For internal staff use

MARYLAND HEALTH CARE COMMISSION

_____

MATTER/DOCKET NO.

_____

DATE DOCKETED

HOSPITAL
APPLICATION FOR CERTIFICATE OF NEED

PART I - PROJECT IDENTIFICATION AND GENERAL INFORMATION

1. FACILITY

Name of Facility: Suburban Hospital

Address:

8600 Old Georgetown Rd	Bethesda	20814	Montgomery
Street	City	Zip	County

Name of Owner (if differs from applicant):
N/A

2. OWNER

Name of owner: Suburban Hospital, Inc.

3. APPLICANT. ***If the application has co-applicants, provide the detail regarding each co-applicant in sections 3, 4, and 5 as an attachment.***

Legal Name of Project Applicant
Suburban Hospital, Inc.

Address:
(Above)

Street	City	Zip	State	County

Telephone: 301-896-3100

Name of Owner/Chief Executive: Jacqueline Schultz

4. NAME OF LICENSEE OR PROPOSED LICENSEE, if different from applicant:
N/A

5. LEGAL STRUCTURE OF APPLICANT (and LICENSEE, if different from applicant).

Check ☑ or fill in applicable information below and attach an organizational chart showing the owners of applicant (and licensee, if different).

A.	Governmental	☐	
B.	Corporation		
	(1) Non-profit	☒	
	(2) For-profit	☐	
	(3) Close	☐	State & date of incorporation Maryland; May 22, 1942
C.	Partnership		
	General	☐	
	Limited	☐	
	Limited liability partnership	☐	
	Limited liability limited partnership	☐	
	Other (Specify):		
D.	Limited Liability Company	☐	
E.	Other (Specify):		
	To be formed:	☐	
	Existing:	☒	

6. PERSON(S) TO WHOM QUESTIONS REGARDING THIS APPLICATION SHOULD BE DIRECTED

A. Lead or primary contact:

Name and Title: Anne Langley, Sr. Director, Health Planning & Community Engagement

Mailing Address:

3910 Keswick Road, Suite N-2200	Baltimore	MD	21211
Street	City	Zip	State

Telephone: 443-997-0727

E-mail Address (required): alangle2@jhmi.edu

Fax: 443-614-9709

B. Additional or alternate contact:

Name and Title: Spencer Wildonger, Director, Health Planning

Mailing Address:

3910 Keswick Road, Suite N-2200	Baltimore	MD	21211
Street	City	Zip	State

Telephone: 443-997-0727

E-mail Address (required): swildon1@jhmi.edu

Fax: 443-614-9709

Name and Title:	William K. Meyer, Esq.			
Mailing Address:				
100 East Pratt Street, Suite 2440		Baltimore	MD	21202
Street		City	Zip	State
Telephone:	410-332-0444			
E-mail Address (required):	wmeyer@zuckerman.com			
Fax:	410-659-0436			

7. TYPE OF PROJECT

The following list includes all project categories that require a CON under Maryland law. Please mark all that apply.

If approved, this CON would result in:

(1) A new health care facility built, developed, or established ☐

(2) An existing health care facility moved to another site ☐

(3) A change in the bed capacity of a health care facility ☐

(4) A change in the type or scope of any health care service offered by a health care facility ☒

(5) A health care facility making a capital expenditure that exceeds the current threshold for capital expenditures found at: http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_con/documents/con_capital_threshold_20140301.pdf ☐

8. PROJECT DESCRIPTION

A. Executive Summary of the Project: The purpose of this BRIEF executive summary is to convey to the reader a holistic understanding of the proposed project: what it is; why you need/want to do it; and what it will cost. A one-page response will suffice. Please include:

(1) Brief description of the project – what the applicant proposes to do;
(2) Rationale for the project – the need and/or business case for the proposed project;
(3) Cost – the total cost of implementing the proposed project; and
(4) Master Facility Plans – how the proposed project fits in long term plans.

Suburban Hospital, part of Johns Hopkins Medicine, applies for a Certificate of Need for a new liver transplant service to address disparities between the two transplant Donation Service Areas serving Maryland: the Washington Regional Transplant Community ("WRTC") and the Living Legacy Foundation ("LLF"). A second WRTC transplant center at Suburban will reduce these disparities, while at the same time offering liver transplant patients Hopkins-level clinical expertise and administration.

B. Comprehensive Project Description: The description must include details, as applicable, regarding:

(1) Construction, renovation, and demolition plans;
(2) Changes in square footage of departments and units;
(3) Physical plant or location changes;
(4) Changes to affected services following completion of the project; and
(5) If the project is a multi-phase project, describe the work that will be done in each phase. If the phases will be constructed under more than one construction contract, describe the phases and work that will be done under each contract.

I. Executive Summary

Suburban Hospital ("Suburban"), part of Johns Hopkins Medicine, applies for a Certificate of Need ("CON") for a new liver transplant service. Suburban seeks a CON to address disparities between the two transplant Donation Service Areas ("DSAs") serving Maryland: the Washington Regional Transplant Community ("WRTC") and the Living Legacy Foundation ("LLF"). A second WRTC transplant center at Suburban will reduce these disparities, while at the same time offering liver transplant patients Hopkins-level clinical expertise and administration in a lower cost setting than the three existing transplant centers in these two DSAs.

The need for a second transplant center in the WRTC is demonstrated by data concerning volume, access, acuity, supply, and wait listing. *First,* the only transplant center in the WRTC DSA serves a population of 5.4 million people (1.5 million, or 40%, more than the LLF DSA). Yet that single program performs far fewer liver transplants than the two LLF transplant programs. *Second*, access in the WRTC is restricted. This is made clear by the fact that in 2015 (the most recent year for which this data is available), more than half of WRTC transplant recipients left the WRTC to obtain a transplant. By comparison, only 7% of LLF residents obtained their liver transplant outside the LLF. *Third*, the single WRTC facility performs transplants on healthier adult patients than either of the two LLF programs—even though the outcomes at all three centers are comparable. *Fourth*, the WRTC produces less than 1/3 the supply of donor livers than the LLF produces, and that gap is growing. *Fifth*, WRTC residents stand a lower chance of being wait-listed, a necessary step for receiving a liver transplant. Currently, there are three times as many names on the LLF wait list than on the WRTC wait list.

These striking disparities are not coincidences. Rather, they are what academic research and recent transplant experience in the District of Columbia indicate are the result of a lack of competition within the single-center DSA. The proposed liver transplant service at Suburban will address the need for a second transplant program in the WRTC and reduce these disparities. Suburban will: (1) increase the total number of transplants in the WRTC; (2) allow more WRTC residents to obtain transplants within their DSA; (3) enable sicker adult patients to access transplantation; (4) increase the supply of donated organs; and (5) place more patients on the WRTC wait list. The data also show that these results can be obtained without causing less desirable outcomes. In short, competition among transplant programs within a DSA is a tide that raises all boats.

The two million Marylanders living in the WRTC DSA are currently being denied equal access to liver transplant services compared to Maryland residents of the LLF. Granting Suburban's CON application will ensure greater access to transplant services, thereby bringing immediate and long-term benefits to WRTC residents.

II. LIVER TRANSPLANTATION

The liver is the largest internal organ. It is responsible for removing bacteria and toxins from the blood; preventing infection and regulating immune response; processing nutrients, medications, and hormones; making proteins; and producing bile, which helps the body absorb fats.

Patients experiencing liver failure suffer from symptoms including nausea, loss of appetite, fatigue, diarrhea, and jaundice (yellowing of the skin). As liver failure progresses, patients can experience hepatic encephalopathy (mental confusion) and other complications due to cirrhosis, which is scarring within the liver that impedes blood flow. Fluid can build up and cause painful swelling in the legs and abdomen. Patients may bruise or bleed easily and can develop enlarged veins in the lower esophagus or stomach which can begin to bleed without warning, causing a life-threatening situation. Patients also may develop painful gallstones. Some patients with advanced liver disease develop liver cancer, which is uniformly fatal. When the liver fails, a patient will die without a liver transplant.

Liver transplantation is a complex procedure for two reasons. First, patients in need of a liver transplant have a high level of acuity—they are very sick and have usually been in declining health for years, with health issues including chronic infection, malnutrition, obesity, and other co-morbidities. Second, there are many risks associated with liver transplants, including failure or rejection of the donated liver, bleeding (because of the extremely vascular nature of the liver), bile duct complications, blood clots, infection, and mental confusion or seizures. For these reasons, liver transplants are typically performed in a tertiary/quaternary care location by a multidisciplinary team of medical and surgical specialists. In spite of this complexity, the national one-year survival rate now exceeds 85%, and nearly 75% of liver transplant patients are alive five years after their transplants. However, an increasing incidence of liver diseases in recent years has led to a corresponding increase in the number of, and need for, liver transplants.

A. Trends in Disease Prevalence

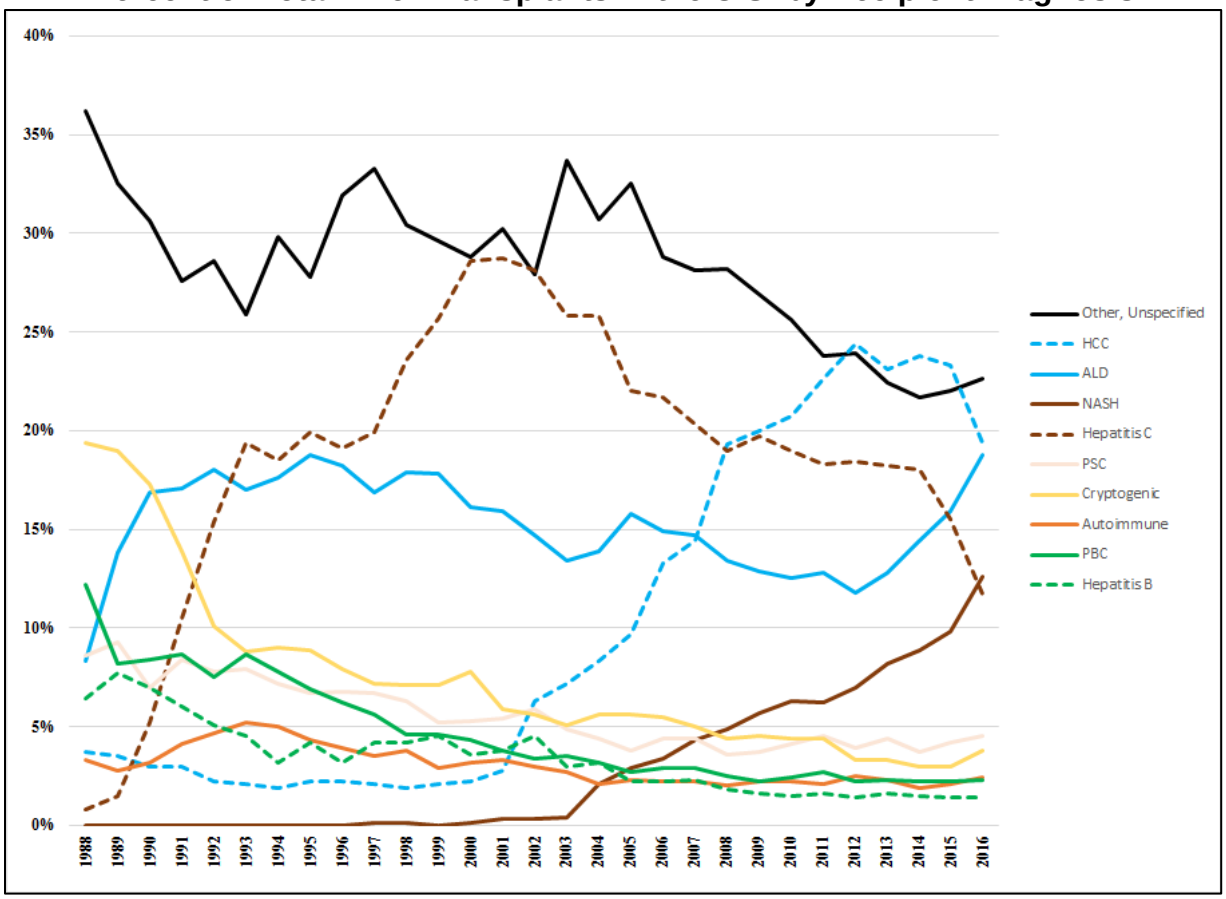
Liver disease is now the eleventh leading cause of death in this country, and rising. This phenomenon, coupled with an alarming increase in fatty liver disease, demonstrates the need for additional access to liver transplant services. While not every patient with liver failure will be a candidate for a liver transplant, there will always be many more candidates than there are suitable donor organs, and for these patients, the alternative to transplant is death.

1. Changing Landscape of Liver Disease

Data from the Organ Procurement and Transplantation Network ("OPTN") and the Scientific Registry of Transplant Recipients ("SRTR") reveal transplant trends that help forecast disease burden in the years to come. The figure below displays the changes over the last few decades in the primary causes of liver failure leading to transplantation.

The four most important points from this data are: (1) the high prevalence of hepatocellular carcinoma ("HCC," a primary liver cancer); (2) the continued persistence of Alcoholic Liver Disease ("ALD"); (3) the decreasing rate of Hepatitis C ("HCV"); and (4) the rapidly increasing rate of cirrhosis related to non-alcoholic fatty liver disease ("NAFLD") and its inflammatory counterpart steato-hepatitis ("NASH").

Percent of Total Liver Transplants in the U.S. by Recipient Diagnosis



Source: OPTN, Recipient Diagnosis, Accessed April 2017

The table below lists the diagnoses leading to liver transplantation in 2016. Some of these conditions are interrelated. For example, while HCV can damage the liver and cause cirrhosis, it is also a risk factor for hepatocellular carcinoma.

Diagnosis	2016
Other, Unspecified	22.6%
HCC	19.4%
ALD	18.8%
NASH	12.6%
Hepatitis C	11.7%
PSC	4.5%
Cryptogenic	3.8%
Autoimmune	2.4%
PBC	2.3%
Hepatitis B	1.4%
Cholangiocarcinoma	0.5%

Hepatocellular Carcinoma ("HCC")

HCC incidence has tripled in the United States in the past two decades and is the fastest rising cause of cancer mortality in this country. In this decade, the increase is primarily due to the maturation of Hepatitis C. As the obesity epidemic sweeps across the country, the incidence of NAFLD and its inflammatory counterpart NASH predict a continued rise in the incidence of HCC. Even as patients are cured of HCV with direct acting antivirals ("DAAs") (see below), they continue to remain at risk of developing HCC.[1] In 2016, HCC was associated with more than 19% of all liver transplants performed nationally.

The good news is that for patients with HCC, liver transplantation has the highest cure rate, and is therefore the treatment of choice for disease confined to the liver.

Alcoholic Liver Disease ("ALD")

ALD has been one of the top three diagnoses accounting for liver transplants from 1990 to 2016, with a steeper increase in the last five years. The National Institutes of Health published a report on trends in alcohol-related morbidity among hospital discharges between 2000 and 2012.[2] The most significant increase in alcohol-related discharges was in adults ages 45 to 64. In 2000, there were 90 alcohol-related discharges per 10,000 population, and in 2012 this rose to 146 per 10,000 population.

The increase in ALD as a primary diagnosis for liver transplant is nevertheless disproportionate to the prevalence of ALD in the population. This may reflect changes in behavior and attitudes with respect to wait-listing and transplantation for patients with ALD.[3] Acute alcoholic hepatitis unresponsive to medical therapy has an 80% mortality. Transplantation for the select few that present with adequate social support has been extremely successful, with relapse equal to or better than patients who have undergone a six-month abstinence period.[4]

[1] Conti, Fabio, *et al.* "Early occurrence and recurrence of hepatocellular carcinoma in HCV-related cirrhosis treated with direct-acting antivirals." *Journal of Hepatology* 65.4 (2016): 727-733.

[2] Chen, Chiung M., and Yi Hy. "Surveillance Report # 99: Trends in Alcohol-Related Morbidity Among Community Hospital Discharges, United States 2000–2012." Series National Institute on Alcohol Abuse and Alcoholism (NIAAA), Bethesda, MD (2014).

[3] Goldberg, David, *et al*. "Changes in the Prevalence of Hepatitis C Virus Infection, Nonalcoholic Steatohepatitis, and Alcoholic Liver Disease Among Patients With Cirrhosis or Liver Failure on the Waitlist for Liver Transplantation." *Gastroenterology* (2017), in press.

[4] Three-year Results of a Pilot Program in Early Liver Transplantation for Severe Alcoholic Hepatitis. Lee BP, Chen PH, Haugen C, Hernaez R, Gurakar A, Philosophe B, Dagher N, Moore SA, Li Z, Cameron AM. Ann Surg. 2017 Jan;265(1):20-29

Non-alcoholic Steatohepatitis ("NASH")

The proportion of transplants because of NASH is skyrocketing.[5] As a primary diagnosis in liver transplant recipients, NASH was negligible as recently as 2003. Since then, it has risen to 13% of liver transplants performed in 2016, surpassing Hepatitis C.

Similarly, the incidence of a precursor disease, non-alcoholic fatty liver disease ("NAFLD"), is also on the rise in the United States and globally. The CDC estimates that 30-40% of adults in the U.S. have NAFLD, and about 3-12% of adults have NASH.[6] This growth has been linked to the rising incidence of obesity and metabolic syndrome. Experts predict that NASH will become the leading cause of liver disease and cirrhosis in the next decade as a result of the increasing rates of obesity.[7] In fact, despite advances in the treatment of HCV (see below), "there has been an increase in the burden related to NASH to a degree almost as great as the decline for HCV, occurring parallel to the well-described increase in prevalence of obesity."[8]

Hepatitis C ("HCV")

Though there are more than 3 million people in the U.S. with chronic hepatitis C infection, HCV is declining as the primary indication for liver transplant. HCV peaked as the primary cause of liver transplant in 2001 at 29% and has steadily declined to 12% in 2016. This declining trend was evident even prior to the availability of DAAs that have come to market in the past few years. Despite this, however, HCV remains a significant disease burden.

To better understand barriers to reducing the prevalence of chronic HCV, Yehia *et al.* developed the "Hepatitis C Treatment Cascade", depicted below.[9]

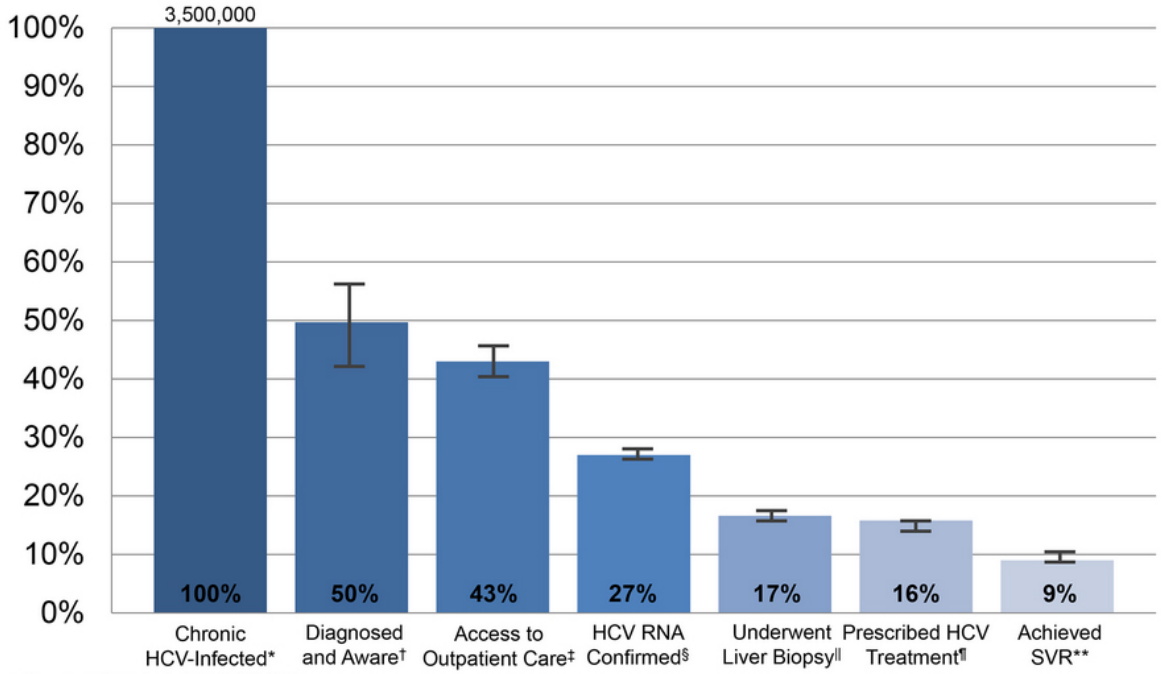
[5] Ibid.

[6] Spengler EK, Loomba R. Recommendations for diagnosis, referral for liver biopsy, and treatment of nonalcoholic fatty liver disease and nonalcoholic steatohepatitis. Mayo Clinic Proceedings. 2015;90(9):1233–1246.

[7] Goldberg *et al*. (2017).

[8] Ibid.

[9] Yehia, Baligh R., *et al*. "The treatment cascade for chronic hepatitis C virus infection in the United States: a systematic review and meta-analysis." PLOS one 9.7 (2014): e101554.



* Chronic HCV-Infected; N=3,500,000.
† Calculated as estimated number chronic HCV-infected (3,500,000) x estimated percentage diagnosed and aware of their infection (49.8%); n=1,743,000.
‡ Calculated as estimated number diagnosed and aware (1,743,000) x estimated percentage with access to outpatient care (86.9%); n=1,514,667.
§ Calculated as estimated number with access to outpatient care (1,514,667) x estimated percentage HCV RNA confirmed (62.9%); n=952,726.
|| Calculated as estimated number with access to outpatient care (1,514,667) x estimated percentage who underwent liver biopsy (38.4%); n=581,632.
¶ Calculated as estimated number with access to outpatient care (1,514,667) x estimated percentage prescribed HCV treatment (36.7%); n=555,883.
** Calculated as estimated number prescribed HCV treatment (555,883) x estimated percentage who achieved SVR (58.8%); n=326,859.
Note: Only non-VA studies are included in the above HCV treatment cascade.

Yehia estimated the number of individuals chronically infected with HCV to be 3.5 million,[10] a value that may be on the high end of some estimates because they attempted to account for certain high-risk groups (individuals incarcerated, homeless, or institutionalized) often left out of other prevalence analyses. Of the approximately 3.5 million people with HCV, the authors estimated:

- 50% are diagnosed and aware of their infection.
- 43% are diagnosed, aware of their infection, and have access to outpatient care.
- 9% are diagnosed, aware of their infection, have access to outpatient care, have received HCV therapy, and achieved Sustained Virological Response ("SVR").[11]

The advent of DAAs as a treatment for HCV is not likely to result in a significant reduction of this disease burden in the immediate future. That is because DAAs do not necessarily close the gaps in the cascade pertaining to awareness, diagnosis, HCV RNA confirmation, and access to outpatient care. In addition, there are unresolved obstacles to availability of DAAs. Dr. Mark Sebastian Sulkowski, Professor of Medicine and Medical Director of the Viral Hepatitis Center at Johns Hopkins Hospital, estimates that of the more than 3.2 million individuals with a chronic HCV infection, only about 80,000 (2.5%) have access to these new drugs. One reason for this low rate of DAA access may be cost. These regimens currently cost up to $90,000, limiting access to

[10] Ibid, pp 2-4, citing NHANES data collected 1999-2002.

[11] The success of HCV treatment is defined as an undetectable HCV viral load test six months after completing a successful course of SVR.

treatment even for those with insurance.[12]

Projections about HCV disease burden are further complicated by uncertainty concerning future changes to the Affordable Care Act and Medicaid which make it difficult to project insurance coverage rates. However, as of 2015, only an estimated 13.8% of baby boomers had been tested for HCV, an underwhelming increase from 12.3% in 2013.[13]

2. Chronic Liver Disease Prevalence

Studies have concluded that while the predominant diagnoses leading to liver transplant have shifted over time, the prevalence of liver disease in general continues to increase. Kim *et al.* confirmed this continued increase even as they observed a decrease in age-adjusted death rates from all other causes, including cancer, cardiovascular disease and diabetes.[14] Udompap also concluded that the net result of these shifts within disease prevalence was an overall increase in liver disease burden:

> The overall burden, including mortality, associated with [chronic liver disease] has increased in the United States. On the basis of available epidemiologic data, viral hepatitis, [alcoholic liver disease], and NAFLD are the most common etiologies for [chronic liver disease]. Over the foreseeable future, the burden of viral hepatitis is expected to decrease and that for NAFLD to increase, where no significant change in [alcoholic liver disease] is anticipated.[15]

This was also the conclusion of Younossi who found "strong evidence for the steadily increasing prevalence of [chronic liver disease] in the United States."[16]

In sum, though the reasons for chronic liver disease requiring transplantation have changed over time, the incidence of disease-caused liver failure is growing at an alarming rate. The need for transplantation services is now greater than ever.

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[12] https://www.usatoday.com/story/news/2017/03/08/baby-boomers-hepatitis-c-tests/98857314/

[13] Jemal, Ahmedin, and Stacey A. Fedewa. "Recent Hepatitis C Virus Testing Patterns Among Baby Boomers." *American Journal of Preventive Medicine* (2017).

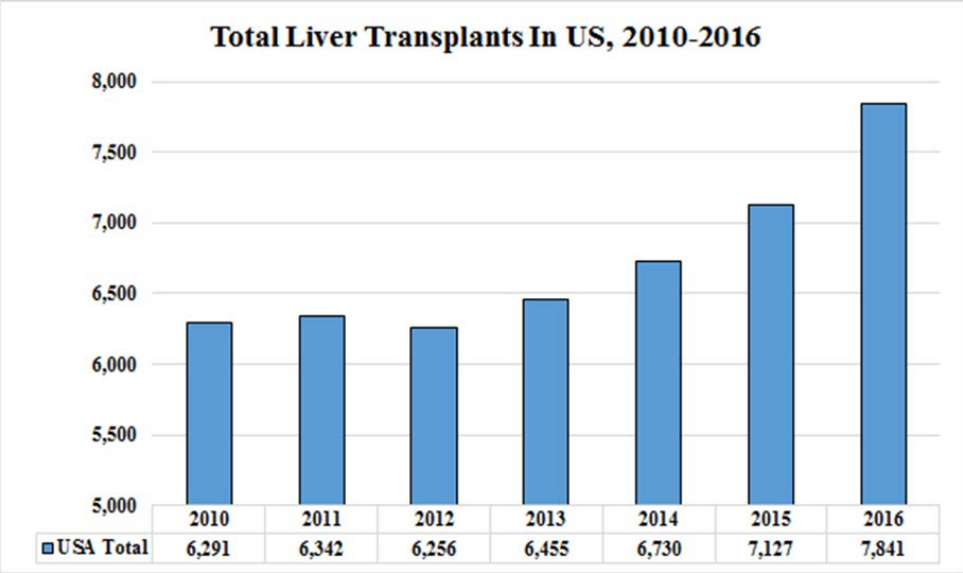
[14] Kim, Ejaz, Tayal, Spolveratoo, Bridges, Anders, and Pawlik. "Temporal Trends in Population-Based Death Rates Associated with Chronic Liver Disease and Liver Cancer in the United States Over the Last 30 Years." *Cancer* (October 1, 2014), p 3061.

[15] Udompap, D Kim, and WR Kim. "Current and Future Burden of Chronic Nonmalignant Liver Disease." *Clinical Gastroenterology and Hepatology* (2015)13:2031-2041, p 2039.

[16] Younossi *et al*., "Changes in the Prevalence of the Most Common Causes of Chronic Liver Diseases in the United States from 1988-2008." *Clinical Gastroenterology and Hepatology* (2011)9:524-530, 529.

B. The Growing Need for Transplants

As a result of the growing incidence of liver disease, the volume of liver transplants nationally has also been increasing steadily since 2012:



Source: OPTN Build Advanced[17]

Like other types of solid organ transplants, the need for liver transplants in the United States greatly exceeds the supply of organs. As of February 2017, there were more than 14,000 candidates on the national liver waiting list in the United States. The average wait time for a candidate on this list is 11 months.[18] The wait times at transplant centers vary due to a number of factors, beyond the shortage of supply, including: blood type, tissue type, body mass index, medical urgency, time on the wait list, distance between patient's hospital and a potential donor organ, number of local area donors, and individual transplant center criteria for accepting organ offers.

[17] These transplants were performed at 136 centers. There were 84 centers that performed adult-only transplants, 27 centers performed pediatric-only transplants, and the remaining 25 performed both adult and pediatric transplants.

[18] Source: http://www.donors1.org/learn2/organs/liver/

C. Donor Types

Liver transplants can be subdivided by donor type (living or deceased), age (adult or pediatric), and by the complexity of the procedure (multi-organ or single-organ).

Living donor liver transplantation ("LDLT") was introduced for pediatric recipients in 1989 to overcome the severe shortage of deceased donor organs across the world.[19] In 1993 the first adult-to-adult LDLT was performed using a right lobe, proving live donor liver transplantation feasible for adults in areas of the world where deceased donors are very limited. In adults, LDLT involves removing (usually) the right lobe of the liver from a healthy donor and implanting it in the recipient, where the whole diseased liver has been removed. Both liver segments grow to near normal size in a relatively short time. Although in some areas of the world LDLT continues to be the only modality, in the United States it remains a small percentage. According to OPTN, in 2016, only 283 adult LDLT were performed nationally, representing 3.6% of the total number.

Centers performing LDLT often face ethical issues regarding donor safety, because a healthy adult donor must undergo a complicated major surgery and the loss of a liver lobe without receiving any health benefit. There is a risk associated with the surgery to remove the liver segment from a living donor, appreciably higher than the risk associated with live kidney donation. All potential living donors are educated about the risks and evaluated psychologically to ensure that living donation is appropriate for the individual donor. Unfortunately, there have been a number of deaths after living donation. The risk of death is estimated to be 0.2%. Five-year survival for living donor liver transplants is around 80%, equal to deceased donor transplants.

Deceased donor liver transplants ("DDLT") makes up the vast majority of liver transplants in the United States. According to OPTN, in 2016, 6,985 adult DDLT were performed. Deceased donation results from victims of massive head injuries that result in brain death or near brain death. Unlike vegetative states, brain death occurs when blood no longer flows to the brain, a condition that is irreversible.

The diagnosis of brain death often triggers a referral to the Organ Procurement Organization ("OPO"), which is responsible for serving as the link between a donor and the transplant centers. This organization is designated by CMS to serve this role within a geographical area.[20] Representatives from the local OPO meet with the family members of patients, who either follow the transplant directive of the patient (if known) or make a decision on behalf of the patient whether to donate organs. Potential deceased donors undergo extensive screening to look for evidence of organ disease, cancer, or infection. All donors are tested for hepatitis, HIV, and other infections.

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[19] Strong RW, Lynch SV, Ong TH, Matsunami H, Koido Y, Balderson GA. Successful liver transplantation from a living donor to her son. *N. Engl. J. Med.* 1990; 322:1505-7.

[20] In addition to being the liaison between donors and recipients, OPOs are also responsible for: procurement of organs for transplantation; promotion of organ donation; and the identification of donors; as well as the retrieval, preservation, and transportation of organs for transplantation.

If the organ is suitable for transplant and consent obtained for donation, the transplant centers are then notified. The allocation of the liver is then prioritized by severity of illness, which is represented by the MELD score of the listed patients. In other words, the patients in the local area with the highest MELD score, irrespective of their designated transplant center, will receive the organ.

D. Transplant Process and Priorities

The process of determining if a patient is an appropriate candidate to receive a liver transplant requires input from a range of specialists who review the patient's medical, family, social, and psychological history, and perform an extensive physical evaluation. Tests that help in the determination of eligibility for a transplant include:

- Computed tomography ("CT") or MRI of the liver to assess vasculature and to rule in/out liver cancer.
- Echocardiogram and stress test to assess heart function and to ensure it is adequate to withstand the cardiac stress associated with liver transplantation.
- A myriad of blood tests to determine blood type, clotting ability, biochemical analysis including liver function, viral screening that includes HIV and hepatitis, and other screening tests.

To undergo a deceased donor liver transplant, a patient must first be referred to a liver transplant center. Next, the patient is evaluated at that center and his/her candidacy for transplantation determined by the center's multi-disciplinary team. If a center deems a patient to be a transplant candidate, the center adds the patient to its wait list. When a patient is listed with a transplant center, he or she is simultaneously listed with the OPO. Each OPO serves a single DSA. A DSA will have various numbers of transplant centers within their geographical borders. All centers within an OPO add patients to the same, unitary OPO list; for that reason, there is no reason for patients to seek listing at multiple centers within the same OPO. Patients may seek to be evaluated and listed in more than one OPO, which may increase their chances of getting a liver transplant by tapping into a separate pool of donor organs

Patients are listed according to blood type, body size, and medical condition, as measured by their MELD score. The MELD score is derived based on three blood tests: creatinine, bilirubin, and INR. There is a PELD score (pediatric end-stage liver disease) for children based on blood tests for albumin, bilirubin, and INR. MELD and PELD scores range from 6 to 40. Higher scores reflect a higher disease severity. All patients on wait lists are consistently reevaluated and MELD/PELD scores recalculated in an effort to transplant the sickest patients in as short a time as possible. In this current MELD allocation scheme, waiting time is deemphasized as severity of illness takes precedent. The 3 months predicted mortality associated with MELD score is depicted below:

MELD	3-Month Mortality
7	1%
20	8%
24	10%
26	15%
29	20%
31	30%
33	40%
35	50%
37	60%
38	70%
40	90%

A patient remains on the wait list until he or she matches with a deceased donor liver through the OPTN Match System operated by the United Network for Organ Sharing ("UNOS"). Under federal law, UNOS sets organ allocation policy based on (a) MELD/PELD scores, and (b) age.[21]

When a match occurs, the patient's transplant surgeon acts as a surrogate decision maker and either accepts or rejects the offered organ. If the transplant surgeon accepts the offered organ, the patient is transplanted at the center. If the transplant surgeon rejects the offered organ, the patient remains on the wait list and the organ is offered to the next individual to match on the wait list.

Organs are offered for transplant according to established priority rules. After a list of patients who match the donor is generated, the organ is offered to the first patient on the match list (highest MELD score) and continues down the list until an organ is matched. Organs not matched within the DSA are shared with patients within the UNOS region, and organs not matched within the region are shared with other regions of the country.

UNOS has divided the United States into 11 separate sharing Regions and 58 separate DSAs, which are used for organ allocation (see "Allocation," below). In any DSA, when a deceased donor liver becomes available for transplant, that organ is most commonly matched with, and subsequently transplanted by, a center within the same DSA. That is because individuals on the local wait list are typically given priority ("local priority") over those listed in other DSAs within the same Region, or those listed in other Regions. Status 1 patients are given top priority on a wait list. These patients have a life expectancy of less than a few days without a transplant. The system also considers the source of the organ in its match process, differentiating between organs obtained at a national, regional, or local level. The result is a complex model that combines the source of the organ and the acuity level of the patient with the aim of getting the sickest

[21] UNOS has created three liver allocation age groups based on the age of the donor: child (0-10 years), adolescent (11-17 years), and adult (≥ 18 years).

individuals access to a liver in the shortest amount of time in the most efficient manner.

There are three exceptions to local priority that can result in the export or import of deceased donor livers:

1. Status 1: Patients with the most pressing need for a liver transplant within the OPTN Donor Matching System are given priority within a region ("Regional Priority"). A Status 1 patient thus has priority above other individuals within the DSA, as well as patients with a less urgent designation within their region.

2. Physician Preference: A liver may be procured locally and matched locally but rejected by the physician for clinical reasons beyond the match.[22] The next individual to match with the organ within the Region is then offered the organ.

3. Share 35: Started in June 2013, a new policy, "Share 35", gives priority to patients with a MELD score of 35 or greater. As a result, deceased donor livers are offered first to such patients within a Region, ahead of those within the Region with a lesser MELD score but still behind Status 1 designees.

[22] There are several variables which can influence whether a physician determines that an organ is an appropriate fit for a given patient. Goldberg found wide variability in transplant center behavior regarding acceptance of donated livers based on physician preference, with acceptance rates for patients ranked first on a waitlist ranging from 15.7% to 58.1%. Goldberg, David S., *et al*. "Liver transplant center variability in accepting organ offers and its impact on patient survival." *Journal of Hepatology* 64.4 (2016): 843-851. Not surprisingly, patients at centers with lower acceptance rates have significantly higher risks of dying without a transplant. *Ibid*.

E. Allocation

UNOS has divided the country into 11 separate geographical sharing Regions which, in turn, are divided into 58 separate DSAs.

1. 11 Sharing Regions

The 11 UNOS sharing Regions are:

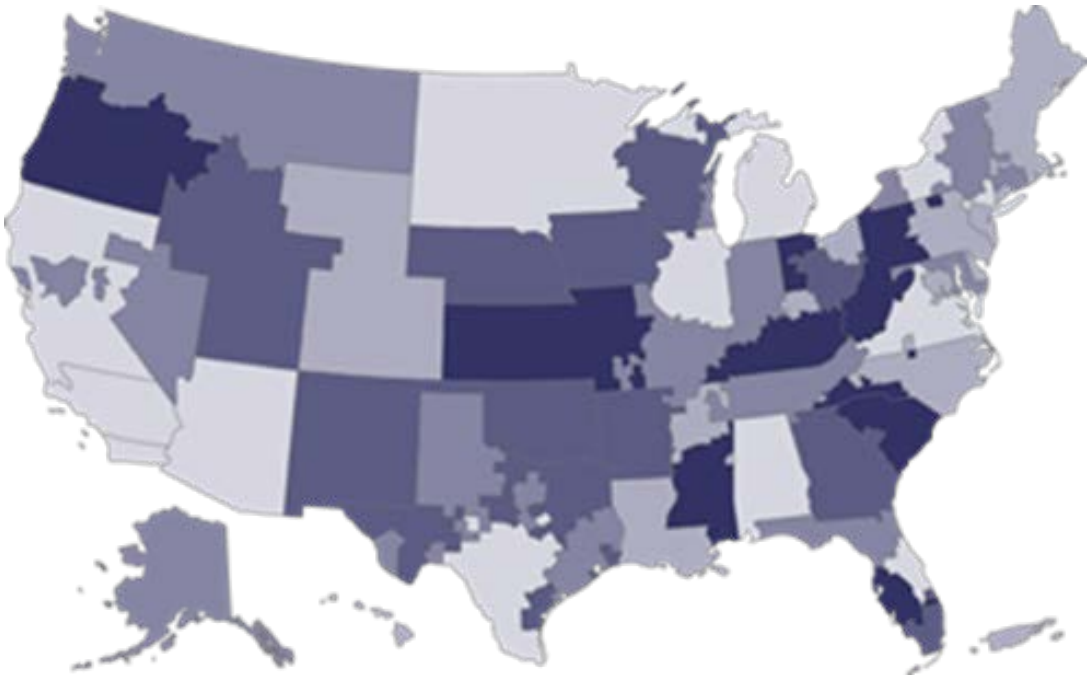
Image Source: http://www.news.pitt.edu/news/Schaefer-donor-liver-redesign

UNOS designed these Regions based on geographic considerations and the working relationships between transplant centers. Thus, while regions mostly cover entire states, some regions include counties in bordering states (e.g., Region 2 includes all of the District of Columbia and the states of Delaware, Maryland, New Jersey, Pennsylvania, and West Virginia, as well as counties in Northern Virginia, while the rest of Virginia is in Region 11). However, because regions were designed based on geography and not on the supply and demand of donor organs, there are "[s]evere geographic disparities in allocation of livers for transplant [which] persist in the United States."[23]

[23] Gentry, Sommer E., *et al*. "Addressing geographic disparities in liver transplantation through redistricting." *American Journal of Transplantation* 13.8 (2013): 2052-2058.

2. 58 Donation Service Areas

UNOS has subdivided its 11 Sharing Regions into 58 DSAs:



OPTN/SRTR 2015 Annual Data Report
Image Source: https://www.srtr.org/media/1025/dsa_map.png

A DSA is a geographical area served by a single OPO. The DSA and OPO are usually referred to by the same name, e.g., the "Washington Regional Transplant Community" or "WRTC" refers to the geographic area designated by UNOS (WRTC DSA) and to the OPO serving that DSA (WRTC OPO). DSAs can have one or more transplant centers.

Like UNOS Regions, DSAs also reflect historical working relationships, not the supply and demand of organs in that geographic area. As a result, DSA designations have resulted in disparities in organ access. These disparities in access are reflected in the table below, which shows the number of transplant centers serving each DSA in Region 2, and the number of centers per capita for each DSA:

Region 2					
DSA / OPO	**Areas Serviced**	**Liver Transplant Centers**	**DSA Population (2014 Census)**	**Population Ranking (58 DSAs)**	**Centers Per Capita (1 center per)**
Washington Regional Transplant Community	DC Northern VA Southern Maryland	1.) Georgetown	5,405,251	25th highest	5,405,251
Living Legacy Foundation	Maryland	1.) Johns Hopkins 2.) University of Maryland	3,886,783	34th highest	1,943,392
New Jersey Organ and Tissue Sharing Network	New Jersey	1.) Our Lady of Lourdes 2.) University Hospital	7,093,807	14th highest	3,546,904
Center for Organ Recovery and Education	Pennsylvania West Virginia Southern New York	1.) Allegheny General 2.) U. of Pittsburgh 3.) VA of Pittsburgh 4.) Children's UPMC (Peds)	5,576,711	21th highest	1,394,178
Gift of Life Donor Program	Pennsylvania Delaware New Jersey	1.) Albert Einstein 2.) Geisinger 3.) Penn State/Hershey 4.) Thomas Jefferson 5.) Temple 6.) U. of Pennsylvania 7.) Hahnemann 8.) Alfred I duPont (Peds) 9.) Children's Phil. (Peds)	11,434,142	6th highest	1,270,460

Table Sources: SRTR OPO-Specific Reports

As shown, two of these DSAs are served by two liver transplant centers, one DSA is served by four liver transplant centers, and one DSA is served by nine transplant centers.

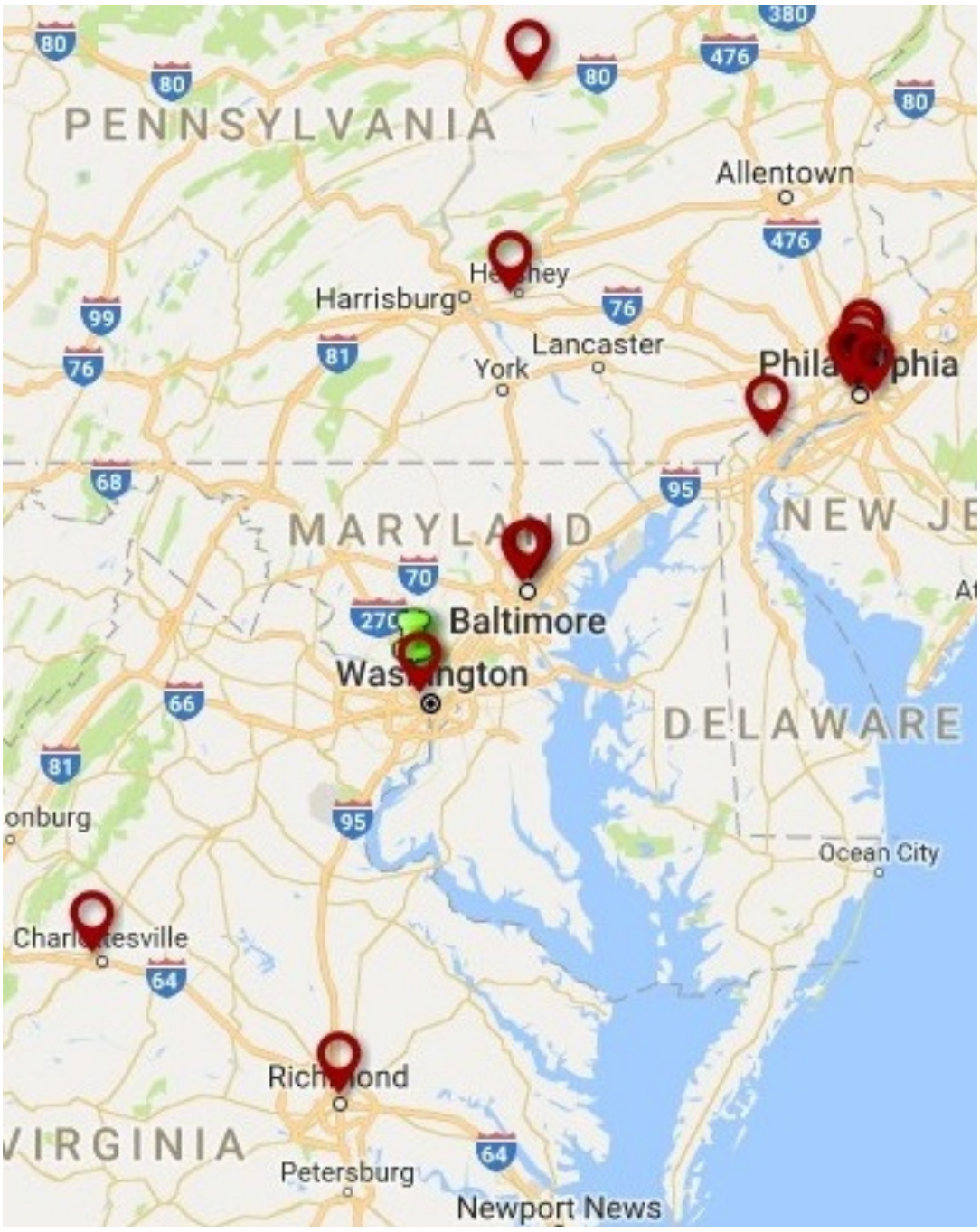
The WRTC, however, is served by a single transplant center. The most comparable Region 2 DSA by population—the Center for Organ Recovery and Education DSA which serves all of West Virginia, western Pennsylvania and Chemung County in New York—has four liver transplant centers.

These disparities are even more striking when viewed in the context of centers per capita. For three of the region's five DSAs, there is 1 transplant center for every ≤ 2 million residents and a fourth DSA with 1 center for every 3.5 million residents. The WRTC however has only one center for the entire population of 5.4 million.

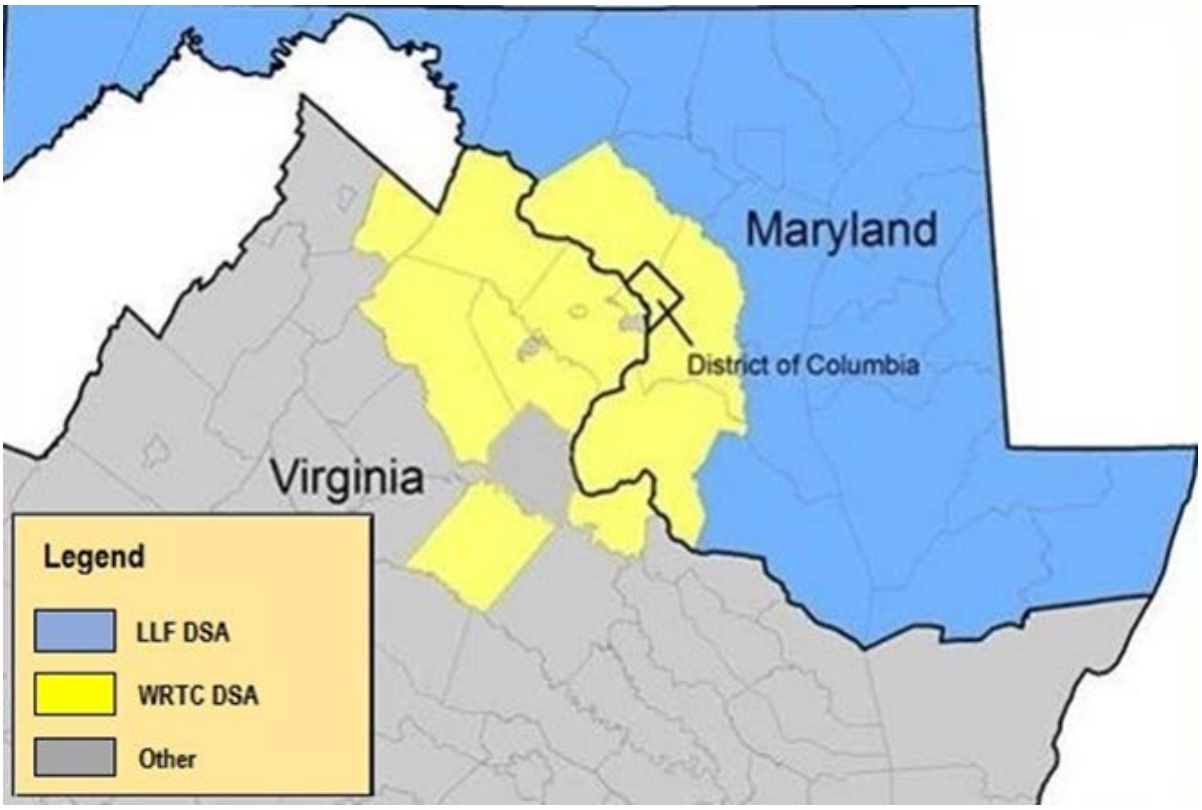
3. Liver Transplant Centers In and Near Maryland

Maryland is split into two DSAs: The WRTC and The Living Legacy Foundation ("LLF"). The LLF DSA includes all Maryland counties except for Prince George's County, Montgomery County, and Charles County. Two transplant centers operate in the LLF: The Johns Hopkins Hospital and the University of Maryland Medical Center. The WRTC DSA is served by a single transplant center, MedStar Georgetown University Hospital ("Georgetown" or "MGUH" or "G'town").

The map below depicts all liver transplant programs, including adult, pediatric, and combined adult-pediatric, within a 150-mile radius of Bethesda (where Suburban Hospital is located). A list of these centers, their distance from Bethesda, and their associated OPO is attached in Exhibit 2.



The map below depicts the geography of the DSAs of the two OPOs that serve Maryland, the LLF and the WRTC, (a list of counties in each DSA is included in Exhibit 3.



The three Maryland counties in the WRTC DSA (Prince George's, Montgomery, and Charles Counties) account for more than one-third of Maryland's total population (2.11 Million of 6.01 Million). This means that over one-third of the population in Maryland resides in counties whose hospitals are designated as donor hospitals of the WRTC DSA.

III. NEED FOR NEW TRANSPLANT SERVICE AT SUBURBAN

A. Summary

There are 5.5 million residents of the WRTC DSA, including more than 2 million Maryland residents. Yet to serve this large population, there is currently only one liver transplant center, Georgetown. By contrast, the 3.9 million residents of the LLF DSA are served by two liver transplant centers, Johns Hopkins Hospital and the University of Maryland.

Data reflecting liver transplants performed and liver transplants received within these two DSAs reveal striking disparities in transplant volume, access, acuity, organ supply, and wait lists:

Volume: Despite serving a larger population, the single WRTC transplant facility performs fewer liver transplants than the two LLF facilities, and this gap is widening.

Access: A similar discrepancy exists with regard to access. LLF residents are nearly four times more likely to obtain a transplant within their DSA than WRTC residents are to receive a transplant within their DSA.

Acuity: The average MELD score for patients receiving a transplant in the WRTC center is much lower than for patients receiving a transplant in the LLF centers, meaning that the single WRTC facility tends to perform transplants on healthier adult patients.

Supply: The WRTC procures fewer livers than the LLF and exports a higher proportion of the livers it procures. The WRTC center also imports fewer livers per year. This discrepancy is also growing.

Wait List: The LLF waitlist currently has more than three times as many patients as the WRTC wait list.

A likely contributor to some or all of these disparities is the absence of competition within the WRTC DSA. As research cited by the Maryland Health Care Commission has concluded, competition leads to more patients on wait lists and consequently more patients receiving transplants, while "DSAs with a single transplant center were . . . more likely to have higher patient mortality and worse graft outcomes." SHP Organ Transplant Services Chapter at 22. Although this same research suggests that competition can result in less desirable outcomes (id.), competition has not led to worse outcomes in the LLF DSA, and all three area transplant centers are meeting or exceeding national outcome standards. Any risk associated with competition being introduced into the WRTC DSA can be managed effectively, as the Johns Hopkins Comprehensive Transplant Center ("CTC") has done in the LLF DSA.

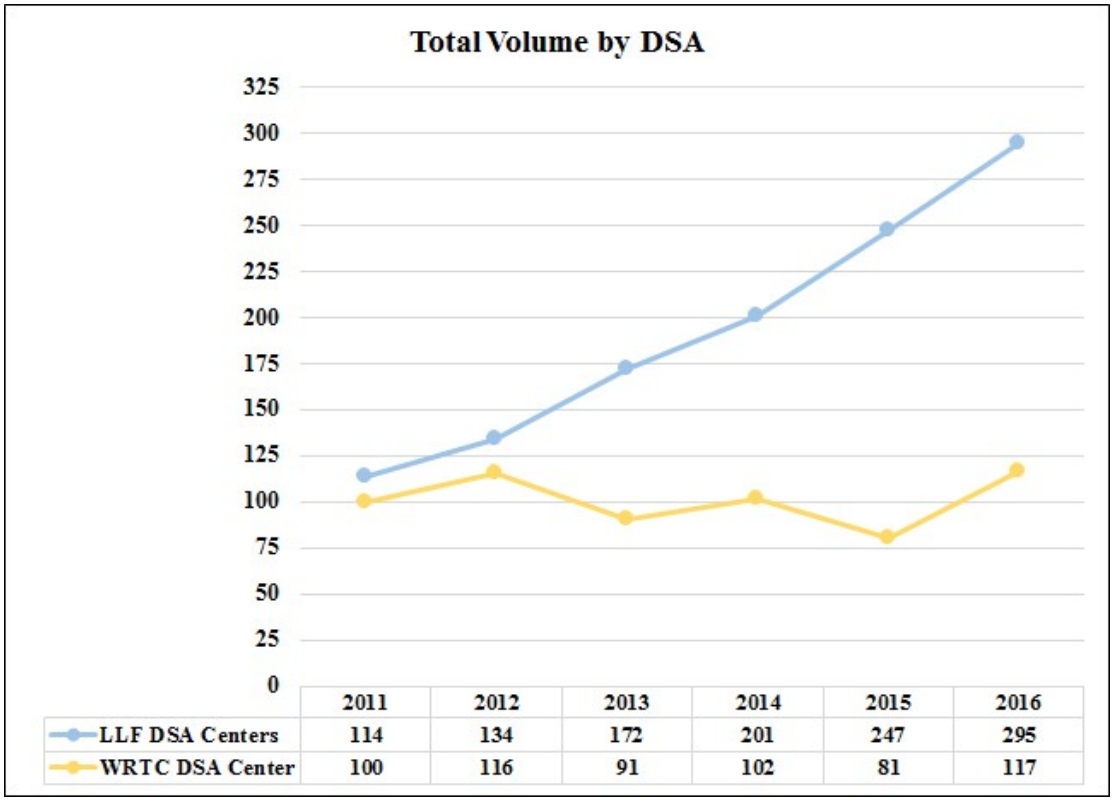
Suburban Hospital's proposed liver transplant program provides an opportunity to address the unmet need for liver transplant services within the WRTC. The data demonstrate that, if the new transplant service at Suburban achieves performance comparable to the Johns Hopkins CTC, more Maryland residents in the WRTC would receive transplants, and more Maryland residents in the WRTC would receive transplants closer to home. Approval of Suburban's CON application would therefore advance the Commission's goal to "safely and effectively meet the health care needs of appropriate patients." SHP Organ Transplant Services Chapter, Policy 1.

B. Disparities Are Pronounced Between the LLF and the WRTC Among Indicators of Need.

There are existing—and growing—disparities between the LLF and the WRTC DSAs in transplant volume, access to transplant services, acuity of transplant patients, organ supply, and wait listing that a second transplant center in the WRTC would reduce. Each of these disparities is discussed in detail, below.

1. The Growing Gap in Transplant Volume

The population of the WRTC DSA (5.5 million) is 40% greater than the population of the LLF (3.9 million). Yet the LLF centers performed more than twice as many liver transplants in 2016:

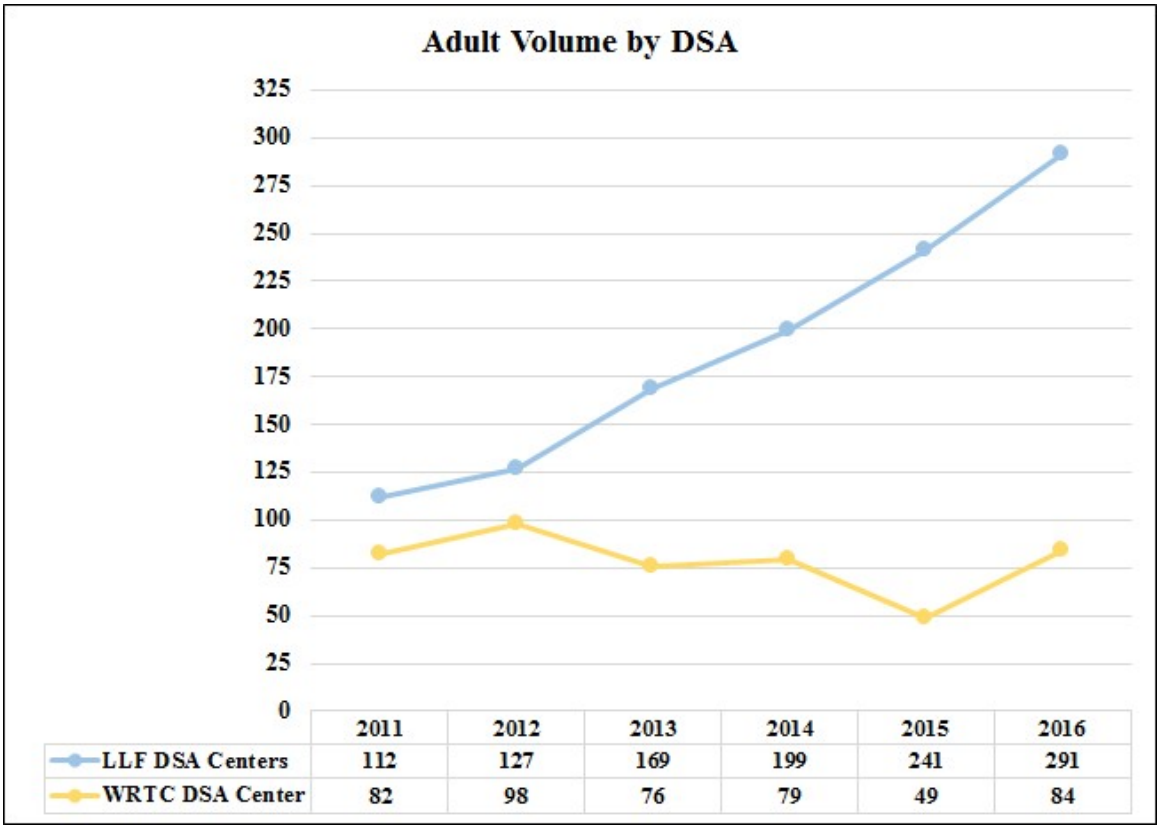


	2011	2012	2013	2014	2015	2016
LLF DSA Centers	114	134	172	201	247	295
WRTC DSA Center	100	116	91	102	81	117

Source: OPTN

As shown, this gap between the two DSAs has been widening since 2012. While the total number of liver transplants performed at the two LLF centers has increased every year and has more than doubled from 2011 to 2016 (114 to 295), total transplants at the single WRTC facility has remained fairly constant at approximately 100 per year with minor fluctuations (± 15 per year) for six years.

This same difference, and the same growing gap, exists when comparing only adult transplants:



	2011	2012	2013	2014	2015	2016
LLF DSA Centers	112	127	169	199	241	291
WRTC DSA Center	82	98	76	79	49	84

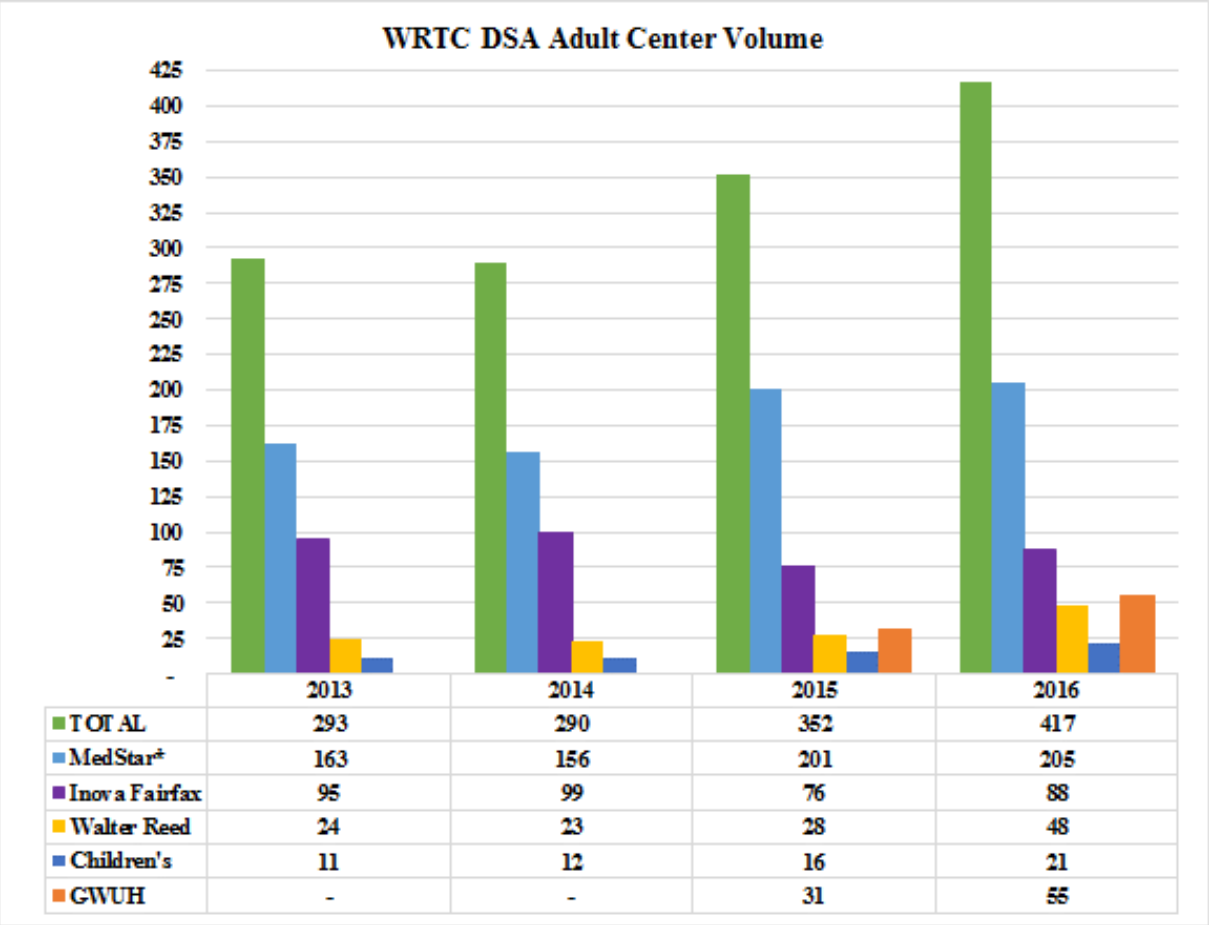
Source: OPTN

A recent decision by the State Health Planning and Development Agency for the District of Columbia ("SHPDA") shows how the addition of a second transplant service in an area previously served by a single center can result in increased volumes, for both the new center *and the existing center*. The issue before SHPDA was whether to allow an earlier-granted CON for a kidney transplant service at George Washington University Hospital ("GWUH") to remain in place.[24] Before GWUH began kidney transplants in

[24] SHPDA originally denied the CON, but in 2014, the Office of Administrative Hearings ("OAH") reversed and directed SHPDA to issue the CON. MedStar appealed to the District of Columbia Court of Appeals, which in 2016 reversed the OAH's order. However, because GWUH had been operating the kidney transplant service for two years under the OAH order, the Court of Appeals remanded the matter to SHPDA in order to determine whether to allow the CON to remain in place, or to modify or retract the CON "in light of current circumstances." See SHPDA Notice of Official Action, CON No. 12-2-8 (March 30, 2017) ("SHPDA Decision") at 1-2 (copy attached as Exhibit 4).

2015, the only other kidney transplant services for adult non-military patients in the District were operated by MedStar.[25]

The evidence presented to SHPDA was that the addition of a transplant service had resulted not only in new kidney transplant volume at GWUH, *but also led to MedStar increasing its transplant volume* by more than 30% over pre-competition years:



	2013	2014	2015	2016
TOTAL	293	290	352	417
MedStar*	163	156	201	205
Inova Fairfax	95	99	76	88
Walter Reed	24	23	28	48
Children's	11	12	16	21
GWUH	-	-	31	55

*****MedStar = MGUH and WHC
Source: OPTN

The beneficial effect of this competition was one of the principal reasons cited by SHPDA in its March 30, 2017 decision allowing the new transplant service at GWUH to remain in place. *See* SHPDA Decision at 14 ("the number of transplants performed at MedStar … has not been negatively affected. In fact, the number of transplants performed at MedStar over the last two years has increased, not decreased."). There is every reason to believe that similar beneficial effects on transplant volume will result from increased competition for liver transplants in the WRTC.

[25] A second kidney transplant service operated by MedStar at Washington Hospital Center ("WHC") closed in 2015, making Medstar Georgetown the only operating kidney transplant center in the District before GWUH's center began operations. The WRTC had another adult non-military kidney transplant center, at Inova Fairfax Hospital. Additional WRTC DSA kidney transplant centers include Children's National (pediatric-only) and Walter Reed (military-only).

2. Disparity in Access to Transplant Services

Volume is only the beginning of the analysis, however, because an individual transplanted at any of the three transplant centers in the LLF and WRTC could reside anywhere in the nation. When comparing the relative access to transplantation services for residents of the two DSAs, the need for an additional transplant facility in the WRTC service area becomes even clearer.

All Patients – Overall Access

Patient access is measured by looking at a patient's DSA of origin and quantifying how many residents were transplanted, as well as whether those patients were transplanted at a local center (Local Access) or if they left their DSA of residency to access services elsewhere (Overall Access).

The table below analyzes Overall Access, by quantifying the number of LLF residents and WRTC residents who received a liver transplant in 2015 [26] and identifies the center that performed the transplant:

CY	DSA	JHH	UMMS	G'town	Other Centers	TOTAL
2015	LLF	57	104	7	5	173
	WRTC	22	25	62	25	134

In other words:

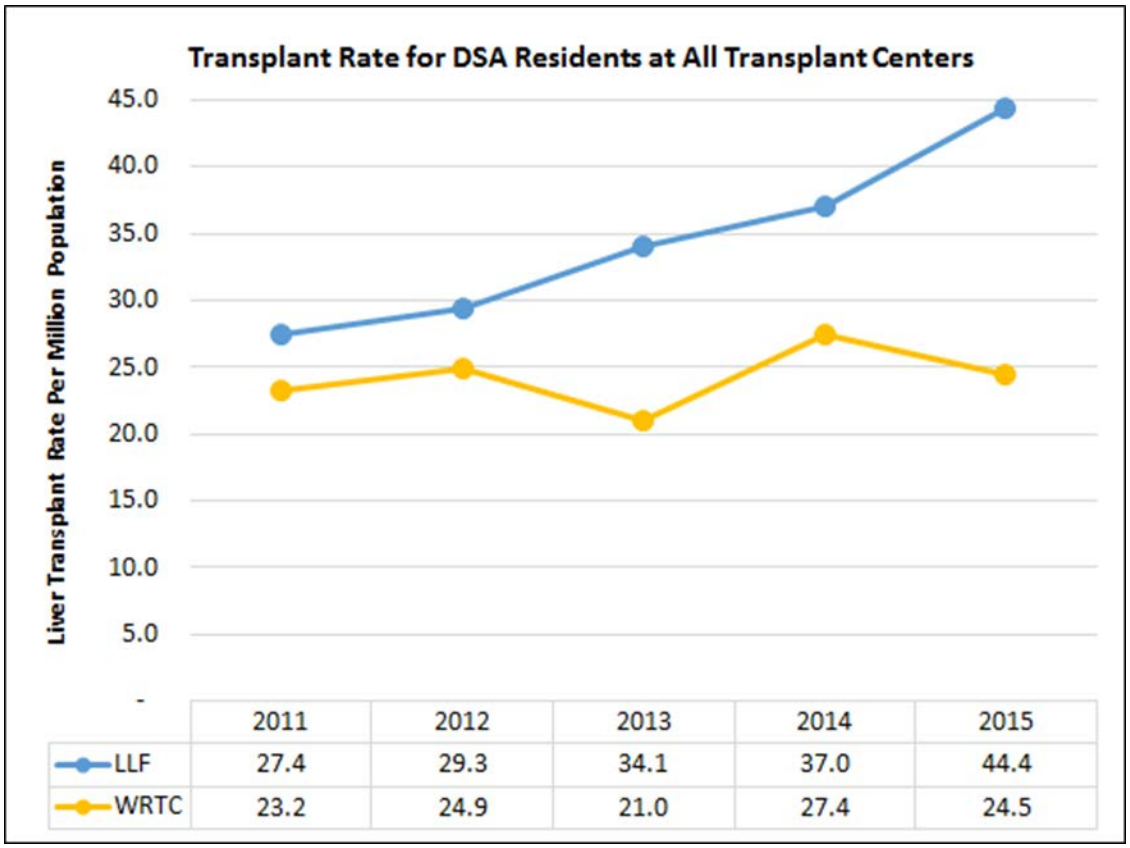
- Of the 173 LLF residents who received a liver transplant in 2015, 161 (57+104) or 93% received the transplant at one of the two LLF facilities.
- Only 12 LLF residents (7+5) or 7% were transplanted at a non-local center
- By comparison, only 62 of 134 WRTC residents, 46%, received their transplant at the single WRTC facility, less than half the LLF rate of 93%.
- The remaining 72 WRTC residents (22+25+25, or 54%) were transplanted outside of the WRTC.

[26] The most recent data available is used throughout this analysis. Some 2016 data is available on public websites, such as the volumes by DSA in the table above. Other information is only available through a formal request to UNOS, such as data that combines patient residence and transplant center, and for this type of information the most recent data available is 2015.

The disparity in access between Maryland's two DSAs also is seen when examined on a per capita basis, i.e., the number of residents transplanted per million population ("PMP"). The table below shows the number of DSA residents who received a liver transplant in 2015:

CY	DSA	JHH	UMMS	G'town	Other Centers	TOTAL	Population	Overall Rate PMP (Total)
2015	LLF	57	104	7	5	173	3,900,632	44.4
	WRTC	22	25	62	25	134	5,464,786	24.5

Thus, when considering all centers which performed transplants on LLF and WRTC residents in 2015, LLF residents were nearly twice as likely to be transplanted per capita as WRTC residents (44.4 PMP versus 24.5 PMP). This disparity was not unique to 2015, as the gap in transplant rates for DSA residents at all transplant centers has persisted, as depicted below:

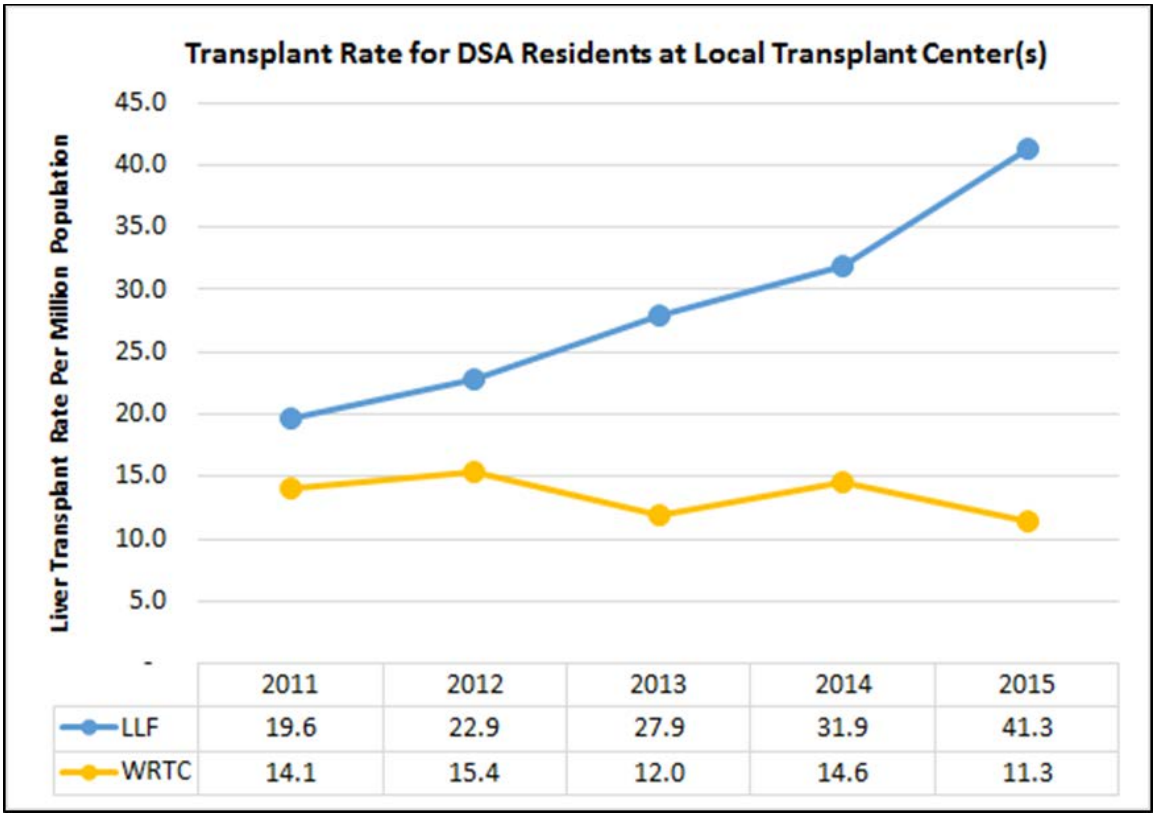


All Patients – Local Access

The disparity is magnified when considering how many DSA residents were transplanted at a liver transplant center in their DSA of residence (a local center) in 2015. In 2015, 161 LLF residents were transplanted locally, or a per capita rate of 41.3 PMP. By contrast, only 62 WRTC DSA residents were transplanted locally for a much larger population of 5.5 million, equal to a rate of 11.4 PMP.

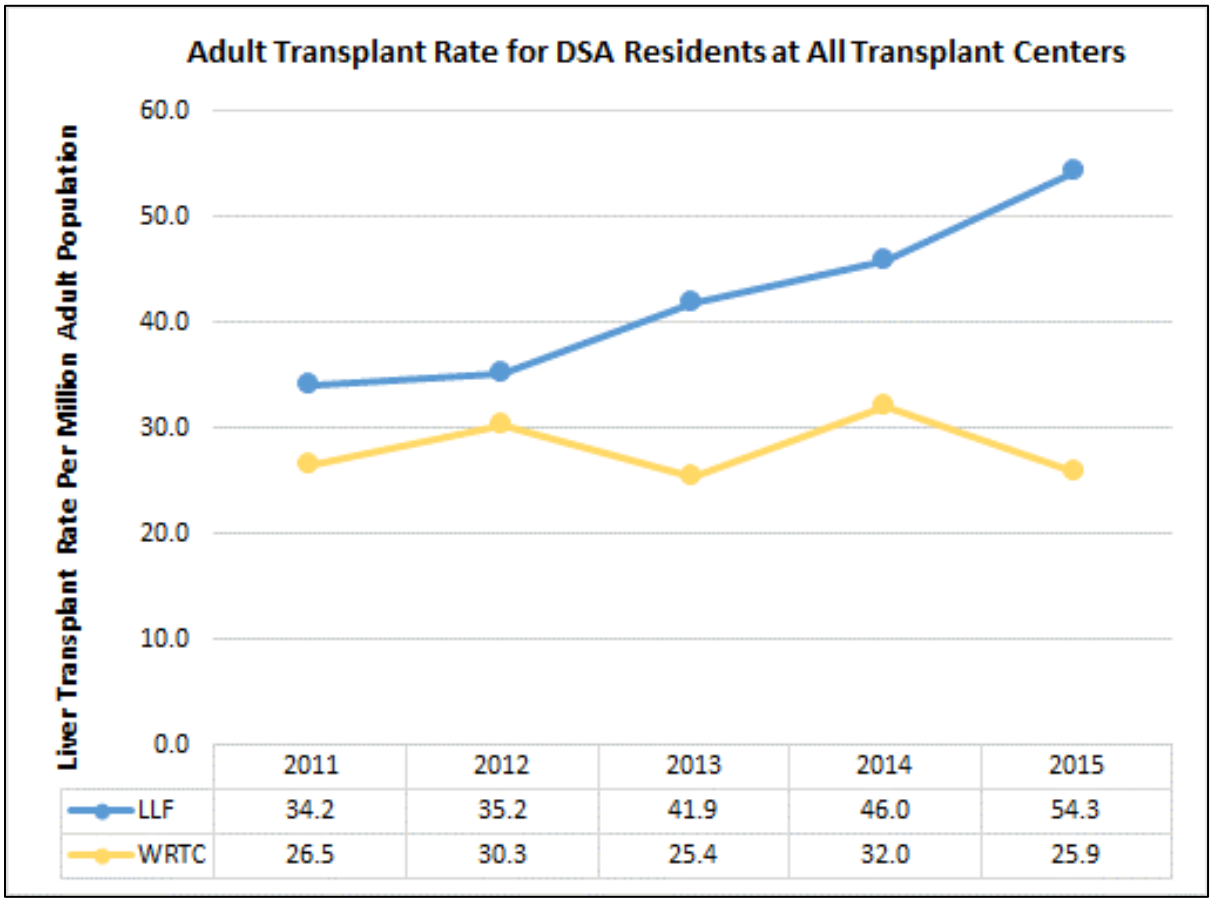
CY	DSA	JHH	UMMS	G'town	LOCAL Subtotal	Population	Local Rate PMP (Subtotal)
2015	LLF	57	104	-	161	3,900,632	41.28
	WRTC	-	-	62	62	5,464,786	11.35

Here again, 2015 was not an anomaly. Rather, as measured over a five-year period, the per capita disparity in transplant access between WRTC residents and LLF residents to their local center(s) has worsened:



Adult Patients – Access

Because Suburban intends to serve adults seeking a liver transplant, focus on access by adults is warranted. Here, disparities in access are even further magnified. Using the same methods described above, adult liver transplant rates at all transplant centers (i.e., Overall Access) shows the same marked discrepancy:

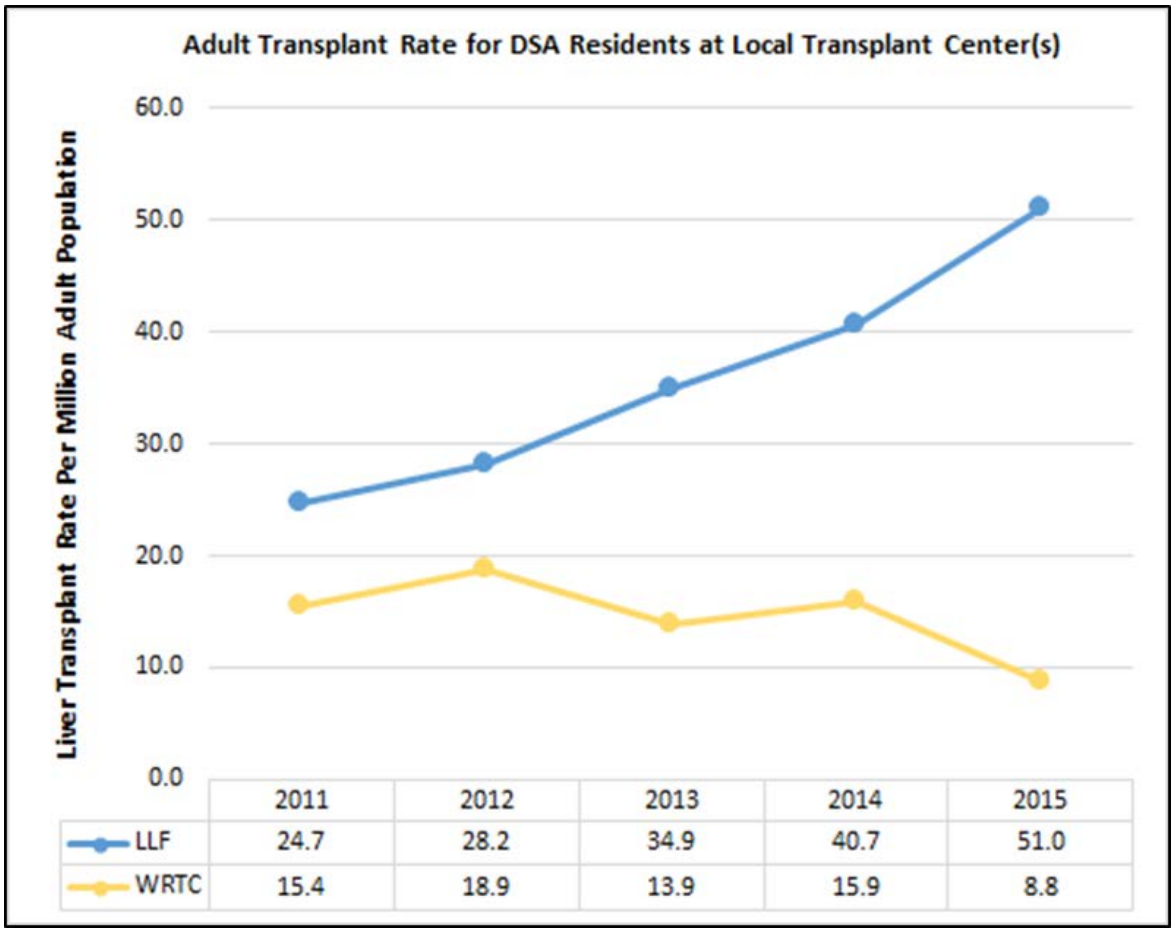


	2011	2012	2013	2014	2015
LLF	34.2	35.2	41.9	46.0	54.3
WRTC	26.5	30.3	25.4	32.0	25.9

Thus, LLF adult access to liver transplantation in 2015 was more than twice the rate of WRTC adult access (54.3 versus 25.9 PMP).[27] This gap is considerably wider than the discrepancy among access by all patients (i.e., the 44.4 PMP in the LLF versus 24.5 PMP in the WRTC, see above).

[27] Calculated using the total adult population 18 and over.

The gap in adult liver transplants at the three existing centers in the LLF and WRTC (i.e., Local Access) is even more striking:



	2011	2012	2013	2014	2015
LLF	24.7	28.2	34.9	40.7	51.0
WRTC	15.4	18.9	13.9	15.9	8.8

In other words, access by adults to liver transplantation within their own DSA was more than five times greater for residents of the LLF (51.0) than for residents of the WRTC (8.8). Here again, this gap was wider than the gap among all patients (41.3 PMP versus 11.3 PMP, see above).

Access Disparity

These glaring discrepancies between the two DSAs strongly indicate the existence of a substantial unmet need for additional transplantation services within the WRTC DSA. Data showing increased organ utilization when centers compete within a DSA strongly suggests that adding a second center in the at Suburban Hospital would significantly impact this unmet need and lead to higher per capita transplant rates in the WRTC region.

A related explanation for this disparity in access is that a DSA with only one center is more vulnerable to disruptions that occur within the single transplant center than a DSA with multiple centers. For instance, when a single center suffers an

unexpected loss of personnel (e.g., the loss of a surgeon, of hepatologists, a nurse coordinator, etc.) or experiences other operational issues (e.g., bed shortage, ICU shortage, infectious outbreaks), the adverse effects on patient access within the service area are immediately felt and can last for months. Such circumstances ultimately depress the ability of single-center DSA residents to obtain transplant services locally.[28]

Also, patients residing in a single-center DSA with means can travel to another DSA; those without such means lack the ability to access services elsewhere. The presence of a second transplant center within a DSA can protect against such inequality. Put simply, patient access is less vulnerable to disruption and inequality of means in DSAs with multiple transplant centers.

That a second transplant center in the WRTC would increase access is also shown by the last two columns of the following table:

CY	DSA	JHH	UMMS	G'town	Other Centers	TOTAL	Population	Overall Rate PMP (Total)	Transplants Projected at LLF Rate	Opportunity for Additional Transplants
2015	LLF	57	104	7	5	173	3,900,632	44.4	-	-
	WRTC	22	25	62	25	134	5,464,786	24.5	242	108

These data demonstrate that, if the WRTC residents were transplanted at the same per capita rate as its LLF residents, there would have been an 81% increase in transplants for WRTC residents [(242-134)/134], or 108 additional transplants in 2015.

We do not project that a second transplant center in the WRTC will lead to 108 additional transplants in that center's first year. But this extrapolation reveals the scope of the unmet need within the WRTC. Even if only 10% of those 108 cases were performed in the WRTC by the additional transplant center, there would be an additional 10-11 transplants performed yearly. The number of additional transplants will increase over time as the new center gains experience, new referral patterns are established, and the patient/donor education efforts initiated by the new center bear fruit.

The assumption that local access to transplant services would improve with an additional center at Suburban is also warranted because the new center would be operated by the CTC, which operates one of the two transplant centers in the LLF. The CTC has a 50-year track record of transplantation innovation, leadership, outcomes, and volume (see Section IV below).

[28] For example, Georgetown's adult transplant volume dropped from 79 in 2014 to 49 in 2015 (a 38% drop). Volume rebounded in 2016, but the year-long regression in 2015 demonstrates the vulnerability of a single-center DSA to operational issues.

Disparity in Patient Migration

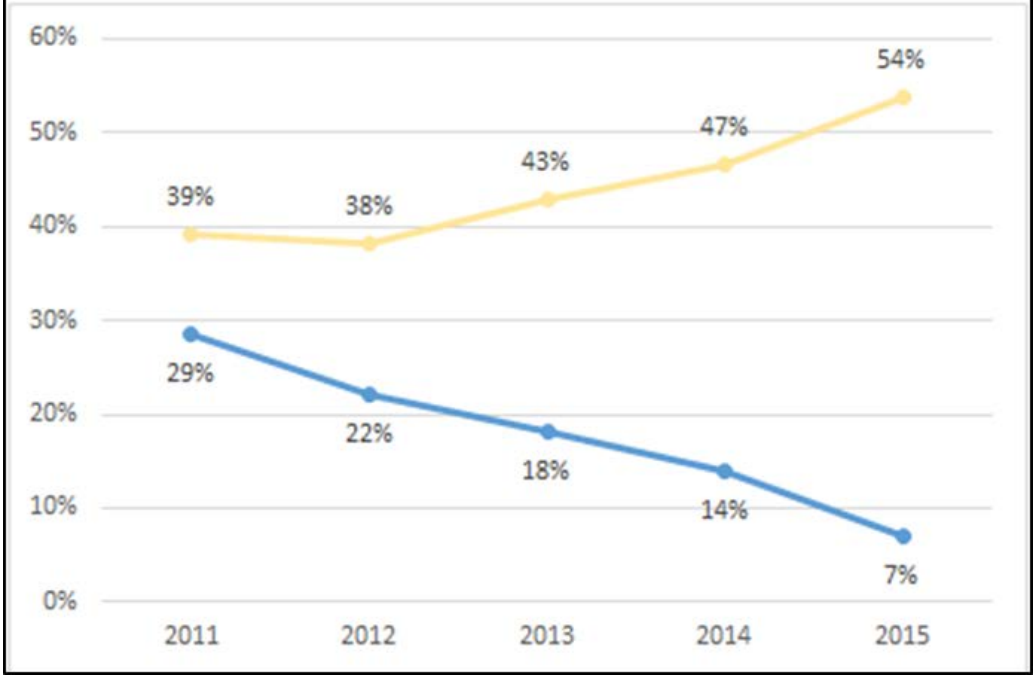
Another way to analyze access is by looking at "migration" patterns, i.e., where DSA residents go for transplant services.

a. All-Patients – Out-Migration

CY	DSA	JHH	UMMS	G'town	Other Centers	TOTAL	Total Out-migrants	% of Out-migrants
2015	LLF	57	104	7	5	173	12	7%
	WRTC	22	25	62	25	134	72	54%

"Out-migrant" means a patient leaving their DSA of residence. In 2015, only 12 of 173 LLF residents receiving transplants went outside their DSA of residence (7%). For the WRTC, that figure jumps nearly eight-fold to 54%, with 72 of 134 WRTC residents receiving a transplant outside their DSA. This means that more than half the residents in the WRTC needed to leave their DSA to obtain a transplant. 2015 was not an outlier in this regard. Similar to other measurements of access, the historical migration data shows an ever-widening gap:

% of Residents Out-Migrating for a Transplant						
DSA	State	2011	2012	2013	2014	2015
LLF	MD	29%	22%	18%	14%	7%
WRTC	TOTAL	39%	38%	43%	47%	54%



The disparity in migration primarily affects Maryland residents of the WRTC. As shown in this jurisdiction-by-jurisdiction breakdown of WRTC "Out-migrants" in 2015, the largest group (62%) resides in Maryland:

CY	DSA	State	JHH	UMMS	G'town	Other Centers	TOTAL	Total Out-migrants	% of Out-migrants
2015	LLF	MD	57	104	7	5	173	12	7%
	WRTC	DC	1	1	6	7	15	9	60%
	WRTC	MD	11	20	24	8	63	39	62%
	WRTC	VA	10	4	32	10	56	24	43%
	WRTC	TOTAL	22	25	62	25	134	72	54%

This migration data strongly supports the existence of unmet need within the WRTC because it shows that more than half of all WRTC residents needing a liver transplant are leaving the WRTC to obtain this life-saving procedure. Given the time and expense involved in such travel, in addition to the emotional cost of being away from home and family during hospitalization, the conclusion is compelling that WRTC residents do so primarily because their need for transplantation services is not being met adequately by the single facility available in their DSA.

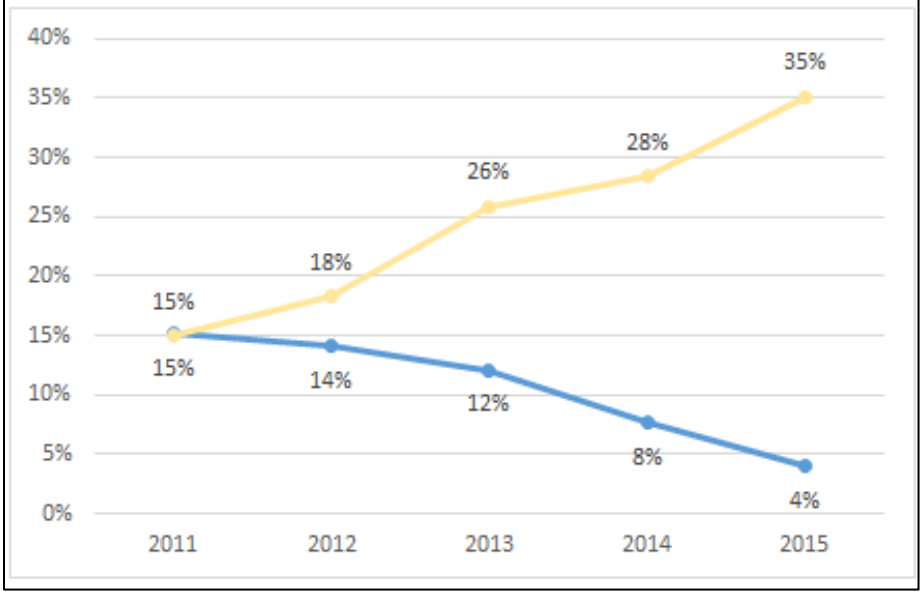
b. All Patients – Cross-over Migration

This conclusion is buttressed by examining "cross-over" migration, i.e., how many WRTC residents go to one of the two LLF facilities for transplants compared to the number of LLF residents who go to the WRTC facility for transplants:

CY	DSA	JHH	UMMS	G'town	Other Centers	TOTAL	Residents Crossing Over LLF <--> WRTC	% Residents Crossing Over LLF <--> WRTC
2015	LLF	57	104	7	5	173	7	4%
	WRTC	22	25	62	25	134	47	35%

In other words, only 4% of the LLF residents transplanted in 2015 were served by Georgetown in the WRTC, while 35% of the WRTC residents receiving a transplant were served at an LLF center. Again, 2015 was not unique in this regard but rather the latest data point in a historical—and growing—gap between the two DSAs:

% Residents Crossing Over: LLF <--> WRTC						
DSA	State	2011	2012	2013	2014	2015
LLF	MD	15%	14%	12%	8%	4%
WRTC	TOTAL	15%	18%	26%	28%	35%



And like the other migration data, this cross-over data shows an outsized impact on Maryland residents of the WRTC:

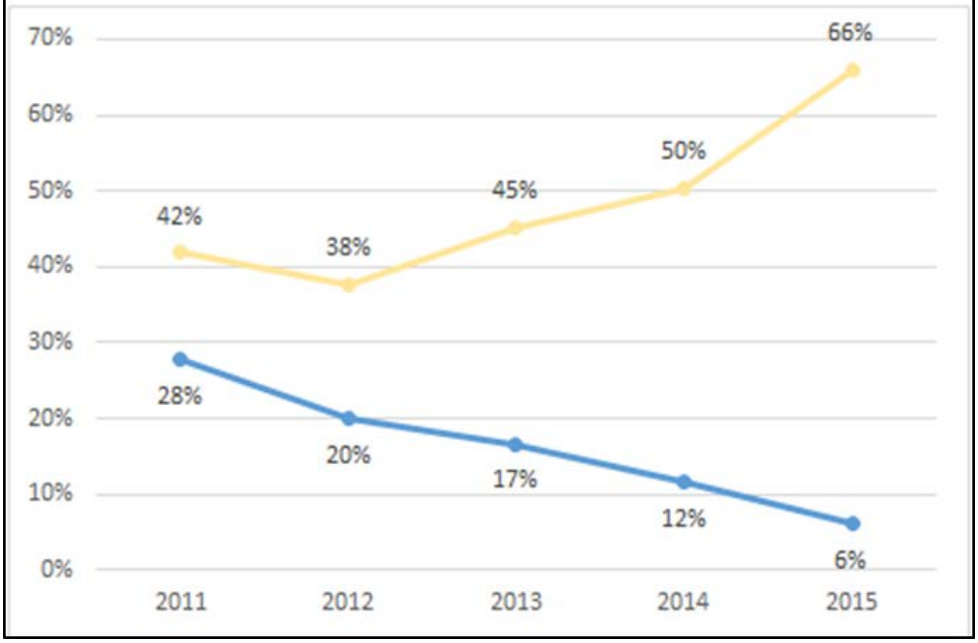
CY	DSA	State	JHH	UMMS	G'town	Other Centers	TOTAL	Residents Crossing Over LLF <--> WRTC	% Residents Crossing Over LLF <--> WRTC
2015	LLF	MD	57	104	7	5	173	7	4%
	WRTC	DC	1	1	6	7	15	2	13%
	WRTC	MD	11	20	24	8	63	31	49%
	WRTC	VA	10	4	32	10	56	14	25%
	WRTC	TOTAL	22	25	62	25	134	47	35%

This table reveals that most “cross-over migration” is occurring because of Maryland residents of the WRTC leaving that DSA for the two LLF centers (i.e., the 11 Johns Hopkins Hospital and 20 University of Maryland patients out of 47 total WRTC migrants), far more than migrants from any other jurisdiction. If access to transplant services were equivalent between the WRTC and LLF, one would expect equivalent cross-over migration rates. The opposite is true: WRTC residents came to the LLF for transplants in 2015 at nearly 9 times the rate of LLF residents going to the WRTC for this procedure (35% versus 4%).

c. Adult Out-Migration & Cross-Over Migration

The out-migration and cross-over patterns are even more pronounced when focusing on adults:

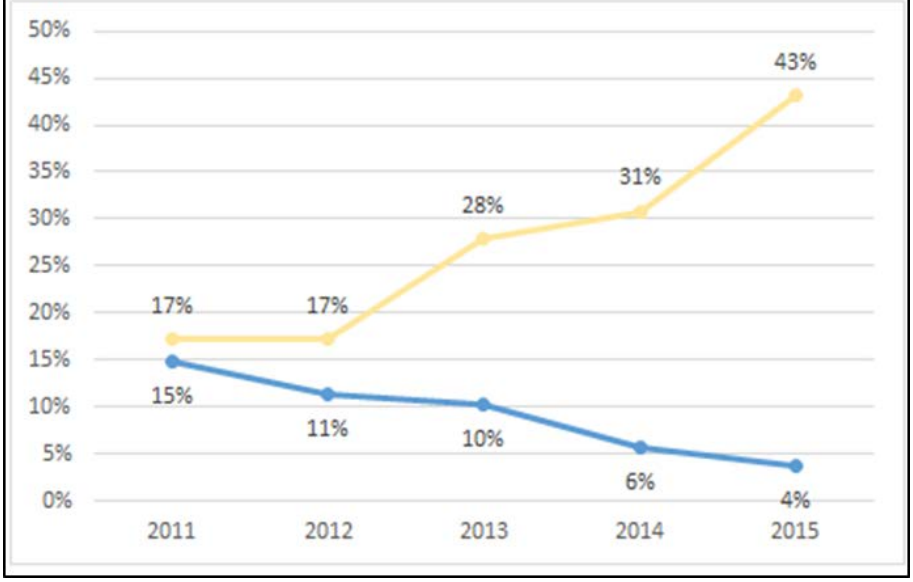
% of ADULT Residents Out-Migrating for a Transplant						
DSA	State	2011	2012	2013	2014	2015
LLF	MD	28%	20%	17%	12%	6%
WRTC	TOTAL	42%	38%	45%	50%	66%



While 54% of all patients residing in the WRTC left their DSA for a liver transplant in 2015 (see above), that number climbs to 66% when examining adult-only migration.

Similarly, the migration rate between the LLF and the WRTC is even more pronounced when looking at adults only:

% of ADULT Residents Crossing Over: LLF <--> WRTC						
DSA	State	2011	2012	2013	2014	2015
LLF	MD	15%	11%	10%	6%	4%
WRTC	TOTAL	17%	17%	28%	31%	43%



In other words, the 35% of all transplant patients who left the WRTC for the LLF grows significantly to 43% when counting only WRTC adults.

Migration Conclusions

It is important to note that those migrating from their DSA of residency are by definition those with the means to do so. A study by Dzebisashvili revealed the association between socioeconomic status ("SES") and traveling to alternative DSAs, and the impact of that travel on patient survival.[29] The study found a strong association between higher SES and ability to travel, with transplant candidates in the highest SES quartile being 70% more likely to travel than candidates in the lowest SES quartile. The ability to travel, in turn, led to dramatic differences in transplantation and survival:

- Patients able to travel had a 74% increased likelihood of transplantation; and
- Patients able to travel had a 20% reduction in risk of death due to end stage liver disease.

This study provides strong evidence that lower SES individuals in one DSA cannot and will not readily travel to another DSA in order to improve their chances of getting transplanted. For these patients, therefore, increasing the number of local transplant options offers the best—and only—way to improve access to transplant services.

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

The migration patterns detailed above will change with the opening of a second transplant center within the WRTC. Fewer WRTC residents will need to travel to the LLF for transplants, especially adults. Reducing migration in this manner will further the Commission's goal of making transplant services "accessible consistent with efficiently meeting the health care needs of patients." SHP Organ Transplant Services Chapter, Policy 5.

The recent decision by SHPDA allowing continuation of a second kidney transplant center in the District of Columbia shows how access to transplant services within a DSA will reduce "Out-migration." The evidence presented to SHPDA was that the second transplant center opened by GWUH in 2015 increased access to District residents, with 44% of the additional transplants at GWUH being performed on District residents. SHPDA Decision 4. In other words, the additional transplant center reduced the need for District residents to migrate out of the WRTC for transplant services.

One explanation cited by SHPDA was the existence of barriers to access at Georgetown, including that it does not participate in all Medicaid managed care organizations in the District, while GWUH had contracts with all D.C. Medicaid MCOs. SHPDA Decision 9. The agency concluded:

> Kidney transplants provide significant life-saving and quality of life benefits and it is important that patients have access to the services. Given the fact that GWUH is the one adult kidney transplant program in the District that has contracts with all D.C. Medicaid Managed Care Organizations, continuation of GWUH's kidney transplant services will allow for greater access by patients*. It therefore makes health planning sense to ensure that patients have a choice of access to the lifesaving services*. As a result, SHPDA has determined that GWUH continue to provide kidney transplant services for adult patients.
>
> SHPDA Decision 15 (emphasis added).

The increased access and reduced migration for District kidney transplant patients as the result of an additional kidney transplant center in the WRTC foreshadows similar results for the WRTC from a second liver transplant service at Suburban.

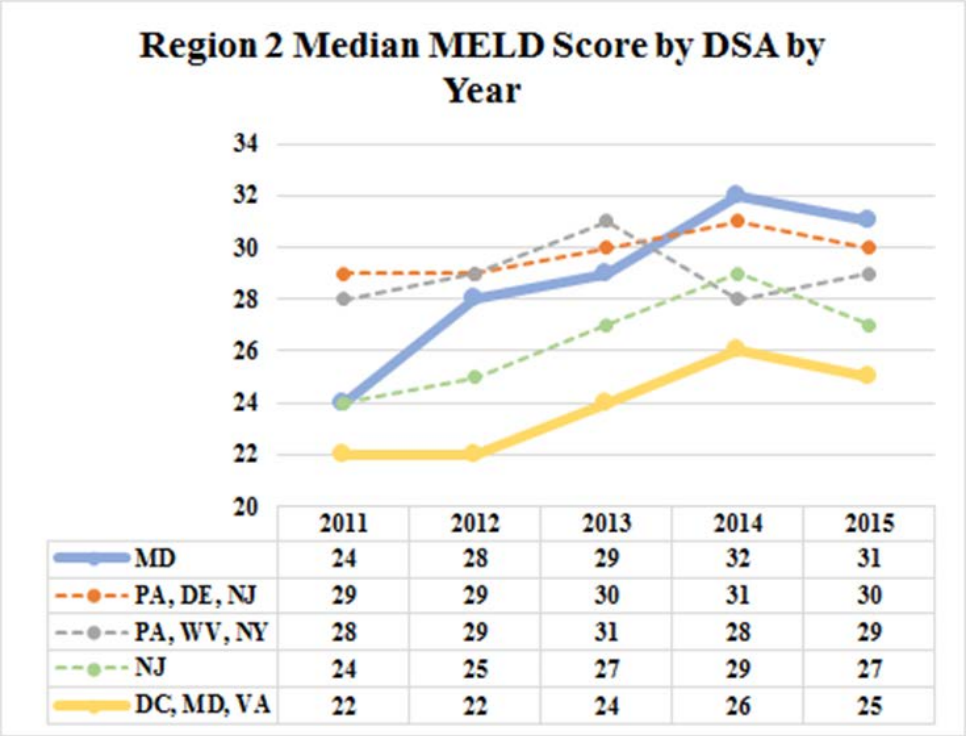
In sum, the disparity in access between the two DSAs serving Maryland strongly indicates the existence of a substantial unmet need for additional transplantation services within the WRTC. A second center in the WRTC at Suburban would address this unmet need and lead to higher per capita transplant rates in the WRTC.

3. The Consistent Difference in Acuity

Volume and access data reveal how many residents of the WRTC are receiving transplants compared to their LLF counterparts. Acuity data compares the relative health of those patients at time of transplant.

The relative acuity of transplant patients in these two DSAs is shown by examining the median MELD scores at time of transplantation. The single WRTC center at Georgetown has historically transplanted less sick patients, even when compared to the four other DSAs located within Region 2:

Region 2 Median MELD Score by DSA by Year						
DSA	**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: OPTN/SRTR Annual Reports 2011-15

The median MELD scores at time of transplant for the two LLF transplant centers were consistently higher by 5 or 6 points than the single WRTC center starting in 2012. In each year shown here, the WRTC had the lowest median MELD score of the five DSAs. The WRTC DSA is the only one-center (non-competitive) DSA in the region. A second center would introduce competition and would likely alleviate the discrepancy, resulting is a greater number of sicker WRTC DSA residents receiving a transplant.

4. The Increasing Supply Imbalance

Need can also be evaluated by comparing the respective performances of the WRTC and LLF in supplying deceased donor organs for transplant. Deceased donor organs can be (a) procured[30] and used within a DSA, (b) imported from outside the DSA, or (c) exported to another DSA. The SRTR compiles reports on livers procured by each OPO and where those organs were used. Using this SRTR data, an OPO's supply of organs can be measured by the following formula:

OPO Liver Supply =
(Livers Procured) – (Livers Exported) + (Livers Imported)

As discussed previously, liver imports and exports occur within the context of established rules. In any DSA, when a deceased donor liver becomes available for transplant, that organ is most commonly matched with, and subsequently transplanted by, a center within the same DSA (local priority). The three exceptions to local priority that can result in the importation or exportation of livers are (a) Status 1, where the most critically ill patients are given priority within a region (Regional Priority); (b) physician preference, where organs rejected by one transplant physician are offered to the next match within a region; and (c) beginning in June 2013, the Share 35 preference, where patients with a MELD score of 35 or greater are given regional priority.

The supply of livers procured, imported, and exported shows marked and growing differences between the LLF and the WRTC OPOs.

a. Deceased Donor Livers Procured

OPO Liver Supply =
(Livers Procured) – (Livers Exported) + (Livers Imported)

	Livers Procured		
	FY 2013	CY 2014	CY 2015
LLF	102	119	121
WRTC	92	97	89

The number of livers procured is consistently higher in the LLF OPO than the WRTC OPO, despite the larger population in the WRTC DSA.[31]

[30] Organ procurement is the removal or retrieval of organs from a deceased donor for transplantation.

[31] Data presented in this section depicts the number of livers procured in fiscal year 2013 and calendar years 2014 and 2015. This is done deliberately in an effort to provide the most recent data available while accounting for the introduction of Share 35. Share 35 was implemented on June 18, 2013. By including FY2013, we show the last full year of data before Share 35 was implemented. This is the only instance in this analysis where fiscal year data is presented. By moving to CY2014 we return to our standard interval. The missing 6 months of data, July-Dec 2013, cover the initial months of Share 35 implementation.

b. Livers Exported

OPO Liver Supply =
(Livers Procured) **– (Livers Exported)** + (Livers Imported)

Prior to Share 35,[32] in FY 2013, the LLF OPO used 95.1% of the organs it procured, exporting only 4.9%. The WRTC OPO used only 80.4% of locally-procured organs, exporting nearly 20%.

Fiscal Year 2013 (7/1/2012 - 6/30/2013)				
OPO	Livers Procured by OPO	Procured by OPO and Transplanted at Local Center(s)	Livers Exported	Percentage of Livers Exported
LLF	102	97	5	4.9%
WRTC	92	74	18	19.6%

It was expected that an increase in organ exports would occur with the launch of the Share 35 program in June 2013 because that policy allowed transplant centers with patients with higher MELD scores to import more organs from within a region. A study by Massie confirmed this prediction, compiling liver distribution data for the 12 months preceding and following the start of Share 35.[33]

Calendar Year 2014				
OPO	Livers Procured by OPO	Procured by OPO and Transplanted at Local Center(s)	Livers Exported	Percentage of Livers Exported
LLF	119	96	23	19.3%
WRTC	97	59	38	39.2%

For both WRTC and LLF, exported livers rose after the Share 35 program began. LLF exports rose from 4.9% in FY 2013 to 19.3% in CY 2014; and WRTC exports in that same period rose from 19.6% to 39.2%. The latest data, for CY 2015, shows that this gap widened further:

Calendar Year 2015				
OPO	Livers Procured by OPO	Procured by OPO and Transplanted at Local Center(s)	Livers Exported	Percentage of Livers Exported
LLF	121	97	24	19.8%
WRTC	89	36	53	59.6%

[32] As discussed previously, the Share 35 program (begun in June 2013) created a new priority for patients with MELD scores of 35 or greater, i.e., not as sick as Status 1 patients but sick enough to warrant preference over other, non-Status 1 patients on a waitlist in the region.

[33] Massie, A. B., et al. "Early changes in liver distribution following implementation of Share 35." *American Journal of Transplantation* 15.3 (2015): 659-667.

While the LLF's post-Share 35 export rate held steady at 19.8% in CY 2015, WRTC's export rate shot up to nearly 60% for CY 2015, a 52% increase in one year.

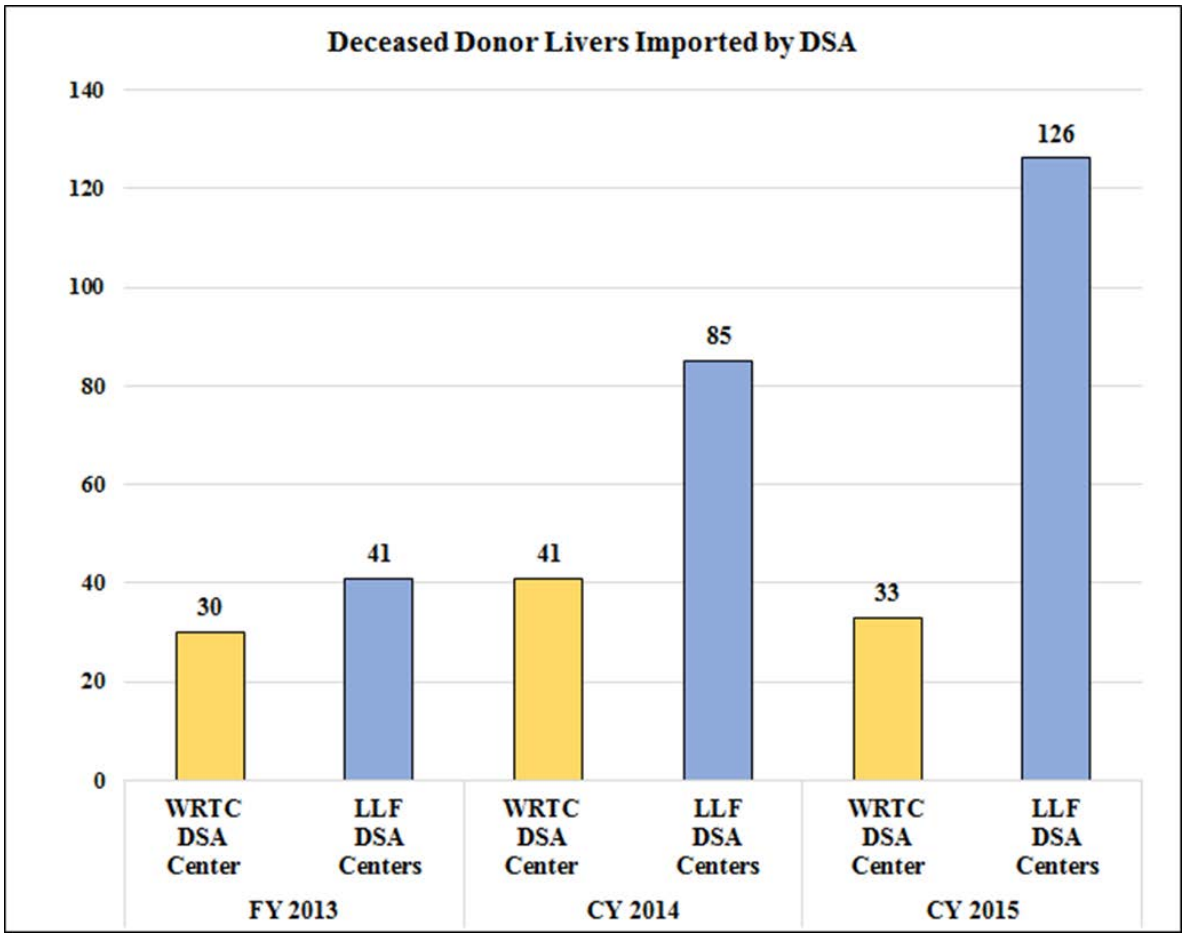
There are several likely explanations for this jump in WRTC exports in the post-Share 35 era. Again, the lower MELD scores at time of transplant for WRTC patients on the WRTC wait list means that the single WRTC center does not have sufficient high-MELD score patients to retain more of their deceased donor organs, i.e., higher-MELD patients from other DSAs can "pull" livers out of the WRTC. The loss of nearly 60% of the organs procured in the Washington metropolitan area undoubtedly has a negative impact on WRTC residents dependent on these organs for local access.

c. Livers Imported

OPO Liver Supply =
(Livers Procured) – (Livers Exported) + **(Livers Imported)**

Donor livers imported by the two DSAs tell a similar story. By tending to transplant less sick patients, the WRTC Center does not "pull" livers from other OPOs in Region 2 in the same way the LLF does. Despite serving a 40% greater population, the single WRTC transplant center lags far behind the two-center LLF in liver imports.

In 2014 and 2015, the LLF imported nearly three times as many livers as the WRTC (211 versus 74, or 2.85 times more). Moreover, the gap widened from 2014 to 2015: in 2014, the LLF imported just over twice the livers as the WRTC (2.07), and that figure nearly doubled in 2015 (3.82).



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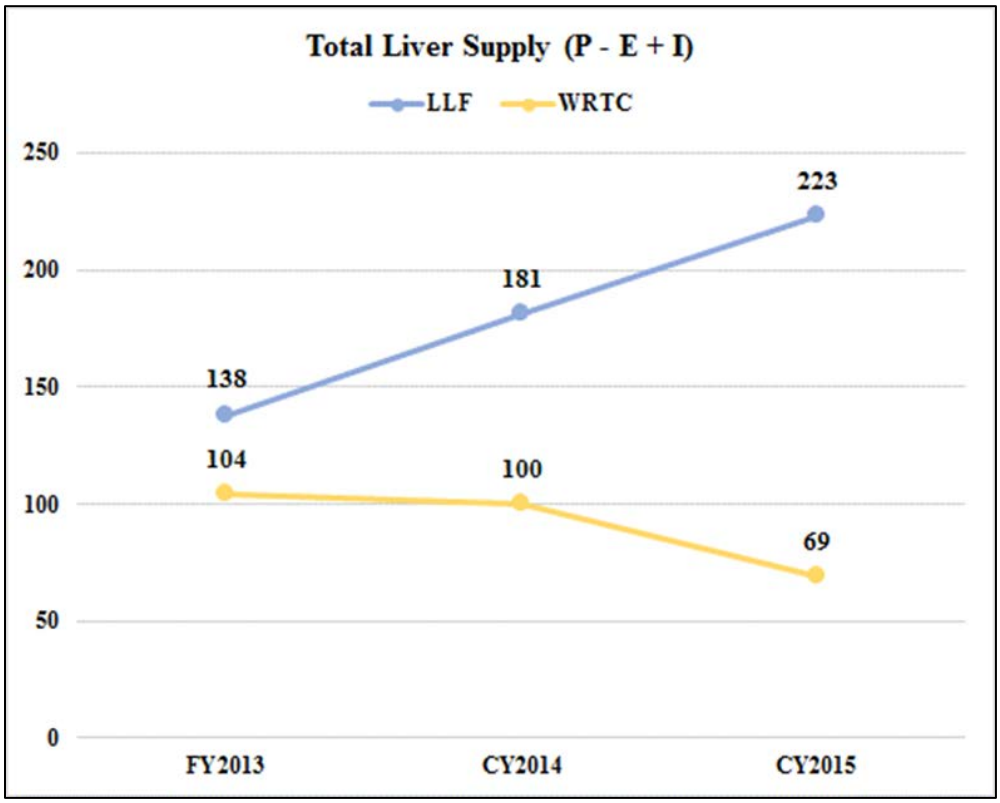
d. Organ Supply Conclusions

OPO Liver Supply =
(Livers Procured) – (Livers Exported) + (Livers Imported)

Returning to the formula for measuring deceased donor organ supply, the table below shows the data for all three categories for both the LLF and the WRTC, as well as the growing gap between those two DSAs:

	Procured			Exported (-)			Imported (+)			Total Supply (P-E+I)		
	FY2013	CY2014	CY2015	FY2013	CY2014	CY2015	FY2013	CY2014	CY2015	FY2013	CY2014	CY2015
LLF	102	119	121	5	23	24	41	85	126	138	181	223
WRTC	92	97	89	18	38	53	30	41	33	104	100	69
									Ratio LLF:WRTC	1.33	1.81	3.23



Two observations leap out from this supply data. *First*, in 2015, the two LLF transplant centers transplanted (net) more than three times (3.23) the organs transplanted by the single WRTC center, a multiple that has surged since 2013 (1.33 times greater) and 2014 (1.81 times greater). *Second*, just like declining transplant volume and MELD scores, the single WRTC center's total net supply of deceased donor organs has *decreased* 33.7% since 2013 (104 to 69), while the two LLF centers had a 61.6% increase over that same period (138 to 223). This deficiency is all the more remarkable given that the WRTC DSA has a 40% greater population than the LLF DSA.

e. Supply: Live Donor Liver Transplants

As discussed above, most liver transplants in the U.S. are performed with deceased donor organs, including the livers procured, imported, and exported through UNOS's OPTN Match System. Although a small part of overall transplant volume (4.4% in 2016), live donor liver transplant offers patients the ability to identify a donor outside of the Match System, which can reduce wait time and allow for a quicker recovery.

It is much more challenging to identify and select appropriate living donors for liver transplant than to perform a deceased donor transplant, especially in adult-to-adult donation. Live liver donation requires a healthy donor matched to the recipient. This donor must be fully evaluated for any health issues that would complicate the donation surgery. He or she must fully consider the risks of surgery, which are not insignificant.

Because of the highly complex nature of this procedure, patients that present for transplantation at Suburban Hospital who have a potential living donor are likely to initially be referred to either Johns Hopkins CTC or another center reflecting the patient's preference. Suburban's presence in the WRTC will allow Johns Hopkins physicians and staff to expand their outreach and education efforts in order to identify more live donors. Because every live donor transplant "frees up" a deceased donor liver for another individual on the waitlist, local residents within the WRTC area remain the beneficiaries regardless of where the live donor transplant takes place. Increasing transplant access in the WRTC area would ultimately increase the number of patients undergoing living donor liver transplantation.

<u>All Patients – Live Donor Transplants</u>

Both LLF centers and the single WRTC center have offered live donor liver transplant services since at least 2012. Here too, the gap between the two DSAs is striking and growing:

	All Patients - Living Donors						
	2011	2012	2013	2014	2015	2016	6 Year Total
LLF CENTERS	0	6	14	20	24	19	83
WRTC CENTER	4	3	2	2	12	6	29
DSA VARIANCE (LLF-WRTC)	-4	3	12	18	12	13	54

Since 2011, the two LLF centers have performed 54 more live donor liver transplants than the lone WRTC center, or nearly three times as many live donor transplants.

Adult – Live Donor Transplants

The disparity in live liver transplants between the two DSAs is even greater when only live adult liver transplants are examined:

	Adults - Living Donors						
	2011	2012	2013	2014	2015	2016	6 Year Total
LLF CENTERS	0	5	12	18	21	18	74
WRTC CENTER	0	1	0	1	3	2	7
DSA VARIANCE (LLF-WRTC)	0	4	12	17	18	16	67

Since 2011, the two LLF centers performed 74 adult-to-adult living donor liver transplants. In contrast, only 7 adult-to-adult living donor transplants were performed at the WRTC center in that time span, and only 2 in 2016. In other words, 67 more livers were made available for adult LLF patients during this time span.

In sum, organ supply data for the LLF and WRTC reveals sharp and growing disparities in organs procured, exported and imported – all of which leads to fewer organs being available to WRTC residents. A second, competing transplant center at Suburban will result in more organs being made available to these residents.

5. There Are Far Fewer Patients on the WRTC Wait List

The rules governing organ wait lists are set forth in policies adopted by OPTN.[34] Transplant programs evaluate liver wait list candidates using a variety of tests, and make an independent determination whether to add a patient to an organ wait list. Each transplant program maintains its own wait list, and there is a combined organ wait list for the entire DSA (OPTN Policy 1.3.A(4)). Thus there is no need for patients to be evaluated at multiple centers within a single DSA. Patients can be evaluated and placed on wait lists in other DSAs in order to improve their odds of matching (OPTN Policy 3.4.F).

As this Commission has noted, "[t]he inclusion of more patients on the wait list may be regarded as positive because more patients potentially will receive a . . . transplant." SHP Organ Transplant Services Chapter at 22. Having a second center in the WRTC DSA is likely to increase patients' chances of being placed on the DSA wait list in two ways. *First*, centers are limited in their capacity to evaluate and review patients. A second center will increase the evaluation capacity in the WRTC. *Second*, centers vary in their acceptance policies. A patient rejected by one center may be a suitable candidate at another and placed on the wait list. This is akin to getting a second opinion for a complex medical issue. WRTC patients are dependent on the policies and practice of that single transplant center with no other options unless they are capable of traveling outside their DSA. Having multiple transplant programs within a DSA

[34] https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf

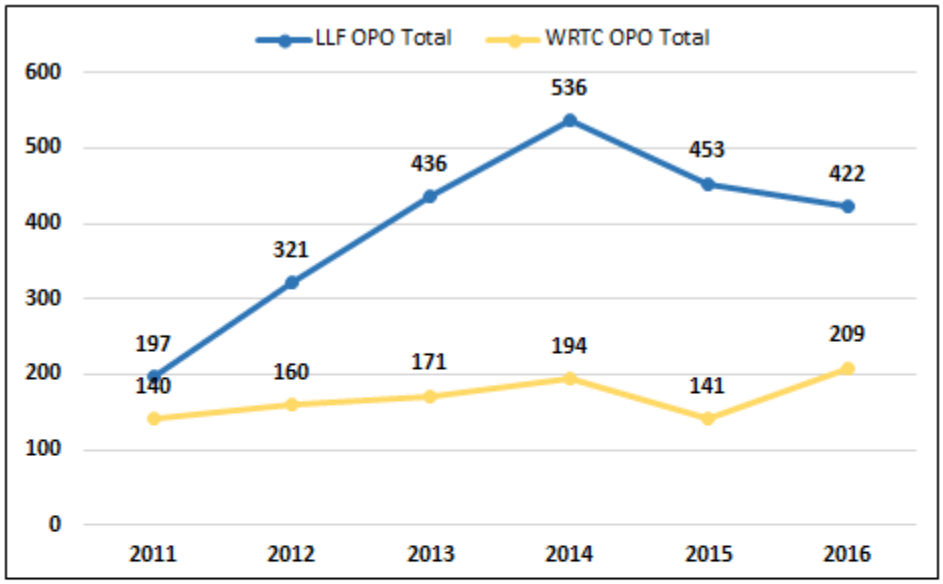
increases a patient's chances of being listed, and thus increases the chances of getting a liver transplant.

Comparing the wait lists of the WRTC and the LLF, as of March 1, 2017, the WRTC liver transplant wait list—populated by the single WRTC transplant center—had one-third (1/3) the number of patients as the LLF liver transplant wait list, which is populated by two transplant centers.[35]

	Candidates	Ratio (LLF/WRTC)
JHH Waitlist	448	
UMMS Waitlist	405	
LLF Waitlist (JHH + UMMS)	853	3.09
MGUH Waitlist	276	
WRTC Waitlist (MGUH)	276	

[35] Because Georgetown is the only center in the WRTC, the WRTC liver waitlist and the Georgetown liver wait list are identical.

The current (March 2017) wait list discrepancy is not an anomaly. As shown by the following table of wait list additions [36] for the last six years (2011-16), the WRTC liver wait list has lagged behind the LLF liver wait list since 2012:



Wait List Addtions By Year						
	2011	2012	2013	2014	2015	2016
JHH	57	129	256	231	205	190
UMMS	140	192	180	305	248	232
LLF OPO Total	197	321	436	536	453	422
MGUH	140	160	171	194	141	209
WRTC OPO Total	140	160	171	194	141	209
Variance (WRTC-LLF)	-57	-161	-265	-342	-312	-213

Thus, over the last four years, between 213 and 342 ***more*** patients were added to the LLF wait list each year than were added to the WRTC wait list. Again, this disparity is even more striking given that the WRTC serves a population that is 40% greater than the LLF. The bottom line is that the single transplant center within the WRTC lags far behind the LLF in identifying, evaluating, and listing transplant-eligible patients.

* * *

In sum, disparities between the single-center WRTC and the multi-center LLF in transplant volume, access, acuity, supply, and wait list strongly support the addition of a second transplant center in the WRTC at Suburban.

[36] Data here reflects patients added to the waitlist each year. Waitlists are dynamic. Patients come on and off based on a range of factors. The number of patients evaluated and added to the DSA list each year is the commonly used metric.

C. Research and Experience Demonstrate the Benefits of Competition.

As the above data comparing the performance of the single-center WRTC with the multi-center LLF show, competition among transplant centers within a DSA can have positive effects on volume, access, supply, and wait lists. This phenomenon is also borne out by research and recent experience, which demonstrate, in addition, that the risk of undesirable outcomes associated with competition can be effectively managed.

1. Studies Regarding Competition

Three recent studies have concluded that competition within a DSA leads to a variety of favorable results.

a. Halldorson (2013)[37]

This study by Halldorson examined the impact of intra-DSA competition (i.e., having more than one transplant center within a DSA) on post-transplant outcomes and variation in patients wait listed. The study stated a number of observations when comparing centers with no intra-DSA competition to centers with intra-DSA competition.

First, when a DSA has more than one center, patients listed at the individual centers are ultimately combined into a single DSA list. Because of this, centers within a DSA compete to be the center where patients want to be wait listed and ultimately transplanted.

Second, the study found that in the presence of competition, centers are more likely to transplant sicker patients (increase access). This was evidenced by observations that transplanted recipients were more likely to be Status 1; have a 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.

Third, the study found that competition led to the utilization of higher risk organs (increased supply), with more frequent donors with a donor risk index in the upper quartile.[38]

Fourth, the study found that DSAs without competition had significantly fewer listings per million population.

b. Adler (2015)[39]

A 2015 study by Adler further analyzed the concept of intra-DSA competition by

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

[38] The Donor Risk Index is a continuous scoring system for analyzing donor risk developed within the OPTN.

[39] 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.

assessing how market competition and liver transplantation center density are associated with liver transplantation volume with individual DSAs. The authors found that more liver transplants were associated with more liver transplant centers, greater market competition, more listings, more donors, and higher Liver Donor Risk Index. The authors also found that transplant center density was associated with market competition, more listings for transplant, and higher MELD at transplant.

c. Adler (2016)[40]

Another study by Adler a year later examined the impact of transplant market characteristics on OPO performance. The 2016 Adler study found that competition within DSAs was strongly associated with OPO performance. For liver transplant, more competitive DSAs were associated with:

- Higher number of donors per million
- Higher conversion rate
- More livers transplanted per donor
- Higher percent of liver donation after cardiac death
- Higher mean Liver Donor Risk Index
- Higher local Liver Donor Risk Index
- Higher imported Liver Donor Risk Index
- Higher waiting time
- Higher MELD score
- More new listings per 100,000
- Higher percentage of transplants with MELD greater than 30
- Fewer livers recovered per donor, suggesting a more aggressive pursuit of marginal donors that yielded only kidneys

Based on the findings of these three studies, it appears that centers with no competition tend to be more selective with both their recipients and donors. Centers in a competitive environment appear more willing to (1) transplant sicker recipients, (2) use higher risk donor organs, or (3) both. This is likely due in part to a recognition that being more selective with regards to potential recipients and donors may cause patients to seek out other area centers with a higher risk tolerance. The patients in more urgent need of a transplant residing in a non-competitive DSA may either be bypassed (and die), or seek other DSA's to list and be transplanted, assuming they have the resources to do so.

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

2. Competition Experience

The positive benefits of competition shown by these studies are supported by recent experience in the WRTC and the LLF. When considering liver transplants performed in the WRTC DSA (non-competitive) and the LLF DSA (competitive), the competitive DSA (LLF):

- Performs more transplants per year
- Has a higher median MELD score
- Has a higher organ supply utilization rate
- Lists more patients
- Has more new listings
- Has a higher number of donors

This competitive advantage is also seen in the recent experience with kidney transplants in the WRTC after 2015, when GWUH began its transplant service. As discussed above, not only did the new service at GWUH lead to additional volume at the new center, but it also resulted in Georgetown increasing its transplant volume by more than 30%.

3. Competition Will Not Lead to Less Desirable Outcomes.

As noted above, there is evidence—supported by studies—that competition between centers within a DSA results in more transplants performed, more efficient use of organs, and more donors per capita. The literature suggests that one possible disadvantage of competition could be poorer outcomes.[41] However, when comparing the outcomes of the competitive LLF DSA and non-competitive WRTC, no such disadvantage is observed.

The most widely-used outcome measure to evaluate program performance is a risk-adjusted assessment of how many patients are alive with a functioning transplanted organ 1 year after transplant. For at least the most recent four reporting periods (dating back to January 1, 2012), at no point did the outcomes achieved by the competitive LLF centers fall below those of the non-competitive WRTC center (Exhibit 5).[42]

In short, competition between the LLF centers has not resulted in less desirable outcomes. To the contrary: (1) positive outcomes are achieved and maintained in both LLF centers, and (2) these outcomes are at least as good as the outcomes achieved in the WRTC, where there is no competition. This data supports the conclusion that any possible additional risks associated with competition within the WRTC can be effectively managed, and thus the advantages of competition outweigh any disadvantages.

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41 Halldorson (2013) found that areas with competition had higher risks of graft failure and patient death, as well as being more likely to match higher risk organs with recipients with higher MELD scores. See ibid at 96-104.

42 Additional information about the performance of each program is available on the SRTR website: https://www.srtr.org/)

Here again, the experience in the District from competition among kidney transplant centers suggests that the risk of undesirable outcomes can be effectively managed. As the March 30, 2017 SHPDA decision notes, the evidence established that there were no adverse effects from the addition of a second, competing transplant service:

- The new transplant service operated by GWUH had shown acceptable one-year outcomes (SHPDA Decision 6); and

- Even though the new transplant service had performed transplants on high-risk patients, outcomes were better than those at other kidney transplant services in the WRTC and LLF (SHPDA Decision 8-9).

There is no reason to believe that similar achievements will not result from competition in the WRTC for liver transplants.

Finally, this conclusion is buttressed by the fact that The Johns Hopkins Hospital's CTC—which will manage the new transplant center at Suburban—achieved the best survival rate of all three centers (91.7%), despite transplanting riskier patients and using higher risk organs relative to those transplanted in the WRTC (see Section IV, below). Because the CTC will bring its nearly 50 years of experience, innovation, and success in organ transplants to the new center at Suburban, the same positive outcomes results are expected.

D. Conclusions

Data concerning access, acuity, supply, and wait listing in the single-center WRTC strongly suggest an unmet need for liver transplant services. Lack of competition, as identified in the scientific literature, is likely a significant contributor to this unmet need. Indeed, the disparities observed between the competitive DSA (the LLF) and the non-competitive DSA (the WRTC) are what one would expect to find based on the research by Halldorson and Adler, cited above. In this case, the competitive DSA:

- has a higher median MELD score
- transplants far more patients per year
- has more DSA residents transplanted per million population per year
- procures more livers, exports fewer livers, and imports more livers
- lists far more patients on the wait list per year
- performs more live donor cases per year

As the Commission has recognized, this same research identifies possible disadvantages and a risk of poorer outcomes from increased competition within a DSA, primarily the increased risk associated with transplanting sicker patients and the use of higher risk organs. SHP Organ Transplant Services Chapter at 21-23. This negative result of competition is not observed in the outcomes for the two LLF centers.

In sum, the application by Suburban Hospital for a new liver transplant center presents the Commission with the opportunity to address—and reduce—the observed disparities between the LLF and the WRTC, without an increase in adverse patient outcomes.

IV. THE JOHNS HOPKINS COMPREHENSIVE TRANSPLANT CENTER ("CTC")

Johns Hopkins began transplanting organs in 1968, and in the ensuing half-century has developed groundbreaking programs for organ matching, organ donation, transplant procedures, and pediatric care. For the last 20 years, these programs have been coordinated and managed by the CTC, one of the nation's leading centers for transplantation services. This unmatched combination of experience and infrastructure will provide the backbone for the new liver transplant service at Suburban.

A. CTC Background

The CTC was created in 1996 by combining The Johns Hopkins Hospital's existing transplant programs into a single center. The goal was to provide an all-inclusive program of transplant services which could bring the full resources of Johns Hopkins Medicine to address the complex and unique issues which surround transplantation. The result is a multidisciplinary approach which makes CTC team members from surgery, medicine, nursing, psychology, social work, pharmacy, nutrition, finance, substance abuse, infectious disease, immunogenetics, and more available to adult and pediatric transplant patients.

B. CTC Programs

The CTC operates four solid-organ transplant programs: liver, kidney/pancreas, lung, and heart. The CTC also has more than 30 years' experience in multi-organ transplantation, including heart-lung, heart-kidney, heart-liver, lung-kidney, kidney-pancreas, and liver-kidney. Simultaneous liver-kidney transplants are the CTC's most common multi-organ transplant.

As summarized below, each of the CTC's four organ programs has been a leader in expanding the availability of transplant services.

1. Liver Transplant Program

The CTC launched its Liver Transplant Program in 1986, and for the July 2013-December 2015 period achieved a one-year survival rate of 91.7% (the national average is 85%). The CTC's unadjusted survival rate exceeds those of the two other transplant centers serving Maryland, Georgetown (85.7%) and the University of Maryland Hospital (83.1%).

Johns Hopkins surgeons have been able to achieve these outcomes despite transplanting very high MELD patients and using higher risk organs. For instance, Dr. Andrew Cameron has been successful in performing urgent transplant on very high MELD patients who come into the emergency department with acute liver failure from alcoholic cirrhosis. Ordinarily, these patients would not be eligible for transplant due to their active drinking history. These patients tend to be young and on the brink of death as a result of binge drinking. In a cohort of 30 patients, urgent transplant has been successful in terms of graft and patient survival, and recidivism in these patients is actually lower than in the population of transplant patients who have stopped drinking

for six months prior to transplant.

Because the CTC will operate the new transplant center at Suburban, it will be able to leverage this expertise and success to achieve comparable outcomes at Suburban. Other notable achievements of the CTC's liver transplant program include:

- Pediatric Liver Transplant Program: Since 1986, the Pediatric Liver Transplant Program has performed more than 200 liver transplants.

- Live Liver Donation: The Johns Hopkins Hospital has been performing living donor liver transplants since 1992, using three types of live donor liver grafts (left lateral section graft, left lobe graft, and right lobe graft).

- Adult-to-Pediatric Transplant: In 1992, the Liver Transplant Program performed the region's first adult-to-pediatric live liver transplant. Medical and surgical advancements have made this once formidable endeavor a routine procedure at the CTC.

- Managing Hepatitis C Virus: The CTC collaborates with the Johns Hopkins Infectious Disease Center for Viral Hepatitis, which includes a multidisciplinary team of physicians and support staff who offer a comprehensive spectrum of services to manage hepatitis C virus infections in patients.

- Liver Dialysis: The CTC offers albumin dialysis, a treatment that removes toxins that accumulate with liver failure. This treatment can be used as a bridge to transplantation for patients with acute or chronic liver disease.

2. Kidney and Pancreas Transplant Program

The Johns Hopkins Kidney Transplant Program was established in 1968. In 1973, Johns Hopkins expanded the program to become the Kidney and Pancreas Transplant Program, which performed the first pancreas transplant in the mid-Atlantic region.

Innovations by the CTC's Kidney and Pancreas Transplant Program have set the standard for organ matching and transplant procedures, including:

- Incompatible Transplants: CTC's unique Incompatible Kidney Transplant Program was founded in 1998 and offers kidney transplant patients the ability to receive a kidney from a live donor with a different blood or tissue type and to overcome other donor sensitization issues.

- Non-directed Donor Program: In 1999, Johns Hopkins Hospital performed the first known kidney transplant from a stranger to a child. This prompted

the CTC to launch the Non-directed Donor Program which coordinates the allocation of organs from altruistic donors to needy patients.

- Kidney Paired Exchanges: Johns Hopkins is known world-wide for its pioneering work in large "domino chain" kidney transplants. Begun in 2001, this program matches otherwise incompatible recipients and donors, including the first triple-swap donation transplant (2003); the first double and triple domino transplant (2005); the first five-way domino transplant (2006); the first six-way domino transplant (2007); the first multihospital, transcontinental three-way swap transplant (2007); and the first multihospital, transcontinental six-way swap transplant (2009).

- Pediatric Kidney Transplants: Begun in 1983, this program has performed more than 250 pediatric and adolescent transplants.

- Pediatric Outpatient Hemodialysis: The CTC operates the only pediatric outpatient hemodialysis unit in the State of Maryland, and includes a 24/7 pheresis service.

- Laparoscopic Nephrectomy: In 1995, The Johns Hopkins Hospital pioneered laparoscopic nephrectomy, which uses only four small incisions to remove a kidney from a living donor. This and other innovative surgical procedures have led to increased living kidney donations, shorter hospital stays for donors, and decreased risk of postoperative infection.

- TPIAT: Johns Hopkins was the first to offer Total Pancreatectomy and Islet Auto Transplantation (TPIAT), a unique therapy for patients with chronic pancreas inflammation (pancreatitis). With TPIAT, an autologous islet cell transplantation is performed with a total pancreatectomy to store functioning islet cells that will release insulin and delay or prevent the onset of brittle diabetes. TPIAT has been able to provide patients with decreased pain, high islet cell yield and overall function, and improved quality of life.

- Live Donor Champion Program: The CTC's Live Donor Champion Program trains family members and friends of transplant recipients to encourage living donors to come forward and donate.

3. Heart Transplant Program

Established in 1983, the Johns Hopkins Heart Transplant Program performs both adult and pediatric heart transplants, while also offering preventive care to improve the quality of life for patients and decrease mortality rates. These programs include:

- Pediatric heart transplants: Johns Hopkins has led the way in pediatric heart transplants, relying on close collaboration between the pediatric cardiology and cardiac surgery programs.

- Incompatible transplants: The CTC's pediatric heart transplant group performs ABO blood group-incompatible heart transplants for infants.

- LVAD: Johns Hopkins was one of the first hospitals in the country to use the continuous-flow left ventricular assist devices (LVADs). For select patients, an LVAD can serve as a bridge to transplant and achieve improved survival pre-transplant and a better quality of life post-transplant.

- Congestive heart failure treatment: This program combines an aggressive medical approach (medical therapy, surgery, and/or mechanical circulatory support) with intensive education and lifestyle counseling.

4. Lung Transplant Program

The Johns Hopkins Hospital performed its first lung transplant in 1983. Since then, the CTC has performed more than 300 lung transplants. The two basic goals of the program are to provide outstanding clinical care and to generate new knowledge in the lung transplant field through research.

C. Existing Transplant Outpatient Presence in WRTC Service Area

The majority of transplant care is provided in an outpatient setting, including pre-transplant evaluation and post-transplant follow up care. Recognizing the need for hepatology and liver transplant services and care in the WRTC Service Area, the CTC since 2014 has operated two outpatient hepatology clinics in the WRTC serving Washington, its suburbs, northern Virginia, and southern Maryland.

1. Hepatology Clinic at Sibley

The Johns Hopkins hepatology team serving patients in the WRTC has its primary location at Sibley Hospital in Washington, D.C. The team is composed of two hepatologists, a nurse practitioner, a nurse/outreach coordinator and an administrative coordinator, with additional support from the multidisciplinary CTC team based in Baltimore. In addition to outpatient care, the Sibley hepatologists provide inpatient hepatology care and consultation services.

2. Hepatology Clinic at Suburban

Since 2014, the CTC has worked with Johns Hopkins Community Physicians to provide liver transplant evaluation, post-liver transplant hepatology, and liver cancer clinics at Suburban. In addition to outpatient care, the Johns Hopkins hepatologists provide inpatient hepatology care and consultation services at Suburban. The

hepatologists have also established and are leading clinical trials at Suburban for refractory encephalopathy and severe alcoholic hepatitis.

* * *

In sum, the new liver transplant service at Suburban will continue, build upon, and expand the leading work being done by the Johns Hopkins Comprehensive Transplant Center, including the existing transplant outpatient services offered in the WRTC.

V. CTC ACHIEVEMENTS IN ORGAN SUPPLY

The Johns Hopkins CTC has increased the total number of potential organs available for liver transplantation in the LLF. It has done so through a combination of patient and donor education and outreach, innovation, unique programming, and technology. If Suburban's CON application is granted, the CTC will use this experience to increase organ availability and usability in the WRTC and to address the disparity in transplants shown by the data above.

Because the reasons for this disparity are multifactorial, our plan for addressing it has several components:

A. Patient and Donor Education and Outreach

The Johns Hopkins CTC conducts continuing patient education and outreach programs via public education, reaching out through church and civic groups, and partnering with organizations like the American Liver Foundation, The American Transplant Foundation, and Donate Life America. The CTC provides other educational opportunities, including:

- "Lobby days" at dialysis centers – CTC staff educate dialysis patients on the option of kidney transplant, the option to double list, and answer any questions they may have about the complex transplantation process

- Physician-to-Physician meetings – CTC physicians present on advancements in transplantation and novel therapies to community physicians

- Consumer webinars – CTC physicians record webinars on topics relating to transplantation for audiences ranging from patients to providers, allowing them to access this information online in a convenient manner

- Community organization meetings – CTC physicians and staff present on topics relating to transplantation at transplant-related community events, physician group meetings and more

- Minority Organ Tissue Transplant Education Program (MOTTEP) – The CTC met with MOTTEP leadership and is working to develop a collaboration around outreach, education, support for end stage liver failure as well as donor education

An additional component of the education and outreach efforts will be in creative campaigns to teach the public about organ donation so that a significant percentage of the population registers as an organ donor in the event of sudden brain death. Johns Hopkins has proven to be creative in this arena with programs that include relationships with various donor advocacy and education organizations via volunteer efforts and the monetary donations of our staff members.

B. Facebook

One of the most innovative—and successful—donor outreach and education efforts developed by Johns Hopkins faculty has been the use of Facebook, the world's most popular social media platform. The idea for this outreach came from multiple conversations between CTC transplant surgeon Andrew M. Cameron, M.D., Ph.D. and Sheryl Sandberg, Facebook's Chief Operating Officer. On May 1, 2012, Facebook modified its platform to allow users to specify their organ donor status in their profiles. Facebook provided links to educational materials, as well as state registries for users to complete the necessary forms to officially become registered organ donors. Upon obtaining this designation, users were able to share their new organ donor status with their social networks.

The impact of this initiative was profound. As published in the American Journal of Transplantation, the results were immediate and transformative:

- On May 2, 2012, the day the initiative began, 57,451 Facebook users updated their profiles to share their organ donor status.
- There were 13,012 new online donor registrations on the first day.
- New online donor registrations represented a 21.2-fold increase over the average daily registration rate of 616 nationwide.
- While registrations varied when analyzed at the state-level, the first-day effect in Michigan resulted in nearly a seven-fold increase.
- A nearly 109-fold increase occurred in Georgia.
- New York and Texas, states where organ donation rates are among the lowest, had some of the most significant increases on the first day.
- After 12 days, the number of online registrations dropped but were still twice the normal rate.

C. Epidemiology Research Group in Organ Transplantation (ERGOT)

Another innovative effort by Johns Hopkins to increase organ donation is one of the most active transplantation research programs in the United States – the Epidemiology Research Group in Organ Transplantation ("ERGOT"). ERGOT has made significant scientific contributions in the areas of living donor recruitment and outcomes, development of transplantation models, grants, and publications, focused areas of research interest, and in development of a multidisciplinary team of faculty and staff who are transplant-focused.

Under the direction of Dorry Segev, M.D., Ph.D., the Marjory K. and Thomas

Pozefsky Professor of Surgery and Epidemiology, the team is composed of more than 13 faculty members and 70 in total staff. Dr. Segev is an abdominal transplant surgeon focusing on minimally invasive live donor surgery and incompatible organ transplantation. His research uses advanced statistical methods for mathematical modeling and simulation of medical data, analysis of large healthcare datasets and outcomes research.

The interdisciplinary core faculty of ERGOT provide expertise, teaching and scientific leadership in areas including epidemiology, transplant surgery, infectious disease, health disparities, health policy and ethics, health economics, computational science, operations and management, mobile health technology, and patient-centered and community-based interventions.

The program partners with the Scientific Registry of Transplant Recipients (SRTR), the Johns Hopkins Welch Center for Prevention, Epidemiology, and Clinical Research, the Center for Surgical Trials and Outcomes Research, and Facebook for organ donation.

Focused areas of research, grant funding, and publications include:

- Frailty and End Stage Renal Disease
- HIV Organ Policy Equity
- Incompatible organ transplantation
- Live Donor Champion Program
- Development of Donor App
- Wellness and Health Outcomes of Live Donors (WHOLE) Study

Currently, ERGOT has 20 multiyear National Institutes of Health studies underway, as well as nearly 100 other studies in progress.

D. Live Donor Organs

Living organ donation can help to address the critical shortage in organs available for patients who might otherwise die waiting for a liver. Because one in four living donors are not related biologically to the recipient, living donations require a one-on-one discussion with a transplant center. Johns Hopkins is prepared to invest in the nurse educators and coordinators required to identify and educate potential donors, and in the efficient and timely evaluation of any potential living donor.

In the State of Maryland, 179 live donor liver transplants have been performed since 1996.[43] Live donor selection is a very intensive process, because it must be assured that all potential live donors are viable donors, healthy enough to donate, and educated as to the risks and rewards of live liver donation. This is a lengthy process, and it requires the attention and time of experienced liver surgeons, hepatologists, and

[43] Source: https://optn.transplant.hrsa.gov/data/view-data-reports/state-data/#

coordinators.

Initially, the new liver transplant center at Suburban will not perform live donor transplants, which would continue to be performed at Johns Hopkins Hospital in Baltimore. However, increasing the number of live donor transplants from the WRTC is an important part of our proposal to address the disparity between LLF and WRTC transplants.

Johns Hopkins is ready and willing to make this investment in the WRTC, in order to identify as many live donors as possible to meet the needs of more patients on the wait lists. Some live donors are related to the recipients, with significant personal incentive to donate for a relative or loved one who is desperately ill. Other potential live donors are altruistic donors, who want to contribute to society to help others they don't even know.

E. Multi-Listing

Another effort by the CTC to educate about organ donation is the option to multi-list. This education is done for all patients at the initial evaluation appointment by the transplant nurse coordinator. Like all transplant centers, the CTC is mandated to provide this education as per UNOS (policy 3.2). The education includes information on registering at multiple transplant hospitals, transferring primary waiting time, and transferring care to a different transplant hospital without losing accrued waiting time.

As UNOS has described, patients benefit from multi-listing when they are listed at centers in different DSAs because it increases the odds that a patient will match with a deceased donor organ. Some patients who are listed for a liver transplant at Johns Hopkins Hospital will be eligible to multi-list for liver transplant at Suburban. This provides a unique care model: a patient can multi-list at two different centers in two different DSAs, but will share certain providers and oversight across the centers. This model allows the results of the extensive evaluation process to be shared easily between the two centers because they are on the same medical record system, reducing redundant tests and visits and ensuring that both centers are kept apprised of any changes in a patient's condition.

The model of two transplant centers within one health system provides additional programmatic benefits, including, but not limited to:

- Shared administrative, regulatory and quality oversight of The Johns Hopkins Hospital and Suburban transplant centers, minimizing overhead costs

- Shared best practices across multidisciplinary components of transplant between The Johns Hopkins Hospital and Suburban

- Shared clinical coverage for transplant at Johns Hopkins Hospital and Suburban; the well-established and experienced Hopkins transplant team

will assist with managing the medical and surgical needs of transplant patients at Suburban, allowing further development and enhancement of the Suburban's clinical team's capabilities and experience

- Shared electronic medical records, improving efficiency, continuity of care and patient safety

- Shared nursing management of transplant patients across Johns Hopkins Hospital and Suburban, allowing for continued communication among teams regarding patient status and care needs

- Single financial clearance office to allow for efficient notice to insurers regarding multi-listing and receipt of approval

F. Organ Donation Culture and Donor Advocate

As described above, the CTC has been a leader in developing techniques to increase donor education and organ donations. The CTC has also been a leader in efforts to facilitate and enrich the transplant experience. One of the most important efforts in this regard has been the development, in collaboration with the Living Legacy Foundation ("LLF"), of an Organ Donation Culture, which facilitates the solicitation and procurement of donated cadaver organs in an effective, yet caring and compassionate, manner. ICU and other hospital staff participate with CTC staff to develop a plan to ensure excellent communication and supportive end of life care for the family.

The CTC team includes a Donor Advocate, a nurse co-employed by the CTC and the LLF. The Donor Advocate's responsibilities include:

- Medically managing donors
- Managing organ donation education efforts
- Leading organ donation simulation lab efforts for medical staff including physicians, residents, fellows, advanced practice professionals, and nurses
- Arranging lectures regarding organ donation
- Responding to donor management needs, including working with inpatient unit staff, pastoral care, the LLF, and the donor's family/friends to manage the donation process
- Leading the Johns Hopkins Hospital Donor Council [44]
- Organizing the annual Johns Hopkins Hospital Donor Memorial Ceremony
- Organizing the annual Donate Life Month activities, including the "Flags Across America" flag raising, "Be Seen in Green" day, and more

[44] The Johns Hopkins Donor Council has been a formal donor process improvement, education and donation advocacy group for over 18 years. The Donor Council is composed of physician, nursing and other transplant professionals that, in collaboration with the LLF, work to educate internal and external audiences on the importance of organ donation, create, review and modify organ donor processes at JHH, and meet 2-3 times per year to increase opportunities for organ donation at the Johns Hopkins Hospital.

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.

G. Outreach and Education for Minority and Indigent Patients

Johns Hopkins has a 140-year history of service to the poor and underserved in our community. This mandate came from our benefactor, Mr. Johns Hopkins in the original documents bequeathing his estate to the University and Hospital that now bear his name. At the time of the bequest, he stipulated that the hospital admit and provide care to all in need, regardless of race or religion, and he provided for the care of the indigent, a legacy that is continued in his name today. With this legacy, Johns Hopkins has a long history of providing care to those in need, and a network of collaborators who support this mission. Suburban Hospital became a member of the Johns Hopkins Health System in 2009, bringing its own rich history of caring for disadvantaged populations in need and a strong network of community partners. In the national capital region, we have relationships with Howard University, United Medical Center, the National Institutes of Health, the US military hospitals, and social and support agencies that will help us identify patients with liver disease in need of care. We will work with the Centers for Medicare and Medicaid to assure that there is access for patients in need, and that all patients have the same quality of care.

The pathway to liver transplantation is lengthy and arduous, and it requires a sound support system prior to, during, and after transplantation. All patients with liver disease should have access to the same education, diagnostic, treatment, and supportive care programming, even if liver transplant is not medically indicated. Establishment of a liver transplant program at Suburban will include the full range of services for the diagnosis and treatment of liver diseases in the national capital region, and for the evaluation of potential transplant recipients and living donors based on nationally accepted criteria.

H. Physician Outreach

The CTC maintains relationships with referring providers in the community and provides their patients with comprehensive transplant care. The CTC stays in communication with these providers regarding their patients from the time of referral to evaluation for transplant, to listing and through post-transplant management. Program Outreach Coordinators are committed to ensuring that there is a constant line of communication between a patient's community provider and the CTC team. Both of these groups are committed to ensuring optimal long-term health outcomes of their patients.

In addition to communication and referral management, the CTC coordinates efforts for community providers to meet with the CTC physicians and teams to help develop personal relationships. Both parties find great importance in becoming familiar with one another.

I. Community Partnerships

Transplantation can be an emotional process and have a lifelong impact on patients and their families. There are several local, regional, and national organizations committed to educating patients about the transplant process and about living with a transplant, and to bringing those who have been affected by transplant together. The CTC recognizes the importance of these efforts and commits resources to these transplant partners to help further their efforts. Some of these organizations include but are not limited to:

- Donate Life America
- Living Legacy Foundation
- National Kidney Foundation of Maryland
- Organ Donation and Transplantation Alliance
- Transplant Recipients International Organization, Inc.
- United Network for Organ Sharing
- MOTTEP

J. Organ Risk

The potential reluctance of single-center DSA programs to use higher-risk organs means that (i) liver transplant patients in that DSA are less likely to receive a transplant, and (ii) those organs are more likely to be exported out of the DSA. Many patients are accepting of additional risk when faced with no other timely options for survival, and UNOS has a system for adjusting risk of survival when higher risk organs are used. However, this option is more likely to be unavailable to liver transplant patients in single-center DSAs.

Experience and skill of the surgeons is key to the ability to use higher risk organs. The decision to transplant is directly related to the risk adjusted mandatory outcomes (by CMS) for survival of the graft and the patient. The balance of organ and recipient selection and the ability to maintain expected survival outcomes is the challenge facing all transplant surgeons at all times.

Johns Hopkins transplant surgeons have the requisite experience and skill. This is shown by the fact that they (as well as University of Maryland surgeons) have and will accept organs that have been turned down by the single center in the WRTC, and that these organs have been and are successfully transplanted into patients on wait lists. This is one example of how competition has increased transplants.

K. Use of Organs from HIV-positive Donors

Before 2013, the National Organ Transplant Act of 1984, as amended in 1988, barred the transplant of organs from HIV-positive donors. But subsequent research proved that organs from HIV-positive donors could safely be transplanted into HIV-positive recipients, with any marginal additional risk to the patient from receiving the

organ substantially outweighed by the benefits of the transplant.

Johns Hopkins led the charge to have the law changed. As a result of the advocacy of Dorry Segev, M.D. and other members of the Johns Hopkins transplantation faculty, Congress enacted the HIV Organ Policy Equity (HOPE) Act in November 2013. This Hopkins-led initiative has proved to be doubly effective, because it has both increased the supply of organs (i.e., organs from HIV-positive donors) and enlarged the pool of transplant recipients (i.e., HIV-positive patients), with no additional burden to patients already on the transplant wait list. It is estimated that an additional 500-600 HIV-positive patients could be transplanted and saved every year.[45]

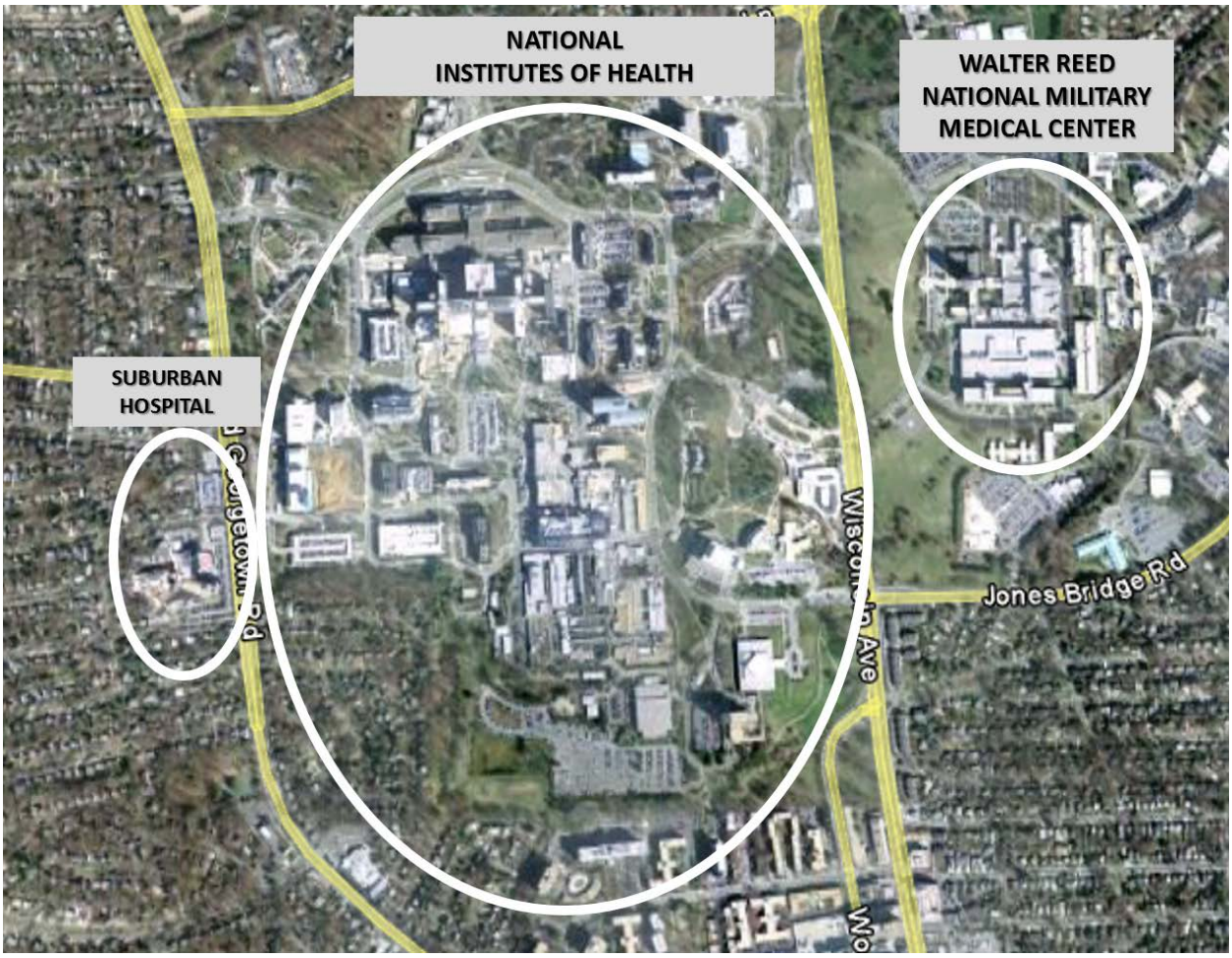
Johns Hopkins has already begun this work, performing the world's first HIV-positive liver (CTC surgeon Andrew Cameron) and kidney (CTC surgeon Niraj Desai) transplants on March 26, 2016.

[45] Boyarsky, Brian J., et al. "Estimating the Potential Pool of HIV-Infected Deceased Organ Donors in the United States." American Journal of Transplantation 11.6 (2011): 1209-1217.

VI. SUBURBAN HOSPITAL

A. Existing Facilities

Suburban is a 222 licensed-bed, not-for-profit community hospital on Old Georgetown Road in Bethesda, Maryland. Suburban opened in 1943, and was built and expanded in five phases. The last major clinical addition was built in 1979. Suburban became a member of Johns Hopkins Medicine on June 30, 2009.



Suburban's primary and secondary service area includes most of Montgomery County as well as nearby portions of the District of Columbia and Prince George's County. Suburban is fully accredited by The Joint Commission and offers a comprehensive range of acute, ambulatory, and ancillary services with the exception of obstetrics. Suburban is best known for clinical excellence in stroke care, cardiology, cardiovascular surgery, emergency/trauma services, neurosurgery, orthopedics and physical medicine, behavioral health and addiction treatment.

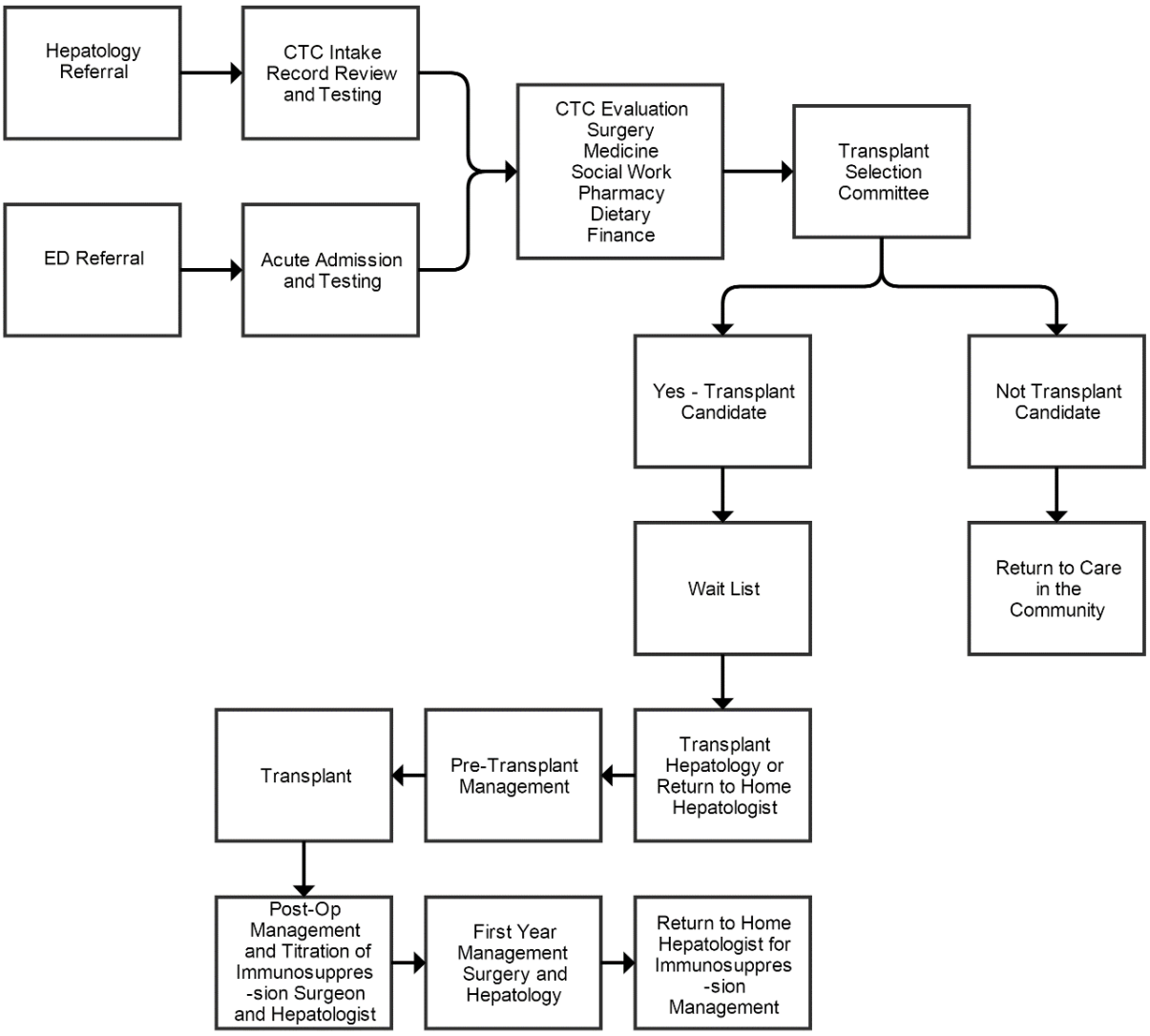
In addition to being a part of Johns Hopkins Medicine, Suburban has various strategic partnerships with other local and national healthcare providers, including the National Institutes of Health ("NIH"), located across the street, and the Walter Reed National Military Medical Center ("Walter Reed"), located two blocks away. Suburban's

partnership with NIH includes cardiac imaging, traumatic brain injury and stroke care, as well as being able to offer patients specialized procedures and participation in NIH research protocols. Suburban partners with NIH, Walter Reed, and the National Library of Medicine to provide coordinated emergency response during disasters. The partnership focuses on accommodating as many patients as possible in an emergency situation and includes systems of mutual assistance such as transferring patients from Suburban to NIH and Walter Reed to accommodate more trauma cases at Suburban, cross-privileged physicians, and the sharing of critical supplies.

Suburban also is Montgomery County's only Level II Trauma Center designated by the Maryland Institute for Emergency Medical Services Systems ("MIEMSS"). Suburban obtained that designation in 1976. As one of only nine regional trauma centers in Maryland, Suburban treats approximately 1,400 trauma patients each year.

On May 19, 2016, the Maryland Health Care Commission issued a Certificate of Need for Expansion and Modernization at Suburban Hospital, Docket No. 15-15-2368 (Exhibit 6). Suburban has been authorized to construct a 301,000 square-foot addition and to renovate approximately 18,000 square feet of the existing facility to address connections and retro-fitting of a small number of existing spaces. The primary objective of the building addition is to replace outdated patient and clinical service facilities. The project will create private patient rooms, modernize the hospital's surgical facilities, and is intended to create improved circulation and departmental adjacencies. A depiction of the completed Expansion and Modernization project is included below:

B. Proposed Transplant Service



The proposed liver transplant service will use Suburban's existing facilities. The flow chart above outlines the path of a liver disease patient through the Johns Hopkins CTC continuum of care. Additional explanation for steps in the pathway is included below:

- **Referral**: Many potential transplant candidates are referred by their hepatologist, who manages the patient's liver disease. Some patients experiencing acute distress access care through emergency room care.

- **Evaluation**: Patient evaluation is conducted by the following services: cardiology, radiology, pathology, surgery, hepatology, immunogenetics, interventional radiology, and interventional gastroenterology. When necessary, other specialists, such as hematology, urology and pulmonary are consulted, to be

sure the patient does not have co-morbidities that would influence the decision to transplant. The Suburban Liver Transplant Program will have its own evaluation process and Transplant Selection Committee, but they will use many of the same protocols and processes and will be tightly integrated with those in place at The Johns Hopkins Hospital.

- **Transplant Selection Committee**: The Committee is comprised of the liver transplant surgeon(s), transplant hepatologist(s), liver nurse coordinators, social worker, dietician, transplant pharmacist, transplant psychiatric services, and transplant financial advocate. The Committee reviews each case considering multiple factors including: clinical comorbidities, type and extent of liver disease, general health and ability to withstand major surgery, screening for cancer and cancer history, psychosocial factors that may impact the transplant decision, ability to comply with post-transplant care regimens, social support system, and drug/alcohol use or history. The Committee then determines whether the patient is a transplant candidate.

- **Wait List:** A transplant candidate is placed on the wait list and then either enters into care with the transplant hepatologist or returns to the care of a hepatologist in their community for pre-transplant management. The CTC team remains in regular contact with the patient and the patient's physician, monitoring for any changes in severity and ensuring that the patient is ready for transplant if an organ becomes available and is a match.

- **Post-Op Management:** After the transplant, the patient undergoes post-operative management and titration of immunosuppressants. The patient continues to receive care with the transplant team for at least one year. When the patient is stable, care is transitioned to the home hepatologist for immunosuppression management.

C. Existing and Planned Prevention and Treatment Efforts

A crucial goal of a new liver transplant program at Suburban Hospital is to aggressively work to reduce the preventable causes of liver failure in the national capital region and to manage liver disease before a patient's condition advances to a stage that requires transplant.

That effort has already begun. Two years ago, Johns Hopkins recruited two experienced hepatologists to treat patients in the WRTC through their work at Sibley Memorial Hospital: Dr. Kirti Shetty (director of hepatology) and Dr. Jacqueline M. Laurin (transplant hepatologist). Dr. Shetty and Dr. Laurin treat patients at Sibley's Hepatology Multidisciplinary Center by managing medical conditions that can lead to liver failure. By actively addressing underlying problems, the need for liver transplant can be reduced.

In connection with the new transplant center at Suburban, Johns Hopkins plans to expand the practice of Drs. Shetty and Laurin and to undertake additional prevention efforts. Johns Hopkins will:

- Build a regional Center of Excellence for Liver Disease, with expertise and capabilities in critical care, interventional radiology, and a complete range of wraparound support services for patients with liver disease.

- Deploy trained nurse coordinators/educators to engage in community education and outreach.

- Increase access to experienced liver specialists to provide care that prevents progression of liver disease, including access to bariatric treatment options.

- Collaborate with local community-based programs to address drug and alcohol dependency and obesity.

- Link existing programs in the WRTC to programs at Sibley, Suburban, and in 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.

Complete the DEPARTMENTAL GROSS SQUARE FEET WORKSHEET (Table B**) in the CON TABLE PACKAGE for the departments and functional areas to be affected.**

Applicant Response:

Inapplicable.

9. CURRENT PHYSICAL CAPACITY AND PROPOSED CHANGES

Complete the Bed Capacity (Table A) worksheet in the CON Table Package if the proposed project impacts any nursing units.

Applicant Response:

Please see Exhibit 1A for Bed Capacity Table A.

10. REQUIRED APPROVALS AND SITE CONTROL

A. Site size: _____ acres

B. Have all necessary State and local land use approvals, including zoning, for the project as proposed been obtained? YES_____ NO _____ (If NO, describe below the current status and timetable for receiving necessary approvals.)

C. Form of Site Control (Respond to the one that applies. If more than one, explain.):

(1) Owned by: _____
Please provide a copy of the deed.

(2) Options to purchase held by: _____
Please provide a copy of the purchase option as an attachment.

(3) Land Lease held by: _____
Please provide a copy of the land lease as an attachment.

(4) Option to lease held by: _____
Please provide a copy of the option to lease as an attachment.

(5) Other: _____
Explain and provide legal documents as an attachment.

Applicant Response:

Inapplicable.

11. Project Schedule

In completing this section, please note applicable performance requirement time frames set forth at COMAR 10.24.01.12B & C. Ensure that the information presented in the following table reflects information presented in Application Item 7 (Project Description).

	Proposed Project Timeline	
Single Phase Project		
Obligation of 51% of capital expenditure from CON approval date		months
Initiation of Construction within 4 months of the effective date of a binding construction contract, if construction project		months
Completion of project from capital obligation or purchase order, as applicable		months
Multi-Phase Project for an existing health care facility (Add rows as needed under this section)		
One Construction Contract		months
Obligation of not less than 51% of capital expenditure up to 12 months from CON approval, as documented by a binding construction contract.		months
Initiation of Construction within 4 months of the effective date of the binding construction contract.		months
Completion of 1st Phase of Construction within 24 months of the effective date of the binding construction contract		months
Fill out the following section for each phase. (Add rows as needed)		
Completion of each subsequent phase within 24 months of completion of each previous phase		months
Multiple Construction Contracts for an existing health care facility (Add rows as needed under this section)		
Obligation of not less than 51% of capital expenditure for the 1st Phase within 12 months of the CON approval date		months
Initiation of Construction on Phase 1 within 4 months of the effective date of the binding construction contract for Phase 1		months
Completion of Phase 1 within 24 months of the effective date of the binding construction contract.		months
To Be Completed for each subsequent Phase of Construction		
Obligation of not less than 51% of each subsequent phase of construction within 12 months after completion of immediately preceding phase		months
Initiation of Construction on each phase within 4 months of the effective date of binding construction contract for that phase		months
Completion of each phase within 24 months of the effective date of binding construction contract for that phase		months

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Applicant Response:

There are no capital expenditures and no construction contract associated with this project.

12. PROJECT DRAWINGS

A project involving new construction and/or renovations must include scalable schematic drawings of the facility at least a 1/16” scale. Drawings should be completely legible and include dates.

Project drawings must include the following before (existing) and after (proposed) components, as applicable:

A. Floor plans for each floor affected with all rooms labeled by purpose or function, room sizes, number of beds, location of bathrooms, nursing stations, and any proposed space for future expansion to be constructed, but not finished at the completion of the project, labeled as “shell space”.

B. For a project involving new construction and/or site work a Plot Plan, showing the "footprint" and location of the facility before and after the project.

C. For a project involving site work schematic drawings showing entrances, roads, parking, sidewalks and other significant site structures before and after the proposed project.

D. Exterior elevation drawings and stacking diagrams that show the location and relationship of functions for each floor affected.

Applicant Response:

Inapplicable.

13. **FEATURES OF PROJECT CONSTRUCTION**

A. If the project involves new construction or renovation, complete the Construction Characteristics (Table C) and Onsite and Offsite Costs (Table D) worksheets in the CON Table Package.

B. Discuss the availability and adequacy of utilities (water, electricity, sewage, natural gas, etc.) for the proposed project, and the steps necessary to obtain utilities. Please either provide documentation that adequate utilities are available or explain the plan(s) and anticipated timeframe(s) to obtain them.

Applicant Response:

Inapplicable.

PART II - PROJECT BUDGET

Complete the Project Budget (Table E) worksheet in the CON Table Package.

Note: Applicant must include a list of all assumptions and specify what is included in all costs, as well the source of cost estimates and the manner in which all cost estimates are derived.

Applicant Response:

Inapplicable.

PART III - APPLICANT HISTORY, STATEMENT OF RESPONSIBILITY, AUTHORIZATION AND RELEASE OF INFORMATION, AND SIGNATURE

1. **List names and addresses of all owners and individuals responsible for the proposed project.**

   Suburban Hospital is a non-stock not-for-profit corporation. Suburban's sole corporate member is The Johns Hopkins Health System Corporation. Jacqueline Schultz, President and Chief Executive Officer of Suburban Hospital, is responsible for the proposed project (Exhibit 7).

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2. **Is any applicant, owner, or responsible person listed above now involved, or has any such person ever been involved, in the ownership, development, or management of another health care facility? If yes, provide a listing of each such facility, including facility name, address, the relationship(s), and dates of involvement.**

   Prior to becoming a member of The Johns Hopkins Health System Corporation, Suburban Hospital was wholly owned by Suburban Hospital Healthcare System, Inc. (SHHS). Since the 1980s, various members of Suburban Hospital Inc.'s (SHI) executive and management team were involved in the development and oversight of various wholly owned subsidiaries and joint ventures of Suburban Hospital and Suburban Hospital Healthcare System. Exhibit 8 includes a listing of all of such facilities for which SHI and SHHS still have an ownership interest.

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3. **In the last 5 years, has the Maryland license or certification of the applicant facility, or the license or certification from any state or the District of Columbia of any of the facilities listed in response to Question 2, above, ever been suspended or revoked, or been subject to any disciplinary action (such as a ban on admissions) ? If yes, provide a written explanation of the circumstances, including the date(s) of the actions and the disposition. If the applicant(s), owners, or individuals responsible for implementation of the Project were not involved with the facility at the time a suspension, revocation, or disciplinary action took place, indicate in the explanation.**

   No.

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4. **Other than the licensure or certification actions described in the response to Question 3, above, has any facility with which any applicant is involved, or has any facility with which any applicant has in the past been involved (listed in response to Question 2, above) ever received inquiries from a federal or any state authority, the Joint Commission, or other regulatory body regarding possible non-compliance with Maryland, another state, federal, or Joint Commission requirements for the provision of, the quality of, or the payment for health care services that have resulted in actions leading to the possibility of penalties, admission bans, probationary status, or other sanctions at the applicant facility or at any facility listed in response to Question 2? If yes, provide, for each such instance, copies of any settlement reached, proposed findings or final findings of non-compliance and related documentation including reports of non-compliance, responses of the facility, and any final disposition or conclusions reached by the applicable authority.**

   In May of 2012, the Joint Commission (TJC) triennial survey at Suburban Hospital resulted in an adverse accreditation decision – Accreditation With Follow-Up Survey. Suburban Hospital submitted corrective action plans on 7/9/12 and 7/24/12, which were accepted on 9/18/12 and TJC then granted an accreditation decision of Accredited with an effective date of 7/24/12**.** See Exhibit 9 for a copy of the final letter from TJC.

   On 6/1/12, DHMH Office of Health Care Quality (OHCQ) conducted a complaint survey on behalf of CMS, which resulted in a condition-level deficiency. Suburban Hospital submitted a corrective action plan on 7/19/12. OHCQ re-surveyed on behalf of CMS on 8/15/12 – 8/16/12 and cited the hospital for a different condition-level deficiency due to Life Safety Code deficiencies, and removed the hospital's deemed status. Suburban Hospital submitted a corrective action plan on 10/4/12. OHCQ conducted a hospital revisit survey on behalf of CMS on 11/9/12. On 3/14/13, Suburban Hospital received a letter from OHCQ, on behalf of CMS, restoring the hospital's deemed status as of 11/9/12. See Exhibit 10 for a copy of the letter.

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5. **Has any applicant, owner, or responsible individual listed in response to Question 1, above, ever pled guilty to, received any type of diversionary disposition, or been convicted of a criminal offense in any way connected with the ownership, development, or management of the applicant facility or any of the health care facilities listed in response to Question 2, above? If yes, provide a written explanation of the circumstances, including as applicable the court, the date(s) of conviction(s), diversionary disposition(s) of any type, or guilty plea(s).**

   No.

One or more persons shall be officially authorized in writing by the applicant to sign for and act for the applicant for the project which is the subject of this application. Copies of this authorization shall be attached to the application. The undersigned is the owner(s), or Board-designated official of the applicant regarding the project proposed in the application.

I hereby declare and affirm under the penalties of perjury that the facts stated in this application and its attachments are true and correct to the best of my knowledge, information, and belief.

06/28/2017
Date

Jacky Schultz
Signature of Owner or Board-designated Official

President and CEO, Suburban Hospital
Position/Title

Jacky Schultz
Printed Name

PART IV - CONSISTENCY WITH GENERAL REVIEW CRITERIA AT COMAR 10.24.01.08G(3):

INSTRUCTION: Each applicant must respond to all criteria included in COMAR 0.24.01.08G(3), listed below.

An application for a Certificate of Need shall be evaluated according to all relevant State Health Plan standards and other review criteria.

If a particular standard or criteria is covered in the response to a previous standard or criteria, the applicant may cite the specific location of those discussions in order to avoid duplication. When doing so, the applicant should ensure that the previous material directly pertains to the requirement and the directions included in this application form. Incomplete responses to any requirement will result in an information request from Commission Staff to ensure adequacy of the response, which will prolong the application's review period.

10.24.01.08G(3)(a). <u>The State Health Plan</u>.

To respond adequately to this criterion, the applicant must address each applicable standard from each chapter of the State Health Plan that governs the services being proposed or affected, and provide a direct, concise response explaining the project's consistency with each standard. <u>In cases where demonstrating compliance with a standard requires the provision of specific documentation, documentation must be included as a part of the application.</u>

Every acute care hospital applicant must address the standards in **COMAR 10.24.10: Acute Care Hospital Services**. A Microsoft Word version is available for the applicant's convenience on the Commission's website. Use of the *CON Project Review Checklist for Acute Care Hospitals General Standards* is encouraged. This document can be provided by staff.

Other State Health Plan chapters that may apply to a project proposed by an acute care hospital are listed in the table below. A pre-application conference will be scheduled by Commission Staff to cover this and other topics. It is highly advisable to discuss with Staff which State Health Plan chapters and standards will apply to a proposed project before application submission. Applicants are encouraged to contact Staff with any questions regarding an application.

Applicant Response:

Please see responses to 10.24.10.04A and 10.24.15.05 below.

COMAR 10.24.10 ACUTE CARE CHAPTER
.04A. GENERAL STANDARDS

The following general standards encompass Commission expectations for the delivery of acute care services by all hospitals in Maryland. Each hospital that seeks a Certificate of Need for a project covered by this Chapter of the State Health Plan must address and document its compliance with each of the following general standards as part of its Certificate of Need application. Each hospital that seeks a Certificate of Need exemption for a project covered by this Chapter of the State Health Plan must address and demonstrate consistency with each of the following general standards as part of its exemption request.

Standard .04A (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 Response:

A copy of Suburban's policy regarding the provision of information about charges is attached as Exhibit 11 Suburban provides estimated charges on our website, http://www.hopkinsmedicine.org/suburban_hospital/planning_your_visit/financial_information/estimated_charges.html Written copies of the charges are also provided to staff in registration and financial counseling offices. Patients can receive a copy of the list of charges upon request.

Estimates of charges for most frequently occurring services and procedures are updated quarterly. Upon request, patients are provided with written estimates for hospital services by our Financial Counseling staff. Patients with inquiries related to hospital charges prior to or on the day of service can contact Financial Counseling for a copy of the list of charges, or request current charges for specific service/procedure(s).

A copy of the charges is also mailed upon request.

Staff is trained regularly to respond appropriately to the requests for information regarding charges and is aware of the location of the information. Financial staff is educated about the criteria to build the charge report and how to update the list of representative charges quarterly on our website.

Standard .04A(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 Response:

Suburban Hospital provides quality care to all patients regardless of their ability to pay. Suburban's financial assistance policy is attached as Exhibit 12, and it is posted on the website, http://www.hopkinsmedicine.org/suburban_hospital/planning_your_visit/financial_information/billing_information.html for public view and is available for review upon request. Notice is published in the Washington Post on an annual basis and was last published on December 23, 2016. See Exhibit 13 for proof of publication.

Free care, sliding fee scales and extended payment plans are offered to eligible patients. Approval for financial assistance, sliding fee scales or payment plans is based on submission of a financial assistance application available upon request at each of

our registration points of entry and on the website at the link noted above.

Suburban Hospital provides each patient registered for emergency care, same day care, or inpatient care information about financial assistance and how to apply. Signs are posted in English and Spanish explaining the availability of financial assistance and contact information in the Emergency Department Lobby, inside the Emergency Department, the Pediatric Emergency Department, the Front Registration Desk, and the Cath Lab waiting area. See Exhibit 14 for photographs of the posted notifications. Free care, sliding fee scales and extended payment plans are offered to eligible patients. Approval for financial assistance, sliding fee scales or payment plans 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. This information is also available in Spanish.

In addition, Financial Counselors and Social Workers are trained to answer patient questions regarding financial assistance and linkage to other community assistance resources prior to discharge. Registration staff is trained to answer questions regarding financial assistance and who to contact with billing questions or other financial questions. Patient Financial Services staff is also trained to answer questions and provide information to patients regarding financial assistance and billing. Suburban Hospital uses contractors from Financial Health Services and Deco who assist patients in applying for Maryland Medical Assistance. The Financial Health Services and Deco contractors 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. Patients will be given an indication of probable eligibility at least within two business days of their inquiry, but usually the same day.

(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 Response:

According to the FY15 Health Services Cost Review Commission Community Benefit Financial Report, published on the HSCRC website, Suburban Hospital's charity care as a percent of total operating expenses was 1.55%. Suburban ranks 33rd out of 53 Maryland non-profit hospitals for this measure, placing Suburban in the third quartile, not the bottom quartile, of all Maryland hospitals.

Standard .04A (3) – <u>Quality of Care.</u>

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.

(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 Response:

Suburban complies with all applicable federal, state and local health and safety regulations. A copy of the license to operate as an acute general hospital facility in Montgomery County is attached as Exhibit 15.

The Maryland Department of Health and Mental Hygiene has also given Suburban authority to operate (Exhibit 15).

A copy of Suburban's Joint Commission on Accreditation of Healthcare Organizations ("TJC") accreditation for a three-year period beginning May 15, 2015 is attached as Exhibit 16. The next triennial survey by the Joint Commission will occur in the spring of 2018.

Suburban Hospital provides high quality patient care. Historically our performance on most core measures has been at or above 96%. The data that are reported in the most recent Maryland Hospital Performance Evaluation Guide (January – December 2015 shows our Clostridium difficile infection rate to be higher than average., Suburban Hospital's Infection Control team, Housekeeping Department and staff have worked diligently and collaboratively to improve on this measure. Focus of efforts has been on basic room cleaning procedures, use of ultraviolet light post cleaning of ICU rooms and C. difficile rooms, a review and revision of testing procedures, hand hygiene monitoring and establishment of an antibiotic stewardship. Infection rates are monitored closely and reported to appropriate committees including the Medical Quality Committee of the Board of Trustees on a regular basis.

COMAR 10.24.15 ORGAN TRANSPLANT SERVICES CHAPTER
.05A GENERAL STANDARDS

Standard .05A (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.

Applicant Response:

Please see 10.24.10.04A (1)-(3) above.

Standard .05A (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 Response:

(a)

Suburban Hospital 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 operations.

(b)

Accreditation by the Foundation for Accreditation of Cellular Therapy is not applicable.

COMAR 10.24.15 ORGAN TRANSPLANT SERVICES CHAPTER
.05B PROJECT REVIEW STANDARDS

Standard .05B(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. 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.

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

(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 Response:

(a)

Ability to Increase Supply & Use of Donor Organs

There exists an imbalance in liver supply between the LLF DSA and WRTC DSA. The two-center, competitive LLF DSA has grown its Total Organ Supply, procuring more livers, importing more livers, and exporting fewer livers per year than the single-center, non-competitive WRTC DSA. The sections below, also discussed in the Project Description, describes the supply differences between the two DSAs, and demonstrate how the creation of the proposed program at Suburban will increase the supply of organs in the WRTC.

The Increasing Supply Imbalance

Deceased donor organs can be (a) procured[46] and used within the DSA, (b) imported from outside the DSA, or (c) exported to another DSA. The Scientific Registry

[46] Organ procurement is the removal or retrieval of organs from a deceased donor for transplantation.

of Transplant Recipients ("SRTR") compiles reports on livers procured by each OPO and where those organs were used. Using SRTR data, an OPO's supply of organs can be measured by the following formula:

OPO Liver Supply =
(Livers Procured) – (Livers Exported) + (Livers Imported)

Liver imports and exports occur within the context of established rules. In any DSA, when a deceased donor liver becomes available for transplant, that organ is most commonly matched with, and subsequently transplanted by, a center within the same DSA (local priority). The three exceptions to local priority that can result in the importation or exportation of livers are (a) Status 1, where the most critically ill patients are given priority within a region (Regional Priority); (b) physician preference, where organs rejected by one transplant physician are offered to the next match within a region; and (c) beginning in June 2013, the Share 35 preference, where patients with a MELD score of 35 or greater are given regional priority.

The supply of livers procured, imported, and exported shows marked and growing differences between the LLF DSA and the WRTC DSA.

Deceased Donor Livers Procured

OPO Liver Supply =
(Livers Procured) – (Livers Exported) + (Livers Imported)

	Livers Procured		
	FY 2013	CY 2014	CY 2015
LLF	102	119	121
WRTC	92	97	89

The number of livers procured is consistently higher in the LLF than the WRTC, despite the larger population in the WRTC.[47]

[47] Data presented in this section depicts the number of livers procured in fiscal year 2013 and calendar years 2014 and 2015. This is done deliberately in an effort to provide the most recent data available while accounting for the introduction of Share 35. Share 35 was implemented on June 18, 2013. By including FY2013, we show the last full year of data before Share 35 was implemented. This is the only instance in this application where fiscal year data is presented. By moving to CY2014 we return to our standard interval. The missing 6 months of data, July-Dec 2013, cover the initial months of Share 35 implementation.

Livers Exported

OPO Liver Supply =
(Livers Procured) **– (Livers Exported)** + (Livers Imported)

Prior to Share 35,[48] in FY 2013, the LLF used 95.1% of the organs it procured, exporting only 4.9%. The WRTC used only 80.4% of locally-procured organs, exporting nearly 20%.

Fiscal Year 2013 (7/1/2012 - 6/30/2013)				
OPO	Livers Procured by OPO	Procured by OPO and Transplanted at Local Center(s)	Livers Exported	Percentage of Livers Exported
LLF	102	97	5	4.9%
WRTC	92	74	18	19.6%

It was expected that an increase in organ exports would occur with the launch of the Share 35 program in June 2013 because that policy allowed transplant centers with patients with higher MELD scores to import more organs from within a region. A study by Massie confirmed this prediction, compiling liver distribution data for the 12 months preceding and following the start of Share 35.[49]

Calendar Year 2014				
OPO	Livers Procured by OPO	Procured by OPO and Transplanted at Local Center(s)	Livers Exported	Percentage of Livers Exported
LLF	119	96	23	19.3%
WRTC	97	59	38	39.2%

For both WRTC and LLF, the number of exported livers rose after the Share 35 program began. LLF exports rose from 4.9% in FY 2013 to 19.3% in CY 2014; and WRTC exports in that same period rose from 19.6% to 39.2%. The latest data, for CY 2015, shows that this gap widened further:

Calendar Year 2015				
OPO	Livers Procured by OPO	Procured by OPO and Transplanted at Local Center(s)	Livers Exported	Percentage of Livers Exported
LLF	121	97	24	19.8%
WRTC	89	36	53	59.6%

[48] The Share 35 program (begun in June 2013) created a new priority for patients with MELD scores of 35 or greater, i.e., not as sick as Status 1 patients but sick enough to warrant preference over other, non-Status 1 patients on a waitlist in the region.

[49] Massie, A. B., et al. "Early changes in liver distribution following implementation of Share 35." American Journal of Transplantation 15.3 (2015): 659-667.

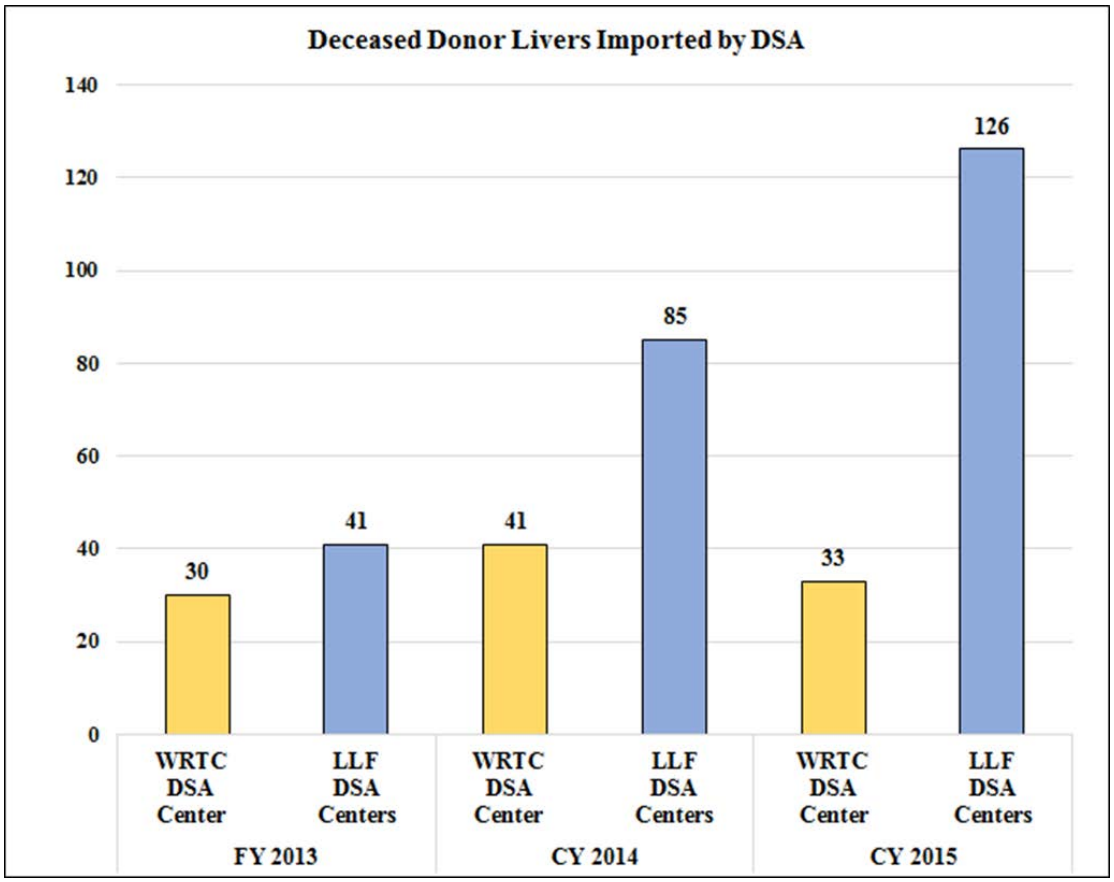
While the LLF's post-Share 35 export rate held steady at 19.8% in CY 2015, WRTC's export rate shot up to nearly 60% for CY 2015, a 52% increase in one year.

There are several likely explanations for this jump in WRTC exports in the post-Share 35 era. Again, the lower MELD scores for WRTC patients on the WRTC wait list means that the single WRTC center does not have sufficient high-MELD score patients to retain more of their deceased donor organs, i.e., higher-MELD patients from other DSAs can "pull" livers out of the WRTC.

Livers Imported

OPO Liver Supply =
(Livers Procured) – (Livers Exported) + **(Livers Imported)**

Donated livers imported by the two DSAs tell a similar story. Despite serving a 40% larger population, the single WRTC transplant center lags far behind the two-center LLF in liver imports. In 2014, the LLF imported just over twice as many livers as the WRTC (2.07), and that figure nearly doubled in 2015 (3.82).



One likely explanation for fewer imports by the WRTC derives from the acuity data discussed earlier: because the single WRTC center performs transplants on patients with lower MELD scores, the center's patients have lower priority and the center has corresponding less ability to "pull" donor organs from other DSAs through

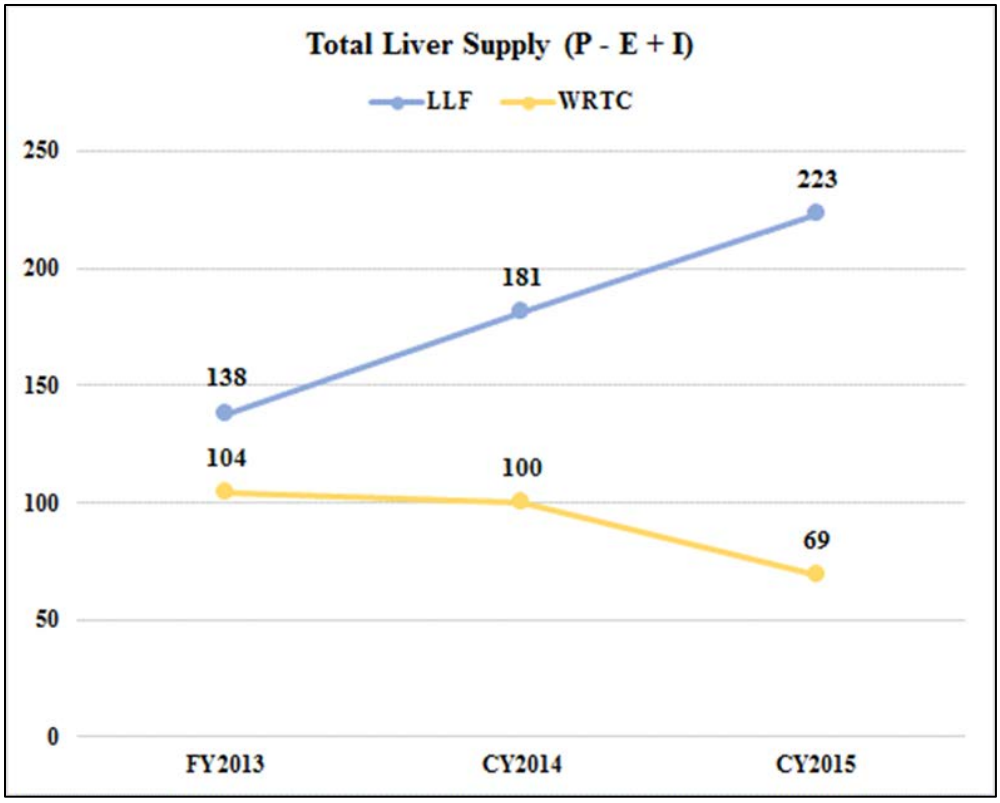
Status 1 or Share 35 recipients.

Organ Supply Conclusions

OPO Liver Supply =
(Livers Procured) – (Livers Exported) + (Livers Imported)

Returning to the formula for measuring deceased donor organ supply, the table below shows the data for all three sources of organs for both the LLF and the WRTC, as well as the growing gap between those two DSAs:

	Procured			Exported (-)			Imported (+)			Total Supply (P-E+I)		
	FY2013	CY2014	CY2015	FY2013	CY2014	CY2015	FY2013	CY2014	CY2015	FY2013	CY2014	CY2015
LLF	102	119	121	5	23	24	41	85	126	138	181	223
WRTC	92	97	89	18	38	53	30	41	33	104	100	69
									Ratio LLF:WRTC	1.33	1.81	3.23



Two observations leap out from this supply data. *First*, in 2015, the two LLF transplant centers transplanted (net) more than three times (3.23) the organs transplanted by the single WRTC center, a multiple that has surged since 2013 (1.33 times greater) and 2014 (1.81 times greater). *Second*, just like declining transplant volume and MELD scores, the single WRTC center's total net supply of deceased donor organs has *decreased* 33.7% since 2013 (104 to 69), while the two LLF centers had a combined 61.6% increase over that same period (138 to 223). This deficiency is all the more remarkable given that the WRTC has a 40% larger population than the LLF.

In sum, it is highly likely that the addition of a second liver transplant center in the WRTC DSA will result in an increase in organ supply. This is based on the evidence that the two-center LLF DSA has achieved a higher level of performance, and further that one of the two very successful LLF DSA centers will operate the new center in the WRTC DSA, and is very likely to achieve the same high level of performance at the new location.

CTC Achievements In Organ Supply

The Johns Hopkins Comprehensive Transplant Center is one of the leading programs in the world in developing innovative approaches to increasing organ supply. The Johns Hopkins CTC has increased the total number of potential organs available for liver transplantation in the LLF DSA through patient and donor education and outreach, innovation, unique programming, and technology. If Suburban's CON application is granted, the CTC will use this experience to increase organ availability and usability in the WRTC and to address the disparity in transplants shown by the data above. Described below are some of the recent work by the CTC to address organ supply.

Patient and Donor Education and Outreach

The Johns Hopkins CTC conducts continuing patient education and outreach programs via public education, reaching out through church and civic groups, and partnering with organizations like the American Liver Foundation, The American Transplant Foundation, and Donate Life America. The CTC provides other educational opportunities, including:

- "Lobby days" at dialysis centers – CTC staff educate dialysis patients on the option of kidney transplant, the option to double list, and answer any questions they may have about the complex transplantation process

- Physician-to-Physician meetings – CTC physicians present on advancements in transplantation and novel therapies to community physicians

- Consumer webinars – CTC physicians record webinars on topics relating to transplantation for audiences ranging from patients to providers, allowing them to access this information online in a convenient manner

- Community organization meetings – CTC physicians and staff present on topics relating to transplantation at transplant-related community events, physician group meetings

An additional component of the education and outreach efforts will be in creative campaigns to teach the public about organ donation so that a significant percentage of the population registers as an organ donor in the event of sudden brain death. Johns Hopkins has proven to be creative in this arena with programs that include relationships

with various donor advocacy and education organizations via volunteer efforts and the monetary donations of our staff members.

Facebook

One of the most innovative—and successful—donor outreach and education efforts developed by Johns Hopkins faculty has been the use of Facebook, the world's most popular social media platform. The idea for this outreach came from multiple conversations between CTC transplant surgeon Andrew M. Cameron, M.D., Ph.D. and Sheryl Sandberg, Facebook's Chief Operating Officer. On May 1, 2012, Facebook modified its platform to allow users to specify their organ donor status in their profiles. Facebook provided links to educational materials, as well as state registries for users to complete the necessary forms to officially become registered organ donors. Upon obtaining this designation, users were able to share their new organ donor status with their social networks.

The impact of this initiative was profound. As published in the American Journal of Transplantation, the results were immediate and transformative:

- On May 2, 2012, the day the initiative began, 57,451 Facebook users updated their profiles to share their organ donor status.
- There were 13,012 new online donor registrations on the first day.
- New online donor registrations represented a 21.2-fold increase over the average daily registration rate of 616 nationwide.
- While registrations varied when analyzed at the state-level, the first-day effect in Michigan resulted in nearly a seven-fold increase.
- A nearly 109-fold increase occurred in Georgia.
- New York and Texas, states where organ donation rates are among the lowest, had some of the most significant increases on the first day.
- After 12 days, the number of daily new online registrations dropped but were still twice the normal rate.

Epidemiology Research Group in Organ Transplantation (ERGOT)

Another innovative effort by Johns Hopkins to increase organ donation is one of the most active transplantation research programs in the United States – the Epidemiology Research Group in Organ Transplantation ("ERGOT"). ERGOT has made significant scientific contributions in the areas of living donor recruitment and outcomes, development of transplantation models, grants, and publications, focused areas of research interest, and in development of a multidisciplinary team of faculty and staff

who are transplant-focused.

Under the direction of Dorry Segev, M.D., Ph.D., the Marjory K. and Thomas Pozefsky Professor of Surgery and Epidemiology at the Johns Hopkins University School of Medicine, the team is composed of more than 13 Hopkins faculty members, 70 staff in total. Dr. Segev is an abdominal transplant surgeon focusing on minimally invasive live donor surgery and incompatible organ transplantation. His research uses advanced statistical methods for mathematical modeling and simulation of medical data, analysis of large healthcare datasets and outcomes research.

The interdisciplinary core faculty of ERGOT provide expertise, teaching and scientific leadership in areas including epidemiology, transplant surgery, infectious disease, health disparities, health policy and ethics, health economics, computational science, operations and management, mobile health technology, and patient-centered and community-based interventions.

The program partners with the Scientific Registry of Transplant Recipients (SRTR), the Johns Hopkins Welch Center for Prevention, Epidemiology, and Clinical Research, the Center for Surgical Trials and Outcomes Research, and Facebook for organ donation.

Focused areas of research, grant funding and publications include:

- Frailty and End Stage Renal Disease
- HIV Organ Policy Equity
- Incompatible organ transplantation
- Live Donor Champion Program
- Development of Donor App
- Wellness and Health Outcomes of Live Donors (WHOLE) Study

Currently, ERGOT has 20 multiyear National Institutes of Health studies underway, as well as nearly 100 other studies in progress.

Live Donor Organs

Living organ donation can help to address the critical shortage in organs available for patients who might otherwise die waiting for a liver.

In the State of Maryland, 179 live donor liver transplants have been performed since 1996.[50] Live donor selection is a very intensive process, because it must be assured that all potential live donors are viable donors, healthy enough to donate, and educated as to the risks and rewards of live liver donation. This is a lengthy process, and it requires the attention and time of experienced liver surgeons, hepatologists, and coordinators.

[50] Source: https://optn.transplant.hrsa.gov/data/view-data-reports/state-data/#

Initially, the new liver transplant center at Suburban will not perform live donor transplants, which would continue to be performed at The Johns Hopkins Hospital in Baltimore. However, increasing the number of live donor transplants from the WRTC is an important part of our proposal to address the disparity between LLF and WRTC transplants.

Johns Hopkins will invest in the additional nurse educators and coordinators required to identify and educate potential donors, and in the efficient and timely evaluation of any potential living donor in the WRTC. Recipients with identified live donors will be transplanted at The Johns Hopkins Hospital for now. In the future, we hope to be able to serve these donors and recipients at either hospital. Johns Hopkins is ready and willing to make this investment in the WRTC, in order to identify as many live donors as possible to meet the needs of more patients on the wait lists.

Multi-Listing

Another effort by the CTC to educate potential recipients is the option to multi-list. This education is done for all patients at the initial evaluation appointment by the transplant nurse coordinator.

Patients benefit from multi-listing at centers in different DSAs because it increases their odds of matching with a deceased donor organ. The establishment of a transplant center at Suburban Hospital by the Johns Hopkins CTC creates a unique opportunity available in a very few places in the United Stated: Appropriate patients can be listed at two centers in two different DSAs under a shared clinical program, with a shared evaluation process and medical record system, reducing redundant tests and visits and ensuring that both centers are kept apprised of any changes in a patient's condition.

The model of two transplant centers within one health system provides additional programmatic benefits, including, but not limited to:

- Single financial clearance office to allow for efficient notice to insurers regarding multi-listing and receipt of approval

- Shared electronic medical records, improving efficiency, continuity of care and patient safety

- Shared nursing management of transplant patients across Johns Hopkins Hospital and Suburban, allowing for continued communication among teams regarding patient status and care needs

- Shared clinical coverage for transplant at Johns Hopkins Hospital and Suburban; well-established and experienced Hopkins transplant team will assist with managing the medical and surgical needs of transplant patients at Suburban, allowing further development and enhancement of the Suburban's clinical team's capabilities and experience

- Shared administrative, regulatory and quality oversight of the Johns Hopkins Hospital and Suburban transplant centers, minimizing overhead costs

- Shared best practices across multidisciplinary components of transplant between Johns Hopkins Hospital and Suburban

Organ Donation Culture and Donor Advocate

The CTC has been a leader in developing techniques to increase donor education and organ donations. The CTC has also been a leader in efforts to facilitate and enrich the transplant experience. One of the most important efforts in this regard has been the development, in collaboration with the Living Legacy Foundation ("LLF"), of an Organ Donation Culture, which facilitates the solicitation and procurement of donated cadaver organs in an effective, yet caring and compassionate, manner. ICU and other hospital staff participate with CTC staff to develop a plan to ensure excellent communication and supportive end of life care for the family.

The CTC team includes a Donor Advocate, who is a nurse co-employed by the CTC and the LLF. The Donor Advocate's responsibilities include:

- Medically managing donors
- Managing organ donation education efforts
- Leading organ donation simulation lab efforts for medical staff including physicians, residents, fellows, advanced practice professionals, and nurses
- Arranging lectures regarding organ donation
- Responding to donor management needs, including working with inpatient unit staff, pastoral care, the LLF, and the donor's family/friends to manage the donation process
- Leading the Johns Hopkins Hospital Donor Council[51]
- Organizing the annual Johns Hopkins Hospital Donor Memorial Ceremony
- Organizing the annual Donate Life Month activities, including the "Flags Across America" flag raising, "Be Seen in Green" day, and more

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. It is also an example of shared resources and collaboration between the CTC and the LLF OPO in order to create the biggest positive impact.

Use of Organs from HIV-positive Donors

Before 2013, the National Organ Transplant Act of 1984, as amended in 1988,

[51] The Johns Hopkins Donor Council has been a formal donor process improvement, education and donation advocacy group for over 18 years. The Donor Council is composed of physician, nursing and other transplant professionals that, in collaboration with the LLF, work to educate internal and external audiences on the importance of organ donation, create, review and modify organ donor processes at JHH, and meet 2-3 times per year to increase opportunities for organ donation at the Johns Hopkins Hospital.

barred the transplant of organs from HIV-positive donors. Subsequent research proved that organs from HIV-positive donors could safely be transplanted into HIV-positive recipients, with any marginal additional risk to the patient from receiving the organ substantially outweighed by the benefits of the transplant.

Johns Hopkins led the charge to have the law changed. As a result of the advocacy of Dorry Segev, M.D. and other members of the Johns Hopkins transplantation faculty, Congress enacted the HIV Organ Policy Equity (HOPE) Act in November 2013. This Hopkins-led initiative has proved to be doubly effective, because it has both increased the supply of organs (i.e., organs from HIV-positive donors) and enlarged the pool of transplant recipients (i.e., HIV-positive patients), with no additional burden to patients already on the transplant wait list. It is estimated that an additional 500-600 HIV-positive patients could be transplanted and saved every year.[52]

Johns Hopkins has already begun this work, performing the world's first HIV-positive liver (CTC surgeon Andrew Cameron) and kidney (CTC surgeon Niraj Desai) transplants on March 26, 2016.

Living Donation Initiatives

The imbalance that exists in organ supply between the LLF DSA and WRTC DSA is not limited to deceased donor livers, but is seen in live donor livers as well.

Because of the highly complex nature of these procedures, Suburban Hospital is not proposing to perform live donor liver procedures upon initiation of operations. However, examining the relative performance of the LLF and the WRTC in performing live donor transplants sheds further light on the supply component of the need analysis because every live donor transplant effectively "frees up" a deceased donor liver for another individual on the wait list. By increasing the overall supply of livers in this way, not only can more patients be transplanted, but the wait times for patients who are unable to identify a live donor can be reduced.

Both LLF centers and the single WRTC center have offered live donor liver transplant services since at least 2012. Here too, the gap between the two DSAs is striking and growing:

	Living Donors						
	2011	2012	2013	2014	2015	2016	6 Year Total
LLF CENTERS	0	6	14	20	24	19	83
WRTC CENTER	4	3	2	2	12	6	29
DSA VARIANCE (LLF-WRTC)	-4	3	12	18	12	13	54

[52] Boyarsky, Brian J., et al. "Estimating the Potential Pool of HIV-Infected Deceased Organ Donors in the United States." American Journal of Transplantation 11.6 (2011): 1209-1217.

Since 2011, the two LLF centers have performed 54 more live donor liver transplants than the lone WRTC center, or nearly three times as many live donor transplants.

This is a further indication that an additional center in the WRTC operated by Johns Hopkins Medicine would have a positive effect on the supply of deceased donor organs. Even though Suburban Hospital will not be performing live donor liver transplants when those operations begin, Suburban's presence in the WRTC DSA will allow Johns Hopkins physicians and staff to expand their outreach and education efforts in order to identify more live donors. When that happens, Johns Hopkins physicians and staff will transition the care of the donor and recipient to Johns Hopkins Hospital in order to perform the live donor procedure, while retaining the pre- and post-operative care closer to home. This identification of new live donors because of Johns Hopkins' increased presence in the WRTC will thus "free up" additional deceased donor organs for transplant in the WRTC.

(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 Response:

(b)

Suburban liver transplant volume is projected to be a combination of market shifts, market growth, volume shifting from centers outside of the two Maryland DSAs, and new volume.

The Suburban Volume Projection Methodology is detailed in response to *10.24.01.08G(3)(f). Impact on Existing Providers and the Health Care Delivery System* question (a). Below, sections are referenced from this response that include the "Status Quo Projection" and "Adjusted Projection".

Projected 2016-2022 Center Impact

The Status Quo Projection estimates volume at each of the three existing local centers, with no new center added, through CY 2022. Based on the historical growth rate in the LLF DSA and WRTC DSA combined, this model grows the volumes at each of the three centers by 10 cases per year.

	Status Quo Projection						
	2016	2017	2018	2019	2020	2021	2022
Georgetown	91.0	101.0	111.0	121.0	131.0	141.0	151.0
Johns Hopkins	110.0	120.0	130.0	140.0	150.0	160.0	170.0
Univ of Maryland	157.0	167.0	177.0	187.0	197.0	207.0	217.0
TOTAL	358.0	388.0	418.0	448.0	478.0	508.0	538.0

The Adjusted Projection depicted below estimates volume through CY 2022 at the three existing centers with a new center added at Suburban. The volumes for the Suburban program are a combination of cases shifted from the other three centers and additional volume resulting from competition in the WRTC DSA.

	Adjusted Projection						
	2016	2017	2018	2019	2020	2021	2022
Georgetown	91.0	101.0	105.2	114.0	122.9	131.7	140.5
Johns Hopkins	110.0	120.0	126.1	134.9	143.7	152.5	161.4
Univ of Maryland	157.0	167.0	171.6	180.5	189.3	198.1	206.9
Suburban	-	-	17.4	32.1	36.8	41.5	46.2
TOTAL	358.0	388.0	420.4	461.5	492.7	523.9	555.1

The table below shows the estimated number of cases that will shift from each existing center to the new Suburban center, by year:

	Adjusted Projection - Status Quo Projection						
	2016	2017	2018	2019	2020	2021	2022
Georgetown	-	-	(5.8)	(7.0)	(8.1)	(9.3)	(10.5)
Johns Hopkins	-	-	(3.9)	(5.1)	(6.3)	(7.5)	(8.6)
Univ of Maryland	-	-	(5.4)	(6.5)	(7.7)	(8.9)	(10.1)
Suburban	-	-	17.4	32.1	36.8	41.5	46.2

The final table shows the impact of the cases shifting from each of the three centers to the Suburban center as a percentage of the total cases projected at the existing centers if no new center were added (Status Quo Projection):

	Percent Reduction over Status Quo (% Impact)						
	2016	2017	2018	2019	2020	2021	2022
Georgetown	-	-	-5.2%	-5.7%	-6.2%	-6.6%	-6.9%
Johns Hopkins	-	-	-3.0%	-3.7%	-4.2%	-4.7%	-5.1%
Univ of Maryland	-	-	-3.0%	-3.5%	-3.9%	-4.3%	-4.6%

Both in raw numbers and as a percentage of their total cases, none of the existing centers will experience a significant impact from moved cases. According to this projection, all existing centers are now and will remain well above the minimum volume threshold. This analysis employs conservative assumptions. It 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 started a new kidney transplant program in competition with the Georgetown kidney program. Ideally, volumes at all the centers will continue to grow through increased education, outreach, recruitment of donors, and use of more organs, and as a result of the increased level of competition in the region.

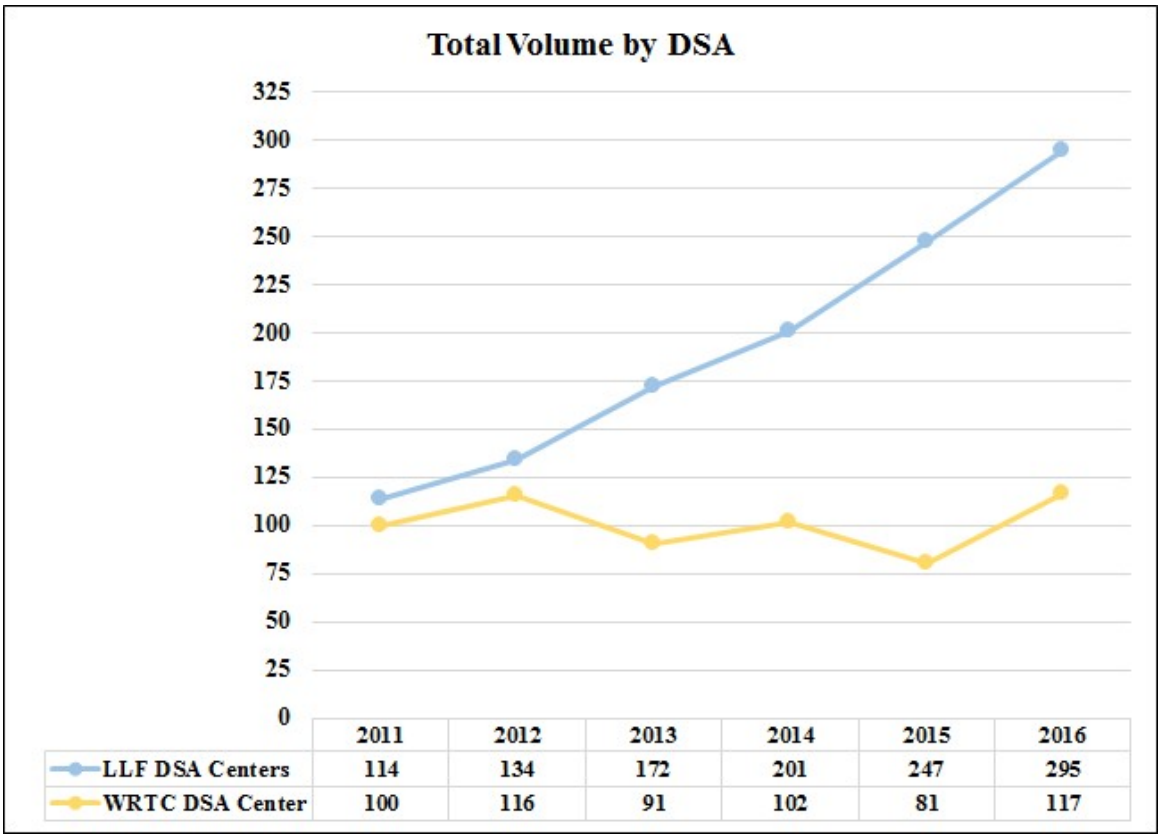
(c) The utilization trends for the health planning region in which the proposed organ transplant service will be located and the jurisdictions in which the population to be served resides. If the proposed service will be located in a jurisdiction that shares a border with another health planning region,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

Applicant Response:

(c)

Utilization Trends: Liver Transplants Performed at Centers in the WRTC and LLF DSAs (Center Volume)

The population of the WRTC (5.5 million) is 40% greater than the population of the LLF (3.9 million). Yet the LLF performed more than twice as many liver transplants in 2016:

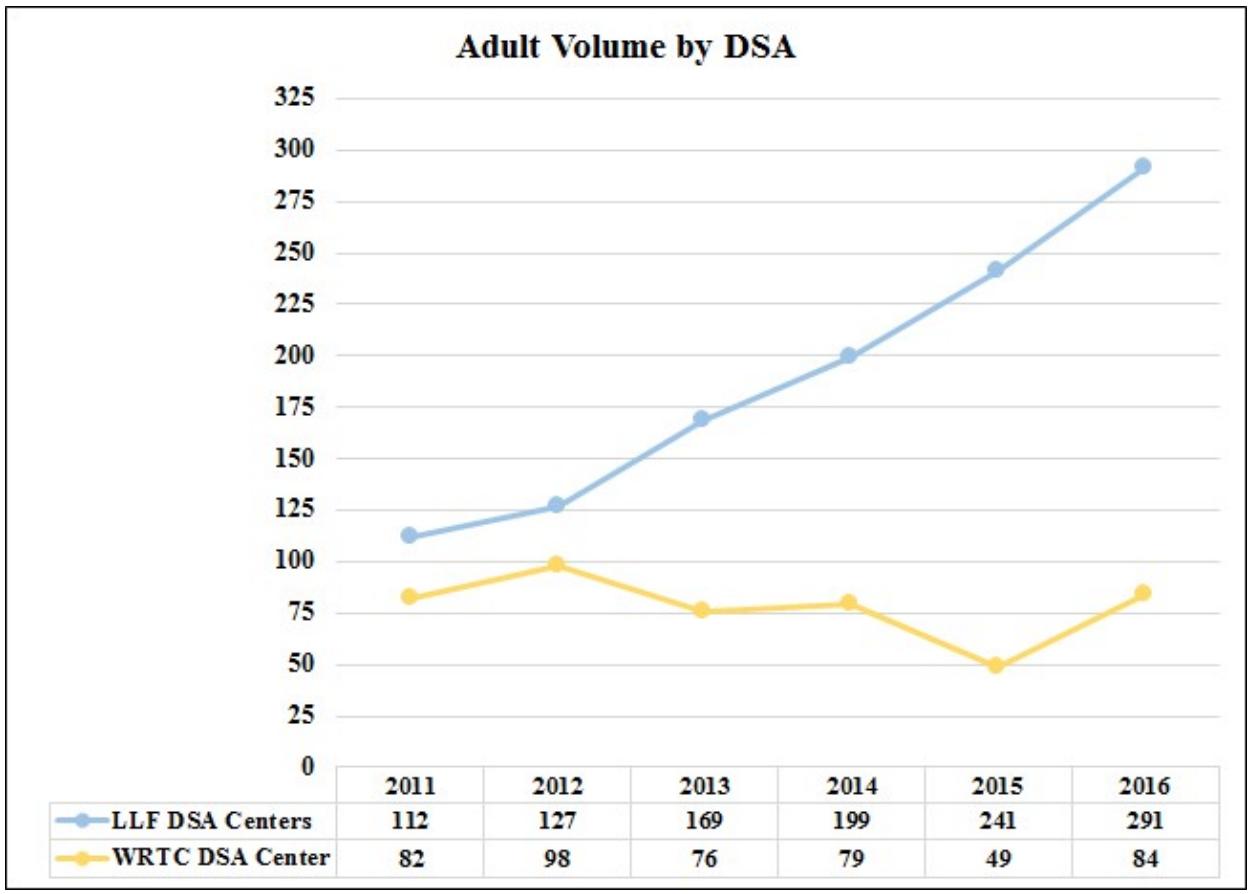


	2011	2012	2013	2014	2015	2016
LLF DSA Centers	114	134	172	201	247	295
WRTC DSA Center	100	116	91	102	81	117

Source: OPTN

This gap between the two DSAs has been widening since 2012. While the total number of liver transplants performed at the two LLF centers has increased every year and has more than doubled from 2011 to 2016 (114 to 295), total transplants at the single WRTC facility has remained fairly constant at approximately 100 per year with minor fluctuations (± 15 per year) for six years.

This same difference, and the same growing gap, exists when comparing only adult transplants:



	2011	2012	2013	2014	2015	2016
LLF DSA Centers	112	127	169	199	241	291
WRTC DSA Center	82	98	76	79	49	84

Source: OPTN

Utilization Trends: Liver Transplants Received by WRTC and LLF DSA Residents (Resident Volume)

Patient access is measured by looking at a patient's DSA of residency. The table below quantifies the number of LLF residents and WRTC residents who received a liver transplant in 2015[53] and identifies the center that performed the transplant:

CY	DSA	JHH	UMMS	G'town	Other Centers	TOTAL
2015	LLF	57	104	7	5	173
	WRTC	22	25	62	25	134

In other words:

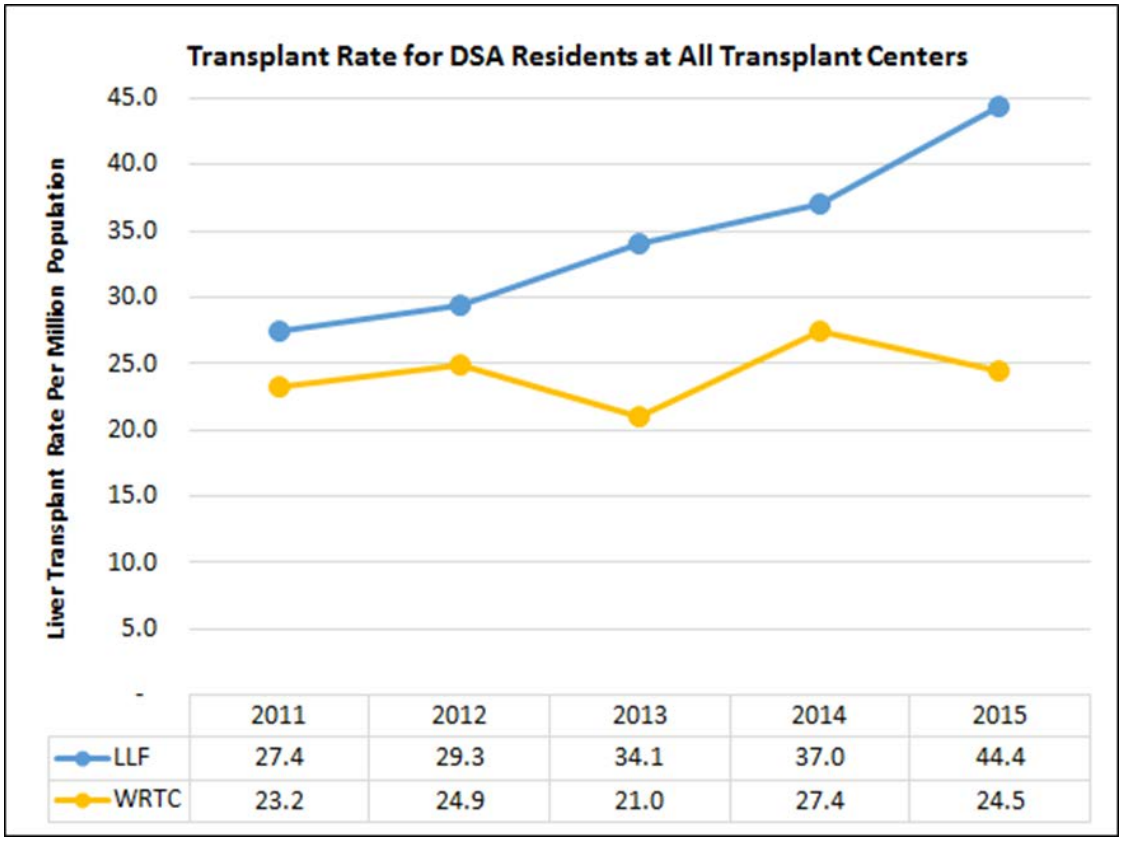
- Of the 173 LLF residents who received a liver transplant in 2015, 161 (57+104) or 93% received the transplant at one of the two LLF facilities.
- Only 12 LLF residents (7+5) or 7% were transplanted at a non-local center
- By comparison, only 62 of 134 WRTC residents, 46%, received their transplant at the single WRTC facility, less than half the LLF rate of 93%.
- The remaining 72 WRTC residents (22+25+25, or 54%) went to other transplant centers outside the WRTC.

Utilization Trends: Population-Adjusted Utilization Trends for Residents of the WRTC and LLF DSAs

CY	DSA	JHH	UMMS	G'town	Other Centers	TOTAL	Population	Overall Rate PMP (Total)
2015	LLF	57	104	7	5	173	3,900,632	44.4
	WRTC	22	25	62	25	134	5,464,786	24.5

Thus, when considering all centers which performed transplants on LLF and WRTC residents in 2015, LLF residents were nearly twice as likely to be transplanted per capita as WRTC residents (44.4 PMP versus 24.5 PMP). This disparity was not unique to 2015, as the gap in transplant rates for DSA residents at all transplant centers has persisted, as depicted below:

[53] The most recent data available is used throughout this analysis. Some 2016 data is available on public websites, such as the volumes by DSA in the table above. Other information is only available through a formal request to UNOS, such as data that combines patient residence and transplant center, and for this type of information the most recent data available is 2015.

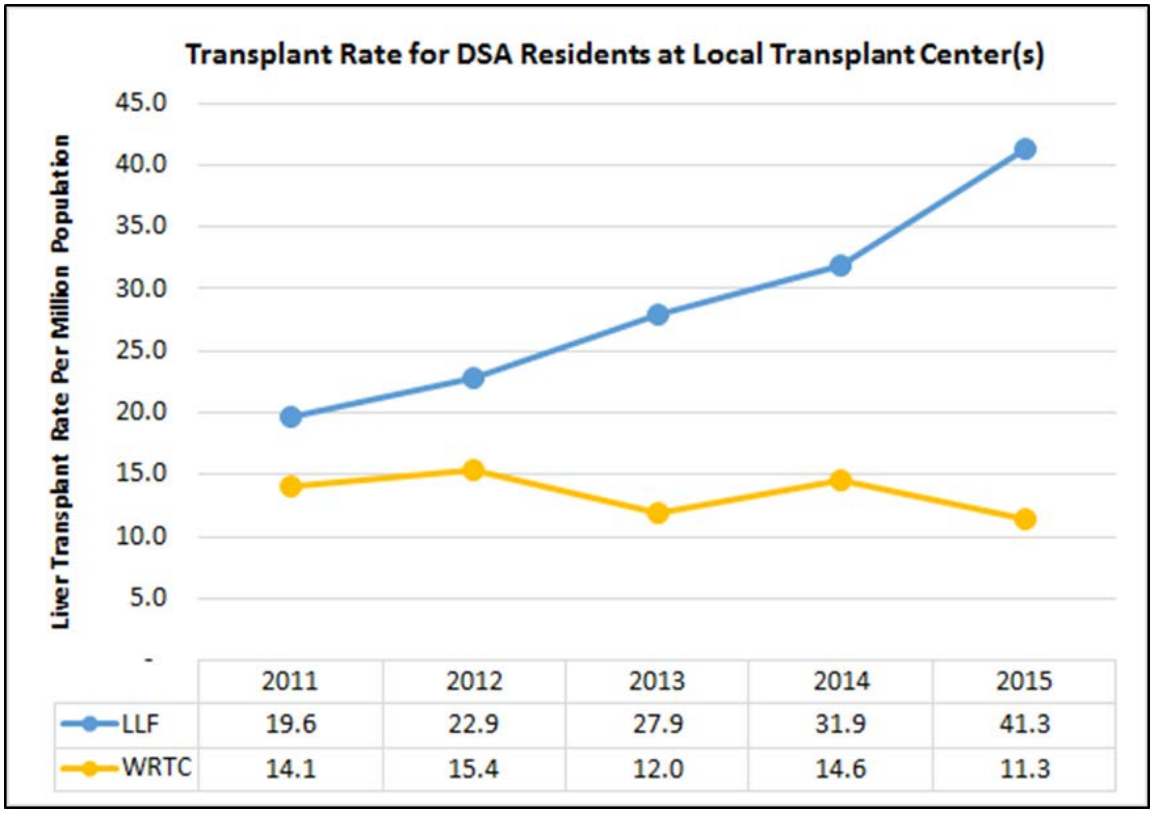


Utilization Trends: Population-Adjusted Local Transplant Rate for WRTC and LLF DSA Residents

The disparity is magnified when considering how many DSA residents were transplanted at a liver transplant center in their DSA of residence (a local center) in 2015:

CY	DSA	JHH	UMMS	G'town	LOCAL SUBTOTAL	Population	Rate PMP (Total)
2015	LLF	57	104	-	161	3,900,632	41.28
	WRTC	-	-	62	62	5,464,786	11.35

Here again, 2015 was not an anomaly. Rather, as measured over a five-year period, the per capita disparity in transplant access between WRTC residents and LLF residents to their local center(s) has worsened:



In summary, the LLF DSA has had an upward utilization trend for liver transplant from 2011 through 2015. This is true when looking at the volume of transplants at the LLF centers, the volume of adult liver transplants, the number of LLF residents transplanted, and the number of LLF residents transplanted “locally”, meaning at an LLF center. In contrast, utilization in the WRTC starts lower than in the LLF and is either flat or trending downward for the same period. The difference between the two areas is even more pronounced when utilization is adjusted for the population in the two different DSAs.

Standard .05B(2) – <u>Minimum Volume Requirements</u>

(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 Response:

(a)

The year three minimum annual case volume for liver transplant programs is 12 cases per year. By year 3, Suburban projects to perform 36.8 cases – exceeding the minimum requirement in year 3 and each year thereafter. Projected volume for years 1 through 5 is depicted below.

	Volume Projection				
	2018	**2019**	**2020**	**2021**	**2022**
Suburban	17.4	32.1	36.8	41.5	46.2

(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

(iii) 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.

Applicant Response:

(b)

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).

Standard .05B(3) – <u>Access</u>

(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

(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.

(c) 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.

(d) 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 Response:

(a)

There are two liver transplant centers operating in Baltimore, Maryland, making liver transplant 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

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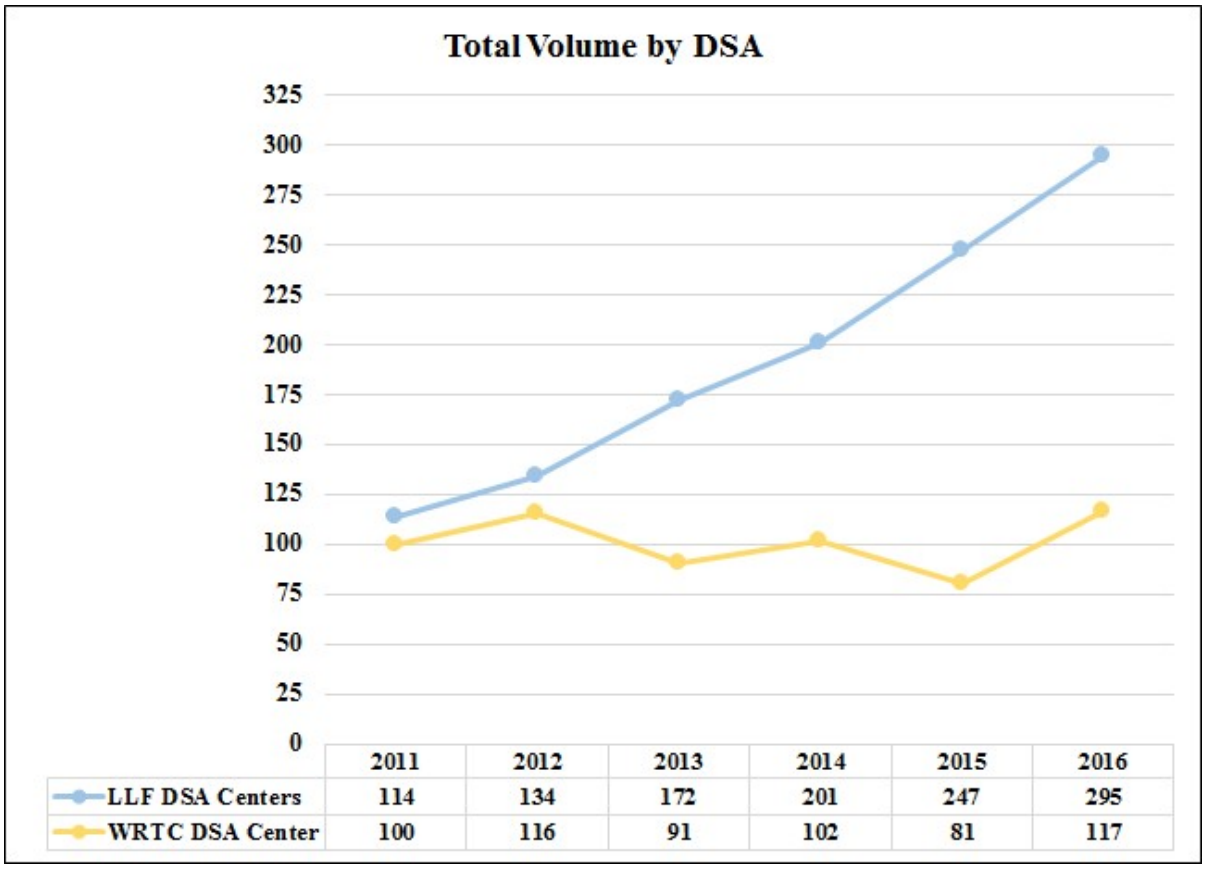
Applicant Response:

(b)(i)

There are multiple ways to assess barriers in access to liver transplantation, including center volume, transplant rates, migration of residents in order to access transplant, acuity of patients, and wait listing.

Volume

The population of the WRTC (5.5 million) is 40% greater than the population of the LLF (3.9 million). Yet the LLF performed more than twice as many liver transplants in 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: OPTN

As shown, this gap between the two DSAs has been widening since 2012. While the total number of liver transplants performed at the two LLF centers has increased every year and has more than doubled from 2011 to 2016 (114 to 295), total transplants at the single WRTC facility has remained fairly constant at approximately 100 per year with minor fluctuations (± 15 per year) for six years.

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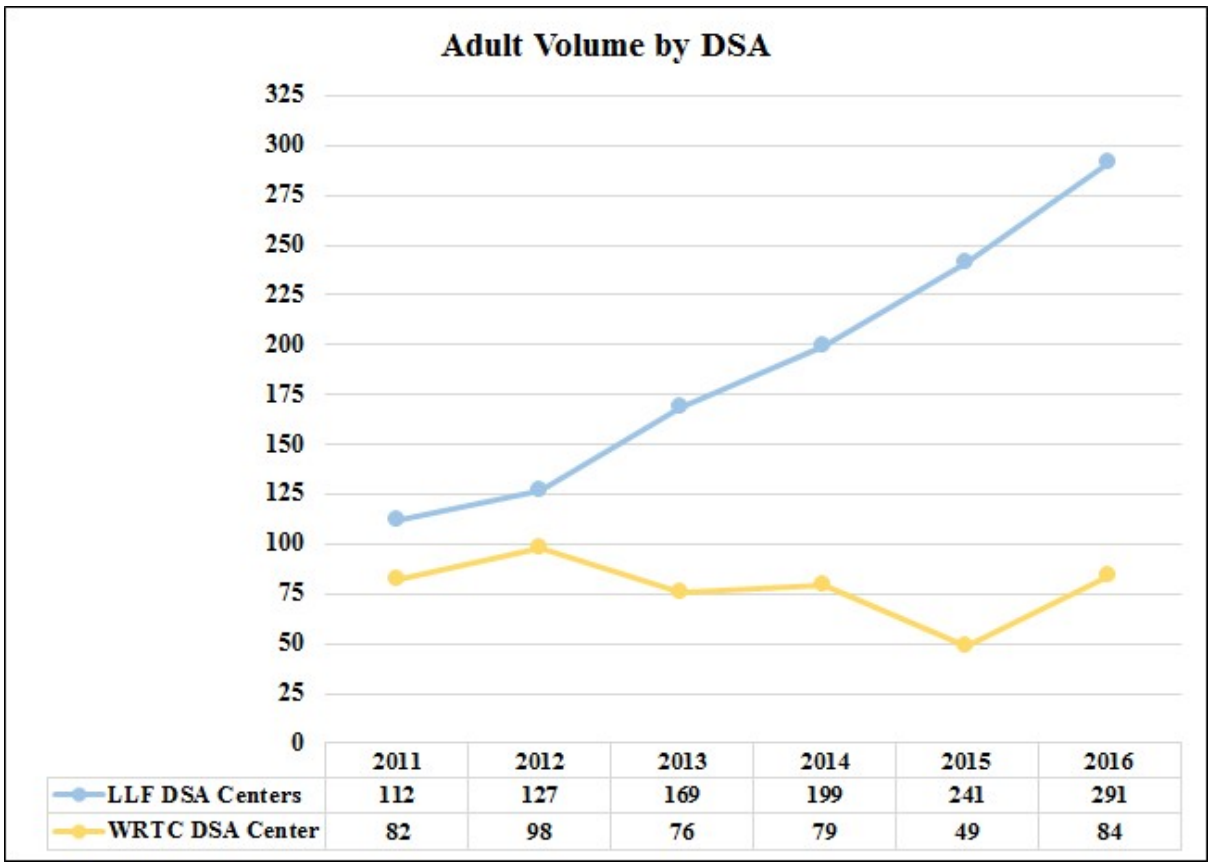

	2011	2012	2013	2014	2015	2016
LLF DSA Centers	112	127	169	199	241	291
WRTC DSA Center	82	98	76	79	49	84

Source: OPTN

Access

Patient access can be measured by looking at a patient's DSA of origin and where he or she received a transplant. The table below quantifies the number of LLF residents and WRTC residents who received a liver transplant in 2015[54] and identifies the center that performed the transplant:

CY	DSA	JHH	UMMS	G'town	Other Centers	TOTAL
2015	LLF	57	104	7	5	173
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- The remaining 72 WRTC residents (22+25+25, or 54%) went to other transplant centers outside the WRTC.

The disparity in access between Maryland's two DSAs also is seen when examined on a per capita basis, i.e., the number of residents transplanted per million population ("PMP"). The table below shows the number of DSA residents who received a liver transplant in 2015:

CY	DSA	JHH	UMMS	G'town	Other Centers	TOTAL	Population	Overall Rate PMP (Total)
2015	LLF	57	104	7	5	173	3,900,632	44.4
	WRTC	22	25	62	25	134	5,464,786	24.5

Thus, when considering all centers which performed transplants on LLF and WRTC residents in 2015, LLF residents were nearly twice as likely to be transplanted per capita as WRTC residents (44.4 PMP versus 24.5 PMP). This disparity was not unique to 2015, as the gap in transplant rates for DSA residents at all transplant centers has persisted, as depicted below:

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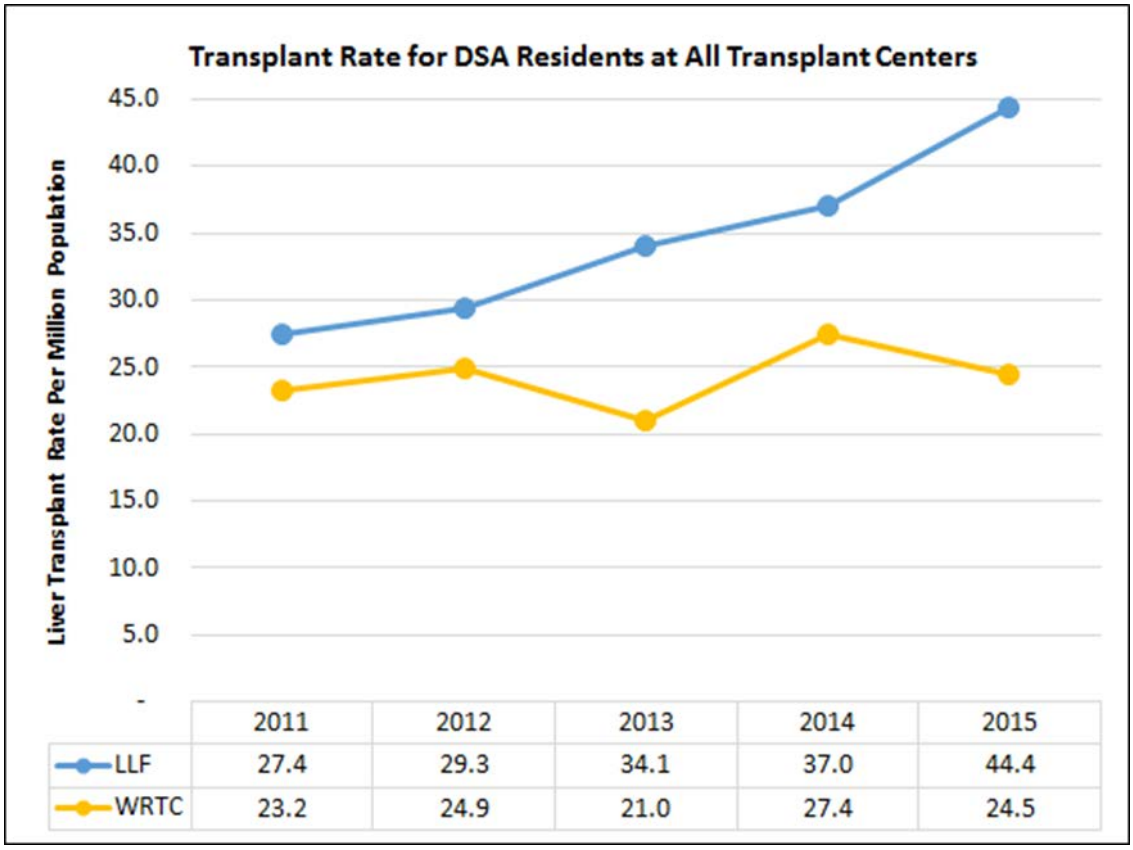

The disparity is magnified when considering how many DSA residents were transplanted at a liver transplant center in their DSA of residence (a local center) in 2015:

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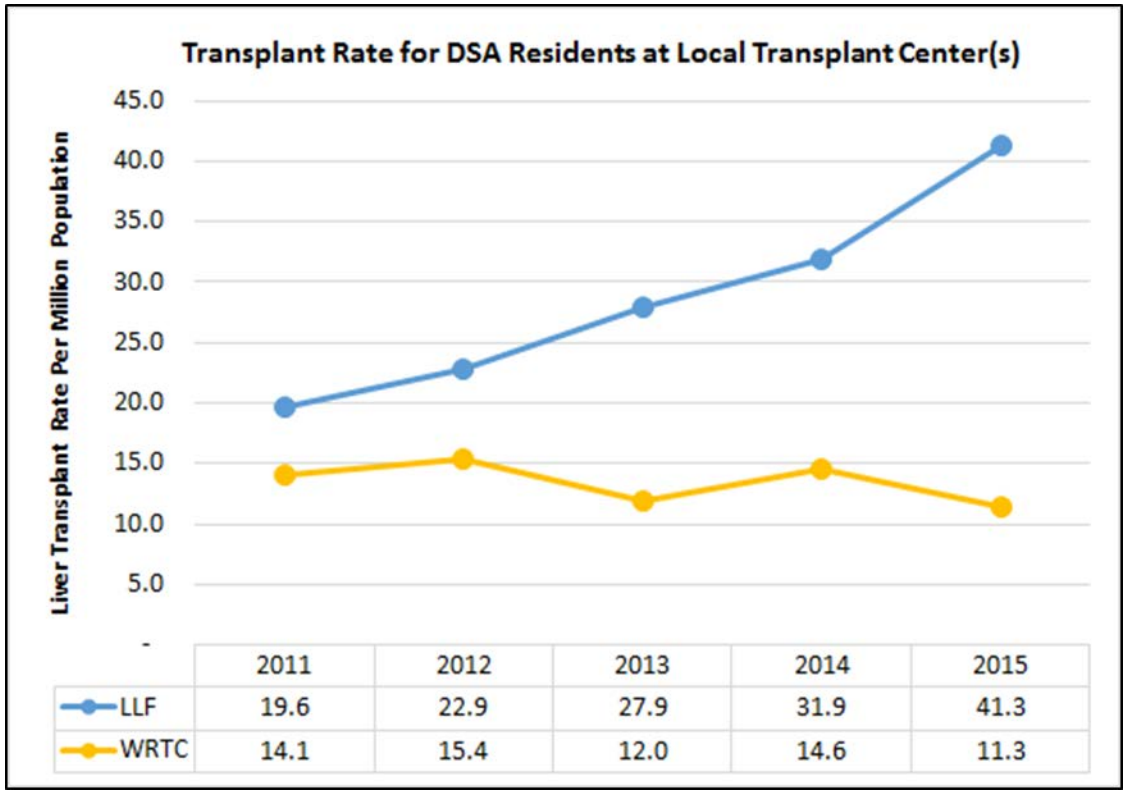


This disparity in access between the two DSAs serving Maryland strongly indicates the existence of a substantial unmet need for additional transplantation services within the WRTC. A second center in the WRTC at Suburban would address this unmet need and lead to higher per capita transplant rates in the WRTC.

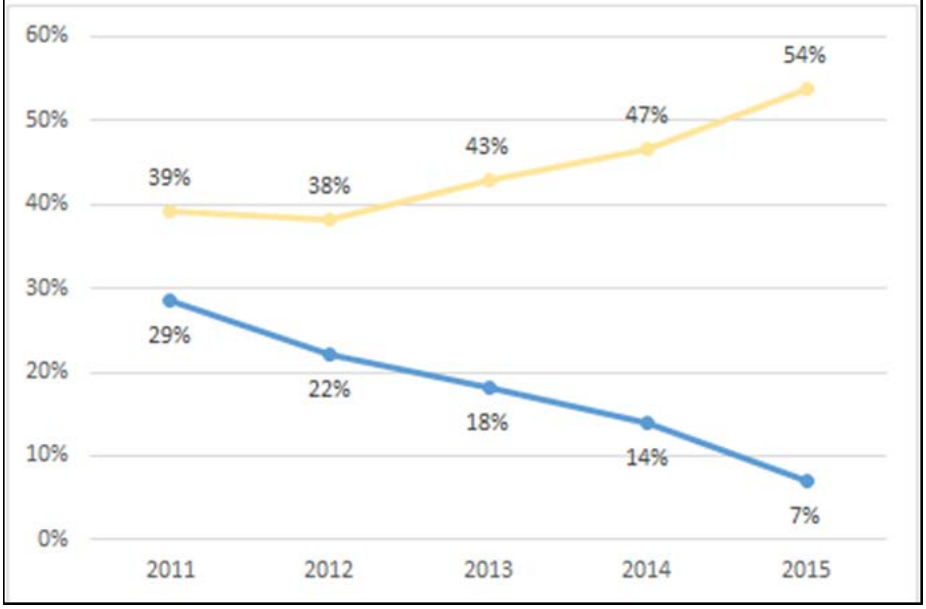
Patient Migration

Another way to analyze access is by looking at "migration" patterns, i.e., where DSA residents leaving their DSA go for transplant services. The table below calculates this data for 2015 ("Out-migrant" means a patient leaving their DSA of residence):

CY	DSA	JHH	UMMS	G'town	Other Centers	TOTAL	Total Out-migrants	% of Out-migrants
2015	LLF	57	104	7	5	173	12	7%
	WRTC	22	25	62	25	134	72	54%

Thus, in 2015, only 12 of 173 LLF residents receiving transplants went outside their DSA of residence (7%). For the WRTC, that figure jumps nearly eight-fold to 54%, with 72 of 134 WRTC residents receiving a transplant outside their DSA. This means that more than half the residents in the WRTC needed to leave their DSA to obtain a transplant. 2015 was not an outlier in this regard. Similar to other measurements of access, the historical migration data shows an ever-widening gap:

% of Residents Out-Migrating for a Transplant						
DSA	State	2011	2012	2013	2014	2015
LLF	MD	29%	22%	18%	14%	7%
WRTC	TOTAL	39%	38%	43%	47%	54%



The disparity in migration primarily affects Maryland residents of the WRTC. As shown in this jurisdiction-by-jurisdiction breakdown of WRTC "Out-migrants" in 2015, the largest group (62%) resides in Maryland:

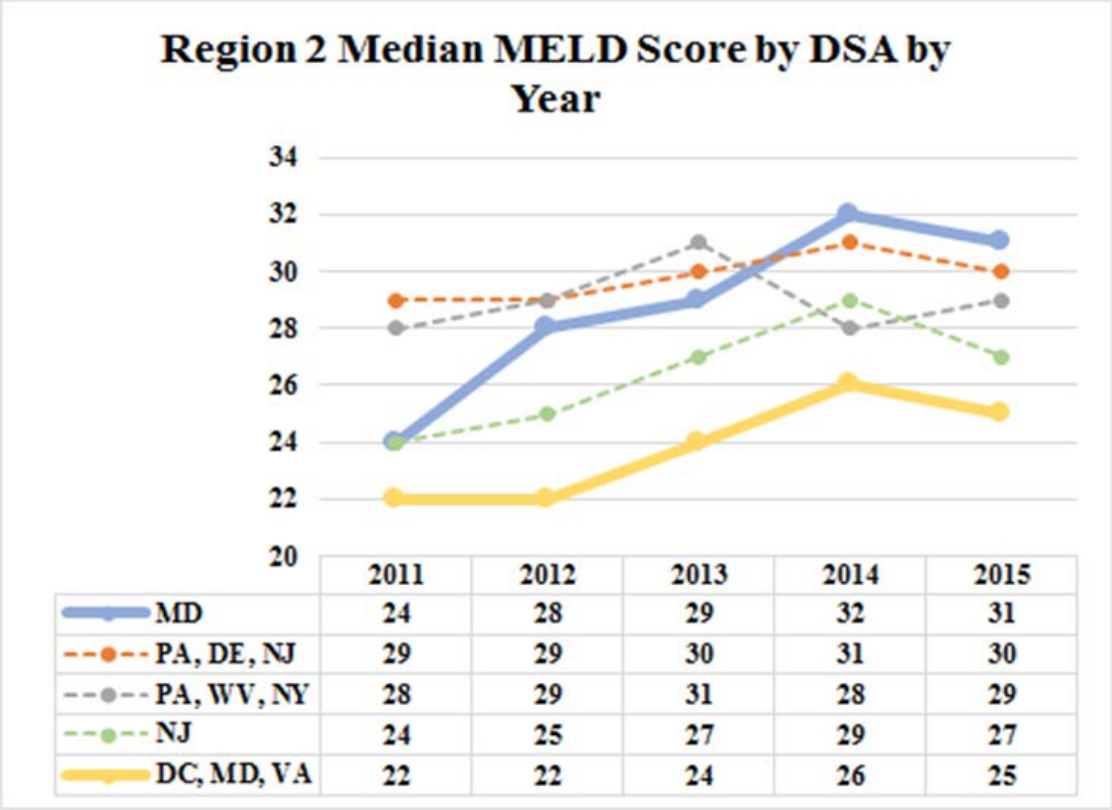
CY	DSA	State	JHH	UMMS	G'town	Other Centers	TOTAL	Total Out-migrants	% of Out-migrants
2015	LLF	MD	57	104	7	5	173	12	7%
	WRTC	DC	1	1	6	7	15	9	60%
	WRTC	MD	11	20	24	8	63	39	62%
	WRTC	VA	10	4	32	10	56	24	43%
	WRTC	TOTAL	22	25	62	25	134	72	54%

This migration data strongly supports the existence of access issues within the WRTC because it shows that more than half of all WRTC residents needing a liver transplant had to leave the WRTC to obtain this life-saving procedure. Given the time and expense involved in such travel, in addition to the emotional cost of being away from home and family during hospitalization, the conclusion is compelling that WRTC residents do so primarily because their need for transplantation services is not being met adequately by the single facility available in their DSA. Additionally, this issue of out-migration reveals a risk that residents of the WRTC DSA who of a lower socio-economic status likely have increased and perhaps insurmountable barriers to accessing liver transplant at all. In 2015, 72 WRTC DSA residents traveled elsewhere for care. We do not know how many more needed a transplant but could not travel elsewhere to get it.

Acuity

The relative acuity of transplant patients in these two DSAs is shown by examining MELD scores. The single WRTC center has historically transplanted less sick patients, even when compared to all five DSAs of the transplant centers located within Region 2:

Region 2 Median MELD Score by DSA by Year						
DSA	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: OPTN/SRTR Annual Reports 2011-15

The MELD scores of the two LLF transplant centers were consistently higher by 5 or 6 points than the single WRTC center starting in 2012. In each year shown here, the WRTC had the lowest median MELD score of the five DSAs. This gap in MELD scores between the LLF and WRTC means that the single WRTC center consistently performs transplants on less sick adult patients than the two LLF centers. Of note, the WRTC is the only single-center DSA of the five.

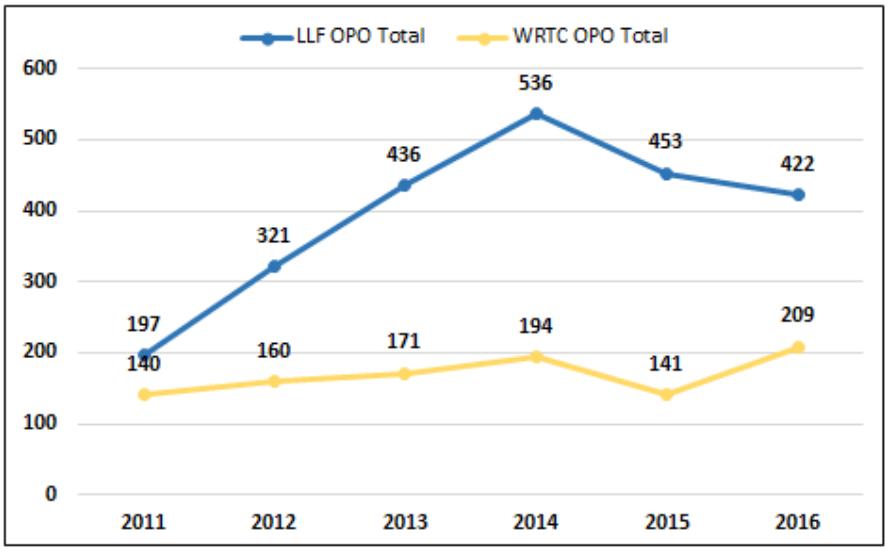
Waitlist

Comparing the wait lists of the WRTC and the LLF, as of March 1, 2017, the WRTC liver transplant wait list—populated by the single WRTC transplant center—had one-third (1/3) the number of patients as the LLF liver transplant wait list, which is populated by two transplant centers.[55]

	Candidates	Ratio (LLF/WRTC)
JHH Waitlist	448	
UMMS Waitlist	405	
LLF Waitlist (JHH + UMMS)	853	3.09
MGUH Waitlist	276	
WRTC Waitlist (MGUH)	276	

[55] Because Georgetown is the only center in the WRTC, the WRTC liver waitlist and the Georgetown liver wait list are identical.

The current (March 2017) wait list discrepancy is not an anomaly. As shown by the following table of wait list additions[56] for the last six years (2011-16), the WRTC liver wait list has lagged behind the LLF liver wait list since 2012:



Wait List Addtions By Year						
	2011	2012	2013	2014	2015	2016
JHH	57	129	256	231	205	190
UMMS	140	192	180	305	248	232
LLF OPO Total	197	321	436	536	453	422
MGUH	140	160	171	194	141	209
WRTC OPO Total	140	160	171	194	141	209
Variance (WRTC-LLF)	-57	-161	-265	-342	-312	-213

Over the last four years, between 213 and 342 ***more*** patients were added to the LLF wait list each year than were added to the WRTC wait list. This disparity is even more striking given that the WRTC serves a population that is 40% greater than the LLF. The bottom line is that the single transplant center within the WRTC lags far behind the LLF in identifying, evaluating, and listing transplant-eligible patients. Getting on the waitlist is an essential step toward receiving a liver transplant. The disparity in wait listing patients is evidence of yet another barrier to access to liver transplant in the WRTC DSA.

[56] Data reflects patients added to the waitlist each year. Waitlists are dynamic. Patients come on and off based on a range of factors. The number of patients evaluated and added to the DSA list each year is the commonly used metric.

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

(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 Response:

(b)(ii)

Previous responses described the barriers to access to liver transplant in the WRTC DSA, which are demonstrated by lower center volume, a lower rate of transplant in the population, higher rates of migration out of the DSA to receive a transplant, lower acuity of patients transplanted in the WRTC DSA center, and lower numbers of patients being placed on the wait list. Peer reviewed studies on the topic of transplant center competition by Halldorson[57] and Adler[58,59] found that DSAs with competition reduce these barrier to access by increasing the total number of patients transplanted per year, raising the median MELD score for patients transplanted in the DSA, and increasing the number of patients placed on the wait list per year.

To address barriers to access, the non-competitive WRTC DSA should be made into a competitive DSA via the addition of a new liver transplant center within the DSA. The question then becomes, what would the ideal characteristics of the new center be? A liver transplant program at Suburban Hospital, run by the Johns Hopkins Comprehensive Transplant Center, is the best way to achieve this competition and improved access, for the reasons outlined below.

Experience/Expertise

The proposed liver transplant center at Suburban Hospital will be operationalized using the experience and infrastructure of one of the nations' leading centers in transplant services. The CTC's long-sustained track record of excellence in operating highly specialized, highly regulated transplant programs will allow Suburban Hospital to hit the ground running in ways that a new program operating independently of health system could not.

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

[58] 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.

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

Hospital Capabilities

Liver transplant patients are medically complex and require a high level of intensive care unit capabilities. Suburban Hospital's experience with high acuity patients, via its designation as a Level II Trauma Center and programs like its cardiac surgery program, make it an ideal fit for serving patients with liver disease and liver failure. Many of the resources that would be required to be invested in order to develop a new transplant program are already in place at Suburban.

Minimal Start-Up Costs

The proposed liver transplant center at Suburban Hospital will have minimal start-up costs because it will leverage available resources from the Johns Hopkins CTC. Sharing personnel, physician support, and operating support wherever possible benefits from economies of scale in ways a new program operating independently could not.

Improved Access: New Cases and More Local Cases

Given the disproportionate rate of patients out-migrating from the WRTC DSA to the LLF DSA and other DSAs to be transplanted, the benefits of the proposed center at Suburban are two-fold. First, the new center will lead to more total individuals transplanted, as the competition literature cited has observed. Second, the new center will provide WRTC residents an option to be transplanted more locally, allowing patient migration patterns to shift in the direction of fewer WRTC residents having to leave their DSA of residence for care.

Lower Cost Setting

Suburban Hospital offers a lower-cost setting relative to other area transplant centers. This means that any cases that shift from one of the other three area centers to Suburban will be performed at lower cost for pre-transplant, transplant, and post-transplant care. Further, any new cases, resulting from increased access to care, will occur at a lower incremental cost.

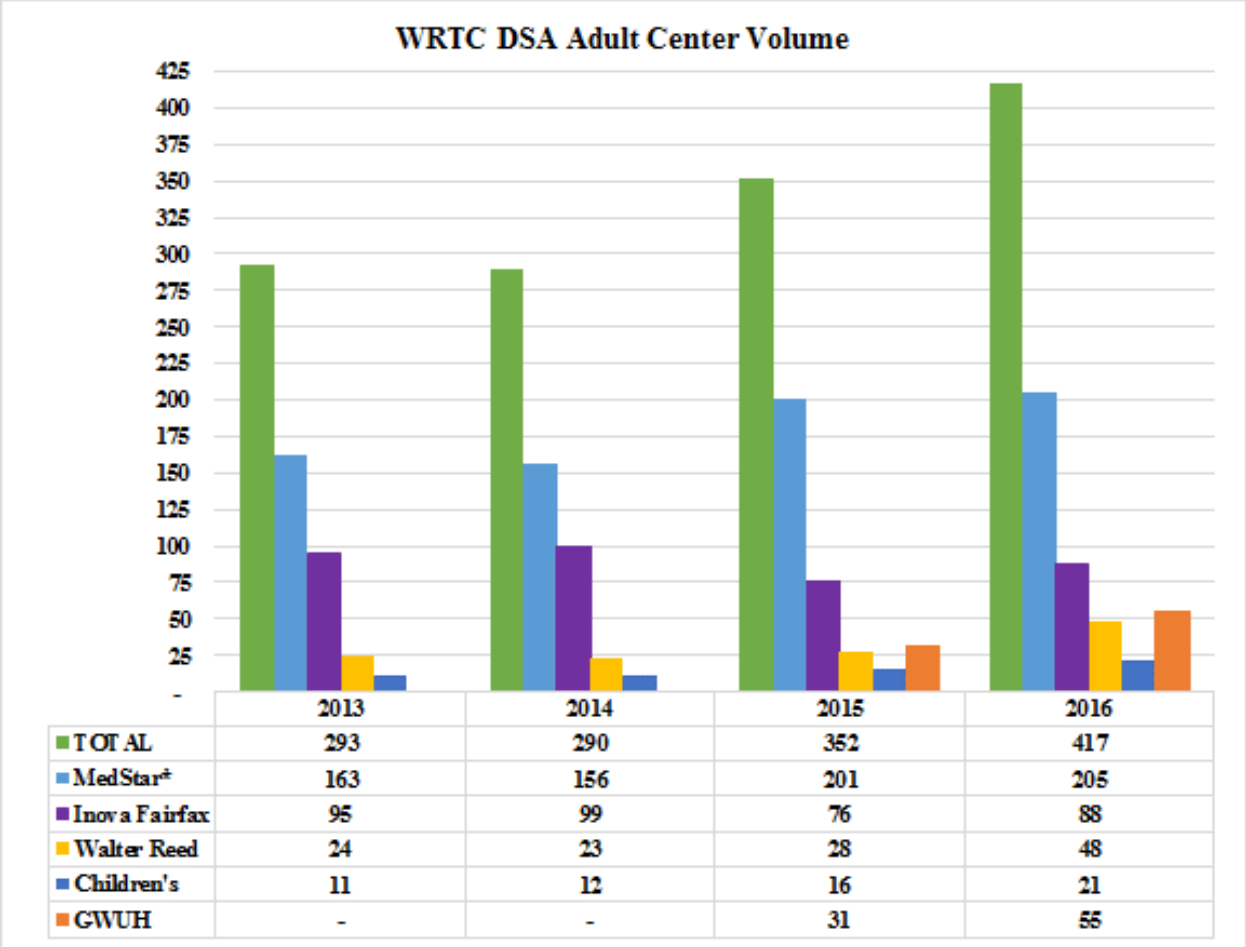
Ability to Double List

A program at Suburban Hospital creates a unique opportunity for liver transplant patients to double list in the WRTC DSA at Suburban and at Johns Hopkins in the LLF DSA. In instances where patients are deemed clinically appropriate for either transplant center, patients will have the option to list at both centers, which has the potential to increase their odds of matching with a donor organ. Additionally, access to listing in the two different DSAs comes in this case with a reduced burden for evaluation due Suburban and The Johns Hopkins Hospital operating as part of the same health system.

Increased Access as a Result of Competition—The GWUH Kidney Transplant Program Experience

A recent decision by the State Health Planning and Development Agency for the District of Columbia ("SHPDA") recognizes that the addition of a second transplant service in an area previously served by a single center can result in increased volumes, for both the new center *and the existing center*. The issue before SHPDA was whether to allow an earlier-granted CON for a kidney transplant service at George Washington University Hospital ("GWUH") to remain in place. Before GWUH began kidney transplants in 2015, the only other kidney transplant services for adult non-military patients in the District were operated by MedStar.

The evidence presented to SHPDA was that the addition of a kidney transplant service had resulted not only in new kidney transplant volume at GWUH, *but also led to MedStar increasing its kidney transplant volume* by more than 30% over pre-competition years:



	2013	2014	2015	2016
TOTAL	293	290	352	417
MedStar*	163	156	201	205
Inova Fairfax	95	99	76	88
Walter Reed	24	23	28	48
Children's	11	12	16	21
GWUH	-	-	31	55

*MedStar = MGUH and WHC
Source: OPTN

The beneficial effect of this competition was one of the principal reasons cited by SHPDA in its March 30, 2017 decision allowing the new transplant service at GWUH to remain in place.

Community Support

The proposed liver transplant center at Suburban Hospital has garnered the support of (Exhibit 17):

- George Washington University Hospital: Chief Executive Officer, Kimberly D. Russo, MS, MBA
- Sibley Memorial Hospital: Director of Hepatology, Kirti Shetty, MD FAASLD FAICG, and Assistant Professor of Medicine and Transplant Hepatologist, Jacqueline Laurin, MD
- Maryland General Assembly, 16th Legislative District, Montgomery County: Senator Susan C Lee, Delegate C. William Frick, Delegate Ariana Kelly, Delegate Marc Korman
- Montgomery County Department of Health and Human Services: Director Uma S Ahluwalia and County Executive Isiah Leggett
- TRIO (Transplant Recipients International Organization, Inc.) Maryland: President Marty Maren
- American Liver Foundation, Mid-Atlantic Division: Executive Director Ivory Allison

(c) 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.

Applicant Response:

(c) The applicant does not suggest closure of an existing service as evidence of the need to establish a new organ transplant service.

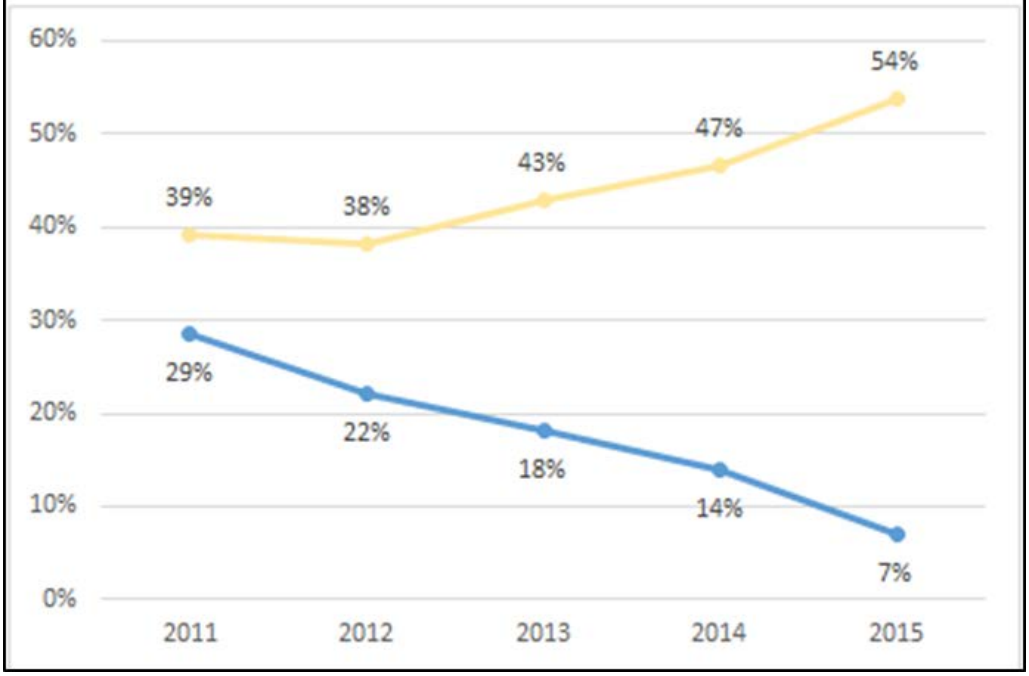
(d) Travel to an organ transplant center located in a health planning region other than where the organ transplant recipient resides is not, in and of itself, considered a barrier to access, if the drive time in less than three hours one-way.

Applicant Response:

(d)

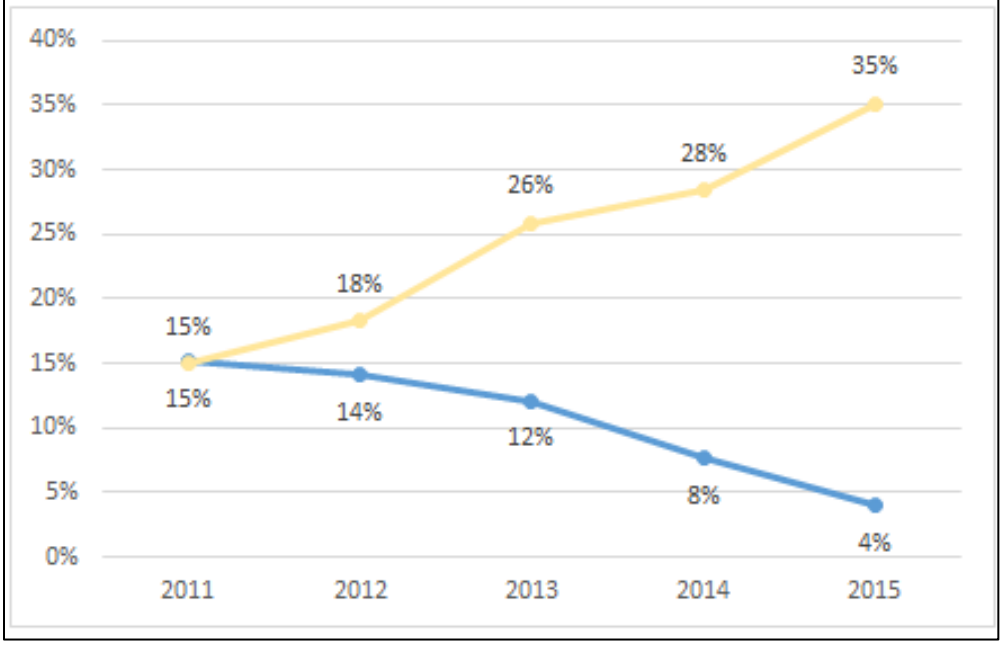
Residents in the LLF DSA and the WRTC DSA display disproportionate migration patterns – meaning WRTC DSA residents are far more likely to leave their DSA of residence to receive liver transplant services than LLF residents are to leave their DSA of residence, as depicted below:

% of Residents Out-Migrating for a Transplant						
DSA	State	2011	2012	2013	2014	2015
LLF	MD	29%	22%	18%	14%	7%
WRTC	TOTAL	39%	38%	43%	47%	54%



In 2015, 72 WRTC residents out-migrated while only 12 LLF residents out-migrated. To that end WRTC DSA residents are far more likely to travel to the LLF DSA for a liver transplant than LLF DSA residents are to travel to the WRTC DSA for a liver transplant:

% Residents Crossing Over: LLF <--> WRTC						
DSA	State	2011	2012	2013	2014	2015
LLF	MD	15%	14%	12%	8%	4%
WRTC	TOTAL	15%	18%	26%	28%	35%



In 2015, 47 WRTC DSA residents were transplanted in the LLF DSA and only 7 LLF residents were transplanted in the WRTC DSA. These represent instances where patients traveled less than three hours one way to be transplanted. While this may not be considered a barrier to access, it will disproportionately negatively impact patients of a lower SES.

It is important to note that those migrating from their DSA of residence are by definition those with the means to do so. A study by Dzebisashvili revealed the association between socioeconomic status (SES) and traveling to alternative DSAs, and the impact of that travel on patient survival.[60] The study found a strong association between higher SES and ability to travel, with transplant candidates in the highest SES quartile being 70% more likely to travel than candidates in the lowest SES quartile. The ability to travel, in turn, led to dramatic differences in transplantation and survival:

- Patients able to travel had a 74% increased likelihood of transplantation; and
- Patients able to travel had a 20% reduction in risk of death due to end stage liver disease.

This study provides strong evidence that lower SES individuals in one DSA cannot and will not readily travel to another DSA in order to improve their chances of getting transplanted. And the 47 WRTC DSA residents who did travel to the LLF

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

represents 35% of all WRTC patients transplanted.

We agree that simply the fact that a transplant recipient might travel outside of his or her DSA of residence to receive a transplant is not evidence of a barrier to access. In this case, however, the fact that over half of the residents of the WRTC DSA who received a liver transplant had to leave the DSA is concerning. Further, the significant disparity in migration rates between the LLF, 7%, and the WRTC, 54%, in 2015 suggests that WRTC residents migrate out of necessity due to an access barrier—there is no other discernible reason for the significant disparity. The high migration rate combined with the findings of Dzebisashvili lead us to conclude that WRTC residents of lower SES are disproportionately negatively impacted by access barriers. The addition of a second center in the WRTC will reduce these barriers and make liver transplant a possibility for patients without the means to travel.

Standard .05B(4) – <u>Cost Effectiveness</u>

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.

(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.

(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 Response:

(a)

"Section III. Need for New Transplant Service at Suburban," of this application provides an analysis of the current liver transplant services for the LLF DSA and WRTC DSA and reveals stark differences in annual volume, resident transplant rates, adult patient acuity, optimization of liver supply, patient migration patterns and access to the wait list. These differences are enduring, and growing, and they lead to the conclusion that the needs of the residents in the WRTC DSA are not being met. The existing program in the WRTC DSA is not meeting the need in the resident population for this service, and while some residents are able to access services elsewhere, many residents of the WRTC DSA go without a transplant who would receive one if local access was expanded.

One possible factor contributing to the fact that the existing liver transplant program in the WRTC DSA does not meet the needs of the population is a lack of competition within the DSA. As described in the peer-reviewed literature, intra-DSA competition has been found to result in the following:

- More transplants are performed in the DSA per year
- Sicker patients receive transplants at higher rates (higher median MELD score)
- Access to the wait list is improved (more patients are added to the wait list)

All of the above findings are observed when comparing the LLF DSA (competitive, with two centers) and the WRTC DSA (non-competitive, with only one center), and the difference between the DSAs is getting larger over time. This is further

evidence that the needs of the population in the WRTC DSA could be served better, and it suggests that lack of competition within the DSA is likely one of the reasons that the existing program in the WRTC DSA cannot meet the need.

(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.

Applicant Response:

(b)

Benefits of a New Liver Transplant Program at Suburban Hospital

The establishment of a liver transplant center at Suburban will result in:

- More WRTC DSA residents receiving a liver transplant 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 Other Centers to receive a liver transplant, and will instead be transplanted locally at Suburban.
- Some of the WRTC DSA residents who currently travel to one of the LLF centers for transplant will instead be transplanted at Suburban, which will potentially free up transplantable livers in the LLF DSA for LLF DSA patients.
- Patients transplanted at Suburban will access care at a lower cost relative to the existing two LLF centers and one WRTC center.

The Suburban Volume Projection Methodology is described in detail in response to *10.24.01.08G(3)(f). Impact on Existing Providers and the Health Care Delivery System* question (a). The methodology takes into consideration patient DSA of residence, patient type (adult, deceased donor, MELD less than or equal to 30), and historical growth rates for the LLF and WRTC DSA centers to conservatively project annual volume for Georgetown, UMMS, and JHH for 2016 to 2022, and to project annual volume for the new program at Suburban for 2018 to 2022.

This methodology grows the number of individuals transplanted per year at area centers based on the growth rate from 2010 to 2015. The projections are a blend of new cases resulting from increased access, growing the total volume of patients transplanted by area centers consistent with historical trends, and an accounting of future cases shifting from JHH, UMMS, Georgetown and Other Centers (centers outside the two DSAs) to Suburban. A summary of the benefits is provided below, including a table comparing the projections resulting from Suburban's new program to the status quo.

	New Cases & Sources of Shifted Cases							
	2016	2017	2018	2019	2020	2021	2022	5 Year Total
Georgetown → Suburban	-	-	5.8	7.0	8.1	9.3	10.5	40.6
Johns Hopkins → Suburban	-	-	3.9	5.1	6.3	7.5	8.6	31.5
Univ of Maryland → Suburban	-	-	5.4	6.5	7.7	8.9	10.1	38.6
"Other Centers" → Suburban	-	-	2.4	3.5	4.7	5.9	7.0	23.5
New Cases	-	-	-	10.0	10.0	10.0	10.0	40.0
Suburban	-	-	17.4	32.1	36.8	41.5	46.2	174.2

- More WRTC DSA residents will receive a liver transplant. The table above shows 40 new cases at Suburban in 2018-2022. This is a very conservative estimate—we actually expect and hope that more than 40 new cases will be performed at Suburban, and as cited elsewhere, there is evidence that the establishment of a second program in the WRTC DSA will result in increased volume at the existing WRTC DSA as well. But for the purposes of conservatively estimating benefits of this proposal to the population, at least 40 people will receive a needed transplant who otherwise would not, resulting in prolonged life and a higher quality of life for these patients.

- Fewer patients will travel out of state to Other Centers to receive a liver transplant. From 2018 to 2022, we estimate that 23.5 transplants will shift from Other Centers to Suburban. These are cases currently performed outside of the LLF and WRTC DSAs that will now be performed locally as access is improved. This, too, is a conservative estimate, and the actual number could be higher.

- Decrease in patient migration. Some of the WRTC DSA residents who would have received a transplant at one of the LLF centers will shift to Suburban, using organs from the WRTC and potentially freeing up organs in the LLF DSA for LLF DSA residents. For instance, 17.4 cases are projected at Suburban in 2018. Of those, 6.1 are expected to be WRTC DSA residents who currently travel to LLF centers for transplant but would now have access in the WRTC DSA, at Suburban (2.8 cases from JHH and 3.3 cases from UMMS).

- Lower cost of care at Suburban. As described below in response to (c), cases performed at Suburban will be about 14% lower in cost than cases performed at JHH. A similar comparison can be made with cases at University of Maryland and Georgetown, as both are, like JHH, academic medical centers.

Projected annual costs for the new service at Suburban. The Total Operating Expenses of the program (inflated) for the first five years are included below. These expenses include Salaries & Wages (including benefits), Contractual Services, Supplies & Drugs, Other Expenses (Contingency, Outpatient Activity, and Organ Acquisition).

	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	$718,310	$1,367,174	$1,594,672	$1,828,509	$2,020,755
Other Expenses: Contigency, Outpatient Activity, Organ Acqusition	$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**

(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 Response:

(c)

For the first 5 years operating the new service, Suburban projects to perform an aggregate of 174.2 cases. These cases can be subdivided into two categories, New Cases Performed at Suburban (New Cases) and Cases Shifting to Suburban. An analysis of the impact of cases in these two categories on costs to the health care system is provided below.

	New Cases & Sources of Shifted Cases							
	2016	2017	2018	2019	2020	2021	2022	5 Year Total
Georgetown → Suburban	-	-	5.8	7.0	8.1	9.3	10.5	40.6
Johns Hopkins → Suburban	-	-	3.9	5.1	6.3	7.5	8.6	31.5
Univ of Maryland → Suburban	-	-	5.4	6.5	7.7	8.9	10.1	38.6
"Other Centers" → Suburban	-	-	2.4	3.5	4.7	5.9	7.0	23.5
New Cases	-	-	-	10.0	10.0	10.0	10.0	40.0
Suburban	-	-	17.4	32.1	36.8	41.5	46.2	174.2

Estimated Costs of New Cases Performed at Suburban

Suburban is projected to perform 40 cases, specifically from 2019-2022, as a result of the introduction of competition in the WRTC DSA. It is projected that these cases would not have occurred in the absence of Suburban's presence in the market.

Suburban projects the charge per case to be $148,208, or nearly $6 million for 40 new cases over five years. The charges associated with these 40 cases represent new costs, not shifted costs, to the health care system. These 40 new cases account for 23% of the 174.2 total cases projected to be performed at Suburban in the first five years of operation.

The new costs to the health care system resulting from increased access to liver transplantation are justified, given the number of lives that will be saved and the quality of life improvements that will result for the patients receiving a transplant who otherwise would not.

Estimated Costs of Cases Shifting to Suburban

Cases Shifting to Suburban fall under four subcategories:

- Cases Shifting from Johns Hopkins
- Cases Shifting from Georgetown

- Cases Shifting from University of Maryland
- Cases Shifting from Other Centers (centers outside of the LLF and WRTC DSAs)

Estimated Costs of Cases Shifting from Johns Hopkins

Suburban projects 31.5 cases will shift from JHH to Suburban in the first 5 years of the program.

Suburban's projected charge of $148,208 per case was derived using 2015 JHH Charges for Suburban-Eligible patients. By using JHH internal data, Suburban was able to identify Suburban-Eligible patients (adult, deceased donor, MELD <35, liver-only) and the associated detailed charge data that is not available in publicly reported data sets. By identifying the applicable HSCRC Rate Centers for cases performed at JHH, Suburban Rates were substituted for JHH Rates to project the Suburban charge per case.

The corresponding JHH charge per case for Suburban-Eligible patients in 2015 was $172,955, meaning for each case that shifts from JHH to Suburban, the projected charge will be $24,747 lower, or a total reduction of nearly $780,000 for 31.5 cases.

Further, not only will each of the 31.5 cases performed at Suburban occur at a lower charge, all pre-transplant and post-transplant care will be administered in a lower charge setting relative to JHH, yielding a lower relative cost to the health care system.

Estimated Costs of Cases Shifting from Georgetown, University of Maryland, and Other Centers.

Suburban projects the following shifts to occur over the first 5 years of the program:

- 40.6 cases from Georgetown
- 38.6 cases from the University of Maryland
- 23.5 cases from Other Centers (centers outside of the LLF and WRTC DSAs)

Publicly reported data does not allow Suburban to isolate patients transplanted at these institutions using the "Suburban-Eligible" definition to quantify these patients' average charge rate. Center transplant charges can vary significantly between donor types, at different levels of acuity, and whether or not a case is liver-only or multi-organ. For these reasons, Suburban is unable to quantify the difference in charges between Suburban and the centers from which cases are projected to shift.

Suburban can only surmise that the charge experience at JHH is likely more reflective of the charge experience at Georgetown, University of Maryland, and Other Centers, than Suburban. This is based on the fact that Georgetown and University of Maryland, like JHH, are academic medical centers. Further, since most liver transplant

centers are contained within academic medical centers, it is likely that the centers contained in the “Other Centers” category are also academic medical centers. This means that while Suburban cannot quantify the difference in charges, it is highly likely that Suburban is a lower charge setting relative to most of the centers from where cases are projected to shift. The benefits of being in a lower charge setting would apply not only to the cases performed, but also to all pre- and post-transplant care administered.

Conclusion

New Cases account for 23% of Suburban’s projected volume. All new cases will result in new costs to the system, which will include pre-transplant, transplant, and post-transplant costs. These cases represent lives saved and quality of life improvements, and they will all be performed at a lower cost than if performed elsewhere.

Shifted Cases account for 77% of Suburban’s projected volume, all of which is estimated to be shifting to a lower cost setting, meaning there will be a relative reduction in all pre-transplant, transplant, and post-transplant costs for cases that shift to Suburban. Of these Shifted Cases, 28.6% are projected to be Medicare cases (reflecting the case mix of Suburban-Eligible patients at JHH), meaning shifting these cases will yield savings to Medicare for pre-transplant, transplant, and post-transplant care administered.

The numbers and analysis included above are based on the current rate setting methodology and are subject to change as the methodologies change.

Standard .05B(5) – <u>Impact</u>

(a) A new organ transplant service or relocation of an organ transplant service shall not interfere with the ability of existing transplant services of the same organ type to maintain at least the three-year average annual threshold case volumes required by this Chapter, as measured by the most recent data available through UNOS; and

(b) 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

(c) 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.

(d) 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.

(e) 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	50

Pediatric	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 Response:

(a)

The proposed liver transplant program at Suburban will not interfere with the ability of any of the existing liver transplant services to maintain annual threshold case volumes. As described in the Impact section 10.24.01.08G(3)(f), Suburban's volume is projected to be a combination of market shifts, market growth, volume shifting from centers outside of the two Maryland DSAs, and new volume.

Projected 2016-2022 Center Impact

The Status Quo Projection, meaning if no Suburban program were added, includes growth of 10 cases per year for each of the 3 existing centers. This is based on the combined growth in the two DSAs over the last 6 years.

	Status Quo Projection						
	2016	2017	2018	2019	2020	2021	2022
Georgetown	91.0	101.0	111.0	121.0	131.0	141.0	151.0
Johns Hopkins	110.0	120.0	130.0	140.0	150.0	160.0	170.0
Univ of Maryland	157.0	167.0	177.0	187.0	197.0	207.0	217.0
TOTAL	358.0	388.0	418.0	448.0	478.0	508.0	538.0

The Adjusted Projection shows the projected impact of the Suburban liver transplant program.

	Adjusted Projection						
	2016	2017	2018	2019	2020	2021	2022
Georgetown	91.0	101.0	105.2	114.0	122.9	131.7	140.5
Johns Hopkins	110.0	120.0	126.1	134.9	143.7	152.5	161.4
Univ of Maryland	157.0	167.0	171.6	180.5	189.3	198.1	206.9
Suburban	-	-	17.4	32.1	36.8	41.5	46.2
TOTAL	358.0	388.0	420.4	461.5	492.7	523.9	555.1

The table below reports the differences between the Adjusted Projection and the Status Quo Projection and shows the impact of the new Suburban program on future volume at each existing center, by year. Further, the table reports the total "Additional Transplants", new transplants, to be performed (the Adjusted Projection Total minus the Status Quo Projection Total).

	Adjusted Projection - Status Quo Projection						
	2016	2017	2018	2019	2020	2021	2022
Georgetown	-	-	(5.8)	(7.0)	(8.1)	(9.3)	(10.5)
Johns Hopkins	-	-	(3.9)	(5.1)	(6.3)	(7.5)	(8.6)
Univ of Maryland	-	-	(5.4)	(6.5)	(7.7)	(8.9)	(10.1)
Suburban	-	-	17.4	32.1	36.8	41.5	46.2

The final table reports the impact on each existing center, as a percentage reduction relative to the Status Quo Projection.

	Percent Reduction over Status Quo (% Impact)						
	2016	2017	2018	2019	2020	2021	2022
Georgetown	-	-	-5.2%	-5.7%	-6.2%	-6.6%	-6.9%
Johns Hopkins	-	-	-3.0%	-3.7%	-4.2%	-4.7%	-5.1%
Univ of Maryland	-	-	-3.0%	-3.5%	-3.9%	-4.3%	-4.6%

Both in raw numbers and as a percentage of their total cases, none of the existing centers will experience significant impact. All existing centers are now and will remain well above the minimum volume threshold of 12 cases per year. Georgetown is projected to lose between 5 and 7% of its cases each year—a small percentage and certainly worth the additional ten people who are projected to get a needed transplant who would not without the addition of a program at Suburban. UMMS will be the least impacted of the three centers, at between 3 and 5%. Further, it should be emphasized that at each step of this impact analysis we have employed conservative assumptions. It is likely that Georgetown will actually 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.

(b) 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

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Applicant Response:

(b)

There is no evidence to suggest that the proposed liver transplant program at Suburban Hospital will have an unwarranted adverse impact on the financial viability of another hospital's liver transplant service.

The table below reflects the percent impact Suburban is projected to have on other area liver transplant centers:

	Percent Reduction over Status Quo (% Impact)						
	2016	2017	2018	2019	2020	2021	2022
Georgetown	-	-	-5.2%	-5.7%	-6.2%	-6.6%	-6.9%
Johns Hopkins	-	-	-3.0%	-3.7%	-4.2%	-4.7%	-5.1%
Univ of Maryland	-	-	-3.0%	-3.5%	-3.9%	-4.3%	-4.6%

The proposed program at Suburban Hospital is likely only to impact area centers' volume between 3 - 6%, too little to have a significant financial impact on the existing programs.

As described previously, from 2018 to 2022 an additional 63.5 transplants are projected to be performed relative to the status quo as a result of this program's entrance into the market. Of those projected 63.5 additional cases over 5 years, 40 are new cases—additional volume generated as a result of competition in the WRTC DSA and increased access to liver transplant. In other words, 40 more people will receive a transplant, extending their lives and improving their quality of life. No material financial impact on other centers will result from the establishment of a liver transplant program at Suburban, and any minimal financial impact will be out-weighted by the benefits of increased access and the additional cases that will result from the new program.

(c) 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.

Applicant Response:

(c)

When measured in raw numbers and as a percentage of total volume, the impact of the new center on the volume of cases at the other centers will be minimal. As a result, there will be no material impact on access, quality, or patient outcomes. In fact, access is expected to improve overall in the WRTC DSA and at the other WRTC DSA liver transplant center, as a result of competition.

(d) 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

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Applicant Response:

(d)(i)

Please see Section *10.24.01.08G(3)(f).Impact on Existing Providers and the Health Care Delivery System* question (a) for a detailed analysis that quantifies the shifts in case volume for each location.

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

(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

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Applicant Response:

(d)(ii)

Financial

Patient's shifting from other area transplant centers to Suburban Hospital will most frequently be shifting from a higher cost setting to a lower cost setting. This means that their pre-transplant, transplant, and post-transplant care will be administered at a lower cost. To the extent that Suburban Hospital's program is successful at improving access and transplanting more individuals as a result of the WRTC DSA becoming a competitive DSA, all new cases performed relative to the status quo will take place in a lower cost setting.

Geographic Access

WRTC DSA residents disproportionately out-migrate to other DSAs to be transplanted when compared to LLF DSA residents. In light of this, a new transplant center in the WRTC DSA will increase access in two ways. First, a new liver transplant center in the WRTC DSA will convert the DSA from a non-competitive DSA to a competitive DSA. The result will be that more individuals will gain access to transplantation. Second, not only will more individuals access transplantation as a result of the Suburban program, but WRTC DSA residents will be provided an additional local option, making them less likely to out-migrate for services. To that end, LLF DSA residents who possess the means to travel to Suburban Hospital, will also have access to an additional liver transplant center in the state of Maryland. Access to the Suburban liver transplant waiting list will be facilitated by Johns Hopkins CTC as well, by giving patients the option to double-list at both JHH and Suburban when the patient is deemed clinically appropriate for both centers.

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

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

Applicant Response:

(d)(iii)

The quality of care provided by Suburban Hospital's program will reflect the expertise and high quality displayed at the Johns Hopkins CTC. There is no evidence that the quality of care at other area liver transplant centers will be impacted in any way, particularly as the impact on patient volume at the other centers will be minimal. The population residing within a three-hour drive time of the Suburban predominately accesses transplant services at JHH, UMMS, and MGUH – each achieving an acceptable level of quality as monitored by the SRTR. This will continue to be the case once Suburban's program is operational.

(e) 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.

Applicant Response:

(e)

At the time of this application submission, the above standard is inapplicable.

Standard .05B(6) – <u>Certification and Accreditation</u>

(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 Response:

(a)

Suburban Hospital agrees that if awarded a Certificate of Need to establish a liver transplant service, it shall be certified by United Network for Organ Sharing within the first year of operation.

(b)

Inapplicable.

(c)

Suburban Hospital is accredited by the Joint Commission (Exhibit 16).

Standard .05B(7) – <u>Health Promotion and Disease Prevention</u>

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 Response:

A crucial goal of the new liver transplant program at Suburban Hospital is to work aggressively to reduce the preventable causes of liver failure in the national capital region and to manage liver disease before a patient's condition advances to a stage that requires transplant.

That effort has already begun and it continues to grow. Two years ago, Johns Hopkins recruited two experienced hepatologists to treat patients in the WRTC DSA through their work at Sibley Memorial Hospital: Dr. Kirti Shetty (Director of Hepatology) and Dr. Jacqueline M. Laurin (Transplant Hepatologist). Dr. Shetty and Dr. Laurin treat patients at Sibley's Hepatology Multidisciplinary Center by managing medical conditions that can lead to liver failure. By actively addressing underlying problems, the need for liver transplant can be reduced.

Further, Johns Hopkins is in discussion with the Minority Organ Tissue Transplant Education Program (MOTTEP) in the hopes of developing a partnership that would expand and enhance current outreach and preventive health efforts targeting liver disease and its precursors in the national capital region.

In connection with the new transplant center at Suburban, Johns Hopkins will expand the practice of Drs. Shetty and Laurin and undertake additional prevention efforts. Johns Hopkins will:

- Build a regional Center of Excellence for Liver Disease, with expertise and capabilities in critical care, interventional radiology, and a complete range of wraparound support services for patients with liver disease.

- Deploy trained nurse coordinators/educators into the community to work with community organizations to develop screening and prevention programing, and conduct educational seminars.

- Deploy trained nurse coordinators/educators will work with local addiction services in an effort to prevent or modify behaviors that can lead to end stage liver failure, as well as connect patients with addiction support services to prevent and reduce recidivism.

- Increase access to experienced liver specialists to provide care that prevents progression of liver disease, including access to bariatric treatment options.

- Collaborate with local community-based programs to address drug and alcohol dependency and obesity.

- Link existing programs in the WRTC DSA to programs at Sibley, Suburban, and in 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.

Standard .05B(8) – <u>Comparative Reviews</u>

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.

Applicant Response:

Inapplicable.

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.

INSTRUCTIONS: Please identify the need that will be addressed by the proposed project, quantifying the need, to the extent possible, for each facility and service capacity proposed for development, relocation, or renovation in the project. The analysis of need for the project should be population-based, applying utilization rates based on historic trends and expected future changes to those trends. This need analysis should be aimed at demonstrating needs of the population served or to be served by the hospital. The existing and/or intended service area population of the applicant should be clearly defined.

Fully address the way in which the proposed project is consistent with each applicable need standard or need projection methodology in the State Health Plan.

If the project involves modernization of an existing facility through renovation and/or expansion, provide a detailed explanation of why such modernization is needed by the service area population of the hospital. Identify and discuss relevant building or life safety code issues, age of physical plant issues, or standard of care issues that support the need for the proposed modernization.

Please assure that all sources of information used in the need analysis are identified. Fully explain all assumptions made in the need analysis with respect to demand for services, the projected utilization rate(s), the relevant population considered in the analysis, and the service capacity of buildings and equipment included in the project, with information that supports the validity of these assumptions.

Explain how the applicant considered the unmet needs of the population to be served in arriving at a determination that the proposed project is needed. Detail the applicant's consideration of the provision of services in non-hospital settings and/or through population-based health activities in determining the need for the project.

Complete the Statistical Projections (Tables F and I, as applicable) worksheets in the CON Table Package, as required. Instructions are provided in the cover sheet of the CON package.

Applicant Response:

Need

Please see Section "III. Need for New Transplant Service at Suburban" of the Project Description addressing Need.

Projection Methodology

Multiple sections of this application instruct the applicant to answer questions

spanning the first five years of the proposed program. For this reason, volume projections, impact, and financial tables have been completed for years one through five of the proposed program.

The financial tables, included in the MHCC Tables Package, report data in terms of Fiscal Year (07/01/20XX to 06/30/20XX), consistent with the financial reporting practices of Johns Hopkins Health System.

However, the volume projections and impact assessments contained in this application are analyzed and reported using Calendar Year. This is because center volumes (publicly reported) and patient-residence data (provided by UNOS) are reported using Calendar Years. These historical data were incorporated into the Suburban volume projection methodology, used as a baseline for projecting future volume, and subsequently used to estimate the impact on other centers.

Tables

For Tables F and I, please see Exhibit 1F and Exhibit 1I.

Suburban Hospital Liver Transplant Volume Assumptions

Projections of future utilization of hospital services in Table I are based on all episodes of transplant care – pre-transplant, transplant, and post-transplant inpatient care and outpatient visits. Pre-admission post-admission and outpatient volumes were quantified using ratios that reflect JHH's experience (i.e. transplant volume: pre-admission volume, transplant volume: post-admission volume, etc.).

The new program volume is incorporated in the entire facility volume projections in Table F. The future facility projections align with Suburban Hospital's 10-year Plan.

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.

INSTRUCTIONS: Please describe the planning process that was used to develop the proposed project. This should include a full explanation of the primary goals or objectives of the project or the problem(s) being addressed by the proposed project. The applicant should identify the alternative approaches to achieving those goals or objectives or solving those problem(s) that were considered during the project planning process, including:

a) the alternative of the services being provided through existing facilities;

b) or through population-health initiatives that would avoid or lessen hospital admissions.

Describe the hospital's population health initiatives and explain how the projections and proposed capacities take these initiatives into account.

For all alternative approaches, provide information on the level of effectiveness in goal or objective achievement or problem resolution that each alternative would be likely to achieve and the costs of each alternative. The cost analysis should go beyond development costs to consider life cycle costs of project alternatives. This 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, including the alternative of providing the service through existing facilities, including outpatient facilities or population-based planning activities or resources that may lessen hospital admissions, or through an alternative facility that has submitted a competitive application as part of a comparative review.

Applicant Response:

Planning Process

As early as 2013, the Johns Hopkins CTC began analyzing the zip codes of its liver transplant patients and those of other area centers. The CTC found patients increasingly migrating to Baltimore to obtain liver transplant services from the zip codes in the national capital region. It was through this initial finding that additional disparities related to volume, transplant rate, migration, acuity, supply, and wait listing were discovered. Upon thorough review of these findings, the CTC, in conjunction with Johns Hopkins Health System hospitals, Suburban Hospital and Sibley Memorial Hospital, began to develop and deploy resources in the region to address the preventable causes of liver failure.

In response to these findings, Johns Hopkins recruited two experienced hepatologists to treat patients in the WRTC DSA at Sibley Memorial Hospital: Dr. Kirti

Shetty (Director of Hepatology) and Dr. Jacqueline M. Laurin (Transplant Hepatologist). Dr. Shetty and Dr. Laurin treat patients at Sibley's Hepatology Multidisciplinary Center by managing medical conditions that can lead to liver failure. By actively addressing underlying problems, the need for liver transplant can be reduced. This did not, however, address the overwhelming disparity in access between the two DSAs. Johns Hopkins sought strategies that would reduce the disparity and increase access to liver transplant for WRTC DSA residents.

The available peer reviewed literature indicates that lack of competition in a DSA results in increased barriers to access. Johns Hopkins determined that the most effective way to increase liver transplant rates in the WRTC DSA was to open a new liver transplant center, converting the DSA from non-competitive to competitive. Anything short of an additional center in the WRTC DSA would be insufficient to address the access disparity. However, we first considered whether any alternative strategies could achieve the same result.

a) Providing Services through Existing Facilities

One possible way to address the disparity is increase the number of transplants performed at the existing facilities. To close this significant access gap, though, the sole WRTC DSA center would have to greatly expand the number of liver transplants it performs per year. Of that increased volume, the vast majority would need to be for WRTC DSA residents for the access gap to close significantly. The disparity has existed for many years, though, and in fact is increasing—it is not clear what mechanism would cause an increase in volume, other than DSA competition. Further, the two LLF centers are already functioning at a high level, making it difficult for them to increase their volume further. Finally, an increase in volume and performance at the existing LLF centers would only increase the disparity, not decrease it.

Thus, providing services through existing facilities was determined not to be an effective strategy to decrease the access disparity between the LLF DSA and the WRTC DSA. In the absence of a new center, access disparities will persist, and more importantly, the WRTC DSA will continue to operate without intra-DSA competition and the potential benefits that competition can bring.

Establishing a New Center in the LLF DSA

A new center in the LLF DSA would not address the access disparity between the LLF DSA and WRTC DSA, and would potentially exacerbate current patient migration trends. LLF DSA residents experience superior levels of access to liver transplant services relative to WRTC residents. An additional center in the LLF DSA would not invoke the potential benefits of competition, because the LLF DSA is already competitive – with JHH and UMMS displaying strong outcomes and "raising the bar" year over year with respect to patient access.

Further, an additional center in the LLF DSA would likely cause a greater influx of patients to leave the WRTC DSA for the LLF DSA. Patients migrating in

this way are by definition those with the socioeconomic means to do so. A plan that promotes increasing the flow of patients out of the WRTC DSA to the LLF DSA is unlikely to reduce the access disparity between WRTC DSA residents and LLF DSA residents. Further, if any demographic of the WRTC DSA population would benefit, it would likely only be those with the ability to travel, which typical consists of those of high socioeconomic status – therefore not addressing the needs of residents with fewer resources.

Establishing a New Center in the WRTC - Operated by a Hospital System With No Existing Liver Transplant Program

The approval of a new liver transplant center within the WRTC is the best way to address the access disparity between LLF DSA residents and WRTC DSA residents, introducing competition into a DSA that currently has only one center. This is supported in the peer-reviewed literature. Given that, the establishment of a new center by a health system that currently operates a liver transplant program is the superior option. Here are the pros and cons of approving a center affiliated with a hospital or hospital system that does not operate a liver transplant centers:

Pros

- Competition: The WRTC DSA would become a competitive DSA and benefit from all the functional effects shown to result from competition.

Cons

- High Start-Up Cost: If the hospital system does not have a liver transplant team (surgeons, PAs, NPs, Nurse Coordinators, Social Work, etc), it will lack the ability to leverage economies of scale relative to a hospital system that already has a liver transplant program and can share many of its fixed costs (personnel, physician support, operational support).

- Lack of Experience: If the hospital system is not currently running a liver transplant program, it will lack experience, lack knowledge of best practices, lack the requisite protocols, will take longer to ramp up, will be more likely to experience significant operational challenges, and be less likely to accurately predict the impact a new liver transplant program can have on the hospital's overall operations and through-put.

- No Double-Listing: There would be no opportunity for double-listing within a hospital system if the hospital supporting the new center is not currently affiliated with another liver transplant program. Patients would need to seek out opporutnities for double-listing on their own.

Current Option Proposed in this Application: Establishing a New Center in the WRTC - Operated by a Hospital System With an Existing Liver Transplant Program

The approval of a new liver transplant center within the WRTC is the best way to address the access disparity between LLF DSA residents and WRTC DSA residents. Approving a center that is affiliated with a hospital or hospital system that currently operates a certified liver transplant center in another DSA is the superior option when judged against the following criteria:

Pros

- Competition: The WRTC DSA would become a competitive DSA and will benefit from all the functional effects competition can have.

- Lower Start-Up Cost: If the hospital system has a liver transplant team (surgeons, PAs, NPs, Nurse Coordinators, Social Work, etc), it will be able to leverage its current resources and will share many of its fixed costs (personnel, physician support, operational support).

- Experience: If the hospital system is running a liver transplant program, it will have experience, knowledge of best practices, possess the requisite procols, will take less time to ramp up, and is more likely to be both an operationally sound program and able to better predict the impact a new liver transplant program can have on the hospital's overall operations and through-put.

- Double-Listing: There would be an opportunity for double-listing patients at the affiliated liver transplant program.

In summary, a new center in the WRTC DSA that introduces competition, is the most effective strategy for reducing access disparities and increasing the number of WRTC DSA residents in need of a transplant who receive it. A hospital affiliated with an existing liver transplant program is best situated to develop the new center in the shortest time, at the highest quality care and outcomes, and at the lowest cost.

b) Population-Health Initiatives

In connection with the new transplant center at Suburban, Johns Hopkins plans to expand the practice of Drs. Shetty and Laurin and to undertake additional prevention efforts. Johns Hopkins will:

- Build a regional Center of Excellence for Liver Disease, with expertise and capabilities in critical care, interventional radiology, and a complete range of wraparound support services for patients with liver disease.

- Deploy trained nurse coordinators/educators to engage in community education and outreach.

- Increase access to experienced liver specialists to provide care that prevents progression of liver disease, including access to bariatric treatment options.

- Collaborate with local community-based programs to address drug and alcohol dependency and obesity.

- Link existing programs in the WRTC to programs at Sibley, Suburban, and in 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.

We hope that these efforts will prevent some patients from needing a transplant. It will not, however, reduce the access disparity. Many people die every year while waiting for a liver transplant. While population health initiatives that target precursors and slow the progression of liver disease are crucial, and will be an important part of the Suburban Hospital program, they do not diminish the unmet need or the gaping access disparity. A new center providing liver transplants in the WRTC DSA is the only solution that does.

10.24.01.08G(3)(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.

INSTRUCTIONS: Please provide a complete description of the funding plan for the project, documenting the availability of equity, grant(s), or philanthropic sources of funds and demonstrating, to the extent possible, the ability of the applicant to obtain the debt financing proposed. Describe the alternative financing mechanisms considered in project planning and provide an explanation of why the proposed mix of funding sources was chosen.

- Complete applicable Revenues & Expenses (Tables G, H, J and K as applicable), and the Work Force information (Table L) worksheets in the CON Table Package, as required. Instructions are provided in the cover sheet of the CON package. Explain how these tables demonstrate that the proposed project is sustainable and provide a description of the sources and methods for recruitment of needed staff resources for the proposed project, if applicable.

- Describe and document relevant **community support** for the proposed project.

- Identify the **performance requirements** applicable to the proposed project and explain how the applicant will be able to implement the project in compliance with those performance requirements. Explain the process for completing the project design, contracting and obtaining and obligating the funds within the prescribed time frame. Describe the construction process or refer to a description elsewhere in the application that demonstrates that the project can be completed within the applicable time frame.

- **Audited financial statements** for the past two years should be provided by all applicant entities and parent companies.

Applicant Response:

Projection Methodology

Multiple sections of this application instruct the applicant to answer questions spanning the first five years of the proposed program. For this reason, volume projections, impact, and financial tables have been completed for years one through five of the proposed program.

The financial tables, included in the MHCC Tables Package, report data in terms of Fiscal Year (07/01/20XX to 06/30/20XX), consistent with the financial reporting practices of Johns Hopkins Health System.

However, the volume projections and impact assessments contained in this application are analyzed and reported using Calendar Year. This is because center volumes (publicly reported) and patient-residence data (provided by UNOS) are

reported using Calendar Years. These historical data were incorporated into the Suburban volume projection methodology, used as a baseline for projecting future volume, and subsequently used to estimate the impact on other centers.

Regarding revenue projections, these are based on the current rate setting methodology and are subject to change as the methodologies change.

Table G, H, J, K

See Exhibits 1G, 1H, 1J, and 1K.

Suburban Hospital Liver Transplant Financial Assumptions

Financial projections for the entire facility revenues and expenses can be found in Tables G and H. Financial projections for the Liver Transplant Program are outlined in Table J and K.

Expense inflation assumptions are based on average historical inflation rates of 2.5% for salaries and all other expenses.

In Tables J and K, program revenue estimates are based on the projected charge per case of each transplant episode. Charge per case is calculating using FY16 Suburban allowable unit rates and JHH liver transplant patients' utilization of pre-transplant, transplant, post-transplant and outpatient care.

All adjustments to revenue are expected to continue at current experience levels.

We are assuming the first 10 transplant cases will be unreimbursed in Year 1. This is because CMS requires the completion of 10 liver transplant cases prior to applying for CMS Certification. Once CMS Certification is obtained, case number 11 and all cases thereafter are projected to be reimbursed.

No GBR constraints have been applied to the revenue estimates for the liver program.

Staffing and program support are based on current expenditure levels and cover the entirety of each transplant episode including hospitalizations, outpatient visits and organ procurement. It also takes into account changes in utilization and the staffing increases necessary for managing the complexity of liver transplant patients.

Tables G and H portray the financial projections of the entire facility including the liver transplant program. Using these projections, the hospital will generate excess revenues over expenses in the second year following the start of liver transplant program, and Table K demonstrates how this will be achieved.

Table L

Please see Exhibit 1L.

The Johns Hopkins Hospital Comprehensive Transplant Center has a long track record of successfully recruiting highly specialized transplant personnel. Suburban will draw upon this experience and expertise to recruit the necessary transplantation services personnel.

Community Support

Suburban Hospital has garnered considerable support for its proposed liver transplant program in the areas of Health Care, Government, and Patient Advocacy.

Health Care

The Suburban project has received the support of Kimberly D. Russo, MS, MBA, CEO of George Washington University Hospital (GWUH). In her letter, Ms. Russo notes:

> "I … have witnessed firsthand the importance of providing transplant services in the place where they are needed and the tremendous benefits that market competition, particularly centered on community outreach, can have on a transplant community."

Ms. Russo's letter speaks to GWUH's experience opening a new adult kidney transplant center in the District and its impact on the only other nonmilitary, adult kidney transplant center in the District:

> "Because the sole existing kidney transplant program (i.e., adult, nonmilitary) in the District was suddenly faced with competition, that hospital hired a new surgeon and increased its own outreach efforts. As a result, that existing program has actually performed more kidney transplants since our Institute opened than it had in many years. In short, it was forced to "'up its game'."

Ms. Russo concludes:

> "Given our recent experience in the kidney transplant arena, we suspect strongly that the provision of liver transplant services in Montgomery County - and the introduction of liver transplant program competition in the D.C. area - will benefit Maryland and D.C. residents alike and greatly improve access for those Maryland residents for whom Baltimore is not a viable option."

The proposal is also supported by Kirti Shetty, MD FAASLD FAlCG, Director of Hepatology at Sibley Memorial Hospital, and Jacqueline Laurin, MD, Assistant Professor of Medicine and transplant hepatologist at Sibley Memorial Hospital's Hepatology Multidisciplinary Center. In their joint letter, Dr. Shetty and Dr. Laurin note

the ability of Suburban's proposal to increase patient access to specialized care, increase patient access to liver transplantation, and to address an increasing liver disease burden.

Government

Suburban Hospital's proposed liver transplant program has received the support of the Maryland General Assembly's 16th Legislative District, including: Senator Susan C Lee, Delegate C William Frick, Delegate Ariana Kelly, and Delegate Marc Korman.

The proposal is also supported by the Montgomery County Department of Health and Human Services, including Director Uma S. Ahluwalia, and County Executive Isiah Leggett.

Patient Advocacy

Suburban Hospital's proposed liver transplant program is supported by TRIO (Transplant Recipients International Organization, Inc.) Maryland's President Marty Maren. TRIO is a non-profit, international organization that for more than 30 years has been a leading advocate for greater access to liver transplant services while promoting education and awareness.

The proposal is also supported by Ivory Allison, the Executive Director of the American Liver Foundation (ALF) Mid-Atlantic Division. The American Liver Foundation facilitates, advocates and promotes education, support and research for the prevention, treatment and cure of liver disease. The ALF supports the ability of Suburban's proposal to increase access to liver transplantation, bring additional resources for outreach and education of potential donors and recipients, and add resources for the prevention and care of patients with advanced liver disease, pre and post-transplant.

Performance Requirements

There are no capital expenditures associated with this project, and so there are no applicable performance requirements related to obligation of funds or construction schedules.

Audited Financial Statements

Please see Exhibit 18 for the most recent audited financial statements. All Johns Hopkins Health System affiliates are audited on a consolidated basis. The latter part of the document contains the P&L's and balance sheets by affiliate, so Suburban's financial statements can be reviewed separately.

10.24.01.08G(3)(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.

INSTRUCTIONS: List all of the Certificates of Need that have been issued to the applicant or related entities, affiliates, or subsidiaries since 2000, including their terms and conditions, and any changes to approved CONs that were approved. Document that these projects were or are being implemented in compliance with all of their terms and conditions or explain why this was not the case.

Applicant Response:

Suburban 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)
- Expansion and Modernization of Suburban Hospital (Docket No. 15-15-2368)

The Cardiac Surgery and Percutaneous Coronary Intervention Program CON was awarded July 21, 2005. A copy of the CON is attached as Exhibit 19 and describes in detail the four conditions placed on this CON. Suburban Hospital has been and will continue to be compliant with these four conditions.

The Expansion and Modernization of Suburban Hospital CON was awarded on May 19, 2016. A copy of the CON is attached as Exhibit 6. Suburban Hospital is being and will continue to be compliant with its quarterly report submissions.

10.24.01.08G(3)(f). Impact on Existing Providers and the Health Care Delivery System.

An applicant shall provide information and analysis with respect to the impact of the proposed project on existing health care providers in the health planning region, 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.

INSTRUCTIONS: Please provide an analysis of the impact of the proposed project:

a) On the volume of service provided by all other existing health care providers that are likely to experience some impact as a result of this project[61];

b) On access to health care services for the service area population that will be served by the project. (state and support the assumptions used in this analysis of the impact on access);

c) On costs to the health care delivery system.

If the applicant is an existing hospital, provide a summary description of the impact of the proposed project on costs and charges of the applicant hospital, consistent with the information provided in the Project Budget, the projections of revenues and expenses, and the work force information.

Applicant Response:

(a)

There are three liver transplants centers in the LLF DSA and WRTC DSA combined: The Johns Hopkins Hospital (JHH), University of Maryland Medical Center (UMMS), and MedStar Georgetown (Georgetown). Most residents of these two DSAs are transplanted at one of these three centers, with some residents being transplanted at a center elsewhere in the U.S (referred to in this analysis as "Other Centers").

Suburban is proposing to serve a sub-set of these liver transplant patients, (referred to in this analysis as "Suburban-Eligible"), consisting of:

- Adults
- MELD score < 35
- Receiving a deceased donor liver
- Liver-only (not multi-organ)

Suburban is not proposing initially to perform pediatric liver transplants, live donor liver transplants, patients with a MELD score of 35 or above, multi-organ transplants, or Status 1 patient transplants. Due to the heightened complexity of these

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[61] Please assure that all sources of information used in the impact analysis are identified and identify all the assumptions made in the impact analysis with respect to demand for services, the relevant populations considered in the analysis, and changes in market share, with information that supports the validity of these assumptions.

cases, Suburban feels it is most prudent to continue to direct its highest acuity, as well as its pediatric cases, to The Johns Hopkins Hospital as the most appropriate site of care. Suburban intends to consider taking on higher acuity and more complex cases once it has established a sustained track record of center-level experience and strong outcomes.

A. Suburban Volume Projection Methodology

In order to project the Year 1 through Year 5 volumes at Suburban Hospital (CY2018-2022) for this specific sub-set of Suburban-Eligible patients—as well as to quantify the impact on other area centers—the following methodology was used:

1. Determine the number of Suburban-Eligible patients transplanted in 2015 by LLF and WRTC DSA Centers using publicly reported data sources

2. Project total transplant volume at existing centers in LLF and WRTC DSA through 2018 using historical trends

3. Analyze center volumes using patient residency (zip code) data, provided by UNOS, to define current (2015) migration patterns and project 2018 migration patterns

4. Project the shift of Suburban-Eligible patients from other centers to Suburban upon opening of the proposed program

5. Project 2016-2022 Center Volume

6. Project 2016-2022 Center Impact

Each of these calculations and projections is discussed in detail, below.

B. Projections

1. Determine the number of Suburban-Eligible patients transplanted in 2015 by LLF and WRTC DSA Centers using publicly reported data sources

Part 1 of this analysis is to quantify the number patients at JHH, UMMS, and Georgetown that fit the Suburban-Eligible description in 2015.

Internal data for JHH was used to provide an exact count of patients fitting this description. For UMMS and Georgetown, an exact count is not obtainable via publically reported data, so the number of Suburban-Eligible cases performed at UMMS and Georgetown was estimated using the following approach:

Step 1 = Report the number of Deceased Donor Cases of all Ages using OPTN

			2015
Georgetown	All Donor Types	All Ages	81
		Pediatric	32
		Adult	49
	Deceased Donor	All Ages	69
		Pediatric	23
		Adult	46
	Living Donor	All Ages	12
		Pediatric	9
		Adult	3
Univ of Maryland	All Donor Types	All Ages	147
		Pediatric	1
		Adult	146
	Deceased Donor	All Ages	135
		Pediatric	1
		Adult	134
	Living Donor	All Ages	12
		Pediatric	0
		Adult	12

Step 2 = Exclude all Pediatric cases, MELD >30 cases, and Status 1 cases using Scientific Registry of Transplant Recipients (SRTR)

Note: publicly reported data does not include a cut-off at MELD 35, so the cut-off of MELD 30 was used; making this a conservative estimate.

	Georgetown		UMMS	
	All Age Deceased Donor %	All Age Deceased Donor Count	All Age Deceased Donor %	All Age Deceased Donor Count
	(N=69)		(N=135)	
Status 1A	2.9%	2	2.2%	3
Status 1B (PEDS)	18.8%	13	0.0%	0
MELD 6-10	17.4%	12	12.6%	17
MELD 11-14	10.1%	7	7.4%	10
MELD 15-20	7.2%	5	23.0%	31
MELD 21-30	15.9%	11	20.0%	27
MELD 31-40	14.5%	10	34.8%	47
PELD less than or equal 10	10.1%	7	0.0%	0
PELD 11-14	0.0%	0	0.0%	0
PELD 15-20	1.4%	1	0.0%	0
PELD 21-30	1.4%	1	0.0%	0
PELD 31 or greater	0.0%	0	0.0%	0
Temporarily Inactive	0.0%	0	0.0%	0
TOTAL	100%	69	100%	135
Adult Subtotal	-	47	-	135
Peds Subtotal	-	22	-	-
MELD <31	-	35	-	85

Step 3 = Exclude Multi-Organ Cases

Note: multi-organ cases are included in the counts in the table above. The percentage of cases that are multi-organ is available by center, but only for the total cases—not specific to the Suburban-Eligible cases. For the purposes of these projections, the overall multi-organ percentage was applied to the number of Suburban-Eligible cases to estimate the number that were liver-only

	All Deceased Donors	Deceased Donor, All-Age, All MELD, % Multi-Organ	Adult, DD, MELD <31	Adult, DD, MELD <31, Liver Only
Georgetown	69	21.7%	35	27
UMMS	135	7.4%	85	79

Step 4 = Report Proportion of Suburban-Eligible Liver Transplant Patients at Each of the Three Centers

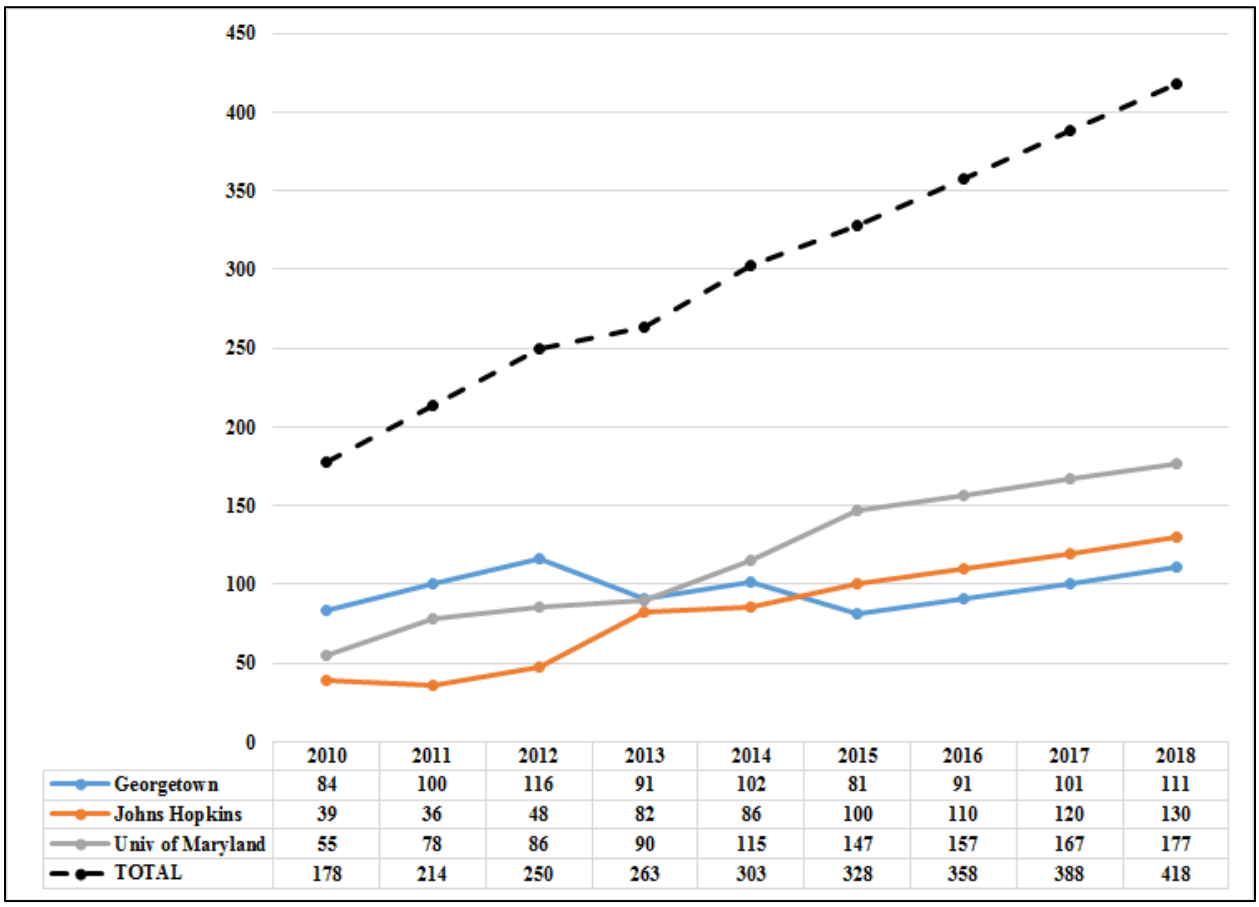
	Adult, DD, MELD <31, Liver Only	Total Volume	% of Total Volume
Georgetown	27	81	34%
UMMS	79	147	54%
Johns Hopkins*	49	100	49%
TOTAL	155	328	47%

**Johns Hopkins value sourced to internal data*

2. Project total transplant volume at existing centers in LLF and WRTC DSA through 2018 using historical trends

From 2010 to 2015, the total volume of the three regional centers grew on average by 30 cases per year. This growth rate was assumed to continue for calendar years 2016, 2017, and 2018. Because center-level growth rates can vary over time, the market growth of 30 cases per year was evenly distributed across the three centers, 10 cases per year at each center.

	Actual Cases						Projection		
	2010	2011	2012	2013	2014	2015	2016	2017	2018
Georgetown	84	100	116	91	102	81	91	101	111
Johns Hopkins	39	36	48	82	86	100	110	120	130
Univ of Maryland	55	78	86	90	115	147	157	167	177
TOTAL	178	214	250	263	303	328	358	388	418
Annual Growth	-	36	36	13	40	25	30	30	30
Avg. Annual Growth Per Year 2010-2015						30			



	2010	2011	2012	2013	2014	2015	2016	2017	2018
Georgetown	84	100	116	91	102	81	91	101	111
Johns Hopkins	39	36	48	82	86	100	110	120	130
Univ of Maryland	55	78	86	90	115	147	157	167	177
TOTAL	178	214	250	263	303	328	358	388	418

Since this volume projection methodology was developed, calendar year 2016 volumes were released. From 2015 to 2016, the total volume for the three centers grew by 84 cases, 54 more cases than this methodology, based on historical trends, predicted.

Center	2016 Actual	Variance (2016-2015)
Georgetown	117	36
Johns Hopkins	126	26
Univ of Maryland	169	22
2016 Actual TOTAL	412	84

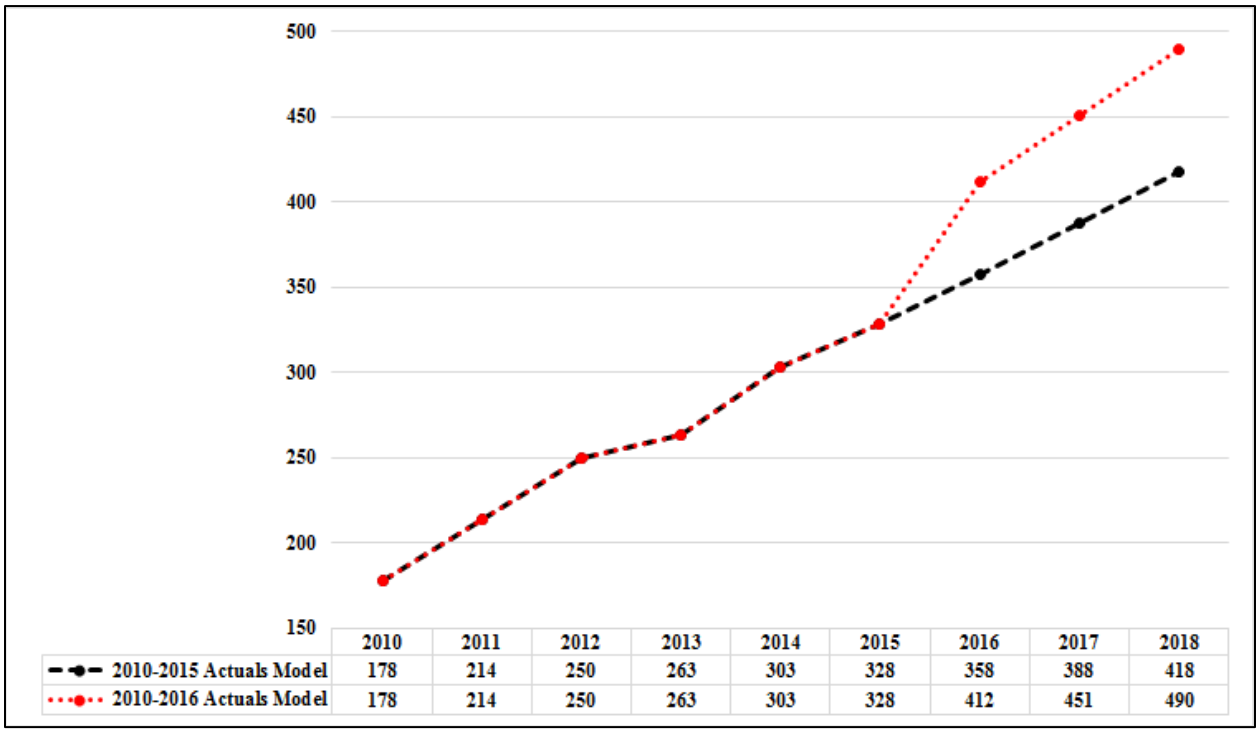
For comparison, the model predicted the volume total growth in the market by the end of 2018 was 90 cases. Despite the release of this new data, the volume projection methodology was kept as is. Meaning, the model predicts a growth rate of 30 cases per year, at 10 per center per year, using 2015 as its last year of “Actual Cases”.

Including the actual 2016 volume growth would greatly impact this model, and cause it to predict significantly more volume in the market in the follow ways:

- The 2010-2015 Actuals Model uses 328 total cases and growth of 30 cases per year, 10 cases per center

- The 2010-2016 Actuals Model would use 412 total cases in its last year, meaning the average growth rate for 2010-2016 would now compute to 39 cases per year, 13 cases per center

- Combining these 2 factors would yield a 2010-2016 Actuals Model with a total of 490 cases in 2018, instead of the 418 reported in the 2010-2015 Actuals Model. This difference is depicted below:



	2010	2011	2012	2013	2014	2015	2016	2017	2018
2010-2015 Actuals Model	178	214	250	263	303	328	358	388	418
2010-2016 Actuals Model	178	214	250	263	303	328	412	451	490

In light of this, the 2010-2015 Actuals Model was used for this volume projection methodology, with 2016 actuals excluded. However, the 2016 actuals strongly support the assumption that the total volume of these three centers will continue to grow, and that 10 cases per year per center is a reasonable, conservative growth assumption. The methodology based on 2010-2015 includes historically-based annual case growth, but protects against the 2016 volume spike resulting in an overestimation of future center-level volumes.

3. Analyze center volumes using patient residency data, provided by UNOS, to define current (2015) migration patterns and project 2018 migration patterns

The table below details the CY2015 liver patients transplanted by DSA of residency and transplant center (source: UNOS data request). All patient types are included and reported as counts and percentages. The column “Other Centers” refers to any U.S. transplant center other than JHH, UMMS, or Georgetown. The WRTC DSA is divided into 3 groups, based on the patient’s state of residency.

Actual 2015 Counts - All Patients						
DSA	State	JHH	UMMS	G'town	Other Centers	TOTAL
LLF	MD	57	104	7	5	173
WRTC	MD	11	20	24	8	63
WRTC	DC	1	1	6	7	15
WRTC	VA	10	4	32	10	56
Other	Other	21	18	12	-	51
TOTAL		100	147	81	30	358

Actual 2015 Percentages - All Patients						
DSA	State	JHH	UMMS	G'town	Other Centers	TOTAL
LLF	MD	57%	71%	9%	17%	48%
WRTC	MD	11%	14%	30%	27%	18%
WRTC	DC	1%	1%	7%	23%	4%
WRTC	VA	10%	3%	40%	33%	16%
Other	Other	21%	12%	15%	0%	14%
TOTAL		100%	100%	100%	100%	100%

Next, center-level volume growth for 2016, 2017, and 2018 was outlined consistent with projections determined in “Part 2” of this methodology, assuming each center’s volume will grow by 10 cases per year.

	Projected Growth Per Year			Projected Volume By Year		
Center	2016	2017	2018	2016	2017	2018
JHH	10	10	10	110	120	130
UMMS	10	10	10	157	167	177
G'town	10	10	10	91	101	111

Next, CY2018 liver volume projections by DSA of residency and transplant center were calculated, in the following manner:

(1) The “TOTAL” for each center was increased by 30 cases (example: JHH TOTAL of 100 in CY2015 was increased to 130 in CY2018)

(2) The number of LLF and WRTC residents going to “Other Centers” was held constant; a conservative estimate

(3) The number of individuals for each center residing in each DSA-State category was assumed to be proportional to CY2015 (example: the JHH CY2018 TOTAL of 130 was multiplied by 57% to project the number of patients residing in LLF-MD who would receive a liver transplant at JHH in CY2018 to be 74.1)

Projected 2018 - All Patients						
DSA	State	JHH	UMMS	G'town	Other Centers	TOTAL
LLF	MD	74.1	125.2	9.6	5.0	213.9
WRTC	MD	14.3	24.1	32.9	8.0	79.3
WRTC	DC	1.3	1.2	8.2	7.0	17.7
WRTC	VA	13.0	4.8	43.9	10.0	71.7
Other	Other	27.3	21.7	16.4	0.0	65.4
TOTAL		130.0	177.0	111.0	30.0	448.0

The last step of this analysis consolidates WRTC-DC and WRTC-VA categories into one WRTC-DC/VA category in an effort to simplify future steps but keep WRTC-MD separate, as they will be in-state patients at the Suburban center, while WRTC-DC and WRTC-VA patients are out of state patients.

Projected 2018 - All Patients						
DSA	State	JHH	UMMS	G'town	Other Centers	TOTAL
LLF	MD	74.1	125.2	9.6	5.0	213.9
WRTC	MD	14.3	24.1	32.9	8.0	79.3
WRTC	DC/VA	14.3	6.0	52.1	17.0	89.4
Other	Other	27.3	21.7	16.4	0.0	65.4
TOTAL		130.0	177.0	111.0	30.0	448.0

4. Project the shift of Suburban-Eligible patients from other centers to Suburban upon opening of the proposed program

Part 4 of this analysis combines the “Proportion of Suburban-Eligible Liver Transplant Patients at Each of the Three Centers” calculated in Part 1, and the “Projected 2018 – All Patients” volume projected in Part 3.

Part 1: Proportion of Suburban-Eligible Liver Transplant Patients at Each of the Three Centers.

	Suburban-Eligible Patients			
	JHH	UMMS	G'town	Total
% of Total Volume	49%	54%	34%	47%

Part 3: Projected 2018 – All Patients

Projected 2018 - All Patients						
DSA	State	JHH	UMMS	G'town	Other Centers	TOTAL
LLF	MD	74.1	125.2	9.6	5.0	213.9
WRTC	MD	14.3	24.1	32.9	8.0	79.3
WRTC	DC/VA	14.3	6.0	52.1	17.0	89.4
Other	Other	27.3	21.7	16.4	0.0	65.4
TOTAL		130.0	177.0	111.0	30.0	448.0

Step 1 = Convert the "Projected 2018 – All Patients" table into a "Projected 2018 Suburban-Eligible" table by assuming the Suburban-Eligible patients are distributed proportional to how all patients are distributed.

Example: 74.1 JHH/LLF-MD All Patients x 49% = 36.3 JHH/LLF-MD Suburban-Eligible Patients

Projected 2018 Suburban-Eligible						
DSA	State	JHH	UMMS	G'town	Other Centers	TOTAL
LLF	MD	36.3	67.6	3.3	2.4	109.5
WRTC	MD	7.0	13.0	11.2	3.8	35.0
WRTC	DC/VA	7.0	3.3	17.7	8.0	36.0
Other	Other	13.4	11.7	5.6	-	30.7
TOTAL		63.7	95.6	37.7	14.1	211.1

Step 2 = Remove "Other-Other" category from projections and calculate WRTC-Subtotal

Note: Suburban is not including in its projections any cases for residents living outside of the LLF and WRTC DSAs, another conservative assumption.

Projected 2018 Suburban-Eligible						
DSA	State	JHH	UMMS	G'town	Other Centers	TOTAL
LLF	**MD**	**36.3**	**67.6**	**3.3**	**2.4**	**109.5**
WRTC	MD	7.0	13.0	11.2	3.8	35.0
WRTC	DC/VA	7.0	3.3	17.7	8.0	36.0
WRTC	**SUBTOTAL**	**14.0**	**16.3**	**28.9**	**11.8**	**70.9**
TOTAL		50.3	83.9	32.1	14.1	180.4

Step 3 = Project the Suburban Transplant 2018 Volume for WRTC DSA Residents Shifting to Suburban

Of the Suburban-Eligible patients in the market, Suburban projects to transplant 20% of the patients residing in the WRTC DSA. This equates to a 20% shift of Suburban-Eligible, WRTC residents, from JHH (-2.8), UMMS (-3.3), Georgetown (-5.8) and Other Centers (-2.4) to Suburban (+14.2).

ADJUSTED Projected 2018 Suburban-Eligible							
DSA	State	JHH	UMMS	G'town	Suburban	Other Centers	TOTAL
LLF	**MD**	**36.3**	**67.6**	**3.3**	**0.0**	**2.4**	**109.5**
WRTC	MD	5.6	10.4	8.9	7.0	3.0	35.0
WRTC	DC/VA	5.6	2.6	14.2	7.2	6.4	36.0
WRTC	**SUBTOTAL**	**11.2**	**13.0**	**23.1**	**14.2**	**9.4**	**70.9**
TOTAL		47.5	80.6	26.4	14.2	11.8	180.4

Step 4 = Project the Suburban Transplant 2018 Volume for LLF DSA Residents Shifting to Suburban

Suburban projects to be equally as likely to transplant Suburban-Eligible patients residing in the LLF DSA as Georgetown. The source of these shifted cases being UMMS (2.1) and JHH (1.1). This means the number of patients who currently leave the LLF DSA for Georgetown will leave the LLF DSA for Suburban.

ADJUSTED Projected 2018 Suburban-Eligible							
DSA	State	JHH	UMMS	G'town	Suburban	Other Centers	TOTAL
LLF	**MD**	**35.2**	**65.5**	**3.3**	**3.3**	**2.4**	**109.5**
WRTC	MD	5.6	10.4	8.9	7.0	3.0	35.0
WRTC	DC/VA	5.6	2.6	14.2	7.2	6.4	36.0
WRTC	SUBTOTAL	**11.2**	**13.0**	**23.1**	**14.2**	**9.4**	**70.9**
TOTAL		46.4	78.5	26.4	17.4	11.8	180.4

Step 5 = Quantify the Volume Impact on JHH, UMMS, Georgetown, and Other Centers in 2018

The table below reports the projected impact (negative values in parenthesis) of the opening of the Suburban program in 2018 on center volumes. The total center volume impact is projected to be:

- 3.9 cases shifting from JHH to Suburban
- 5.4 cases shifting from UMMS to Suburban
- 5.8 cases shifting from Georgetown to Suburban
- 2.4 cases shifting from Other Centers to Suburban

ADJUSTED Projected 2018 Suburban-Eligible						
DSA	State	JHH	UMMS	G'town	Suburban	Other Centers
LLF	MD	(1.1)	(2.1)	-	3.3	-
WRTC	MD	(1.4)	(2.6)	(2.2)	7.0	(0.8)
WRTC	DC/VA	(1.4)	(0.7)	(3.5)	7.2	(1.6)
WRTC	SUBTOTAL	(2.8)	(3.3)	(5.8)	14.2	(2.4)
TOTAL		(3.9)	(5.4)	(5.8)	17.4	(2.4)

Step 6 = Report the Adjusted 2018 All-Patient Volume by Center for 2018

The table below reports the All Patient volumes by center for 2018 (including both Suburban-Eligible and non-Suburban eligible patients), adjusting for Suburban's entrance into the market in 2018.

Projected 2018 - All Patients							
DSA	State	JHH	UMMS	G'town	Suburban	Other Centers	TOTAL
LLF	MD	73.0	123.1	9.6	3.3	5.0	213.9
WRTC	MD	12.9	21.5	30.7	7.0	7.2	79.3
WRTC	DC/VA	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

5. Project 2016-2022 Center Volume

Step 1 = Report Center Volumes 2010-2015 and Projected 2016-2018

Table below restates the volume projection methodology outlined in Part 2, for the 2010-2015 Actuals Model. A minor change was made in the heading of the Projections section, indicating that these projections represent the Status Quo, i.e. without the addition of a fourth center.

	Actual Cases						Projection - Status Quo		
	2010	2011	2012	2013	2014	2015	2016	2017	2018
Georgetown	84	100	116	91	102	81	91.0	101.0	111.0
Johns Hopkins	39	36	48	82	86	100	110.0	120.0	130.0
Univ of Maryland	55	78	86	90	115	147	157.0	167.0	177.0
TOTAL	178	214	250	263	303	328	358.0	388.0	418.0
Additional Liver Transplants	0	36	36	13	40	25	30.0	30.0	30.0
Avg. Annual Growth Per Year						30			

Step 2 = Adjust 2018 to Incorporate Suburban

The table below modifies the projections displayed directly above, by adding Suburban to the list of centers, and shifting the projected volume to Suburban.

	Actual Cases						Projection - Adjusted		
	2010	2011	2012	2013	2014	2015	2016	2017	2018
Georgetown	84	100	116	91	102	81	91.0	101.0	**105.2**
Johns Hopkins	39	36	48	82	86	100	110.0	120.0	**126.1**
Univ of Maryland	55	78	86	90	115	147	157.0	167.0	**171.6**
Suburban	-	-	-	-	-	-	-	-	**17.4**
TOTAL	178	214	250	263	303	328	358.0	388.0	420.4
Additional Liver Transplants	0	36	36	13	40	25	30.0	30.0	32.4

Step 3 = Report Projected Center Volume Growth and Sources

Annual Growth

The historical growth rate of 30 additional cases per year is assumed to continue through 2022. These 30 cases represent all volume types. As previously calculated, 47% of the cases in the market fit the Suburban-Eligible description. Therefore, additional annual growth in the market as a whole, would not be projected to be evenly distributed among the four area centers.

The table below outlines how this volume would be distributed and is summarized as follows:

- The total, all-patient growth of the centers in the market is projected to be **30** cases
- Suburban-Eligible cases account for **47%** of the patients in the market, and therefore 47% of the growth

- 47% of 30 is **14.1**, the projected annual growth of Suburban-Eligible cases per year
- Distributing the cases evenly among the four centers would equal **3.5** cases per center per year
- The remaining growth in the market, Non-Suburban-Eligible patients, would therefore make up **53%** of the new growth, equating to **15.9** cases per year
- This volume would be shared equally among JHH, UMMS, and Georgetown, equaling **5.3** cases per center per year.

Therefore, growth by center for "Annual Growth" would equal:

- Georgetown = Suburban-Eligible 3.5 + Non-Suburban-Eligible 5.3 = 8.8
- JHH = Suburban-Eligible 3.5 + Non-Suburban-Eligible 5.3 = 8.8
- UMMS = Suburban-Eligible 3.5 + Non-Suburban-Eligible 5.3 = 8.8
- Suburban = Suburban-Eligible 3.5

Annual Growth	
Projected Annual Volume Growth Per Year 2019-2022:	30.0
Percentage of Cases that are Suburban-Eligible:	47%
Projected Annual Growth of Suburban-Eligible Cases Per Year:	14.1
Suburban-Eligible Cases Distributed Evenly Four Ways:	**3.5**
Percentage of Cases that are Non-Suburban-Eligible:	53%
Projected Annual Growth of Non-Suburban-Eligible Cases Per Year:	15.9
Non-Suburban Eligible Cases Distributed Evenly Three Ways:	**5.3**
Projected Annual Volume Growth Per Year	
Georgetown (Suburban-Eligible + Non-Suburban-Eligible):	**8.8**
Johns Hopkins (Suburban-Eligible + Non-Suburban-Eligible):	**8.8**
Univ of Maryland (Suburban-Eligible + Non-Suburban-Eligible):	**8.8**
Suburban (Suburban-Eligible):	**3.5**

Suburban Growth Resulting from Shifts from "Other Centers"

WRTC residents tend to disproportionately out-migrate to "Other Centers" relative to LLF residents. In 2018, 2.4 cases are projected to shift from "Other Centers" to Suburban. Each year thereafter, the additional number of cases shifting from "Other Centers" is projected to grow by half this amount, 1.2 per year, a conservative estimate.

Suburban Growth Resulting From Shift From "Other Center"	
Projected 2018 Suburban-Eligible LLF and WRTC DSA Residents Transplanted at "Other Centers":	14.1
Projected 2018 WRTC DSA Residents Transplanted at "Other Centers":	11.8
Number of Cases Shifting to Suburban in 2018:	2.4
Annual Number of Cases in 2019-2022 Shifting from "Other Centers" (half the 2018 amount):	1.2

Suburban Growth Resulting from New Cases

In 2015, LLF residents were transplanted at a rate of 44.4 liver transplants per million people living in the DSA ("PMP"), while WRTC residents were transplanted at a rate of 24.5 PMP. For WRTC residents to be transplanted at an equivalent rate to LLF residents, 242 WRTC residents would have needed to obtain a liver transplant, 108 more than were actually transplanted in 2015.

Recognizing this persistent access disparity, Suburban conservatively estimates that it will capture 10% of this "108 additional transplants" metric, or 10 cases, in Year 2 through Year 5 of the new program. Suburban believes that WRTC residents are entitled to the same level of access as LLF residents, and that it is possible to come closer to that with an additional liver transplant center in the WRTC DSA. Assuming 10 new cases per year as a result of being in the market is a conservative assumption—Suburban hopes and expects to achieve higher volumes of new cases as it will mean more people are receiving needed transplants. Suburban is not projecting that 10 new cases will be realizable in the first year of operations, as it is most likely that the program will need time to ramp-up, as well as raise awareness of its presence in the market.

CY	DSA	JHH	UMMS	G'town	Other Centers	TOTAL	Population	Overall Rate PMP (Total)	Transplants Projected at LLF Rate	Opportunity for Additional Transplants
2015	LLF	57	104	7	5	173	3,900,632	44.4	-	-
	WRTC	22	25	62	25	134	5,464,786	24.5	242	108

Suburban Volume Resulting from New Cases	
Projected Volume Resulting From New WRTC DSA Residents Transplanted:	10

Aggregate Suburban Growth Rate

Suburban's aggregate growth rate is a combination of projected new volume resulting from projected annual growth in the market, cases shifting from "Other Centers", and new cases due to increased access for WRTC DSA residents. To summarize:

- The baseline volume for Suburban in 2018 is projected to be 17.4 (Year 1) resulting from cases shifting from area centers
- An additional 10 cases per year is projected in 2019-2022 (Year 2-5) resulting from increased access
- Projected annual volume growth in the market of Suburban-Eligible cases will result in 3.5 additional cases performed per year
- Projected annual volume shifts from “Other Centers” will result in an additional 1.2 cases per year

Aggregate Suburban Growth Rate	
Baseline Volume in 2018:	17.4
Additional Volume Year 2019-2022 Resulting From New WRTC DSA Residents Accessing Transplant:	10.0
Projected Annual Volume Growth Per Year:	3.5
Projected Annual Volume Shifting from "Other Centers" Per Year:	1.2
Aggregate Suburban Growth 2018 to 2019:	14.7
Aggregate Suburban Growth 2019 to 2022:	4.7

To summarize by year:

Year	Year 1 Baseline	New Cases	Market Growth	Shifts From Other Centers	TOTAL
1	17.4	-	-	-	17.4
2	17.4	10	3.5	1.2	32.1
3	17.4	10	7 (3.5*2)	2.4 (1.2*2)	36.8
4	17.4	10	10.5 (3.5*3)	3.6 (1.2*3)	41.5
5	17.4	10	14 (3.5*4)	4.8 (1.2*4)	46.2

Step 4 = Projected Volume by Center 2016-2022

The table below depicts the projected volumes for Suburban, as detailed directly above, as well as the growth of the three other centers at 8.8 per year.

	Adjusted Projection						
	2016	2017	2018	2019	2020	2021	2022
Georgetown	91.0	101.0	105.2	114.0	122.9	131.7	140.5
Johns Hopkins	110.0	120.0	126.1	134.9	143.7	152.5	161.4
Univ of Maryland	157.0	167.0	171.6	180.5	189.3	198.1	206.9
Suburban	-	-	17.4	32.1	36.8	41.5	46.2
TOTAL	358.0	388.0	420.4	461.5	492.7	523.9	555.1

6. Projected 2016-2022 Center Impact

The Status Quo Projection, meaning if no Suburban program were added, depicted below builds upon the projection method utilized in Part 2, growing each of the 3 centers by 10 cases per year.

	Status Quo Projection						
	2016	2017	2018	2019	2020	2021	2022
Georgetown	91.0	101.0	111.0	121.0	131.0	141.0	151.0
Johns Hopkins	110.0	120.0	130.0	140.0	150.0	160.0	170.0
Univ of Maryland	157.0	167.0	177.0	187.0	197.0	207.0	217.0
TOTAL	358.0	388.0	418.0	448.0	478.0	508.0	538.0

The Adjusted Projection depicted below shows the final projections from Part 5, including Suburban Hospital.

	Adjusted Projection						
	2016	2017	2018	2019	2020	2021	2022
Georgetown	91.0	101.0	105.2	114.0	122.9	131.7	140.5
Johns Hopkins	110.0	120.0	126.1	134.9	143.7	152.5	161.4
Univ of Maryland	157.0	167.0	171.6	180.5	189.3	198.1	206.9
Suburban	-	-	17.4	32.1	36.8	41.5	46.2
TOTAL	358.0	388.0	420.4	461.5	492.7	523.9	555.1

The table below reports the differences between the Adjusted Projection and the Status Quo Projection and shows the impact of the new Suburban program on future volume at each existing center, by year.

	Adjusted Projection - Status Quo Projection						
	2016	2017	2018	2019	2020	2021	2022
Georgetown	-	-	(5.8)	(7.0)	(8.1)	(9.3)	(10.5)
Johns Hopkins	-	-	(3.9)	(5.1)	(6.3)	(7.5)	(8.6)
Univ of Maryland	-	-	(5.4)	(6.5)	(7.7)	(8.9)	(10.1)
Suburban	-	-	17.4	32.1	36.8	41.5	46.2

The final table reports the impact on each existing center, as a percentage reduction relative to the Status Quo Projection.

	Percent Reduction over Status Quo (% Impact)						
	2016	2017	2018	2019	2020	2021	2022
Georgetown	-	-	-5.2%	-5.7%	-6.2%	-6.6%	-6.9%
Johns Hopkins	-	-	-3.0%	-3.7%	-4.2%	-4.7%	-5.1%
Univ of Maryland	-	-	-3.0%	-3.5%	-3.9%	-4.3%	-4.6%

Both in raw numbers and as a percentage of their total cases, none of the existing centers will experience a significant impact from moved cases. According to this projection, all existing centers are now and will remain well above the minimum volume threshold. This analysis employs conservative assumptions. It 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 started a new kidney transplant program in competition with the Georgetown kidney program. Ideally, volumes at all the centers will continue to grow through increased education, outreach, recruitment of donors, and use of more organs, and as a result of the increased level of competition in the region.

b)

Benefits of a New Liver Transplant Program at Suburban Hospital

The establishment of a liver transplant center at Suburban will result in:

- More WRTC DSA residents receiving a liver transplant 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 Other Centers to receive a liver transplant, and will instead be transplanted locally at Suburban.
- Some of the WRTC DSA residents who currently travel to one of the LLF centers for transplant will instead be transplanted at Suburban, which will potentially free up transplantable livers in the LLF DSA for LLF DSA patients.
- Patients transplanted at Suburban will access care at a lower cost relative to the existing two LLF centers and one WRTC center.

The Suburban Volume Projection Methodology is described in detail in response to *10.24.01.08G(3)(f). Impact on Existing Providers and the Health Care Delivery System* question (a). The methodology takes into consideration patient DSA of residence, patient type (adult, deceased donor, MELD less than or equal to 30), and historical growth rates for the LLF and WRTC DSA centers to conservatively project annual volume for Georgetown, UMMS, and JHH for 2016 to 2022, and to project annual volume for the new program at Suburban for 2018 to 2022.

This methodology grows the number of individuals transplanted per year at area centers based on the growth rate from 2010 to 2015. The projections are a blend of new cases resulting from increased access, growing the total volume of patients transplanted by area centers consistent with historical trends, and an accounting of future cases shifting from JHH, UMMS, Georgetown and Other Centers (centers outside the two DSAs) to Suburban. A summary of the benefits is provided below, including a table comparing the projections resulting from Suburban's new program to the status quo.

	New Cases & Sources of Shifted Cases							
	2016	2017	2018	2019	2020	2021	2022	5 Year Total
Georgetown → Suburban	-	-	5.8	7.0	8.1	9.3	10.5	40.6
Johns Hopkins → Suburban	-	-	3.9	5.1	6.3	7.5	8.6	31.5
Univ of Maryland → Suburban	-	-	5.4	6.5	7.7	8.9	10.1	38.6
"Other Centers" → Suburban	-	-	2.4	3.5	4.7	5.9	7.0	23.5
New Cases	-	-	-	10.0	10.0	10.0	10.0	40.0
Suburban	-	-	17.4	32.1	36.8	41.5	46.2	174.2

- More WRTC DSA residents will receive a liver transplant. The table above shows 40 new cases at Suburban in 2018-2022. This is a very conservative estimate—we actually expect and hope that more than 40 new cases will be performed at Suburban, and as cited elsewhere, there is evidence that the establishment of a second program in the WRTC DSA will result in increased volume at the existing WRTC DSA as well. But for the purposes of conservatively estimating benefits of this proposal to the population, at least 40 people will receive a needed transplant who otherwise would not, resulting in prolonged life and a higher quality of life for these patients.

- Fewer patients will travel out of state to Other Centers to receive a liver transplant. From 2018 to 2022, we estimate that 23.5 transplants will shift from Other Centers to Suburban. These are cases currently performed outside of the LLF and WRTC DSAs that will now be performed locally as access is improved. This, too, is a conservative estimate, and the actual number could be higher.

- Decrease in patient migration. Some of the WRTC DSA residents who would have received a transplant at one of the LLF centers will shift to Suburban, using organs from the WRTC and potentially freeing up organs in the LLF DSA for LLF DSA residents. For instance, 17.4 cases are projected at Suburban in 2018. Of those, 6.1 are expected to be WRTC DSA residents who currently travel to LLF centers for transplant but would now have access in the WRTC DSA, at Suburban (2.8 cases from JHH and 3.3 cases from UMMS).

- Lower cost of care at Suburban. As described below in response to (c), cases performed at Suburban will be about 14% lower in cost than cases performed at JHH. A similar comparison can be made with cases at University of Maryland and Georgetown, as both are, like JHH, academic medical centers.

Projected annual costs for the new service at Suburban. The Total Operating Expenses of the program (inflated) for the first five years are included below. These expenses include Salaries & Wages (including benefits), Contractual Services, Supplies & Drugs, Other Expenses (Contingency, Outpatient Activity, and Organ Acquisition).

	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	$718,310	$1,367,174	$1,594,672	$1,828,509	$2,020,755
Other Expenses: Contigency, Outpatient Activity, Organ Acqusition	$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**

(c)

For the first 5 years operating the new service, Suburban projects to perform an aggregate of 174.2 cases. These cases can be subdivided into two categories, New Cases Performed at Suburban (New Cases) and Cases Shifting to Suburban. An analysis of the impact of cases in these two categories on costs to the health care system is provided below.

	New Cases & Sources of Shifted Cases							
	2016	2017	2018	2019	2020	2021	2022	5 Year Total
Georgetown → Suburban	-	-	5.8	7.0	8.1	9.3	10.5	40.6
Johns Hopkins → Suburban	-	-	3.9	5.1	6.3	7.5	8.6	31.5
Univ of Maryland → Suburban	-	-	5.4	6.5	7.7	8.9	10.1	38.6
"Other Centers" → Suburban	-	-	2.4	3.5	4.7	5.9	7.0	23.5
New Cases	-	-	-	10.0	10.0	10.0	10.0	40.0
Suburban	-	-	17.4	32.1	36.8	41.5	46.2	174.2

Estimated Costs of New Cases Performed at Suburban

Suburban is projected to perform 40 cases, specifically from 2019-2022, as a result of the introduction of competition in the WRTC DSA. It is projected that these cases would not have occurred in the absence of Suburban's presence in the market.

Suburban projects the charge per case to be $148,208, or nearly $6 million for 40 new cases over five years. The charges associated with these 40 cases represent new costs, not shifted costs, to the health care system. These 40 new cases account for 23% of the 174.2 total cases projected to be performed at Suburban in the first five years of operation.

The new costs to the health care system resulting from increased access to liver transplantation are justified, given the number of lives that will be saved and the quality of life improvements that will result for the patients receiving a transplant who otherwise would not.

Estimated Costs of Cases Shifting to Suburban

Cases Shifting to Suburban fall under four subcategories:

- Cases Shifting from Johns Hopkins
- Cases Shifting from Georgetown
- Cases Shifting from University of Maryland
- Cases Shifting from Other Centers (centers outside of the LLF and WRTC DSAs)

Estimated Costs of Cases Shifting from Johns Hopkins

Suburban projects 31.5 cases will shift from JHH to Suburban in the first 5 years of the program.

Suburban's projected charge of $148,208 per case was derived using 2015 JHH Charges for Suburban-Eligible patients. By using JHH internal data, Suburban was able to identify Suburban-Eligible patients (adult, deceased donor, MELD <35, liver-only) and the associated detailed charge data that is not available in publicly reported data sets. By identifying the applicable HSCRC Rate Centers for cases performed at JHH, Suburban Rates were substituted for JHH Rates to project the Suburban charge per case.

The corresponding JHH charge per case for Suburban-Eligible patients in 2015 was $172,955, meaning for each case that shifts from JHH to Suburban, the projected charge will be $24,747 lower, or a total reduction of nearly $780,000 for 31.5 cases.

Further, not only will each of the 31.5 cases performed at Suburban occur at a lower charge, all pre-transplant and post-transplant care will be administered in a lower charge setting relative to JHH, yielding a lower relative cost to the health care system.

Estimated Costs of Cases Shifting from Georgetown, University of Maryland, and Other Centers.

Suburban projects the following shifts to occur over the first 5 years of the program:

- 40.6 cases from Georgetown
- 38.6 cases from the University of Maryland
- 23.5 cases from Other Centers (centers outside of the LLF and WRTC DSAs)

Publicly reported data does not allow Suburban to isolate patients transplanted at these institutions using the "Suburban-Eligible" definition to quantify these patients' average charge rate. Center transplant charges can vary significantly between donor types, at different levels of acuity, and whether or not a case is liver-only or multi-organ. For these reasons, Suburban is unable to quantify the difference in charges between Suburban and the centers from which cases are projected to shift.

Suburban can only surmise that the charge experience at JHH is likely more reflective of the charge experience at Georgetown, University of Maryland, and Other Centers, than Suburban. This is based on the fact that Georgetown and University of Maryland, like JHH, are academic medical centers. Further, since most liver transplant centers are contained within academic medical centers, it is likely that the centers contained in the "Other Centers" category are also academic medical centers. This means that while Suburban cannot quantify the difference in charges, it is highly likely that Suburban is a lower charge setting relative to most of the centers from where cases are projected to shift. The benefits of being in a lower charge setting would apply not only to the cases performed, but also to all pre- and post-transplant care administered.

Conclusion

New Cases account for 23% of Suburban's projected volume. All new cases will result in new costs to the system, which will include pre-transplant, transplant, and post-transplant costs. These cases represent lives saved and quality of life improvements, and they will all be performed at a lower cost than if performed elsewhere.

Shifted Cases account for 77% of Suburban's projected volume, all of which is estimated to be shifting to a lower cost setting, meaning there will be a relative reduction in all pre-transplant, transplant, and post-transplant costs for cases that shift to Suburban. Of these Shifted Cases, 28.6% are projected to be Medicare cases (reflecting the case mix of Suburban-Eligible patients at JHH), meaning shifting these cases will yield savings to Medicare for pre-transplant, transplant, and post-transplant care administered.

The numbers and analysis included above are based on the current rate setting methodology and are subject to change as the methodologies change.

Please see Exhibit 20 for Affirmations.