident Transplant Rates

Suburban maintains that, on a per capita basis, residents in the Maryland Region DSA were nearly twice as likely to be transplanted at any center as residents of the Washington Region DSA, pointing out that the overall use rate for this service was 44.4 per million population in the Maryland Region DSA compared to 24.5 per million population in the Washington Region DSA in 2015. The applicant asserts that similar transplant rates per million and similar migration patterns between the two DSAs should be expected. The applicant views the dissimilarities seen between the two regions as due to a lack of access in the Washington Region DSA. (DI #3, p. 116; DI #13, p. 19-20).

Patient Migration

The applicant contends that overall patient access may be measured based on comparing a patient's DSA of origin and where s/he received a transplant.[51] Accordingly, it argues that, because only 46 percent of transplant recipients residing in the Washington Region DSA received a transplant in the District of Columbia, while 93 percent of transplant recipients residing in the Maryland Region DSA received a transplant at one of the two facilities in the Maryland Region DSA, residents in the Washington Region DSA have less access. (DI #3, p. 116).

Waitlist Policies

The applicant describes the liver transplant evaluation process as complex, iterative, and time consuming, with multiple consultations and other diagnostic tests. As also presented in response to The Need standard, it states that patients are listed at the discretion of the center's multidisciplinary team and variations in policy may be found: age; HIV status; certain disease states such as hypercoagulable disorders; alcohol abstinence; tobacco use; social support; pre-existing conditions such as cardiac disease; or re-transplants. Suburban states that an evaluation also requires demonstration of adequate insurance for transplant, transportation, and a capable adult caregiver to assist the potential recipient in the evaluation process and through the transplant process. According to the applicant, a patient's access to liver transplant services can be affected due to lack of these resources, especially for minority patients, low-income patients, and patients without an adequate social support system. (DI #13, p. 44)

The applicant again notes that waitlists in the Maryland Region DSA centers are more than three times the size of the Washington Region DSA center's waitlist, yet the age-adjusted death rate due to chronic liver disease is roughly equal for residents of the jurisdictions comprising the two DSAs (though slightly higher for residents of D.C. and Virginia than Maryland). According to the applicant, this indicates that there are patients in the Washington Region DSA who are not being wait-listed who should be. (DI #13, pp. 48-49).

[51] See the applicant's response to the Need standard regarding *Patient Migration Patterns*, *supra*, pp. 17-18. As noted earlier, I included some of Suburban's response to the Access standard in my description of its response to the Need standard.

Acuity of Liver Transplant Patients

Using median MELD scores to compare the relative acuity of transplant patients, the applicant states that the Washington Region DSA transplant center has consistently transplanted fewer sick patients when compared to the transplant centers in the five Region II DSAs.[52] Refer to Table IV-15, for convenience, which was also presented as Table IV-3 in the Need standard.

Table IV-15: Region 2 Median MELD Score by DSA, 2011-2015

DSA OPO Code	States	2011	2012	2013	2014	2015
LLF	MD	24	28	29	32	31
PADV	PA, DE, NJ	29	29	30	31	30
PADTF	PA, WV, NY	28	29	31	28	29
NJTO	NJ	24	25	27	29	27
WRTC	DC, MD, VA	22	22	24	26	25

Source: DI #3, p. 120.

As stated previously, Suburban points out that the Washington Region DSA is the only single-center DSA of the five DSAs in the Region 2. The lower MELD scores in the WRTC indicate that the Washington Region DSA consistently performs transplants on less sick adult patients. additionally, patients with lower MELD scores have lower priority on the waitlist and, thus, less ability to receive donor organs from other DSAs, resulting in less case volume overall. (DI #3, p. 94).

Referencing data from 2016, the applicant reasons that the fact that 23 percent of the transplants performed by Georgetown, the single liver transplant center in the Washington Region DSA, went to patients with MELD scores $\geq$ 30, compared to 41 percent of the transplants going to such patients in the Maryland Region DSA indicates that sicker patients who reside in the Washington Region DSA lack access. (DI #13, p. 43). Suburban also presents the data shown in Table IV-16, below, repeated from Table IV-1, Row 16, that shows a greater number of transplanted patients with MELD scores $\geq$ 35 (75 in each year for 2015 and 2016 in the Maryland Region DSA compared to just 7 in 2015 and 8 in 2106 in the Washington Region DSA). For this reason, the applicant concludes that residents of the Washington Region DSA with higher MELD scores experience insufficient access. (DI #15, p. 7).

Table IV-16: Number of Transplants with MELD ≥ 35 by DSA, 2015-2016

Year	Maryland Region Centers	Washington Region Center
2015	75	7
2016	75	8

Source DI #15, p. 7.

The applicant also concludes that "Share 35" did not have the intended beneficial impact for sicker patients in the Washington Region DSA. Suburban notes that between 2014 and 2016, 21 livers were exported from the Washington Region DSA and transplanted in the Maryland Region DSA. Of these, six were exported as a result of "Share 35," but 15 were exported after being rejected

[52] See the applicant's response to the Need standard regarding *Patient Acuity*, *supra*, pp. 18-19. As noted earlier, I included some of Suburban's response to the Access standard in my description of its response to the Need standard.

by Georgetown, but were accepted and transplanted at Johns Hopkins. The applicant sees this as evidence that usable livers are rejected in the Washington Region DSA and concludes that "Share 35" did not have the intended beneficial impact for sicker patients in the Washington Region DSA. (DI #13, p. 33-34; DI #15, p. 7). Based on this, the applicant concludes that ", it should not be assumed that a new allocation policy will increase transplants for sicker patients in that region. Rather, Suburban claims that "intra-DSA competition will relieve this disparity and result in a greater number of transplants of sicker patients in the WRTC DSA." (DI #13, p. 43).

Supply of Livers

As previously discussed under the Need standard, the applicant states that the supply of livers is greater in the Maryland Region DSA than in Washington Region DSA. The applicant calculates the supply of livers as the livers recovered, more livers imported, and fewer livers exported per year between FY 2013 and FY 2015 in the Maryland Region DSA when compared to the Washington Region DSA, as shown in Table IV-1,[53] and repeated below for convenience. (DI #3, p. 5).

Table IV-17: Suburban: Comparing Donor Liver in the Two DSAs

	Maryland Region				Washington Region			
	2013	**2014**	**2015**	**2016**	**2013**	**2014**	**2015**	**2016**
Livers Procured	102	119	121	**174**	92	97	89	101
Livers Exported	5	23	24	22	18	38	53	35
Livers Imported	41	85	126	124	30	41	33	45
Total Supply	138	181	223	276	104	100	69	111

Source: DI #3, pp. 40, 41; DI #15, p. 24.

Suburban states that the Washington Region DSA, with a single liver transplant center at Georgetown, "produces less than one-third the supply of livers" as the Maryland Region DSA, despite having a considerably larger population. It believes that this demonstrates a barrier to access (5.4 million compared to 3.9 million).

Travel

Suburban also states that the time and expense involved in travel and the emotional cost of being away from home and family during hospitalization means that the need for liver transplantation services for residents in the Washington Region DSA is not adequately met. The applicant states that this out-migration disproportionately impacts residents of a lower socioeconomic status (SES), and that patients with fewer resources may never be evaluated for transplant nor have their candidacy deemed feasible "because the center is too far from where they live, preventing them from complying with pre- and post-transplant care requirements. When patients are rejected by a center because of the burdens of travel, access is reduced. Proximity to a transplant center is a critical component of access." (DI #13, p. 11).

The applicant references a 2013 study[54] that revealed an association between SES and traveling to alternative DSAs, and the impact of that travel on patient survival. The study reported a

[53] Table IV-1, *supra*, p. 15, Rows 1-4.

[54] Dzebisashvili, Nino, et al. "Following the organ supply: assessing the benefit of inter-DSA travel in liver transplantation." Transplantation 95.2 (2013): 361-371.

strong association between higher SES and ability to travel, with transplant candidates in the highest SES quartile being 70 percent more likely to travel than candidates in the lowest SES quartile. The study concluded that ability to travel leads to increased transplantation and a 20 percent reduction in risk of death due to end stage liver disease.

Research on the Effects of Competition

Citing study findings that were summarized in detail under the Need standard,[55] Suburban asserts that the lack of competition in the Washington Region DSA has led to disparities in the number of transplants performed, the number performed locally, the number of organs used, and the number of patients placed on the waitlist. (DI #3, pp. 49-50, 123). Halldorson's work[56] concluded that when a DSA has more than one center, centers within a DSA compete for patients. As a result, competitive centers are more likely to transplant sicker patients, which increases access,. Competition led to the utilization of higher risk organs, which increases supply, and DSAs without competition had significantly fewer listings per million population. (DI #3, p. 49).

Adler[57] also reported that DSAs with more liver transplant centers were associated with more liver transplants, more listings, more donors, and a higher Liver Donor Risk Index. Transplant center density was associated with market competition, more listings for transplant, and higher MELD at transplant. In a 2016 article, Adler[58] examined the impact of transplant market characteristics on OPO performance and found that competition within DSAs was strongly associated with OPO performance. For liver transplant, more competitive DSAs were associated with favorable metrics pertinent to this discussion such as more donors per population, more livers transplanted per donor, higher percent of liver donation after cardiac death, greater use of riskier organs, higher MELD score, more new listings per 100,000, and higher percentage of transplants with MELD greater than 30. (DI #3, pp. 49, 50).

Suburban asserts that these studies provide evidence that centers with no competition may be more reluctant to transplant organs in sicker recipients or to use organs that may be considered too "high risk." The applicant surmises that, if a single center is more selective with potential recipients and donors, patients seek out other area centers with a higher risk tolerance. Patients in more urgent need of a transplant residing in a non-competitive DSA may either be bypassed (and die), or seek other DSAs to list and be transplanted, if they have the resources.

The applicant applied the findings summarized above and points out that, compared to the less competitive Washington Region DSA, centers in the more competitive Maryland Region DSA perform more transplants per year, have a higher median MELD score, have a higher organ supply utilization rate, list more patients and have more new patient listings, and have a larger number of donors.

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[55] See summaries of studies cited by Suburban, *supra*, pp. 24-25.
[56] Halldorson, Jeffrey B., *et al*. "Center competition and outcomes following liver transplantation." *Liver Transplantation* 19.1 (2013): 96-104.
[57] Adler, Joel T., *et al*. "Market competition and density in liver transplantation: relationship to volume and outcomes." *Journal of the American College of Surgeons* 221.2 (2015): 524-531.
[58] Adler, Joel T., *et al*. "Is Donor Service Area Market Competition Associated With Organ Procurement Organization Performance?" *Transplantation* 100.6 (2016): 1349-1355.

Interested Party's Comments

Georgetown claims that the applicant offered neither objective nor validated evidence that barriers to access exist. In its comments regarding Suburban's compliance with the Access standard,[59] the interested party states that the applicant's "methodologies describing patient 'migration' patterns have no basis in statistical data reporting mandated by national regulatory agencies – CMS, UNOS, SRTR. " (DI #21, p. 25).

Georgetown dismisses Suburban's rationale that historical program volume trends support the need for a program, that experience supports the benefits of increased competition or improved patient survival, and that patient "migration" or the import/export of organs supports the need for a new transplant program. [60] (DI #21, p. 2).

Liver Transplant Center Volume and Capacity

Georgetown argues that the applicant's arguments are flawed, noting that Suburban combines data for Johns Hopkins and UMMC, even though Johns Hopkins has historically performed at a lower volume than Georgetown. As addressed under the Need standard, the interested party states that transplant volume "cannot be tied specifically to population density," and is also affected by program longevity, physician referrals, patient and donor selection criteria that evolve over time, the availability of organs, and allocation policy governed by CMS/UNOS. Georgetown points to the data in Figure IV-B,[61] showing that case volume at the three programs in Maryland and D.C. has fluctuated over the decade as a consequence of factors beyond population. (DI #21, p. 2).

Georgetown notes that the evolving UNOS allocation policy is intended to increased liver sharing and provide greater access to organs for the most severely compromised patients. Increasing the number of transplant centers is not the proper mechanism through which to address differences in OPO performance characteristics (DI #21, p. 15). The interested party states that an import/export comparison between the Washington Region and the Maryland Region DSA in the most recent SRTR data shows little difference in organs exported directly to one region over another. (DI #21, pp. 12, 13).[62]

The interested party suggests that Johns Hopkins may be "artificially creating need" for livers in the LFF DSA, by evaluating patients for liver transplant at two sites within the Washington Region DSA, but then referring candidates to Johns Hopkins in the Maryland Region DSA for transplantation. In this situation, organs from the WRTC OPO would "follow" high acuity patients for whom sharing is mandated under the UNOS allocation policy. For these reasons, Georgetown asserts that these livers are not leaving the DSA due to a lack of access, but rather because of

[59]Georgetown's submission does not include distinct comments with regard to the proposed project's compliance with the Access standard. However, many of the interested party's comments regarding the Need standard relate to what Suburban submitted in response to the Access standard. Because they are interrelated in this matter, I include pertinent comments submitted by the interested party and consider them here.
[60] See Georgetown's comments regarding these areas under the Need standard, *supra*, pp. 27-35.
[61] Table IV-B, supra, p. 31.
[62] See Georgetown's comments regarding *Liver Transplant Center Volume, supra*, pp. 29-30.

allocation policies. Instead, Georgetown states that it will "accept a less-than-ideal organ that may not suit a patient at the highest level of acuity, if it presents a reasonable and viable match for another patient on the waiting list who can benefit." (DI #21, p. 15).

Georgetown also refutes the applicant's assertion that a DSA with one center is more vulnerable to disruptions than a DSA with multiple centers.[63] It also notes that it has sufficient staff and beds available. Further, Georgetown states that its transplant program has never experienced an operational problem that precluded patient access like when Johns Hopkins was sanctioned by CMS due to poor outcomes. In fact, during that time, Georgetown notes that it was offered as an alternative to Johns Hopkins. (DI #21, pp. 3-5).

Patient Migration

Georgetown contests the idea that patient migration across DSA borders is an indicator of lack of access,[64] especially in areas of close geographic proximity. (DI #21, p. 4). Instead, Georgetown states that patients choose one program or another based on factors such as individual preference, referring physician recommendation, family support, perceived reputations of individual centers and other variables that may change over time. (DI #21, p. 4).

Acuity of Liver Transplant Patients

The interested party states that the applicant presents outdated data and critiques its conclusions that considered just one SRTR reporting period to support Suburban's contention that Georgetown's patient acuity is lower than that of patients at Maryland Region DSA transplant centers.[65] Georgetown states that the distribution of high MELD score transplants changes over time and there are not statistically significant differences. (DI #21, p. 6).

As described under the Need standard, Georgetown points out that its Status 1 group combined with other high MELD score categories represent a higher proportion of acutely ill patients than that reflected in the Suburban application. Still, Georgetown states that fluctuation in MELD scores over time does not reflect divergent medical practices at one center and is certainly not indicative of an access barrier. (DI #21, p. 6).

Applicable here again, the interested party references a 2018 publication[66] which found that MELD profile differences exist even within a single DSA, and the interested party states that patient MELD scores are not an indicator of access or lack of access to transplantation. Georgetown describes what it considers an efficient strategy at its center, to accept less-than-ideal grafts for lower MELD patients, in whom those grafts are expected to be successful, which effectively drives down its median MELD score. Georgetown states this practice increases patients' overall access to

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[63] See Georgetown's comments regarding *Attributes of the Washington Region's Existing Liver Transplant Services, supra*, p. 33.

[64] See Georgetown's comments regarding *Disparities in DSA Transplant Rates, Migration, and Waitlists, supra*, p. 30.

[65] See Georgetown's comments regarding *Patient Acuity, supra*, p. 31.

[66] Croome, *et al*. "Intraregional Model for End-Stage Liver Disease Score Variation in Liver Transplantation: Disparity in Our Own Backyard." Liver Transplantation 24, no. 4 (2018).

transplants and would explain its lower MELD scores. (DI #21, p. 6-7).

Supply of Livers

Georgetown also challenges the applicant's assertion that the WRTC OPO is "underperforming" in terms of the number of organs procured. According to SRTR data through October 2017, despite having a slightly larger population than the Maryland Region DSA, the Washington Region DSA had over 4,000 fewer deaths than the Maryland Region DSA. In the preceding year, the Washington Region DSA had 30,639 deaths compared to the Maryland Region DSA's 34,829. Converted to a population-based death rate, the Washington Region DSA ranked 57 out of 58 DSAs, with a death rate of 5.61 per 1,000; the death rate in the Maryland Region DSA of 8.93 per 1,000 placed its rank at 21 out of 58.

Based on this information, Georgetown asserts that the centers in the Maryland Region DSA have access to more organs, and makes the point that adding a transplant center will have no impact on the number of deaths or the death rate within a DSA. (DI #21, p. 12). The interested party points out that the latest-available SRTR *OPO-Specific Report* released on January 5, 2018 shows that during FY 2017 the WRTC actually performed somewhat better than its expected donation rate per 100 eligible deaths, achieving 66.3 donated organs per 100 eligible deaths compared to an expected donation rate of 64.4/100. (DI #21, p. 12, Exh. 5).

Research Regarding Competition

Georgetown rebuts Suburban's claims that increased competition results in an increased number of liver transplants or improved patient survival and cites what it describes as "specific limitations" of the Adler and Halldorson studies. See Georgetown's detailed critique in its comments on Suburban's response to the Need standard,[67] which is incorporated herein by reference. (DI # 21, pp. 16-18).

The interested party states that the Halldorson study is not applicable to liver transplantation in 2018 as the pre-2009 data used in the study preceded changes in organ allocation which resulted in increased regional sharing. Georgetown points out that the Halldorson study notes some negative impacts of increased competition, including: (1) increased competition is associated with increased risk of graft failure; (2) increased competition is associated with increased risk of patient death after liver transplantation; and (3) increased competition is associated with increased costs associated with transplantation. (DI #21, p. 18).

Applicant's Response to Interested Party Comments

Suburban provided comments in response to the interested party's comments on the interrelated need and access standards. As discussed under the Need standard,[68] Suburban contends that competition is a key to decreasing apparent disparities and improving access for Washington Region DSA residents. (DI #22, p. 2). It suggests that the interested party attempts to distract from

[67] See Georgetown's discussion of its assessment of the limitations of the Adler and Halldorson studies under *Comments on Research Regarding Competition*, *supra*, pp. 33-34.
[68] See Applicant's Response to Interested Party's Comments under the Need standard, *supra*, pp. 35-38.

the problems in the Washington Region DSA with alternative data that the applicant characterizes as not relevant. (DI #22, p. 3). The applicant defends its comparison of the DSA volumes, instead of center volumes, by reiterating that the data points to the need for another program in the single-center Washington Region DSA.

The applicant suggests evidence of disparities between the DSAs demonstrate a lack of access.[69] This includes consistently fewer transplants in the Washington Region DSA, even with its greater population; a use rate for residents of the Maryland Region DSA is nearly twice that of the Washington Region DSA; higher out-migration to other DSAs for liver transplants in 2015, which puts those that do not have resources to migrate at a disadvantage; lower median MELD scores from 2011 to 2015; lack of competition to serve patients with higher MELD scores; a greater proportion of organs exported from the Washington Region DSA and a lower number of livers imported into the Washington Region DSA; and a smaller waitlist. (DI #22, pp. 3, 5-10, 12-13, 18).

(ii) Present a credible plan to address those barriers. The credibility of the applicant's plan will be evaluated on whether research studies or empirical evidence from comparable projects support the proposed plan as a mechanism for addressing each barrier identified, whether the plan is feasible, and whether members of the communities affected by the project support the plan.

Applicant's Response

In responding to Subparagraph (ii), the applicant refers to information covered in the preceding sections of this standard that discusses the access barriers to liver transplantation in the Washington Region DSA, as demonstrated by lower transplant center volume, fewer patients being placed on the waitlist, lower rate of transplants, higher rates of migration out of the DSA to receive a transplant, lower acuity level of patients transplanted at the Washington Region DSA center, and lower donor liver procurement volume, as well as descriptions of hospital capacity, to support its claim that the Washington Region DSA has barriers to access.[70]

Suburban states that, based on its experience, transplant candidates choose a transplant center based on: (a) ease of travel to the candidate's home and the candidate's support system (e.g., family); (b) capacity of the center to conduct the candidate evaluation; (c) the availability of a donor organ (i.e., supply); (d) the patient's insurance network for transplant; (e) referral patterns; (f) the center's transplant experience; and (g) the reputation of the transplant center. (DI #13, p. 20).

Suburban states that its goal with the proposed project is to decrease access disparities between the Maryland Region DSA and the Washington Region DSA. Suburban claims that the proposed project will address the barriers to access,[71] including a lack of capacity to waitlist enough candidates and offer enough liver transplants for the population of the Washington Region DSA, restrictive waitlist policies, lack of transplants for patients with higher acuity, vulnerability to

[69] See Suburban's detailed response regarding *Current Liver Supply and Utilization*, *supra*, pp. 14-19.
[70] Ibid.
[71] See Suburban's detailed response regarding *How Suburban Proposes to Increase Supply or Use of Donor Organs, supra,* pp. 19-27.

disruptions with only one center, lower supply of donor livers compared to the Maryland Region DSA, and travel burdens. (DI #13, p. 38).

It states that competition is an "important and powerful tool for improving these measures" based on experience at the Johns Hopkins CTC and a body of peer-reviewed medical literature. (DI #3, p. 49; DI #15, p. 8). Suburban asserts that data and literature show a correlation between such competition and increased access to transplant services. Finally, the applicant highlights the community support for this program, expressed in letters of support previously identified in this Recommended Decision.[72] (DI #3, p. 126, Exh. 17).

To address what Suburban describes as insufficient liver transplant hospital capacity for liver transplant candidates and patients in the Washington Region DSA, Suburban contends that its proposed project will increase the number of transplant evaluations performed and patients added to the waitlist every year, increase the number of ICU beds available to liver transplant patients in the Washington Region DSA from approximately 57 to approximately 99, decrease the need for Washington Region DSA residents to travel outside their DSA for liver transplants, and increase supply through outreach to all regional hospitals to educate staff about approaching the families of potential deceased donors. (DI #13, p. 21).

In order to address a disparity in waitlist policies, the applicant suggests that the proposed project will be able to evaluate and double-list additional patients in a cost-effective way. It may have different acceptance policies, and would increase options, according to the applicant, leading to more patients added to the waitlist. (DI #3, pp. 119-22; DI #13, p. 38; DI #13, p. 44 and DI #15, p. 5).

Increasing the number of available ICU beds at transplant center hospitals within the Washington Region DSA is important because, according to the applicant:

> the availability of intensive care unit (ICU) beds is necessary for a transplant center. Patients with high MELD scores routinely require ICU care, and so the ability to perform liver transplants on those patients depends on ICU bed availability. On occasion, a transplant center may be unable to perform a liver transplant because an ICU bed is not available. That is less likely to occur in a hospital with a higher number of ICU beds. It is also less likely to occur in a DSA with more than one center.
> (DI#15, p. 4).

Thus, the applicant asserts that establishing a liver transplant program at Suburban with its additional 42 ICU beds would alleviate any access restriction that a shortage of ICU beds might impose on transplant patients with high MELD scores. (DI #13, p. 40; DI #15, p. 5).

The applicant believes that increasing the number of "local" transplant options offers the best way to improve access to transplant services for patients with lower SES. (DI #3, p. 29). Although the applicant was not able to quantify how often this results in a potential liver transplant patient being turned away (DI #15, p. 8), Suburban asserts that a second center in the Washington Region

[72] See Suburban's response regarding Community Support, *supra*, pp. 5-6.

DSA at Suburban would address this unmet need and lead to higher per capita transplant rates in the Washington Region DSA. (DI #3, pp. 116-19). The applicant points out that Suburban is in Bethesda, accessible by highways and public transportation, and is well-positioned to address a travel barrier that disproportionately impacts lower-income residents of the Washington Region DSA.

Suburban maintains that patients in the Washington Region DSA will benefit from the establishment of the proposed liver transplant center because it will lead to an increase in resources that support education, identification, and recruitment of live donors in the Washington Region DSA with a new team focused on liver care and liver transplantation. (DI #13, p. 21). The applicant also suggests that it is uniquely qualified to address what it considers to be capacity issues in the Washington Region DSA through outreach and community involvement (DI #3, pp. 64-65), with the experience and expertise of the CTC (DI #3, pp. 54-58), and by expanding the existing hepatology practice at Sibley Hospital and consolidating and integrating it with Suburban's existing clinical resources. (DI #13, pp. 39-40). In order to address the disparity in the supply of livers, Suburban suggests that it is positioned further similar efforts as those currently executed by the CTC at Johns Hopkins to increase the supply of donated organs. The initiatives listed below include a variety of programs that are addressed under the Need standard:[73]

- Additional patient and donor education;
- Continued collaboration with the Minority Organ Tissue Transplant Education Program;
- Innovative donor recruitment techniques such as the aforementioned Facebook campaign;
- Continued work of the Epidemiology Research Group in Organ Transplantation;
- Increasing the number of live donors, which frees up deceased organs for other transplant candidates;
- Multi-listing;
- Development of an organ donation culture in WRTC, similar to that Johns Hopkins has with the LLF;
- Deployment of a Donor Advocate Program;
- Outreach and education for minority and indigent patients;
- Physician outreach and re-directing referral patterns;
- Partnerships with community organizations; and
- Using riskier organs.

(DI #3, pp. 59-66, 98-102; DI #13, p. 39-40).

The applicant suggests that an additional benefit that the proposed project would bring is increased opportunity to multi-list locally, at either Johns Hopkins or UMMS (Maryland Region DSA), and at Suburban (Washington Region DSA), which increases chances of matching with an available deceased donor organ. For many Maryland Region DSA residents, the travel burden to Suburban will not be much different from traveling to JHH or UMMC, so they will have an additional option. At Suburban, patients will receive care from a Johns Hopkins faculty physician

[73] See Suburban's response regarding *Increasing the Supply of Livers through Education and Outreach, supra,* p. 20-21.

and have the benefit of the extensive experience, expertise, clinical trials, and research of the Johns Hopkins CTC team. (DI #13, p. 61)

Referring to the literature presented by Suburban that extolls the merits of competition, it concludes that the solution to resolving what it presents as access disparities is to introduce an additional liver transplant center within the Washington Region DSA, and that Suburban Hospital, an affiliate of the Johns Hopkins Comprehensive Transplant Center, is the best way to increase competition and, thus, improve access. The applicant asserts that this is because of the CTC's experience and expertise, Suburban's capabilities (as evidenced by its Level II Trauma Center and cardiac surgery program), the ability to minimize start-up costs by leveraging resources already available at the Johns Hopkins CTC, and the fact that Suburban is a lower cost setting than the existing providers, which are all academic medical centers. The applicant also states that competition will improve access and reduce migration across DSA borders and offer the ability to list with one health system in both the Washington and Maryland Regions. (DI #3, p. 123-125).

As further evidence, the applicant states that competition in the Maryland Region DSA has influenced the policies and practices of Johns Hopkins and UMMC, claiming that these two programs have experienced steady growth since 2010, transplant sicker patients, and make use of marginal organs, all while maintaining excellent outcomes and reducing outmigration from the Maryland Region DSA. (DI #13, p. 41).

Suburban states that the following factors led to a reduction in out-migration from the Maryland Region DSA between 2011 and 2015:

- Increased access afforded by two competing services within the Maryland Region DSA reduced the need for Maryland Region DSA residents to seek transplants outside the DSA;
- Intra-DSA competition encouraged more patient outreach and more robust referral practices, resulting in greater retention of Maryland Region DSA transplant patients;
- Intra-DSA competition led to an increase in the number of donors in the Maryland Region DSA, thus making more organs available;
- The establishment of Share 35[74] by CMS, which allowed the Maryland Region DSA to use organs from outside the DSA; and
- Enhanced experience, outcomes, and reputations of the two Maryland Region DSA centers.

Finally, the applicant presents recent experience with kidney transplantation services in the Washington Region DSA. In 2015, a new kidney transplant program was added in the Region at George Washington University Hospital. The applicant states that this led to additional kidney transplant volume in the DSA, and also resulted in Georgetown increasing its transplant volume by more than 30 percent. (DI #3, p. 125).

[74] In 2013, CMS adopted a new policy known as "Share 35" which increased regional priority for patients with a MELD score of 35 or greater, or sicker patients labeled Status 1 with acute (sudden and severe) liver failure. In 2017, an additional change in the national policy for liver allocation extended the Share 35 program to apply to patients with a MELD score of 32. In February 2020, the "Acuity Circles" policy replaced Share 35.

Interested Party's Comments

Georgetown believes that the data Suburban presents above on transplant volumes does not support the assertion that a new program is needed. Further, Georgetown notes that neither actual experience at the existing centers nor scientific literature or comparable experience elsewhere support the claim that increased competition in the Washington Region DSA will lead to increased numbers of transplants and improved patient survival. (DI #21, cover letter, p. 2).

Again, Georgetown disputes the applicant's argument that vulnerability to program disruptions such as unexpected loss of personnel or other operational issues at Georgetown is a barrier to access than an additional liver transplant center would address. The interested party states that the existing center has sufficient staff and bed capacity with six full-time liver transplant surgeons and seven full-time hepatologists, critical care beds, and new surgical services and state of the art operating rooms. Georgetown states that its transplant program has never experienced an operational problem that precluded patient access. (DI #21, pp. 4, 5).

Along with disagreeing with Suburban's position that published studies show that competition will be beneficial in this case,[75] the interested party further illustrates its contention by presenting data that it states shows that competition has no effect on OPO performance in the area of liver procurement for transplant. Georgetown contrasts the performance of two OPOs that operate in highly competitive DSAs in the mid-Atlantic region with similar large urban populations. It notes that the Philadelphia area has eight competitive transplant programs and describes its OPO, the Gift of Life Donor Program (OPO Code: PADV), as the highest performing OPO in the country, in terms of livers procured for transplant. In contrast, the New York City metro area's OPO, LiveOnNY (OPO Code: NYRT) has seven competing programs and is one of the nation's lowest, in terms of livers procured for transplantation. (DI #21, pp. 18-20). See Table IV-18 below.

Table IV-18: Georgetown: Comparative Organ Procurement, PADV and NYRT

			National		
Measures	**PADV**	**NYRT**	**Minimum**	**Average**	**Maximum**
Eligible Deaths	570	433	43	195.2	570
Deceased Donors	567	290	35	175.9	567
Deceased Donors Meeting Eligibility Criteria	428	231	29	137.7	428
Observed Donation Rate Per 100 Eligible Deaths	75.1	53.3	53.3	70.6	88.9
Expected Donation Rate Per 100 Eligible Deaths	72.0	65.6	--	--	--
Standardized Donation Rate Ratio	1.04	0.81	--	--	--

Source: DI #21, pp. 19, 20.

Georgetown maintains that this data, which shows that two OPOs located in highly competitive mid-Atlantic markets had markedly different performance in acquiring livers for transplant, undercuts the applicant's theoretical argument for the benefits of competition, which is not reflected in actual programmatic experience. (DI #21, p. 18-20).

The interested party adds that, in the past, the Washington Region DSA did have competing liver transplant programs, with programs at Howard University Hospital (Howard) in the District of

[75] See Georgetown's detailed critique of the studies cited by Suburban in comments regarding *Comments on Research Regarding Competition*, *supra*, pp 33-34.

Columbia and Inova Fairfax Hospital (Inova), in Fairfax County, Virginia, in addition to Georgetown. The applicant states that the result of this more "competitive" landscape was lower total transplant volumes and, eventually, the failure of the programs at Howard and Inova, "a phenomenon," states Georgetown, "that has reversed under a single center with stable leadership." Georgetown suggests that this experience does not advance the theory that competition improves OPO performance. (DI #21, p.20).

Regarding the comparison that Suburban draws to kidney volume increases after a program was added in the Washington Region DSA at George Washington University Hospital, the interested party attributes that increase to the change in kidney allocation policy rather than the addition of a new program, and presents data that shows volume at the new program has not been sustained and is declining after peaking in 2016. (DI #21, pp. 21-23).

Applicant's Response to Interested Party Comments

Suburban disputes Georgetown's contention that competition in the Washington Region DSA will have no effect on the productivity of the OPO because OPOs work closely with the transplant programs in a DSA, contending that the primary benefits will be based on the added program competition. (DI #22, p. 19). Beyond the quantitative measures it cites in making its argument, Suburban contends that its proposed project would lead to additional outreach efforts to potential donors and, thus, an increase in the number of donors and livers procured. Additionally, Suburban could pick up slack if another program faces operational disruptions. (DI #22, p. 8-16).

Suburban dismisses Georgetown's comments about having competitors in its DSA in the past and the failure of that competition to produce the results predicted by Suburban and the eventual failure of the other transplant centers. It notes that this competition was a long time ago. Howard University Hospital last performed a liver transplant in 1997 and Inova Fairfax Hospital in 2006. (DI #22, p. 20).

(b) Closure of an existing service, in and of itself, is not sufficient to demonstrate an access issue or the need to establish a new or replacement organ transplantation service.

No transplant service closure is a factor in this proposed project

(c) Travel to an organ transplant center located in a health planning region other than where the organ transplant recipient resides is not, in and of itself, considered a barrier to access, if the drive time in less than three hours one-way.

Applicant's Response

The applicant states that residents in the Washington Region DSA disproportionately have to leave their DSA of residence to receive liver transplant services compared to residents in the Maryland Region DSA. From 2011 to 2015, between 38 and 54 percent of patients traveled from the Washington Region DSA to receive liver transplants each year, compared to between seven to 29 percent from the Maryland Region DSA over the same period. (DI #3, p. 128).

As an example, Suburban points out that in 2015, 47 Washington Region DSA residents were

transplanted in the Maryland Region DSA and only seven Maryland Region DSA residents were transplanted in the Washington Region DSA. Although the applicant acknowledges that in these instances, where patients traveled less than three hours one way to be transplanted, it may not be viewed as a substantive barrier to access, it will have a disproportionate impact on patients of a lower socioeconomic status. (DI #3, p. 129).

The applicant argues that those migrating from their DSA of residence are by definition those with the means to do so, supported by a study by Dzebisashvili which found an association between higher socioeconomic status and the ability to travel to alternative DSAs, and the impact of that travel on patient survival.[76] The applicant notes that the ability to travel led to dramatic differences in transplantation and survival. The applicant concludes that this study provides strong evidence that lower income individuals in one DSA do not readily travel to another DSA in order to improve their chances of getting transplanted. (DI #3, p. 129-130).

Suburban asserts that the disparity in migration rates between the Maryland Region DSA and the Washington Region DSA suggests that Washington Region DSA residents migrate out of necessity due to a barrier to access. The applicant argues that the addition of a second center in the Washington Region DSA will reduce these barriers and make liver transplant a possibility for more patients without the means to travel. (DI #3, p. 130).

Interested Party Comments

Applicable to this subsection, Suburban notes that patients chose a program based on: the time that a program has been in operation; physician referral patterns that fluctuate over time; patient and donor selection criteria that evolve over time; the availability of organs which is determined by a variety of factors; and allocation policy governed by CMS/UNOS. Patient volumes have historically fluctuated among the three programs due to past programmatic changes and organs travel between centers due to allocation rules mandated by CMS require it, as noted previously in this Access standard.[77] Migration of patients or organs across these DSA boundaries does not provide evidence of a barrier to access.

The interested party suggests that Johns Hopkins fosters this migration trend from the Washington Region DSA to the Maryland Region DSA referring liver transplant candidates at Sibley and Suburban to Johns Hopkins for transplantation. Thus, organs from the WRTC OPO will follow patients for whom sharing is mandated under the UNOS allocation policy. (DI #21, p. 15).

Georgetown points out that, when Johns Hopkins was sanctioned by CMS due to poor outcomes, it was mandated to offer its patients wait listing at other nearby programs, and patients were sent letters offering them Georgetown as an alternative. It also notes that its program has never been sanctioned. (DI #21, pp. 3-5).

[76] Dzebisashvili, Nino, et al. "Following the organ supply: assessing the benefit of inter-DSA travel in liver transplantation." Transplantation 95.2 (2013): 361-371.
[77] See Georgetown's detailed comments regarding *Patient Migration, supra*, p. 63.

Applicant's Response to Interested Party Comments

The applicant notes that an affiliate of the interested party, MedStar Franklin Square Medical Center, submitted CON applications to the Commission to establish both kidney and liver transplant programs at MedStar Franklin Square Medical Center in Baltimore. The rationale for those applications was that a new liver program at Franklin Square will increase access for MedStar patients, despite the fact that each transplant program, if approved, would be the third kidney and liver transplant program in the Maryland Region DSA.

Suburban points out what it sees as contradictory positions being taken by MedStar in the current organ transplant review cycles. As an applicant, MedStar Franklin Square Medical Center maintains that the distance from Baltimore to Georgetown is a "geographic challenge for many," and contends that there are benefits related to having a transplant program closer to patients' homes. However, as an interested party opposing Suburban's application, MedStar does not seem to recognize such benefits for patients in the Washington Region DSA. Suburban claims this inconsistency undermines the interested party's comments regarding its application. (DI #22, p. 21).

Reviewer's Analysis and Findings

Paragraph (a) of this standard prescribes that the organ transplant program in question "should be accessible within a three-hour drive time to at least 95 percent of Maryland residents". I find that all three of the programs in the combined Washington Region and Maryland Region DSAs are accessible in terms of drive time for residents in both the regions, under this drive time standard, and this is particularly the case for Maryland residents of Montgomery, Prince George's, and Charles Counties, in the Washington Region DSA. Based simply on this provision, there is no need to establish a program. However, Paragraph (b) of the standard provides the opportunity for an applicant wishing to propose an additional center to justify such by proving that barriers to access exist and to present a credible plan to overcome those barriers.

In this case, Suburban claims that its proposed project to establish a second liver transplant center in the Washington Region DSA is needed to erase barriers to access. It claims that these barriers are evidenced by what it points to as disparities in liver transplant services available to residents in the two adjacent DSAs, each of which is serviced by a different OPO and largely accessible to the three transplant centers, two in the Maryland Region DSA in Baltimore and one in the Washington Region DSA in the District of Columbia. The applicant attributes its claim of disparities to the fact that there is only one liver transplant center in the Washington Region DSA. The interested party counters that current data and literature presented by the applicant do not support the need for the proposed program as a necessary approach to achieve any improvements in access to liver transplantation.

I find that the applicant did not provide evidence to demonstrate that barriers to access exist and will address each of these contentions separately.

Liver Supply and Transplant Volume

Suburban asserts that the lower per capita liver procurement rate in the Washington Region DSA, 24.5 per million residents compared to the Maryland Region DSA's 44.4 per million, is

evidence that the Washington Region DSA is underserved. Suburban suggests that if it introduced liver transplant services, liver donors would increase as a result of its outreach and engagement in the community, as would the number of liver transplants performed in the DSA.

The interested party counters that there is no evidence to suggest the residents in the Washington Region DSA are underserved. Georgetown contends that:

- An additional center will not change the fact that the DSA's lower death rate results in less organ availability in the Washington Region DSA;
- Recent changes in UNOS allocation policies lead to a greater sharing of organs across DSAs and the cross-migration of organs; and
- There is no reason to conclude that the Washington Region DSA's center is vulnerable to program disruptions since it has been in operation for more than 20 years without flagged concerns.

Finally, Georgetown asserts that research touting the benefits of center competition is not current or applicable to the facts in this case, and is belied by other data.

Regarding the supply of deceased liver donations harvested within individual OPOs, I refer to my previous finding that the varying death rates among OPOs will obviously have an impact on the number of livers locally available; one is a function of the other. I note that the death rate in the Washington Region DSA in FY 2019 was 6.1 deaths per 1,000 population, compared to 9.4 per 1,000 population in the Maryland Region DSA. Thus, it is not surprising that the Washington Region DSA has fewer potential organ donations despite having a significantly larger population than the Maryland Region DSA.

While the potential supply of deceased donors is determined by the eligible death rate, the OPOs (not transplant centers) are responsible for the procurement of organs. As I found in my consideration of the Need standard,[78] my review of recent SRTR OPO-specific program reports indicates that the WRTC is performing as expected in regard to the procurement of deceased livers**.** I again show the pertinent SRTR data in the table below, which data shows that the Washington Region (WRTC) is outperforming the Maryland Region (LLF) with a standardized donation rate ratio of 1.10 compared to 0.97.

Table IV-19: OPO-specific Report Data, FY 2019

Metric	LLF	WRTC
Population	3,919,340	5,593,845
Deaths	36,697	34,115
Death Rate per 1,000	9.36	6.1
Eligible deaths	197	155
Liver donations per 100 eligible deaths	62.4	63.9
Expected rate	64.3	58.3
Standardized donation rate ratio	0.97	1.10

Source: SRTR OPO Specific Reports, released January 7, 2020.

While I agree that liver transplant candidates would benefit from an increase in the number of

[78] See my discussion regarding *Supply of Livers, supra*, pp. 43-44.

donors per capita, the SRTR reports show that the WRTC OPO is performing above expected rates in terms of liver donation in its DSA. Beyond successful procurement of livers by a designated OPO within its DSA, UNOS allocation policies also guide where procured livers will be offered based on the individual patient characteristics of patients on each transplant center's waitlist.

To increase donor organ supply, Suburban describes outreach that it suggests would help increase donations if its application were approved. However, the applicant does not suggest a lack of existing similar activities in the DSA or point to any particular weakness that increased outreach would remedy. It repeatedly notes what it characterizes as a disparity in the per capita donor rate. As I noted under the Need standard, Johns Hopkins currently operates two clinics for liver disease patients at Suburban and Sibley Memorial and engages with the WRTC, including working together under the Montgomery County Latino Donation Awareness Community Taskforce[79] and as donation champions that attended the WRTC's Donation Resource Specialist Program.[80]

I do not agree that adding a liver transplant service at Suburban is necessary to increase donor outreach activities in the DSA. Especially now, with the latest changes to UNOS allocation policies that expand the perimeter of immediate eligibility for an organ, donor outreach activities in either DSA should benefit patients listed at any of the three liver transplant centers. I also find it interesting that Johns Hopkins Hospital has the second lowest observed donation rate of the 25 donor hospitals listed in the LLF's SRTR OPO-Specific Report, suggesting that having a liver transplant program does not correlate with a hospital's ability to secure more donations. According to the LLF, there is no correlation between the number of transplant centers and the size of the donor pool. (DI #40, p. 2).

The applicant also maintains that it will better utilize deceased donor livers procured by the WRTC OPO, suggesting that its higher export rate and its lower import rate when compared to the neighboring Maryland Region DSA indicates that patients in that the Washington Region DSA are underserved. Suburban contends that its adding a liver transplant service will increase access in terms of the overall quantity of liver transplants performed and the quantity of higher acuity liver transplants performed. As I stated in my initial finding regarding Paragraph (a) of the Access standard, all three of the liver transplantation programs in the Washington Region and Maryland Region DSAs are accessible in terms of drive time for residents of both regions. This is particularly the case for the Maryland residents of Montgomery, Prince George's, and Charles Counties, the Maryland jurisdictions in the DSA that Suburban claims to require improvements in access. This close geographic proximity, coupled with the fact that the new UNOS allocation policy is no longer based on DSA boundaries leads me to find that the research the applicant presents on the benefits of competition is no longer current and applicable because it was published prior to the allocation policy change.

Waitlisting at Multiple Centers

I find that double-listing at Johns Hopkins and the proposed center, in different DSAs, is not as beneficial as Suburban suggests. The benefits the applicant ascribed to listing as a liver transplant candidate in the two contiguous DSAs that serve Maryland jurisdictions are generally outdated. The

[79] http://archive.constantcontact.com/fs090/1102584055218/archive/1102712545711.html
[80] https://m.facebook.com/beadonor/posts/10157742228273381

new UNOS allocation policy that went into effect in February 2020 changes the allocation system from one based around prioritizing allocation within a DSA to creating a system of priority for liver transplant patients within a specified distance of the donor hospital. Prior to the 2020 policy, organs recovered for transplant were prioritized to patients within the DSA of origin. Under the new national liver allocation policy implemented in February 2020, DSA boundaries no longer play a role in allocation. Instead, patients on waitlists are eligible for donor livers based on their distance from the location of organ recovery. This means that, for any liver procured by either the LLF or the WRTC, all patients on waitlists at hospitals in Maryland or the District of Columbia would be eligible, consistent with national policies regardless of the DSA in which the patients reside.

Listing at multiple centers could still benefit a patient by expanding the patient's radius of eligibility, but that benefit becomes more marginal as the distance between transplant center hospitals at which the patient is wait listed becomes relatively short. For instance, since Suburban and Johns Hopkins are 40 miles from each other, a patient could extend his/her radius of eligibility by 40 miles by being registered at both centers (assuming that Suburban were a transplant center). However, this benefit is minimized as the distance between transplant hospitals at which a patient is waitlisted gets shorter. I find that, given the fairly close proximity of the three transplant centers, this factor only minimally improves access and does not justify creating an entirely new liver transplantation program.

Live Donor and HIV-Positive Transplants

Suburban also contends that its addition of a liver transplant program will increase live donor transplants, even though live donor transplants will still be referred to Johns Hopkins in Baltimore. As I stated previously, I reject the argument that adding another liver transplant center is required to increase awareness and outreach aimed at increasing the number of live donors. The lack of a liver transplant center under its control in the region should not preclude outreach or awareness campaigns to live donors, especially since Johns Hopkins already operates two clinics for liver disease patients in the area.

The applicant also notes that Johns Hopkins Medicine is capable of increasing the number of liver transplants because it performs HIV-positive transplants. It performed the first HIV-positive transplant in 2016, and, according to UNOS,[81] in the United States, 31 HIV-positive liver transplants were performed from 2016 to 2018. I find that these procedures are accessible to residents in both DSAs at the existing Johns Hopkins facility, and the relatively low volume does not justify the need for an additional new liver transplant center to refer patients to a program that performs HIV-positive liver transplants.

Suburban's application provided the data displayed in Table IV-20[82] below. That data shows that in 2015, 109 of 134 residents within the Washington Region DSA who received a liver transplant (81 percent) and 168 of 173 (93 percent) of residents within the Maryland Region DSA who received a liver transplant received the transplant either in a Maryland Region DSA center or in the Washington Region DSA's transplant center. I do not agree with the applicant that this data

[81] See https://unos.org/news/100-people-transplanted-thanks-to-hope-act/

[82] For the reader's convenience, information provided earlier in my Recommended Decision is repeated in the table.

demonstrates the need for a new liver transplant program or that patients in the Washington Region DSA do not have sufficient access to liver transplantation services. Instead, this data is part of the basis for my finding that these patients are well-served at the existing facilities, which are accessible to them. Further, I find that the applicant's suggestion that patients who live in the Washington Region DSA should not be treated in the Maryland Region DSA to be quite unconvincing, as Johns Hopkins operates Sibley Hospital's clinic, which identifies itself with Johns Hopkins Hospital on its website.[83]

Table IV-20: Residence and Transplant Center for Patients in the Maryland and Washington Region DSAs, 2015

Region of Residence	Johns Hopkins	UMMC	Georgetown	Other Centers	Total
Washington Region	22	25	62	25	134
Maryland Region	57	104	7	5	173

Source: DI #3, p. 2.

I reviewed similar, more recent data for CY 2018 that the Commission received from UNOS, which shows that 84 percent of organ transplant recipients in the Washington Region DSA and 95 percent of Maryland Region DSA residents received a liver transplant in either Maryland or the District of Columbia. See the following table. I am not persuaded of the validity of the applicant's argument that migration rates between DSAs should be roughly equivalent and, if not, this demonstrates unacceptably compromised access to liver transplant services requiring establishment of a new transplant program.

Table IV-21: Residence and Transplant Center for Patients in the Maryland and Washington Region DSAs, CY 2018

Region of Residence	Transplant Location			
	Maryland Region	Washington Region	Other	Total
Washington Region	46	77	24	147
Maryland Region	135	16	10	161
Total	**233**	**110**	**34**	**377**

Source: UNOS.

Existing Program Performance and Capacity

I will repeat a number of findings that also appear in my analysis of compliance with the Need standard.[84]

While the number of liver transplant candidates on waitlists differed among the programs, from fewer than 300 at Georgetown to more than 450 at UMMC, this does not offer insight into the residence of patients on those waitlists. Patients who are treated and evaluated at the Sibley Memorial and Suburban hepatology clinics who live in the Washington Region DSA are referred to Johns Hopkins for waitlist evaluation and, if the Commission awarded Suburban a CON, those patients would simply move from the Johns Hopkins waitlist to the Suburban waitlist. Since there is no benchmark for an expected waitlist volume and each program has hundreds of patients its

[83]See https://www.hopkinsmedicine.org/transplant/programs/liver/contact-us.html.

[84] See my previous analysis regarding *Existing Program Performance and Capacity, supra,* pp. 47-49.

waitlist, I find that program waitlist length comparisons are not a good indication of disparity in access to liver transplantation. As I found under the Need standard, the patient population of the Washington Region DSA may choose among the three programs which are all within an accessible distance and performing higher than the expected rate based on CMS benchmarks.

Regarding Suburban's proposed addition of ICU beds available to liver transplant patients in the region, the applicant presented no evidence that existing capacity was insufficient to meet the current need or foreseeable future growth. I am unconvinced about the risk of potential program disruptions to the single Washington Region DSA liver transplant center. that has been operating for more than 20 years without such disruption as a reasonable basis for demonstrating a barrier to access, especially when there are two other transplant programs within 45 miles of the existing transplant center.

Regarding the applicant's suggestion that an additional transplant program in the Washington Region DSA would address access barriers for "minority patients, low-income patients, and patients without a social support system," I find that Suburban failed to present convincing evidence that these populations are currently underserved in the Washington Region DSA, and if they are, it has not put forth a specific plan to better serve them at Suburban, beyond generic efforts to increase outreach.

The applicant cites a study that observed that patients with high socioeconomic status are "more likely to move to areas where access to the donor pool was improved" and the study did not include multiple listed patients who are maintained on two waiting lists because logistical difficulties in traveling to both centers make this option available only to candidates in a limited number of some geographic areas. However, liver transplant candidates in the Maryland and Washington Region DSAs would not have to move to cross DSAs and they would be more likely to be captured in the latter group who are able to double-list more easily because of geographic proximity. Further, as stated previously, the new UNOS allocation policy is projected to move more livers across greater distance to help ensure increased access for patients.

Finally, the Halldorson and Adler research presented by the applicant pre-date changes in the organ allocation policy, which is projected to increase liver sharing. Notably, one article concludes that, "proposals to increase district size to increase competition among transplant programs could result in improved organ utilization over time by incentivizing the use of marginal donor organs and increasing access to transplantation." The new organ allocation policy aims to do just that.

Patient Acuity

I will repeat a finding that appears under the Need standard.[85]

I find fault in applicant's comparison of regional MELD scores to demonstrate a barrier to access or a way to address those barriers. The most recent SRTR program-specific reports show that **The** in FY 2019, the transplant patients at UMMS skewed much more toward the higher MELD score of 31-40 than the patients at either of the other two programs and that Georgetown performed a higher

[85] See my previous analysis regarding *Patient Acuity, supra,* pp. 49-51.

percentage of transplants on both Status 1 patients and patients with MELD scores between 31-40 than Johns Hopkins. Thus, this FY 2019 data does not provide evidence that supports Suburban's argument that Georgetown serves lower acuity patients than a Hopkins-affiliated hospital would.

Summary

While DSA boundaries previously played a role in the allocation of donated livers, they are now allocated on an equal basis to patients within a specified radius of the donor hospital without consideration of DSA boundaries. Instead of livers being allocated first to patients within the local DSA, livers will initially be offered to matched candidates at transplant centers within 150 nautical miles and Status 1 patients within 500 nautical miles.

I do not subscribe to the applicant's suggestion that residents in the Washington Region DSA have inadequate access to liver transplant services. I find that all three centers in the two DSAs are accessible to Maryland residents in the Washington Region DSA. WRTC appears to be providing services, such as the recovery and allocation of livers, at a level that should be expected. While establishing an additional liver transplant center in the Washington Region DSA may reallocate the number of transplants that take place in that DSA (rather than, say, in the Maryland Region DSA), I do not find that this, in and of itself, demonstrates that additional access to liver transplant services is needed or appropriate under the circumstances presented in this review. A new program would only minimally improve access to this service for some Marylanders.

I will close by noting that, if I had found evidence of a valid concern that outcomes at Georgetown's program were poor or that organ procurement by WRTC was lacking, I would be concerned that residents in the Washington Region DSA were underserved. However, at this time, I find that there are not barriers to access that prevent patients in the Washington Region DSA, particularly Maryland residents, from accessing quality liver transplant services at three existing programs in the District of Columbia and Maryland. The applicant has not successfully borne the burden of proof for this standard.

(4) Cost Effectiveness.

An applicant shall demonstrate that the proposed establishment or relocation of an organ transplant service is cost-effective by providing:

(a) A demonstration that analyzes why existing programs cannot meet the need for the organ transplant service for the proposed population to be served.

Applicant's Response

Suburban presents a comparative analysis of current liver transplant services in the two DSAs that include Maryland jurisdictions. Compared to the Maryland Region (the DSA referred to as the Living Legacy Foundation of Maryland, or LLF), the Washington Region (the DSA referred to as the Washington Regional Transplant Community, or WRTC) shows:

- less transplant volume;
- lower transplant rates per capita;

- fewer patients on the waitlist at the hospital in the region;
- a higher rate of patient out-migration; and
- lower patient acuity for transplant recipients.

This data is presented at length in the applicant's response to the Need standard,[86] and its response to the Access standard.[87] Suburban's assessment led it to conclude that the existing program in the Washington Region DSA does not meet the needs of the residents in that DSA. Suburban asserts that many residents of the Washington Region DSA who are eligible for a liver transplant but do not receive a transplant, would receive a transplant if local access were expanded by adding an additional transplant program. (DI #3, p. 131). It repeats its contention that lack of competition in the Washington Region DSA is a contributing factor, and suggests that intra-DSA competition would result in more transplants in the Washington Region DSA, sicker patients with higher MELD scores receiving transplants at higher rates, and more patients added to wait lists.(DI #3, p. 131).

(b) An analysis of how the establishment or relocation of the proposed organ transplant service will benefit the population to be served, quantifying these benefits to the extent feasible and documenting the projected annual costs of the proposed service over a period of at least five years.

Suburban states that, if this project is approved and implemented:

- In years two through five, ten more residents of the Washington Region DSA would receive a liver transplant per year than are currently, resulting in lives saved and an improvement in the quality of life for these patients;
- Fewer patients will travel out of state to receive a liver transplant, and will instead be transplanted locally at Suburban;
- Some Washington Region DSA residents who currently travel to one of the centers in the Maryland Region DSA will instead be transplanted at Suburban, potentially freeing up transplantable livers in the Maryland Region DSA for patients residing in the Maryland Region; and
  Patients transplanted at Suburban will access care at a lower cost relative to the existing two Maryland Region DSA centers and one Washington Region DSA center. (DI #3, p. 133-35).

The projected annual costs for the first five years of the proposed project's operation are shown in the table below.

[86] See Suburban's response regarding *Current Liver Supply and Utilization*, supra, pp. 14-19.
[87] See Suburban's response regarding barriers to access*, supra,* pp. 56-61.

Table IV-24: Total Estimated Operating Expenses

	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries & Wages (including benefits)	$1,487,858	$2,926,907	$3,404,042	$3,895,623	$4,293,791
Contractual Services	$1,657,322	$1,927,093	$1,998,499	$2,366,299	$2,452,284
Supplies & Drugs	$78,310	$1,367,174	$1,594,672	$1,828,509	$2,020,755
Other Expenses: Contingency, Outpatient Activity, Organ Acquisition	$890,934	$1,953,179	$2,254,507	$2,557,425	$2,805,117
Total Operating Expenses	**$4,754,424**	**$8,174,353**	**$9,251,720**	**$10,647,857**	**$11,571,946**

Source: DI #3, p. 135.

(c) Estimates of the costs to the health care system as a whole and the benefits of the proposed program, quantifying the benefits to the extent feasible over a period of five years.

Applicant's Response

For the first five years of operation, Suburban projects that it will perform 174 cases, which includes a shift of 134 cases from existing facilities over five years and the addition of 40 new cases (10 per year), beginning in Year 2.

Suburban projects that 31.5 cases will shift from Johns Hopkins in the first five years of the program.[88] The applicant estimates that patients transplanted at Suburban will have access to care at lower charges, specifically approximately 14 percent less than the comparable charge if the cases were performed at Johns Hopkins. The average inpatient charge per case at Johns Hopkins in 2015 was $172,955 for patients who would be eligible to list at the proposed liver transplant center at Suburban. Suburban's estimated inpatient charge per case for corresponding rates $148,208, or $24,747 lower. This would equate to a reduction in charges of $780,000 for 31.5 cases over the first five-years of projected operation.

The applicant adds that pre-transplant and post-transplant care will also be administered in a lower charge setting relative to Johns Hopkins. Suburban notes that 28.6 percent of cases are projected to be Medicare cases, so shifting these cases will yield savings to Medicare for pre-transplant, transplant, and post-transplant care administered. (DI #3, pp. 136-138).

In addition to the shift of an estimated 31.5 cases from Johns Hopkins over the first five years, Suburban estimates that 40.6 cases will shift from Georgetown, 38.6 cases will shift from UMMC, and 23.5 cases will shift from other centers. (DI #3, p. 137). The applicant states that it is unable to quantify an average charge per case for the shifts from other facilities because that would require identification of Suburban-eligible cases and center transplant charges at other centers; Suburban cannot access this information. However, the experience at Johns Hopkins is likely more reflective of the charge experience at Georgetown, UMMC, and other transplant centers because the other facilities are also academic medical centers. (DI #3, p. 137-138).

[88] The applicant calculates projections by applying a projected growth rate based on actual volume from 2010 to 2015. Thus, projections are not presented as whole numbers of organ transplant patients.

Interested Party's Comments

Georgetown argues that the applicant fails to present evidence of need for an additional liver transplant service.[89] It argues that "more programs does not equal more transplants". In the Washington Region DSA, there were once three competing liver transplant programs at Georgetown, as well as Howard University Hospital and Inova Fairfax Hospital. The former programs failed, and Georgetown states that it has experienced steady growth in volume of liver transplants in a less competitive environment. (DI #21, p. 20, 24).

As presented at length in the interested party's comments in the Need standard,[90] and the Access standard,[91] in response to the applicant's assertion that the population of the Washington Region DSA is underserved, Georgetown responds that:

- Transplant center volume cannot be projected based on population density, but rather is determined by the program's longevity, physician referral patterns, patient and donor selection, availability of organs, and the allocation policy (governed by CMS/UNOS). (DI #21, p. 2).
- Criteria for waitlisting are center-dependent and change over time, based on variables such as updated disease management standards and clinical protocol modifications, among other variables. (DI #21, pp. 15-16).
- Outmigration from the Washington Region DSA to the Maryland Region DSA is not an indication that the existing program does not meet the needs of its residents. Georgetown asserts that there is not an expectation that residents of a DSA should be transplanted within that same DSA, especially in areas of close geographic proximity. (DI #21, p. 4).
- Georgetown responds to the applicant's accusation that it tends to perform transplants on healthier adult patients, as shown in a lower average MELD score for patient, and is thus underserving its community. The interested party states that patient MELD scores fluctuate over time. (DI #21, p. 6).

Georgetown contends that it currently serves the community with seven evaluation centers around the Baltimore-Washington area, nurse coordinators and social workers assigned on-site at its various locations, and telemedicine. It further states that many patients from the Johns Hopkins sites at Sibley and Suburban enjoy access to liver transplant services at Georgetown. (DI #21, p. 5).

According to Georgetown, at its hospital, physician staffing is never an issue with six full-time liver transplant surgeons and seven full-time hepatologists. Sufficient beds, including critical care beds, are available and 12 intermediate beds have recently been opened that are earmarked for advanced liver disease patients. Georgetown states that it is the process of building a new pavilion

[89] Georgetown's submission does not include distinct comments with regard to the proposed project's compliance with the Cost Effectiveness standard. However, the interested party's comments regarding the Need standard relate to what Suburban submitted in response to the Cost Effectiveness standard. Because they are interrelated in this matter, I include pertinent comments submitted by the interested party here as well.

[90] See Georgetown's comments, *supra*, pp. 27-35.

[91] See Georgetown's comments, *supra*, pp. 62-64.

that will house a variety of surgical services, and new state of the art operating rooms. (DI # 21, p. 4).

Reviewer's Analysis and Findings

I find that the applicant has not satisfied Paragraph (a) of the Access standard, which requires it to demonstrate why existing programs cannot meet the need for organ transplantation for the proposed population to be served. As I found in my analysis of the Need standard, Maryland residents are served by three existing liver transplant programs that perform at or above national averages on performance benchmarks in SRTR reports and that meet CMS' expected outcome requirements. DSA boundaries do not define where patients should be expected to receive a transplant. Rather, the boundaries were established to determine which OPO is responsible for the recovery and assessment of organs at donor hospitals in the designated DSA, which are then offered to transplant centers and their patients in accordance with national policies.[92]

The Access standard, at COMAR 10.24.15.04B(3)(d), provides that a travel to a health planning region other than the one in which a transplant recipient resides is not a barrier to access if the travel time is less than three hours for this specialty service. On this basis, which was determined by the Commission when it adopted the Organ Transplant Services Chapter, I reject Suburban's argument that patients should be transplanted "locally," i.e., within the DSA where a patient resides. Residents of the counties within the Washington Region DSA, Charles, Montgomery, and Prince George's Counties, reside well within the three-hour drive time standard for access to all three centers.

I considered the applicant's argument that the costs of services would be lower in a community hospital setting. While the applicant notes that data is not available to estimate cost comparisons for cases at UMMC, Georgetown, and other centers, I used the applicant's estimated savings of $24,747 per case as a proxy for the other 101 cases projected to shift over the first five-year period. That equates to an additional cost savings of approximately $2.5 million over five years. Added to the cases projected to shift from Johns Hopkins for savings of $780,000, that equates to slightly under $3.3 million in lower charges to the health care system over the first five years. The annual cost savings for the 46 projected cases in Year 5 would be slightly more than $1.1 million (unadjusted for inflation).

Although this presents the possibility of lowering charges for payors of liver transplant services, on balance, I cannot find that Suburban has demonstrated that its proposed establishment of an organ transplant service is cost-effective by: (1) demonstrating that existing programs cannot meet the need for liver transplant services by the proposed population to be served by the Suburban program; or (2) quantifying how the establishment of its proposed organ transplant service will provide a ratio of benefits to costs for the population to be served that clearly demonstrates a finding of cost effectiveness.

[92] See the description of OPOs on the UNOS website at https://unos.org/transplant/opos-increasing-organ-donation/.

(5) Impact.

(a) A new organ transplant service shall not have an unwarranted adverse impact on the financial viability of another hospital's organ transplant service of the same type; and

(b) A new organ transplant service shall not have an unwarranted adverse impact on patient access to the same type of organ transplant services at another hospital, the quality of services provided, or patient outcomes following organ transplantation.

(c) An applicant shall provide documentation and analysis that supports:

(i) Its estimate of the impact of the proposed organ transplant service on patient volume at other organ transplant services of the same type in the same health planning region and in other health planning regions that may be impacted. The applicant shall quantify the shifts in case volume for each location; and

(ii) Describe the anticipated impact on access to transplant services for the population residing within a three-hour drive time of the proposed location, including financial and geographic access; and

(iii) Describe the anticipated impact on the quality of care for the population residing within a three-hour drive time of the proposed location.

(d) If a transplant service of the same organ type has been designated as a member not in good standing by the Organ Transplant and Procurement Network, then the potential adverse impacts of the proposed new or relocated organ transplant service on such a program may be disregarded, at the discretion of the Commission.

Table 3: Three-Year Average Annual Threshold Case Volume Requirements by Type of Organ

Type of Organ	Threshold Case Volume Requirement
Kidney Adult Pediatric	 50 10
Liver	20
Pancreas /Heart Lung	No requirement
Heart	20
Lung	20
Hematopoietic Stem Cell: Autologous Allogeneic	 10 40
Intestine/Small Bowel, Islet Cells, Hepatocytes	No requirement
Vascular Composite Allograft	No requirement

Applicant's Response

Suburban states that its proposed project will not interfere with the ability of any of existing liver transplant services to maintain at least the three-year average annual threshold case volume, nor will it have an adverse impact on the financial viability of any other hospital's liver transplant service. (DI #3, p. 139, 142). The applicant states that access will improve for residents in the Washington Region DSA and even at Georgetown, as a result of competition.

Impact on patient volume

The applicant presents the historical case volumes and utilization projections shown below, showing the shifts from other centers and projected volume in the table below.

Table IV-25: Suburban Analysis: Historical Utilization and Projections for Liver Transplants, 2010-2015

Transplant Center	Actual Cases						
	2010	2011	2012	2013	2014	2015	
Johns Hopkins	39	36	48	82	86	100	
UMMC	55	78	86	90	115	147	
Georgetown	84	100	116	91	102	81	
	Projected Cases						
	2016	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**
Johns Hopkins	**110**	**120**	**126**	**135**	**144**	**153**	**161**
projected loss of cases which will shift to Suburban	-	-	*3.9*	*5.1*	*6.3*	*7.5*	*8.6*
UMMC	**157**	**167**	**172**	**181**	**189**	**198**	**207**
projected loss of cases which will shift to Suburban	-	-	*5.4*	*6.5*	*7.7*	*8.9*	*10.1*
Georgetown	**91**	**101**	**105**	**114**	**123**	**132**	**141**
projected loss of cases which will shift to Suburban	-	-	*5.8*	*7.0*	*8.1*	*9.3*	*10.5*
Shifts from Other Centers	-	-	*2.4*	*3.5*	*4.7*	*5.9*	*7.0*
New Cases	-	-	-	*10.0*	*10.0*	*10.0*	*10.0*
Suburban	**-**	**-**	***17***	***32***	***37***	***42***	***46***

Source: DI #3, pp. 134, 141, 167.

The applicant assumes that its program will ramp-up in Year 1, as it begins operations, conducts outreach to referring providers, and builds a waitlist. (DI #13, p. 63). Shifts in patient volume beginning in Year 2 are based on patient DSA of residence, Suburban-eligibility (adults, deceased donor, MELD less than or equal to 30), and historical growth rates for the DSAs combined. The applicant projects that between three and six percent of existing center volume will shift to Suburban. It notes that all three existing transplant centers operate well above the annual threshold case volume of 20. (DI #3, p. 142).

Impact on financial viability of other liver transplant services

Suburban asserts that the proposed project will not have a material financial impact on other centers, and that any minimal financial impact is outweighed by the benefits of increased access and the additional cases that will result from the new program. (DI #3, p. 143).

Impact on patient access, quality, and patient outcomes

The applicant does not project any adverse impacts on access, quality, or patient outcomes at existing liver transplant programs, as the impact on patient volume at the other centers will be minimal. The proposed project aims to improve access for patients and increase transplant volume in the Washington Region DSA as a result of increased competition. The applicant argues that the project will have a positive financial impact by shifting cases from a higher to a lower charge setting. Liver transplant patients at Suburban will receive the same expertise and high quality of care displayed at the Johns Hopkins CTC. (DI #3, p. 145-146).

Interested Party's Comments

In its assessment of the applicant's deficiencies regarding demonstration of need, Georgetown criticizes the applicant for providing misleading projections by combining data for Johns Hopkins and UMMS. (DI #21, pp. 1-2).[93] Thus, Georgetown considers projections for volume growth unrealistic, as it described under the Need standard.[94]

Reviewer's Analysis and Findings

The applicant projected that growth in the two DSAs would continue at the same pace as between 2010 and 2015. (DI #3, p. 167, 175). Suburban's projections have not been realized, as shown in actual case volume from 2016-2019, which is summarized in Table IV-26, below.

Table IV-26: Actual Liver Transplant Volume Trends, CY 2010-2019

Transplant Center	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Johns Hopkins	39	36	48	82	86	100	126	103	120	120
UMMC	55	78	86	90	115	147	169	161	113	94
Maryland Region DSA	**94**	**114**	**134**	**172**	**201**	**247**	**295**	**264**	**233**	**214**
Georgetown	84	100	116	91	102	81	117	125	110	124
Washington Region DSA	**84**	**100**	**116**	**91**	**102**	**81**	**117**	**125**	**110**	**124**
Total Combined	**178**	**214**	**250**	**263**	**303**	**328**	**412**	**389**	**343**	**338**
Case difference		36	36	13	40	25	84	-23	-46	-5
Average change						**+30**				**-25**

Source: OPTN data, found at https://optn.transplant.hrsa.gov/data/view-data-reports/.

Although Suburban points to average growth of 30 cases per year between 2010 and 2015 to

[93] Georgetown's submission does not include distinct comments with regard to the proposed project's compliance with the Impact criterion. However, the interested party's comments regarding the Need standard relate to what Suburban submitted in response to the Impact criterion. Because they are interrelated in this matter, I include pertinent comments submitted by the interested party here as well.
[94] See Georgetown's comments regarding the applicant's projected volume shifts from programs in the two OPOs that serve Maryland residents and the underlying assumptions upon which each projection is based, *supra*, p. 39-40.

substantiate its growth projections through 2022, the DSAs actually experienced a downward trend during the most recent three-year period (2017 through 2019), resulting in an average annual decline of 25 cases per year. The applicant's overall growth projections for liver transplants were overly optimistic. Still, existing liver transplant centers have operated well above the annual threshold case volumes of 20 liver transplants for at least the past ten years, as shown in Table IV-26. An additional liver transplant service is unlikely to interfere with the ability of these established programs to maintain necessary volumes.

I note that each of these existing centers experienced fluctuations in program volume throughout the previous ten-year period but remained viable. Liver transplant volumes ranged from 36 to 126 at Johns Hopkins, from 55 to 169 at UMMC, and from 84 to 125 at Georgetown. The most recent annual (2019) volumes at these centers were 120, 94, and 124, respectively. I find it highly unlikely that an additional center would shift volumes from these established providers to such a degree that volume would fall below historical lower volumes, which did not adversely impact each program's viability. I also note that Georgetown does not express concern that it would experience an adverse impact from projected volume shifts. It does not suggest that the proposed project would result in an adverse impact on existing providers that is forbidden by the Impact standard.

The applicant states that the proposed project would improve geographic access for some patients of Johns Hopkins Medicine who live closer to Suburban than to the existing John Hopkins transplant center. I find any such improvement in access to be quite minimal. The travel time standard for organ transplantation services is a three-hour drive time. Residents of Charles, Montgomery, and Prince George's Counties currently have no less access than other residents of Maryland. They also have access to the Suburban and Sibley outpatient clinics.

In summary, I find that the applicant has met the impact standard. The proposed liver transplant service would not interfere with the ability of existing liver transplant services to maintain at least 20 liver transplants per year based on historical volume, nor would it have an unwarranted adverse impact on the financial viability of the other hospitals' liver transplant services. While patient access would be minimally improved for local patients, the addition of a liver transplant center would not have a substantive impact on the quality of liver transplant services or patient outcomes.

(6) Certification and Accreditation.

(a) A general hospital awarded a Certificate of Need to establish an organ transplant service shall be certified by United Network for Organ Sharing within the first year of operation.

(b) A general hospital awarded a Certificate of Need to establish a hematopoietic stem cell transplant program shall meet accreditation requirements of the Foundation for the Accreditation of Cellular Therapy (FACT) within the first two years of operation. An applicant shall apply and be FACT-accredited within 12 months of becoming eligible to apply for accreditation and shall maintain its accreditation thereafter.

(c) A general hospital seeking to establish an organ transplant service must be accredited by the Joint Commission.

Applicant's Response

Suburban Hospital agrees that, if it is awarded a Certificate of Need to establish a liver transplant service, the service will be certified by the United Network for Organ Sharing within the first year of operation. Suburban Hospital is accredited by the Joint Commission. (DI #3, p. 148, Exh. 16).

Reviewer's Analysis and Findings

I find that the applicant complies with this standard.

(7) Health Promotion and Disease Prevention.

An organ transplant program shall actively and continuously engage in health promotion and disease prevention activities aimed at reducing the prevalence of end stage organ disease and increasing the availability of donor organs. An applicant must describe the relevant preventive services designed to address those at greatest risk for end stage organ failure.

Applicant's Response

The applicant states that it intends to work aggressively to reduce preventable causes of liver failure in the Washington Region DSA and to manage liver disease before a patient requires liver transplant. It describes current health promotion and disease prevention activities of Johns Hopkins, including:

- In 2014, Johns Hopkins opened two outpatient clinics in the Washington Region DSA at Sibley Memorial and Suburban. These clinics help patients manage medical conditions that can lead to liver failure and address underlying problems that can reduce the need for transplant; and
- Johns Hopkins has met with the Minority Organ Tissue Transplant Education Program (MOTTEP) in hopes of developing a partnership that would expand and enhance current outreach and preventive health efforts targeting liver disease and its precursors in the Washington Region DSA.

In connection with the new transplant center at Suburban, Johns Hopkins states that it would expand the clinic at Sibley and engage in additional prevention efforts, including:

- Building a regional Center of Excellence for Liver Disease, with critical care, interventional radiology, and wraparound support services for patients with liver disease;
- Deploying trained nurse coordinators/educators into the community who would work with community organizations to develop screening and prevention programming, conduct educational seminars, work with local addiction services to prevent or modify behaviors that can lead to end stage liver failure, and connect patients with addiction support services to prevent and reduce recidivism;

- Increasing access to experienced liver specialists to provide care that prevents progression of liver disease, including access to bariatric treatment options;
- Collaborating with local community-based programs to address drug and alcohol dependency and obesity; and
- Linking existing programs in the Washington Region DSA to programs at Sibley Memorial, Suburban, and Suburban's ambulatory practices in Bethesda to provide alcohol and drug dependency programming, surgical and interventional radiology services, advanced imaging, social work, nutrition counseling, and psycho-emotional evaluation.

(DI #3, pp. 149-150).

Reviewer's Analysis and Findings

I find that the applicant complies with this standard. I am satisfied that Johns Hopkins Medicine and its outpatient clinics in the Washington Region DSA engage in health promotion and disease prevention activities aimed at reducing the prevalence of end stage organ disease. The applicant listed plans to engage in activities that would further increase awareness, with the goal of increasing the availability of donor organs in the Washington Region DSA. As I noted previously, the region does not need an additional liver transplant program in order to increase outreach activities.

(8) Comparative Reviews.

In a comparative review of applications to establish a transplant service for the same type of organ in which all applicants have met all policies and standards, the Commission will give preference to the applicant that:

(a) Has established effective community education and outreach programs that focus on prevention, early detection, and treatment of diseases and conditions that may lead to end-stage organ disease, such as diabetes, coronary artery disease, alcohol and substance abuse, and hypertension, with particular outreach to minority and indigent patients in the hospital's regional service area; and

(b) That is most likely to establish a proposed organ transplant service that will reach minority and indigent patients, as demonstrated by:

(i) The applicant's record of serving minority and indigent patients; and

(ii) The applicant's record of establishing programs for outreach to the minority and indigent populations; and

(c) That shows improved outcomes or improved health status of the populations that it serves based on an evaluation of the effectiveness and efficiency of the applicant's disease prevention and intervention programs.

This standard is not applicable to the proposed project.

B. COMAR 10.24.01.08G(3)(b) Need.

The Commission shall consider the applicable need analysis in the State Health Plan. If no State Health Plan need analysis is applicable, the Commission shall consider whether the applicant has demonstrated unmet needs of the population to be served, and established that the proposed project meets those needs.

Introduction to the Need Criterion

The Organ Transplant Services Chapter does not include a need analysis for determining the number of programs needed in a region. However, the Chapter defines organ transplantation as a specialized tertiary health care service that is appropriately provided in a limited number of general hospitals because it requires clinical expertise with the most advanced diagnostic, surgical, and monitoring equipment. Pertinent to this position, higher transplantation case volume is generally assumed to be associated with better patient outcomes. The Chapter maintains a long-standing definition of reasonable geographic access as a three-hour, one-way drive time standard. Currently, over 95 percent of Maryland's population has access to organ transplant services within a three-hour, one-way drive time.

Applicant's Response

Suburban considers its likely service area for liver transplantation to be patients in the Washington Region DSA, including the District of Columbia, its suburbs, northern Virginia, and southern Maryland. (DI #3, p. 57). It repeats its position that a second liver transplant program in the Washington Region DSA will fill an unmet need to "reduce disparities [between the two transplant donation service areas serving Maryland] …, while… offering liver transplant patients Hopkins-level clinical expertise and administration." (DI #3, p. 5).

As discussed in more detail under the Need standard,[95] Suburban believes that the existing liver transplant hospital in the Washington Region DSA does not provide the appropriate level of organ transplantation services for patients in that region, as evidenced by a lower population use rate compared to the Maryland Region DSA, 24.5 per million residents compared to 44.4 per million residents in 2015, respectively. (DI #3, p. 107). Moreover, the applicant asserts that residents in need of a transplant who are of lower socioeconomic status are particularly sensitive to travel time barriers. Suburban states that this project will address the needs of patients in the Washington Region DSA who do not have access to services at a comparable level to patients in the Maryland Region DSA. (DI #3, p. 119).

Suburban bases projected future utilization for the proposed project and existing liver transplant centers on historical growth between 2010 and 2015, which averaged 30 liver transplants per year. The applicant projects this annual growth in volume will continue. (DI #3, p. 167). The applicant also projects that the introduction of the proposed project in the Washington Region DSA will result in an additional 10 liver transplants per year. These additional cases are based on the

[95] See Suburban's comments, which are detailed at length in its comments regarding *Increasing the Use of Livers by Adding a Transplant Center with More Capacity*, *supra*, p. 23, and utilization trends, *supra,* pp. 40-41.

applicant's assumption that the Washington Region DSA would see its transplantation rate grow from its current level of 24.5 per million residents to the same rate as the neighboring Maryland Region DSA, i.e., 44.4 per million. Thus, the ten additional cases Suburban projects is based on its capturing 10 percent of what it estimates as the Washington Region DSA's potential for 108 additional liver transplants. (DI #3, p. 177).

Suburban proposes to serve a subset of "Suburban-eligible" adult liver transplant patients who receive a deceased donor liver, who have a MELD score lower than 35, and are not multi-organ recipients. In order to project cases for this proposal, Suburban first determined the number of "Suburban-eligible" patients at existing centers in Maryland and the District of Columbia. It estimates that 34 percent of Georgetown's volume is Suburban-eligible, as is 54 percent of UMMC's volume, and 49 percent of Johns Hopkins. (DI #3, p. 167).

Using data from 2010 to 2015, which saw an average overall growth for the three existing centers of 30 liver transplant cases per year, Suburban projected continued annual growth of 30 cases across the two regions, ten cases at each center per year. (DI #3, p. 168). The applicant then evaluated patient zip code area residency to project migration patterns and shifts from other centers. Table IV-27 shows the applicant's projection for 2018 and shifts from existing centers.

Table IV-27: Suburban: Liver Transplant Projections for Centers in Maryland and the District of Columbia, CY 2018

DSA	State of Patient Residence	Johns Hopkins	UMMC	Georgetown	Proposed Suburban	Other Centers	Total
Maryland Region DSA	Maryland	73.0	123.1	9.6	3.3	5.0	**213.9**
Washington Region DSA	Maryland	12.9	21.5	30.7	7.0	7.2	**79.3**
	DC/Virginia	12.9	5.4	48.5	7.2	15.4	**89.4**
Other	Other	27.3	21.7	16.4	0.0	-	**65.4**
Total		**126.1**	**171.6**	**105.2**	**17.4**	**27.7**	**448.0**

Source: DI #3, p. 174

Interested Party Comments

Georgetown states that the applicant has not shown that the Washington Region DSA is underserved.[96] In short, it argues that the applicant skews analysis in its favor by comparing data for the two centers in the Maryland Region DSA to the one center in the Washington Region DSA and that Suburban misrepresents historical trends and fluctuations at individual centers. (DI #21, pp. 1-3).

The interested party believes that the applicant uses a flawed assumption when it states that patients should be expected to be wait listed or receive a liver transplant at a center located within the patient's designated DSA. Georgetown views this assumption as especially flawed when two DSAs include centers that are in relatively close geographic proximity. (DI #21, pp. 4). It states that Suburban is ignoring the fact that the Washington Region DSA, and Georgetown in particular,

[96]See Georgetown's comments, which are detailed at length in its comments regarding the Need standard, *supra*, pp. 27-35.

currently provide appropriate liver transplant services with sufficient capacity at its hospital and throughout the community. (DI #21, pp. 4-5). The interested party also states that Suburban errs in implying that projections for liver transplant volume and access to livers should be based on population. (DI #21, p. 20). It points out that, despite having a the slightly smaller population, the Maryland Region DSA has more eligible organs, based on a higher death rate, than the Washington Region DSA. (DI #21, p. 10). Finally, Georgetown disputes the applicant's argument that the literature supports its claim that a second center within the Washington Region DSA would increase the number of liver transplants or address any supposed disparity. (DI #21, pp. 16-18).

Reviewer's Analysis and Findings

I will open by repeating the conclusion that I reached when I analyzed the submissions of the applicant and interested party under the Need standard.[97] Suburban failed to present evidence that liver transplant candidates in the region need an alternative to the existing transplant centers in Baltimore and the District of Columbia. It has the applicant suggested that it would engage in particular donor outreach programming or other any activity that would increase liver supply that it cannot accomplish with the existing complement of transplant centers and liver disease clinics in the Washington Region DSA and the Maryland Region DSA.

I again note that, in the introduction to the Organ Transplant Services Chapter, the Commission stated that we "prepared this Chapter of the State Health Plan … to meet … health care system needs of all *Maryland residents* by assuring access, quality, and cost-efficiency." [COMAR 10.24.15.02.A, Purposes of the State Health Plan (emphasis added)]. I make this point because Suburban presents data that compares the Maryland Region DSA, which includes most of Maryland, to the Washington Region DSA, which includes three Maryland counties, Charles, Montgomery, and Prince George's, as well as the District of Columbia, and numerous jurisdictions in northern Virginia. Residents of the Maryland jurisdictions included in the Washington Region DSA make up about 38 percent of the Washington Region DSA's population.[98]

While the applicant projects that 60 percent of its 17.4 liver transplant patients in 2018 will be Marylanders, the residents of the Maryland jurisdictions that lie within the Washington Region DSA, Charles, Montgomery, and Prince George's Counties, maintain very reasonable access to three existing liver transplant programs. These Marylanders who reside in the Washington Region DSA are closer to the Maryland Region DSA transplant programs in Baltimore than are the other residents in the Washington Region DSA, and thus face less of a travel burden to the existing centers than other residents of the Washington Region DSA might.

I reiterate that the OPO-designated service areas are not meant to determine where patients receive transplant services, particularly when patients reside in close geographic proximity to those same services in another DSA, as is the case in this review. I refer again to the Access standard of the Organ Transplant Services Chapter, COMAR 10.24.15.04B(3)(d), which specifically provides

[97] See my discussion under *Existing Program Performance and Capacity, supra,* p. 47-49.
[98] The population of Charles, Montgomery, and Prince George's Counties totaled 2,097,450 in 2015, according to the population estimates prepared by the Maryland Department of Planning, Projections and State Data Center in August 2017, which is 38.3% of the Washington Region's 5,464,786 population in 2015, as cited by the applicant. (DI #3, p. 29)

that "[t]ravel to an organ transplant center [located in a health planning region outside the transplant recipient's residence] is not, in and of itself, … a barrier to access." Additionally, Suburban's statements regarding better access to organs procured within the DSA of origin are dated at this point. As of February 2020, DSA boundaries no longer play a role in the distribution of organs.

I reject the applicant's assumption that there is a well-defined and universally accepted "ideal or target" ratio of population to number of liver transplant programs that defines whether need for this service is met. I do not believe that increasing the ratio of liver transplant centers to population size would increase the limited supply of liver donations in the Washington Region DSA. I also find that adding a program at Suburban, operated by Johns Hopkins, which already operates an existing program that is accessible to Marylanders, would not make the limited number of procured livers any more generally accessible to residents of Charles, Montgomery, or Prince George's Counties.

As I discussed in more detail in my analysis of compliance with the Need and Access standards,[99] my review of SRTR's performance reports shows that the OPO and the transplant center in the Washington Region DSA operate above expectations. Lower liver transplant rates in the greater Washington Region DSA appear to primarily be a function of factors including a significantly lower death rate and migration of organs in accordance with UNOS policy. I disagree with Suburban that an additional liver transplant center is the key to increasing access to liver transplantation for the population. I reject the applicant's argument that simply adding competition in the form of another center in the Washington Region DSA will result in more liver transplants. Under the new allocation policy, the existing centers in both regions already compete for the same livers.

I also find weakness in the applicant's overstated organ transplant volume projections. Recent data reflected in the following table shows that Suburban overestimated the growth trend in the number of liver transplants. Rather than growing consistently by 30 transplants per year, as assumed by the applicant in making its projections, the actual number of liver transplants across these two regions declined after peaking in 2016, with the result being that 2019 total cases only exceeded 2015 cases by ten. (Table IV-28). This is primarily the result of a major collapse in case volume at UMMC over this period. Thus, it appears that the applicant's projections overstate the case volume that would shift from existing centers to its proposed new liver transplant center, throwing into serious doubt its assumption of growth in demand and the implications of that growth for its proposed project.

[99] See my discussion of the Need standard regarding *Supply of Livers*, *supra*, pp. 43-45, and *Education and Outreach*, supra, pp. 51-52; and my discussion of the Access standard regarding *Supply of Livers*, *supra*, p. 64, and *Liver Supply and Transplant Volume supra,* pp. 72-74.

Table IV-28: Liver Transplant Utilization in Maryland and the District of Columbia, CY 2015-2019

	2015	2016	2017	2018	2019	
Transplant Centers and Regions	**Actual Utilization**	**Suburban's Projected Utilization**				**Suburban's Projected % Growth 2015- 2018**
Johns Hopkins	100	110	120	126	-	26.0%
UMMC	147	157	167	172	-	17.0%
MD Region Total	**247**	**267**	**287**	**298**	**-**	20.6%
Georgetown	81	91	101	105	-	29.6%
Proposed Project	-	-	-	17	-	-
Washington Region DSA Total	**81**	**91**	**101**	**112**	**-**	38.3%
Total Regions Combined	**328**	**358**	**388**	**420**	**-**	**28.0%**
	Actual Utilization					**Actual % Change 2015- 2019**
Johns Hopkins	100	126	103	120	120	20.0%
UMMC	147	169	161	113	94	-36.1%
MD Region Total	**247**	**295**	**264**	**233**	**214**	-13.4%
Georgetown	81	117	125	110	124	53.1%
Washington Region DSA Total	**81**	**117**	**125**	**110**	**124**	53.1%
Total for Combined DSAs	**328**	**412**	**389**	**343**	**338**	3.0%

Source: DI #3, p. 175; OPTN at https://optn.transplant.hrsa.gov/data/view-data-reports/.

Finally, Suburban did not provide outreach plans to increase the supply of transplantable livers that, based on my review, would justify the duplication of liver transplant services at Suburban Hospital. First, the types of outreach and education that the applicant proposes as a means for bringing in more livers do not require the establishment of the proposed project. For instance, the applicant highlighted the success of Hopkins' recent Facebook campaign, which had a *national* reach. (DI #3, p. 97). I previously mentioned the relationships between Johns Hopkins Medicine and the WRTC and other community organizations that obviously exist and function without the presence of a Johns Hopkins CTC liver transplant center in the DSA under the Need standard.[100] Such outreach activity could, and I assume will, continue whether or not a CON is awarded. Second, the more complex donor organ transplants such as those involving live donors and high-MELD cases would still take place at Johns Hopkins Hospital in Baltimore and, thus, many patients would still be required to travel to Baltimore from the Washington DSA.

In summary, I find that Suburban has not demonstrated that there is an unmet need for its proposed liver transplant service. The bases for my finding include the following:

- The applicant failed to provide evidence of the unmet needs of the population to be served and to demonstrate that its establishment of a liver transplant service would meet those needs;
- The applicant did not demonstrate that barriers to access exist for the target population of its proposed program, particularly residents in Charles, Montgomery, and Prince George's Counties;

[100] See my analysis regarding *Education and Outreach*, *supra*, pp. 51-52.

- The applicant failed to show that it had a credible plan to increase liver donations or to put the existing supply of organs to better use;
- Thus, the addition of the proposed organ transplant service will not materially address the problem of an inadequate supply of livers; and
- Liver transplantation case volume has not grown at the pace projected by the applicant when the application was submitted. Case volume has actually grown very little since that time.

Finally, the Organ Transplant Services Chapter makes it clear that liver transplant services are a specialized, tertiary service that should be regionalized. The three existing programs in Maryland and D.C. are quite accessible to Maryland residents.

C. COMAR 10.24.01.08G(3)(c) Availability of More Cost-Effective Alternatives.

The Commission shall compare the cost effectiveness of the proposed project with the cost effectiveness of providing the service through alternative existing facilities, or through an alternative facility that has submitted a competitive application as part of a comparative review.

Introduction

All CON applicants receive additional guidance to respond to this criterion. Instructions within the CON application materials ask the applicant to: describe the planning process that was used to develop the proposed project, including a full explanation of the primary goals or objectives of the project or the problem(s) being addressed by the proposed project; and identify the alternative approaches to achieving those goals or objectives or solving those problem(s) that were considered during the project planning process. Further, the applicant is prompted to include, among the alternatives considered, the possibility of the services being provided through existing facilities or through population-health initiatives that would reduce the need for hospital services. Finally, the applicant is asked to describe the hospital's population health initiatives and explain how the projections and proposed capacities take these initiatives into account.

For each alternative approach, an applicant is expected to describe the alternative's level of effectiveness and its costs, with the cost analysis going beyond development costs to consider life cycle costs. The applicant's narrative should clearly convey the analytical findings and reasoning that supported the project choices made. It should demonstrate why the proposed project provides the most effective method to reach stated goal(s) and objective(s) or the most effective solution to the identified problem(s) for the level of costs required to implement the project, when compared to the effectiveness and costs of alternatives.[101]

Applicant's Response

Suburban states that the Johns Hopkins CTC began analyzing the zip code areas of its liver transplant patients and those of other area centers as early as 2013 and found that patients

[101] The CON application materials include instructions and are available in Adobe PDF and Microsoft Office Suite formats at https://mhcc.maryland.gov/mhcc/Pages/hcfs/hcfs_con/hcfs_con_applications.aspx

increasingly migrate to Baltimore to obtain liver transplant services from the zip code areas in the national capital region. The applicant considers this higher migration itself to be a burden to residents in the Washington Region DSA, and describes that this fact also led them to uncover disparities in the "volume, transplant rate, … acuity, supply, and wait listing" in the Washington Region DSA compared to the Maryland Region DSA. (DI #3, p. 154).

Based on these findings, the applicant states that the CTC and the other Johns Hopkins Health System hospitals, Suburban and Sibley Memorial, set about developing resources in the region to address the causes of liver failure. Johns Hopkins recruited two experienced hepatologists to treat patients in the Washington Region DSA at Sibley Memorial Hospital's Hepatology Multidisciplinary Center. The applicant proposes that this project will build on this initiative with the stated goals of reducing these disparities and increasing access to liver transplants for the residents of the Washington Region DSA.

Suburban determined that the most effective way to increase liver transplant rates in the Washington Region DSA was to increase competition in the DSA by adding a second transplant center at Suburban. The applicant estimates that the operational cost of the proposed service, which it estimates at $11 million annually,[102] would result in an additional 10 liver transplant cases per year. The applicant states that it considered the following alternative strategies, but concluded that "anything short of an additional center … would be insufficient to address the access disparity." (DI #3, pp. 154-157).

- Providing services through existing facilities. One way to address the disparity is to increase the number of transplants performed on residents of the Washington Region DSA at the existing center in that region. However, the applicant states that disparity between DSAs has existed for years and that it has no way to determine the reasons why the center does not have increased case volume or what alternative approaches would facilitate increased case volume, other than competition. The applicant states that the two centers in the Maryland Region DSA function at a "high level" which would make it difficult for them to increase their volume. An increase in volume at the existing Maryland Region DSA centers would increase the disparity, so the applicant determined that this was not an effective strategy to decrease the access disparity between the Maryland Region DSA and the Washington Region DSA;

- Establishing a new center in the Maryland Region DSA. The applicant states that a new center in the Maryland Region DSA would not address the access disparity between the Maryland Region DSA and Washington Region DSA. Instead, it would exacerbate current patient migration trends and have no potential benefit, in terms of competition, for patients in the Washington Region DSA. Suburban believes this option would not reduce the access disparity between Washington Region DSA residents and Maryland Region DSA residents, particularly for those with low socioeconomic status;

- Establishing a new center in the Washington Region DSA operated by a hospital system with no existing liver transplant program. The applicant presents this option as one that would create a competitive environment in the Washington Region DSA. However, if the

[102] Primarily for the labor expenses associated with 50 full-time equivalent (FTE) staff.

hospital system does not have a liver transplant team, there would be a high start-up cost to recruit and create infrastructure for personnel, physician support, and operational support; and

- The chosen option was establishment of a new center in the WRTC DSA operated by a hospital system with an existing liver transplant program. The applicant presents this option, the proposed project, as the preferred option, which would create a competitive environment in the Washington Region DSA. It has a lower start-up cost than the previous option because the applicant will benefit from its hospital system's current liver transplant team including surgeons, physician assistants, nurse practitioners, nurse coordinators, and social workers, thereby leveraging resources and sharing some fixed costs (personnel, physician support, operational support). The applicant also notes the opportunity for double-wait listing patients at the affiliated liver transplant programs.

Suburban concludes that a new liver transplant center within the Washington Region DSA is the best way to address the access disparity between Maryland Region DSA residents and Washington Region DSA residents, by introducing competition for the DSA's single existing center. The applicant presents this as the most effective strategy for reducing access disparities and increasing the number of Washington Region DSA residents who receive liver transplants. It states that this option can be developed in the shortest time at the lowest cost with the highest likelihood of producing high quality care and good patient outcomes. (DI #3, pp. 154-57).

The applicant plans to integrate the proposed transplant center within a broader population-health initiative that would include:

- Building a regional Center of Excellence for Liver Disease, with expertise in critical care, interventional radiology, and wraparound support services for patients with liver disease;
- Deploying trained nurse coordinators/educators for community education and outreach;
- Increasing access to experienced liver specialists to provide care that prevents progression of liver disease, including access to bariatric treatment options;
- Collaborating with local community-based programs to address drug and alcohol dependency and obesity; and
- Linking existing programs in the Washington Region DSA to programs at Sibley, Suburban, and in Suburban's outpatient service sites in Bethesda to provide alcohol and drug dependency programming, surgical and interventional radiology services, advanced imaging, social work, nutrition counseling, and psycho-emotional evaluation.

(DI #3, p. 158).

Interested Party's Comments

Georgetown states that it is already serving patients "closer to their communities" through seven evaluation centers around the Baltimore-Washington area, as well as through telemedicine Thus, the population-health initiatives are already being addressed by Georgetown. (DI #21, p. 5, 25).

Reviewer's Analysis and Findings

I find that the applicant has not demonstrated that its establishment of a liver transplant service is the best alternative for achieving its stated objectives. I find that the most cost-effective alternative is for liver transplant services to be provided through existing facilities because patients in the likely service area of the proposed transplant program do not face barriers to access that the proposed project will address. Liver transplantation is available through several alternative existing facilities. Although adding a liver transplant center at Suburban would reduce travel time from home to hospital for transplant patients who might live in close proximity to the hospital, travel time is not a substantive barrier to use of this service for Maryland's population, given the proximity of other hospitals with liver transplant programs and the definition of reasonable access in the Chapter (a three-hour, one-way travel time). (COMAR 10.24.15.04B(3)(a)).

I considered the review and comments of HSCRC staff appended to this Recommended Decision as Appendix 3. HSCRC staff's comments confirm that if the direct costs are comparable, then the difference in serving patients at Suburban instead of at Johns Hopkins or UMMC[103] would be lower overhead cost, indirect cost, and capital costs. (DI #44, p. 3). While there are benefits to shifting cases from a higher-charge academic medical center to a lower-charge community hospital setting, I cannot accept the argument that it is cost effective to develop a new liver transplantation center that will largely be shifting cases from existing providers. Any additional benefit that may expand outreach and awareness, and thus result in 10 additional liver transplants, could take place without the addition of a transplant center.

In summary, I did not find that the applicant, in comparing the cost effectiveness of the proposed project with the cost effectiveness of providing the service through alternative existing facilities, demonstrated that its proposed project was the most cost-effective alternative. I believe that it is more cost effective for the applicant, working in concert with Johns Hopkins Health, and in collaboration with other hospitals and health systems serving Maryland and D.C., to make progress in increasing the supply of livers for donation and in making more effective use of organ supply through existing outreach, education, research, and clinical practice efforts rather than pursuing these objectives through development of a third liver transplant program in Maryland and a second program in the Washington Region DSA.

D. Viability of the Proposal.

The Commission shall consider the availability of financial and nonfinancial resources, including community support, necessary to implement the project within the time frames set forth in the Commission's performance requirements, as well as the availability of resources necessary to sustain the project.

Applicant's Response

Availability of Resources to Implement the Proposed Project

There are no capital costs associated with this project because the proposed project will use

[103]And, presumably, Georgetown since it is also an academic medical center.

existing hospital space. The estimated annual operating cost includes salaries, supplies, and drugs, and other expenses such as those associated with outpatient services and organ acquisition. Suburban provided audited financial statements which show the availability of resources to implement this project. (DI #3, Exh. 18).

Availability of Resources to Sustain the Proposed Project

The applicant's utilization and financial forecast is summarized in the Table IV-29 immediately below. Suburban states that each individual liver transplant procedure generates an average of 7.5 additional discharges from the hospital pre- and post-transplant. By Year 5, the applicant projects that the service will require 50.1 FTE employees to provide care for 46 new liver transplant cases that will result in 402 discharges. (DI #13, p. 81). The applicant projects hiring 41.4 salaried employees and 8.7 contractual employees for a total cost of $6.6 million in salaries and benefits. (DI #3 Exh. 1L). As shown in the table, the applicant projects that the project will generate net income by the second year of operation, as patient volume increases. Salaries and expenses for supplies are projected to increase along with patient volume. (DI #3, Exh. 1I; DI #13, CQ69).

Table IV-29: Key Utilization and Financial Projections

	Year 1	Year 2	Year 3	Year 4	Year 5
Utilization					
Liver transplants	17	32	37	42	46
Discharges	140	268	314	362	402
Patient Days	1,191	2,269	2,641	3,025	3,337
Revenues					
Gross Patient Revenues	$5,406,377	$10,277,602	$11,970,076	$13,704,921	$15,122,581
Allowance for Bad Debt	1,229,038	-	-	-	-
Contractual Allowance	810,957	1,541,640	1,795,511	2,055,738	2,268,387
Charity Care	-	-	-	-	-
Net Operating Revenue	$3,366,382	$8,735,962	$10,174,564	$11,649,183	$12,854,194
Expenses					
Salaries & Wages	$1,451,569	$2,855,519	$3,321,017	$3,800,608	$4,189,064
Contractual Services	1,616,900	1,880,091	1,949,755	2,308,585	2,392,472
Supplies & Drugs	700,791	1,333,828	1,555,778	1,783,911	1,971,468
Other Expenses	869,204	1,905,541	2,199,519	2,495,049	2,736,699
Total Operating Expenses	$4,638,463	$7,974,979	$9,026,068	$10,388,153	$11,289,703
Net Income	**($1,272,081)**	**$760,983**	**$1,148,496**	**$1,261,030**	**$1,564,491**

Source: DI #3, Exh. 1I; DI #13, CQ69.

Community support

The applicant referred to letters of support from "health care, government, and patient advocacy" organizations.[104]

[104] The writers of these letters are set out in Community Support, *supra*, at pp. 5-6.

Reviewer's Analysis and Findings

This criterion requires consideration of three issues: availability of resources to implement the proposed project; the availability of resources to sustain the proposed project; and community support for the proposed project.

Based on financial performance and the reported availability of cash, I find that Suburban has the available resources to implement this project. I also considered the review and comments of HSCRC staff appended to this Recommended Decision as Appendix 3. The most recently published audited financial statement for Johns Hopkins Health System on the HSCRC's website[105] shows that Suburban Hospitals, Inc. and Other Consolidated Entities had $29,840,000 in excess revenues over expenses in FY 2019, indicative of funds available to implement this project based on the applicant's financial projections.

I also find that, the proposed liver transplantation service would be likely to achieve volume that generates the revenue necessary to sustain the service, as reflected in Year 2 projections, though I previously stated my concern that the volume growth projected in future years is overstated since overall volume growth across the two DSAs has not occurred since 2016.[106] Finally, the applicant has demonstrated that the project is supported by local elected officials, members of the health care community, and advocacy organizations.

Based on the availability of financial resources and the likely level of support the new program can generate, I find that the proposed project is financially feasible and would likely be viable over the long-term.

E. Compliance with Conditions of Previous Certificates of Need

An applicant shall demonstrate compliance with all terms and conditions of each previous Certificate of Need granted to the applicant, and with all commitments made that earned preferences in obtaining each previous Certificate of Need, or provide the Commission with a written notice and explanation as to why the conditions or commitments were not met.

Applicant's Response

Suburban states that the hospital has been issued two Certificates of Need since 2000:

- Establishment of a Cardiac Surgery and Percutaneous Coronary Intervention Program at Suburban Hospital (Docket No. 04-15-2134). Suburban's CON to establish Cardiac Surgery and Percutaneous Coronary Intervention services was awarded July 21, 2005. The CON included four conditions pertaining to maintaining minimum volume, reporting evaluation of program benefits and costs, outreach, and rate offsetting. Suburban states that it has been and will continue to be compliant with these four conditions. The minimum volume condition referenced has since been eliminated by

[105] See https://hscrc.maryland.gov/Pages/hsp-AFS.aspx.
[106] See discussion of the Need criteria, *supra*, pp. 89-93.

the Commission, in accordance with statutory and regulatory changes. (DI # 3, p. 163, Exh. 19).

- Expansion and Modernization of Suburban Hospital (Docket No. 15-15-2368). This CON was awarded on May 19, 2016 and the project is still being implemented. Suburban Hospital has, to date, complied with all conditions and reporting requirements. (DI #3, p. 163, Exh. 6).

Reviewer's Analysis and Findings

The applicant has demonstrated compliance with all terms and conditions of previous Certificate of Needs issued within the last 20 years.

F. Impact on Existing Providers and the Health Care Delivery System

COMAR 10.24.01.08G(3)(f): An applicant shall provide information and analysis with respect to the impact of the proposed project on existing health care providers in the service area, including the impact on geographic and demographic access to services, on occupancy, on costs and charges of other providers, and on costs to the health care delivery system.

With respect to the impact of the proposed project on existing providers of liver transplant services, Suburban's previous response to the Impact standard[107] constitutes a response to that aspect of this criterion. Suburban projected that the proposed liver transplant service will not interfere with the ability of the three existing transplant services in Maryland and D.C. to maintain a three-year average annual threshold case volume of 20 cases. It also projects that the likely reduction in case volume at the three existing programs that will result from introducing a new transplant program in the Washington Region DSA should not have an adverse impact on the financial viability of any of those programs. Furthermore, because of this relatively modest impact on existing center case volume and Suburban's belief that its proposal to add transplant center capacity will increase the supply of donated organs and increase the use of the organ supply, it projects improvements in access to liver transplantation by its projected service area population. Similarly, because of the relatively modest impact on existing center case volume, Suburban argues that the proposed new program will not have any impact on the quality of services that can be achieved in the provision of liver transplant services or on patient outcomes that can be achieved. The applicant submits that the proposed project complies with all aspects of the Impact standard, which defines a major proportion of the relevant impact considerations that MHCC should undertake in its review of this criterion.

As noted, the applicant believes that the proposed project will improve patient access to liver transplantation within the Washington Region DSA and argues that this improvement will be greatest for those of lower socioeconomic status. It describes a future in which more liver transplants take place in a lower charge hospital than any of the existing transplant hospitals. It also argues that access will be improved because the proposed project will add intensive care unit bed capacity operated at a liver transplant hospital, implying that there is insufficient existing bed capacity of this type. (DI #3, 181-183; DI #13, p. 10, 40).

[107]See Suburban's response to the Impact standard, *supra*, pp. 83-85.

Reviewer's Analysis and Findings

The proposed project will have an impact on the three existing liver transplant programs in Maryland and D.C. by reducing the number of liver transplant cases that these programs would handle, in the absence of a new program at Suburban. Because of the case volumes recently experienced by these existing centers, I agree with the applicant that the stability and viability of the existing liver transplant programs are unlikely to be compromised by the establishment of a liver transplant program at Suburban, even if the reductions in existing case volume experienced by these existing programs is greater than that projected by Suburban. I note, however, that the redistribution of potential case volume over a greater number of centers will, at least marginally, reduce economies of scale achievable for this expensive, tertiary medical service.

I find that the proposed project's impact on geographic and demographic access to liver transplantation services in this case is minimal, given the specialized nature of this service. The project seeks to establish a liver transplantation program just outside the boundaries of the District of Columbia in Bethesda, Maryland. One of the three transplant programs that serves a substantial number of Maryland residents is located within the District of Columbia and the other two are located approximately 38 to 39 miles away in Baltimore City. With regard to the applicant's assessments of the positive impact on improved geographic access and access for patients with lower socioeconomic status, my assessment is that it could have presented more specific data regarding the benefits of the proposed project for existing patients in the Washington Region DSA who are served at the outpatient clinics at Suburban and Sibley Memorial. Despite prompts from Commission staff to share more knowledge about any patients who may have been limited from obtaining a liver transplant due to the burdens of travel or socioeconomic status, the applicant failed to provide this information. (DI #13, p. 73). I conclude that Suburban should have been able to provide data on patients currently served within the Johns Hopkins health care system in the Washington Region DSA that supports its claim that patients with lower socioeconomic status who are eligible for a liver transplant are underserved, if that problem truly exists.

I find that the proposed project's impact on occupancy of other liver transplantation services is not substantive, in line with my first finding with respect to the general impact on these hospitals. The applicant insists that adding the intensive care unit bed capacity of Suburban Hospital to the total complement of intensive care beds available to liver transplantation patients is an important positive impact of the proposed project. I do not agree. Suburban did not present evidence, and the experience at Georgetown does not indicate that there are an insufficient number of intensive care beds for liver transplantation patients.

I find that the proposed project's impact on costs and charges of other hospitals providing liver transplantation services is minimal, in line with my first finding with respect to the general impact on these hospitals. These programs will provide fewer liver transplants than they otherwise would provide if a third program is established in Maryland, just outside the District of Columbia. But this reduction is likely to be relatively modest and, thus, will not have a substantial impact on the costs of producing liver transplantation services and, consequently, should not play a significant role in shaping charges for this service, which are regulated in the case of two of the three programs that are used by most Marylanders obtaining this service.

The impact of the proposed project on the health care delivery system's costs to provide liver

transplantation is likely to be mildly negative, because the fixed costs of the three existing centers will be spread over a lower case volume of transplants than these centers would otherwise experience if an additional center was not introduced into their markets. I find that the proposed project's impact on costs to the health care delivery system is likely to be mildly positive, in terms of charges for services. As a rate-regulated Maryland community hospital, Suburban will be able to charge less for liver transplantation than the two academic medical centers that are the only existing providers of this service in Maryland. This impact will be limited, in that it is also likely that those two Maryland hospitals and the existing transplant hospital in the District of Columbia will continue to provide the bulk of the liver transplants provided within the health care delivery systems of Maryland and D.C.

I find that the application complies with the Impact criterion.

V. SUMMARY AND RECOMMENDATION

I recommend that the Maryland Health Care Commission DENY the application of Suburban Hospital to establish of a new liver transplant service at Suburban Hospital. The applicant did not demonstrate that the establishment of proposed liver transplantation service would increase the supply or use of donor livers, or that there is a barrier to access for liver transplantation that its program would address. Suburban Hospital's proposed liver transplantation service is simply not needed.

I found that Suburban failed to meet three standards in the Organ Transplant Services Chapter and two Certificate of Need review criteria, as briefly summarized below.

The Need Standard, COMAR 10.24.15.04B(1)

Suburban Hospital has not demonstrated that its proposed project has the ability to increase the supply or use of donor organs. Most of the utilization that the applicant projects for the proposed project is derived from the projected shift of cases from existing transplant centers to the new center.

The Access Standard, COMAR 10.24.15.04B(3)

Suburban Hospital failed to demonstrate that there is a barrier to access for liver transplantation services that would be effectively addressed by the proposed project. Liver transplantation services are classified in the Organ Transplant Services Chapter of the State Health Plan as a specialized regional service. Thus, the supply of programs should be limited.

Residents of Maryland currently have access to three programs. Based on the Commission's planning approach and the information on travel time, I found that the residents of the Washington Region DSA, where the proposed project will be located, currently enjoy reasonable and adequate access to this service.

The Cost Effectiveness Standard, COMAR 10.24.15.04B(4)

Suburban Hospital failed to demonstrate that the projected need for liver transplant services can most cost-effectively be met through its proposed project. I found that the most cost-effective

approach is reliance on the existing liver transplant providers in the region. While the addition of liver transplant services at Suburban Hospital would minimally reduce travel time for some patients in Maryland who are candidates for this service, liver transplant services currently are accessible.

The Need Criterion, COMAR 10.24.01.08G(b)

Suburban Hospital has not met the requirements of the Need criterion to demonstrate that there is an unmet need for its proposed liver transplant service. It did not demonstrate unmet needs or barriers to access exist for the target population of its proposed program. It failed to present a credible plan to increase liver donations or to better utilize the existing supply of livers.

The Organ Transplant Services Chapter dictates that liver transplant services are a specialized, tertiary service that should be regionalized. The three existing programs in Maryland and D.C. are quite accessible to Maryland residents.

The Availability Of More Cost-Effective Alternatives Criterion, COMAR 10.24.01.08G(c)

Suburban Hospital did not demonstrate that its proposed project is the most cost-effective alternative in comparing the cost effectiveness of the proposed project with the cost effectiveness of providing the service through alternative existing facilities. Increase in the supply of livers for donation and more effective use of organ supply can be accomplished through existing outreach, education, research, and clinical practice efforts rather than through development of a third liver transplant program in Maryland and a second program in the Washington DSA.

IN THE MATTER OF	*	**BEFORE THE**
	*	
SUBURBAN HOSPITAL	*	**MARYLAND HEALTH**
	*	
DOCKET NO. 17-15-2400	*	**CARE COMMISSION**
	*	

*** ***

FINAL ORDER

Based on the analysis and findings in the Reviewer's Recommended Decision, it is this 15th day of October 2020, ORDERED:

That the application of Suburban Hospital for a Certificate of Need to establish a liver transplant service in Montgomery County is **DENIED**.

MARYLAND HEALTH CARE COMMISSION

APPENDIX 1

RECORD OF THE REVIEW

MARYLAND HEALTH CARE COMMISSION

Suburban Hospital (Liver Transplant Service)
Docket No. 17-15-2400
Record of the Review

Docket Item #	Description	Date
1	Commission received a letter of intent for Suburban Hospital to propose a liver transplant center.	3/31/17
2	Commission published the notice soliciting additional letters of intent for transplant programs in the *Maryland Register.*	4/3/17
3	Commission received Suburban's Certificate of Need application to establish a liver transplant program.	6/28/17
4	Commission acknowledged receipt of CON application.	6/29/17
5	Commission requested publication of notification of receipt of the Suburban proposal in the *Washington Times.*	6/29/17
6	Commission requested publication of notification of receipt of the Suburban proposal *Maryland Register*.	6/29/17
7	*Washington Times* provided the notice of the receipt of application.	7/12/17
8	Following completeness review, Commission staff found the application incomplete, and requested additional information.	8/17/17
9	Applicant request and Commission staff approved an extension of time to file completeness questions until 10/23/17.	10/3/17
10	Applicant and Commission emailed correspondence regarding information on the access of UNOS data for completeness review.	10/11/17
11	Applicant request and Commission staff approved an extension of time to file completeness questions until 11/3/17.	11/19/17
12	Commission received responses to Question 1 of the completeness questions.	11/3/17
13	Commission received responses to Question 2-70 of the completeness questions.	11/3/17
14	Commission staff found the application incomplete, and requested additional information.	2/2/18
15	Commission received responses to Question 1 of the completeness questions.	2/15/18
16	Commission notified Suburban that its application is docketed for formal review on March 30, 2018.	3/13/18
17	Commission requested publication of notice of formal start of review for the Suburban proposal in the *Washington Times*.	3/13/18
18	Commission requested publication of the notice of formal start of review in the *Maryland Register.*	3/13/18
19	Commission sent copy of the application to the Montgomery County Department of Health and Human Services for review and comment.	3/13/18
20	Commission received notification of the formal start of review for Suburban as published in the *Washington Times*.	3/29/18
21	Commission received interested party comments from Suburban, from Tobin of Tobin, O'Connor & Ewing.	4/30/18
22	Suburban filed response to interested party comments.	5/15/18
23	Commissioner Reviewer Rymer sent letter to applicant and interested party notifying them that she will be reviewer in case, but requested applicants inform if they have any objections.	10/16/18

24	Commission received an email from Suburban stating that it has no objection.	10/22/18
25	Commission received an email from Georgetown stating that it has no objection.	10/24/18
26	Commission received a request from MedStar Franklin Square for a conditional motion to stay the CON review	11/5/18
27	Commission Reviewer Rymer notified Suburban and Georgetown notifying them that she will be reviewer.	11/15/18
28	Commission sent an email to Suburban requesting a response by November 26, 2018 by agreement of all parties.	11/18/18
29	Commission received a request from Georgetown for a response to the request for conditional motion to stay	11/21/18
30	Commission received a reply from MedStar Franklin Square in support for conditional motion to stay in CON review	12/5/18
31	Commission received a request from Suburban on the status of MedStar Franklin Square motion to stay	2/25/19
32	Commission received a request from Georgetown for motion to submit additional data and set briefing schedule	11/12/19
33	Commissioner Reviewer Rymer sent a request to HSCRC for comments on application	11/15/19
34	Email correspondence regarding an agreement on schedule in response to motions	11/25/19
35	Commission received a response from Georgetown to the motion to submit additional data by Georgetown	12/16/19
36	Commission received a request from Georgetown to reply in support of its motion to submit additional data and set briefing schedule	12/30/19
37	Commission Reviewer Rymer sent a request to the Washington Regional Transplant Community (WRTC) for information regarding application.	1/29/20
38	Commission Reviewer Rymer sent a request to the Living Legacy Foundation of Maryland (LLF) for information regarding application.	1/29/20
39	Commission received a request from University of Maryland Medical Center to renew its arguments set forth in its motion to stay and request Suburban update its analysis.	2/25/20
40	Commission received comments from the LLF on application.	2/27/20
41	Commission received comments from the WRTC on application.	2/28/20
42	Commission received a response from Suburban to letters from the LLF and the WRTC.	6/24/20
43	Commissioner Reviewer Rymer sent Suburban and Georgetown rulings on motions and closed the record on application.	7/16/20
44	Commission received HSCRC comments on project.	8/14/20

APPENDIX 2

Letters from Organ Procurement Organizations:

Living Legacy Foundation of Maryland

Washington Regional Transplant Community

the living legacy foundation of Maryland

February 27, 2020

Martha G. Rymer, Commissioner/Reviewer
Maryland Health Care Commission
4160 Patterson Ave.
Baltimore, Maryland 21215

RE: Maryland Health Care Commission Request for Information Regarding Application to Establish Liver Transplantation Program

Dear Ms. Rymer,

Per your letter request dated January 29, 2020, please find responses to your inquiry regarding Suburban Hospital's application for a Certificate of Need (CON) to establish liver transplantation services. I am responding on behalf of The Living Legacy Foundation (LLF) in the context of a neighboring Organ Procurement Organization (OPO), as Suburban Hospital is not in LLF's designated service area (DSA) for deceased organ donation. LLF serves as the organ recovery program for all Maryland counties with the exception of Montgomery, Prince George's, and Charles Counties (described in any comments below as "Local").

Following are LLF's responses to your questions:

Question 1: Regarding the change in UNOS' policy approved in December 2018 (Policy) that moves from a distribution system based on donation services areas to a system based on acuity circles, (and that was implemented only briefly before being put on hold in May 2019 by a federal district court order, which that court removed on January 17, 2020):

(a) Describe both the Policy's impact to date and its anticipated future impact on liver transplant patients (particularly in Maryland). Please explain.

ANSWER: The liver allocation policy went into effect on February 4, 2020. Accordingly, it is premature to comment meaningfully on its impact, and the below comments regarding anticipated effects are based on statistical modeling of the policy changes. It is also important to note that until the recently implemented liver allocation policy, LLF's primary focus has been serving existing transplant programs at The Johns Hopkins Hospital (JHH) and The University of Maryland Medical Center (UMMC) – LLF's Local transplant centers. Under the prior allocation policies, organs recovered from LLF's program were most often allocated to patients at JHH or UMMC. The current allocation policy has changed to create a system of equal priority to any waiting liver transplant patient within 500 nautical miles (concentric circles) from the donor hospital for the sickest patients on the list. Priority is

then given to patients within 250 nautical miles, and then to 150 nautical miles. Modeling predicts that most livers will be allocated within the 150 nautical mile radius; the second most frequently serviced area/less sick patient population will be within the 150-250-mile radius, and rarely will LLF transport a liver within the 250-500-mile radius. The 150-mile circle is far larger than LLF's DSA and includes transplant centers in Washington DC, Maryland, and waiting recipients from as far away as Northern Pennsylvania, New York City, Richmond, and Norfolk. As one might imagine, this new policy dramatically changes the allocation landscape, as the concept of Local centers is no longer relevant to the policy. The impact of the new allocation policy will be that most livers recovered in our service area will now be allocated to patients outside of Maryland and DC (modeling suggests that a range of 65-85% of all locally recovered livers will leave Maryland), and the transplant centers in Maryland will be receiving livers from donors outside the state of Maryland at a rate that will allow them to maintain their current volumes (although some models indicate a slight increase in volume). I believe it is nearly impossible to predict volumes of transplants for the next 2-3 years until we can assess the true impact of the policy changes. However, by way of example, in 2020 *prior to implementation of the new allocation policy,* 8 of 10 livers recovered by LLF were transplanted at JHH or UMMC. Since implementation of the new policy, only 2 of 6 livers have been transplanted at UMMC or JHH. Notably, there is a 29 nautical mile difference between each existing Maryland Liver Transplant Center and the proposed center at Suburban Hospital, and far less between Suburban and Washington, DC centers, which means that the already reduced number of transplants will likely further be divided between centers.

(b) Describe both the Policy's impact to date and its anticipated future impact on the number of livers available for transplant in each of the organ procurement organizations (OPOs) responsible for the evaluation and procurement of deceased donor organs for hospitals in Maryland (the Living Legacy Foundation the Washington Regional Transplant Community). Please explain.

ANSWER: To reiterate, due to the very recent implementation of the liver allocation policy, its impact is best predicted based upon the statistical modeling referenced above. However, the way in which organs are allocated has no impact on the number of livers available. The number of available livers depends upon the practices of the donor hospitals and OPOs in identifying potential donors. The presence or absence of a transplant center does not impact that process. By way of example, LLF services 33 donor hospitals, only two of which are transplant centers. In LLF's view, there is no correlation between the number of transplant centers and the size of the donor pool. Organ availability will not change if additional transplant centers are established.

(c) Has the impact of the Policy differed (and do you anticipate that the impact will differ) among transplant programs located in jurisdictions covered by the Living Legacy Foundation of Maryland (LLF) OPO based on the number and location of transplant programs in the LLF OPO? If so, please explain.

the living legacy foundation of Maryland

ANSWER: Again, since the implementation of the new policy was delayed until 2/4/20, it is too soon to meaningfully gauge the actual impact. However, we predict that, given the current geographic concentration of existing transplant centers, there will be little variability in the impact of the new allocation policy on Maryland and/or DC transplant centers, particularly given the nautical-mile based system.

(d) Please address each other anticipated impact of the Policy of which I should be made aware.

ANSWER: None to add.

Question 2: What do you view as the most effective ways to increase the number of liver transplants in the jurisdictions covered by the LLF? Please explain.

ANSWER: This is a very complex question that is dependent upon a number of variables, none of which is controlled by a single entity or policy. With that caveat, the most effective way to impact organ availability for Local patients is to the change the allocation policy. Regardless of the allocation policy, LLF will continue to meet and exceed all national standards for organ recovery, but because the new allocation policy requires a broader sharing of organs, there is less chance that Local organs will also be transplanted Locally. Today, despite being one of the highest performing OPOs in the country (by both current and proposed OPO metrics set forth by CMS), LLF still believes that only 70% of its true potential for donation is being reached. We believe that more focused efforts in at-risk communities (such as Baltimore City) will allow LLF to continue to grow the availability of donor organs. Our current leadership team assumed responsibility for OPO operations in 2004. Since then, LLF has grown from 75 organ donors and 176 transplants from locally recovered donors, to over 160 donors and more than 430 transplants from locally recovered donors in 2019. We attribute that remarkable increase to our slow and steady efforts to change perceptions in culture and practice that grow donation.

Question 3: What metrics or outcome measures have customarily been used by LLF to measure the success of an organ transplant program?

ANSWER: OPOs do not measure transplant center performance -- that is a function of UNOS/OPTN and CMS. LLF's ability to affect transplant center practice is determined only by our degree of success in effectively engaging and educating transplant centers about clinical advancements in practice and in encouraging transplant centers' acceptance of organs made available by our program. By way of example, if a Local transplant center declines an organ offered by LLF, and that organ is later transplanted at an outside transplant center, LLF educates the Local center by sharing information on the organ and the outside center's process for acceptance of that organ. This education of our Local centers is meant to help manage Local surgeon and center variability that may be inadvertently

disadvantaging Local patients. The ability of an OPO to impact transplant center acceptance is driven by the willingness of a transplant center to collaborate with the OPO on improving the transplant acceptance rate. As mentioned in 1(a) of this response, LLF's ability to manage or impact Local surgeon/center behavior has been substantially diluted because of the broader allocation policy. More specifically, because the priority of Local organs has been eliminated, those organs are now first offered more broadly into the 500/250/150 concentric circles rather than to JHH and UMMC. The broader sharing of organs will result in more attenuated relationships between transplant centers and OPOs, thus likely decreasing the ability of the OPOs to impact a transplant center's organ acceptance practices.

Question 4: What metrics or outcome measures do you recommend as appropriate to compare the effectiveness of organ transplantation services in a state or region? If these measures are not currently in use by oversight agencies or authorities, please explain why, if known.

ANSWER: The assessment of successful organ transplantation services is not the expertise of the OPO. I would suggest readily available data provided by UNOS/OPTN and the Scientific Registry for Transplant Recipients (SRTR) as the gold standard for these data. There are thorough assessments of pre-transplantation metrics (organ acceptance rates, wait list management, and outcomes) as well as patient and graft survival data and wait list mortality. These collective metrics provide important insights into the performance of a transplant center.

Question 5: From your perspective, what are the likely benefits, if any, of establishing an additional liver transplantation program in the Living Legacy Foundation of Maryland's region? Please also discuss likely drawbacks, if any.

ANSWER: As mentioned above, given the broader sharing of organs recently implemented by the new liver allocation policy and the predictive statistical modeling, LLF believes that the volume of transplants performed locally will likely decrease in the coming years. In fact the decrease in volume has already been realized in the few short weeks since the new policy went into place in early February. An increase in the number of Local transplant programs will not affect transplant rates or increase the numbers of organs available for transplant. While additional programs could offer alternative options for patients, given the predicted decrease in volume, it could also unnecessarily add complexity and cost to the system. However, as it is the goal of LLF, and all OPOs, to maximize the number of organ donors and organs recovered for transplant within its DSA, we would reiterate that donation and recovery rates are dependent upon the practices of the OPOs and the donor hospitals within the DSA. The number of transplant centers within the 500-mile allocation radius does not affect LLF's mission of increasing the number of donors or number of organs available for transplantation. Accordingly, LLF defers to the judgment of the Health Care Commission on the ultimate issue raised within this question.

the living legacy foundation of Maryland

Question 6: From your perspective, what evidence or information would strongly indicate that a hospital has the ability to increase the supply or use of donor organs for patients served in Maryland? Please explain.

ANSWER: As we have mentioned throughout, the organ supply is a function of the practices of donor hospitals and the OPOs. Notably, however, donation rates at hospital transplant centers often underperform those of non-transplant hospitals. We believe the response sought in Question 6 is extremely hospital-specific and a question most appropriately answered by hospitals. With regard to a hospital's ability to increase the *use* of donor organs, this depends on the function of the hospital. A donor hospital has no ability to affect the *use* of donor organs, as that is solely the function of the transplant team and outside the scope of an OPO's work.

Should you have any questions regarding LLF's responses above, please contact me at 410-242-7000 or at calexander@thellf.org.

Sincerely,

Charles Alexander
President & CEO

DONATE LIFE
BeADonor.org

WRTC
WASHINGTON REGIONAL
TRANSPLANT COMMUNITY

February 28, 2020

Martha G. Rymer
Commissioner/Reviewer
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

RE: Response to Letter Request for Information Regarding Application to Establish Liver Transplantation Program

Dear Ms. Rymer:

In response to your letter request dated January 29, 2020, please find the below responses to your questions on behalf of Washington Regional Transplant Community (WRTC). Per your letter, you are seeking responses from WRTC, specifically, because of our expertise. WRTC is pleased to provide the information below as a federally designated organ procurement organization for the Washington, D.C. metropolitan area with specific expertise in donation and recovery of organs for transplantation.

WRTC is the organ procurement organization (OPO) for the greater Washington, D.C. area (including 3 counties in Maryland) with a total population base of 5.5 million. In 2019, WRTC achieved its fourth consecutive record-breaking year of increases in organ and tissues transplanted with more than 35,000 patients saved and healed thanks to the benevolent organ, eye and tissue donors in our donation service area (DSA). Our clinical staff recovered and allocated 485 organs from 145 generous donors, saving the lives of 417 individuals and representing a 6% increase in organ donors from 2018. WRTC assisted with 38 living kidney donor surgeries at our local transplant centers. Whether assessed under current or proposed performance outcome metrics, WRTC continues to be a top performing OPOs nationally. This record-breaking success, and collective goal of saving and healing lives would not be possible without the collaborative joint efforts of our hospital partners, transplant centers, medical professionals and community members. WRTC's relationship with each of these entities is critical to our success. It is from this additional perspective that we offer our responses below.

Question 1: Regarding the change in UNOS' liver allocation policy approved in December 2018 (Policy) that moves from a distribution system based on donation services areas to a system based on acuity circles, (and that was implemented only briefly before being put on hold in May 2019 by a federal district court order, which that court removed on January 17, 2020):

(a) Describe both the Policy's impact to date and its anticipated future impact on liver transplant patients (particularly in Maryland). Please explain.

Because the Policy was implemented on February 4, 2020, WRTC is unable to provide meaningful information regarding its impact to date. As for its future impact, based on simulation modeling

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done by the Scientific Registry of Transplant Recipients (SRTR), the revised liver allocation policy will decrease pre-transplant deaths among liver candidates and increase transplant access for candidates younger than age 18. The modeling does not suggest the system will greatly affect transplant access based on candidates' insurance type (public or private), transplant access whether candidates live in urban settings as opposed to suburban/rural areas. For more information on liver allocation and how livers are allocated, the Organ Procurement and Transplantation Network (OPTN) website offers a liver allocation questions and answers section and extensively details the liver allocation algorithm. *See* **https://optn.transplant.hrsa.gov/data/organ-datasource/liver/liver-allocation-questions-and-answers/ .**

(b) Describe both the Policy's impact to date and its anticipated future impact on the number of livers available for transplant in each of the organ procurement organizations (OPOs) responsible for the evaluation and procurement of deceased donor organs for hospitals in Maryland (the Washington Regional Transplant Community and the Living Legacy Foundation). Please explain.

The number of livers *recovered* for transplant in a DSA is primarily a function of the work of the OPO and is completely unaffected by, or related to, organ allocation policy. WRTC strives daily to recover as many organs as possible and works with its hospital partners to maximize the number of organs procured.

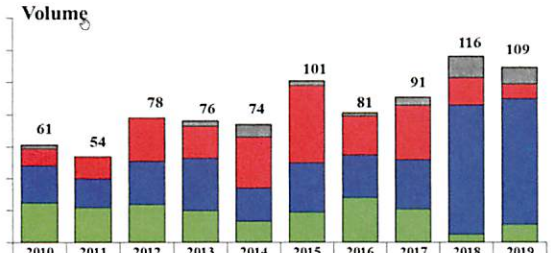
The number of organs that are *transplanted* within WRTC's DSA is, in large measure, a function of how the organs are allocated. At this point we do not have data on how liver allocation/distribution will directly impact the Washington, D.C. metro area or Maryland. However, similar policy changes in lung allocation policy took effect in 2017, and data regarding the subsequent impact of that policy change is potentially instructive.

By way of background, the Department of Health and Human Services recently required the OPTN to place more emphasis on patient equity in the allocation of organs. The resulting changes in the algorithms reduced the emphasis that livers and lungs be allocated within the OPO DSA and replaced it with a nautical mile circle(s) from the donor hospitals, based on patient acuity. The revised liver allocation system took effect on February 4, 2020; not enough data currently exists to allow for meaningful predictions. (Since February 4th WRTC has recovered 5 livers and 4 have been allocated to centers outside of Maryland and DC.) However, changes to the lung allocation system went into effect in 2017. Lung allocation was similarly adjusted to reflect a 250 nautical mile circle of allocation around each donor hospital (Liver is based on acuity and a graduated nautical miles radius from the donor hospital depending on severity of the liver disease (https://unos.org/policy/liver-distribution)). **Each lung patient is given a lung allocation score, similar to a liver patient's MELD/PELD score for medical acuity. Regarding lungs, UNOS/OPTN reported that an increase was seen in the median distance between the donor hospital and the transplant center.[1] More specifically, prior to the changes in the lung allocation system, 40% of the lungs recovered by WRTC were transplanted locally (see graph below). In 2018, that number dropped to 6%, and in 2019, it was 12% -- despite both of those years being record-breaking for**

[1] https://optn.transplant.hrsa.gov/media/2815/20190116_thoracic_committee_report_lung.pdf

WRTC's overall lung recovery efforts. OPOs across the nation are experiencing broader distribution of lungs to transplant centers outside their respective DSAs, and we expect the same will happen with livers.

Disposition
Locally Recovered Lungs
2010 - 2019

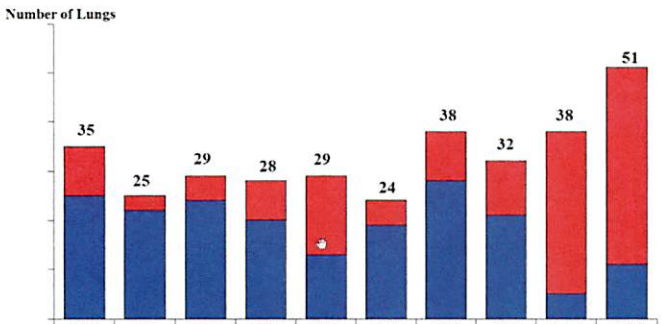


	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Discarded	2			3	8	3	2	5	13	10
Research	11	14	27	20	32	48	24	34	17	9
Exported	23	18	27	33	21	31	27	31	81	79
Locally Transplanted	25	22	24	20	13	19	28	21	5	11

Year

We have also included data from Inova Fairfax Hospital (the single lung program in WRTC's DSA) demonstrating how the changes in the lung allocation system impacted lung transplants locally. The overall number of lung transplants increased, but the lungs were primarily recovered from OPOs outside the WRTC DSA.

Total Lungs Transplanted
and Lung Origin (Local vs Import)



	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Import Lungs	10	3	5	8	16	5	10	11	33	40
Local Lungs	25	22	24	20	13	19	28	21	5	11

Year

32 local recipients transplanted in 2019.

(c) Has the impact of the Policy differed (and do you anticipate that the impact will differ) among transplant programs located in jurisdictions covered by the Washington Regional Transplant Community (WRTC) OPO based on the number and location of transplant programs in the WRTC OPO? If so, please explain.

Again, the liver allocation policy has not been in effect for the length of time needed to accurately assess whether these changes will have a disparate impact on liver transplant programs in our DSA or in Maryland. For information relevant to this inquiry, we refer you to Answer 1(b) above and to the OPTN modeling.

(d) Please address each other anticipated impact of the Policy of which I should be made aware.

None to add.

Question 2: What do you view as the most effective ways to increase the number of liver transplants in the jurisdictions covered by the WRTC? Please explain.

The only way to directly increase the number of liver transplants in WRTC's DSA is to change the liver allocation policy, which is very unlikely to happen. The overarching issue is simply that there are not enough organs for all patients who await transplant. As of February 2020, 253 people were waiting for livers in the District of Columbia, and 738 in Maryland. As of today, a total of 12,669 patients are awaiting liver transplants throughout our country. WRTC strives to recover as many organs as possible, but given the federal allocation policy, it cannot control the number of organs that remain in its DSA. WRTC can work with its hospital partners to increase the number of all organ donors, resulting in more liver transplants, which could indirectly increase the number of liver transplants in the DSA simply due to an overall increase in volume. To that end, WRTC works with its hospital partners to educate them on the importance of timely donor referrals and increasing donation opportunities, issues that have a significant effect on the number of potential livers available for transplant. The referenced data for Suburban Hospital showing 2019 YTD donor potential data is attached hereto as Exhibit A.

It is important to note that for every hospital in the DSA WRTC performs death record reviews to assess hospital compliance with donation identification and timely referral. Overall, the WRTC DSA hospitals have a 99% compliance rate on contacting WRTC on all deaths, or when the donation clinical triggers (Exhibit B) are met. There is only a very rare instance where a hospital in the DSA failed to identify a potential organ donor. The primary limiting factor in donation is family/donor authorization. In 2019, WRTC identified a total of 215 ventilated deaths that appeared medically suitable for organ donation, with 210 requests (2 ruled out due to Medical Examiner case decline, and 3 with no next-of- kin) for a total of 145 donors.

The only way to increase organ donation in the Virginia-Maryland-D.C. metropolitan area is to increase authorization for donation. The donation authorization rate year-to-year averages near or slightly above 70%; which means that approximately 30% of the donors/families approached about donate said no. Public education and registration are the keys to increasing donation and transplantation.

Increasing donation education and awareness is vital to the success of organ donation across the county. WRTC works throughout Maryland, Virginia and Washington, D.C. to raise public awareness about the importance of donation, and to help communities understand the direct lifesaving impact of this selfless act. The WRTC community outreach

and education initiatives are very robust. More than 500 trained WRTC Donate Life Ambassadors logged approximately 1,000 hours in 2019 educating the public at large about the importance of registering to be an organ, eye and tissue donor. As a result, WRTC's donor designation rates remain healthy and steady. Currently, 63.8% of people in Washington, D.C. are registered donors. In the state of Maryland, 62% are registered donors and in the state of Virginia, 65.8% respectively. Nationally, 58% of people are registered donors, so our region trends slightly higher. WRTC actively works in collaboration with Donate Life Maryland to ensure that the state's donor registry is secure, easily accessible and informative.

Question 3: What metrics or outcome measures have customarily been used by WRTC to measure the success of an organ transplant program?

WRTC does not measure the success of organ transplant programs. This assessment is the combined role of CMS, UNOS, and the OPTN. Section 42 CFR Part 482, entitled "Medicare Program: Hospital Conditions of Participation: Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplants; Final Rule," CMS sets forth the conditions of participation (CoPs) with data submission, clinical experience, outcome and process requirements. The requirements focus on an organ transplant center's ability to perform successful transplants and deliver quality patient care as evidenced by outcomes and sound policies and procedures. The CoPs include requirements to protect the health and safety of both transplant recipients and living donors. Additionally, UNOS and OPTN have very specific requirements for transplant centers, some of which can be found here, https://unos.org/wp-content/uploads/unos/Appendix_B_AttachI_XIII.pdf **and at their general websites, here:** https://unos.org/ and https://optn.transplant.hrsa.gov/.

Question 4: What metrics or outcome measures do you recommend as appropriate to compare the effectiveness of organ transplantation services in a state or region? If these measures are not currently in use by oversight agencies or authorities, please explain why, if known.

As stated above, CMS establishes the relevant metrics for performance outcome measures. It is not the role of WRTC or any OPO, to compare the effectiveness of transplant services. The SRTR provides excellent data regarding transplant program comparisons, including deceased and living donor transplants per year, waitlist survival, and one-year survival rates on a program-by-program, organ-by-organ basis. Transplant program comparisons can be found at the SRTR website via this link: https://www.srtr.org/about-the-data/comparing-transplant-programs .

Question 5: From your perspective, what are the likely benefits, if any, of establishing an additional liver transplantation program in the Washington Region[al] Transplant Community's region? Please also discuss likely drawbacks, if any.

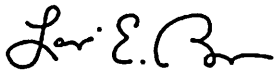
WRTC has supplied the data herein as a neutral third-party per your request for specific information regarding organ availability and allocation. We defer to the Health Care Commission to determine the broader benefits and drawbacks to the establishment of another liver transplant program in WRTC's DSA.

Question 6: From your perspective, what evidence or information would strongly indicate that a hospital has the ability to increase the supply or use of donor organs for patients served in Maryland? Please explain.

It is generally the role of the OPO, in collaboration with the donor hospital, to maximize the number of organs available for transplant. Whether those organs are used for patients in Maryland is dependent first upon where the organ is allocated. As mentioned above, the new liver allocation policy requires a broader sharing of these organs. While OPOs, with the help of their donor hospitals, may be able to increase the number of organs *available* for transplant, whether or not these organs stay within the DSA for local recipients is outside the control of the OPO or hospital. As indicated above, the Maryland hospitals WRTC serves are doing an outstanding job of identifying donation potential. A limited number of deaths meet the criteria for organ donation. There is room for improvement in authorization for donation, but there are a finite number of deaths that die in the manner that make them eligible to donate organs. As indicated, the Maryland hospitals served by WRTC do an excellent job of identifying the donation potential.

Should you have any questions about the above responses, please do not hesitate to contact me at Lori@WRTC.org.

Sincerely,



Lori E. Brigham
President & CEO

APPENDIX 3

HSCRC MEMORANDUM

maryland
health services
cost review commission

MEMORANDUM

TO: Martha G. Rymer, Commissioner/Reviewer, MHCC
Kevin McDonald, Chief, Certificate of Need Division, MHCC

FROM: Katie Wunderlich, Executive Director, HSCRC
Jerry Schmith, Director, Revenue & Regulation Compliance, HSCRC

DATE: August 14, 2020

RE: Suburban Hospital, Inc. ("Suburban")
Application to Establish Liver Transplant Services
Docket No. 17-15-2400

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This memo is in response to your request dated November 15, 2019. Suburban has submitted an application for a Certificate of Need ("CON") to establish liver transplant services. You have requested that the staff of the HSCRC provide its opinion on the general financial feasibility and viability of the proposed liver transplant services and provide insight regarding certain assumptions made. MedStar Georgetown University Hospital ("Georgetown") is recognized as an interested party in this review.

EXISTING PROGRAMS:
Maryland currently has two liver transplant programs, both in Baltimore. One is at The Johns Hopkins Hospital ("JHH") and the other is at University of Maryland Medical Center ("UMMC"). Georgetown has a liver transplant program in the District of Columbia.

THE PROJECT:
Suburban is part of Johns Hopkins Medicine, and the proposed liver transplant program would be staffed by the Johns Hopkins Comprehensive Transplant Center. There are no capital costs associated with the development of this program. Suburban projects that if its program is approved, the existing programs will see a reduction of 10 or fewer cases per year through the first five years of operation. Specifically Suburban projects that, by the fifth year of operation, JHH would lose 5.1%, UMMC 4.6%, and Georgetown 6.9% of existing cases to Suburban. Suburban also projects that an additional 10 liver transplant cases will take place each year as a result of its new program.

Financially Suburban anticipates that the transplant program will have a net loss of $1,187,921 in year one because the first ten transplant cases performed at the hospital will not be reimbursed,. It projects a net income of $979,382 in year two, followed by increasing levels of net income in subsequent years.

BACKGROUND:
The chapter of the State Health Plan that addresses organ transplant services, COMAR 10.24.15, ("Organ Transplant Chapter"), requires an applicant to address whether its proposed program is cost effective as compared to existing programs in its proposed service area. Suburban states that its charges for liver transplantations will be lower than those of JHH. It arrives at this conclusion by identifying applicable HSCRC Rate Centers for qualifying liver transplantation cases performed at JHH, then substituting Suburban's rates. Suburban calculated that its liver transplantation charges ($148,208) would be about 17% lower than charges at JHH ($172,955). Suburban derives these total charges for liver transplant patients by using FY16 Suburban allowable unit rates and JHH liver

transplant patients' utilization of pre-transplant, transplant, post-transplant, and outpatient care. Suburban states that it was unable to quantify charges at the other two existing centers because transplant center charges can vary significantly depending upon donor type, differing levels of acuity, and whether or not a transplant is liver-only or multi-organ. Suburban surmises that the charge experience at JHH is likely more reflective of the charge experience at Georgetown, UMMC, and other academic medical centers than it would be at Suburban, a community hospital.

QUESTIONS from MHCC to HSCRC:

1) Does Suburban present plausible revenue and expense assumptions that reflect appropriate shifts related to new payment models, and account for recent expansions and modernizations at the hospital?

2) Would a new liver transplantation program at Suburban be expected to have lower charges and therefore be more cost effective than the programs at JHH, UMMC, and Georgetown? Can the HSCRC quantify difference in charges for liver transplant services among these providers?

3) How will a shift in liver transplant cases from Georgetown to Suburban, and the resultant Medicare dollar shift for these cases from the District of Columbia to Maryland, impact the spending and savings targets HSCRC must meet under the Medicare Waiver?

HSCRC REVIEW, DISCUSSION, and OPINION:

HSCRC staff has reviewed the CON application dated June 28, 2017 and the subsequent Suburban Completeness Responses dated November 3, 2017, and February 18, 2018, and Suburban Interested Party Responses dated May 15, 2018.

Upon review of the statistical and financial information provided in the CON and subsequent completeness responses, it was noted that such information was most recently updated as submitted November 3, 2017, reflecting actual data through fiscal 2016 and projected data beginning with fiscal 2017. The five (5) years of operations for the transplant services were projected to be fiscal 2019 through fiscal 2023. Given that at this time, fiscal 2020 has come to pass, and it is very likely that the operation if approved, would not begin in earnest before fiscal 2022 or perhaps fiscal 2023, staff is acknowledging that the projections are likely at least three (3) years old, and perhaps four (4). We have received notice from the MHCC that we are not to expect responses to our inquiries previously submitted to them, and we are not to expect to receive updated projections. Therefore, we have based our opinion upon what we have reviewed. Accordingly, our opinion is conditioned upon any material changes to the information reviewed had updated data been made available.

1) Consistent with the assumptions presented in the CON, all of Maryland's facilities (inclusive of Suburban) would continue to achieve liver transplant volumes in excess of the minimums required, even after Suburban's liver transplant service matured and volumes grew. The minimum annual case volume for liver transplant programs is twelve (12) cases per year.

After netting out the revenue projected for the liver transplant services, the projected gross patient service revenues for the entire facility, with inflation, as presented on Table H appear reasonable through fiscal year 2021 compared to the approved Global Budgeted Revenue (GBR) for Suburban. The average annual growth rate projected on such revenue beyond fiscal 2021 is 3.5%, which is reasonable compared to Suburban's average annual GBR growth rate of approximately 4%.

The average annual operating profit margin for the entire facility, as per the audited financial statements, for the five (5) years ended fiscal 2019 was 4.5%. The average annual operating profit margin for the entire facility with inflation as presented on Table H for the five (5) years ending fiscal 2023 is projected to be 2.9%. If the five (5) years ending fiscal 2023 were presented without the profits assumed on the liver transplant services, such average operating margin would measure approximately 2.5%. Holding all else equal this would imply a conservative projection of operating expenses and resulting margins, save for any impact of the current pandemic.

Based upon staff's review of the information presented and conditioned upon any material changes to that information that may have been brought to light, the HSCRC believes that the Liver Transplant services project may be financially feasible. However, staff has not received a response to the questions that were forwarded to the MHCC, nor has the staff been afforded an opportunity to discuss how Suburban calculated the additional revenue assumed in Table K. While staff realizes that Suburban would receive some increase to its GBR revenue if the program is approved, staff is not sure whether the revenue assumed in the projections are reasonable or not.

2) Generally, the organ acquisition and direct transplant costs should be relatively uniform across the hospitals. If all the programs are operating with approximately the same number of physicians, cost of supplies, length of stay, and other direct costs, etc. then the main difference would be overhead cost, indirect cost and capital costs at Suburban versus JHH or UMMC. The indirect costs will be lower at a community hospital when compared to an academic medical center. Staff can't comment on Georgetown since we don't regulate them nor have the data available to do so.

In general, academic medical centers have higher overhead and indirect costs than community hospitals. They are included in a separate peer group to help account for these differences. Holding all else equal the overhead, indirect, and capital costs at Suburban will be less than that of JHH and UMMC, and likely result in a lower overall rate structure that reflects the lower cost of a nonacademic medical center. Additionally, Suburban is a relatively efficient provider as measured in the Inter-hospital Cost Comparison (ICC) compared to other community hospitals. Again, if the direct costs are comparable, then the overhead and indirect costs would be more in line with a community hospital and most likely result in a lower set of unit rates than an academic medical center.

3) In general, this proposal to add liver transplants to Suburban lines up with staff's belief that border or regional/national hospitals have a built in advantage in our model in that they can lower their cost per case while at the same time not negatively affect total cost of care performance, because these hospitals can export a service to a non-Maryland resident, thereby spreading fixed costs over more patients that have no bearing on Maryland resident Total Cost Of Care (TCOC.)

In terms of the impact on the Maryland Medicare Waiver, Suburban would be subject to a market shift adjustment for Maryland residents currently being provided these services at another Maryland hospital. If the charges at Suburban are less than the other academic medical centers, as Suburban has estimated, then the impact would be positive.

For volumes currently being provided outside of Maryland there exists a methodology that was previously used for JHH that staff believes could be employed for Suburban as well. Staff suggests that Suburban may be allowed a charge per case that would consider the full cost of the organ plus a 50% variable cost factor applied to all other charges. If this is the final methodology used, the impact would depend on how much the patient is currently being charged at Georgetown compared to the new GBR allowed revenue.