

November 3, 2017

VIA E-MAIL AND REGULAR MAIL

Kevin McDonald
Chief, Certificate of Need
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

**Re: Suburban Hospital Liver Transplant Application -
Matter No. 17-15-2400**

Dear Mr. McDonald:

Pursuant to COMAR 10.24.01.08(C), Suburban Hospital responds to the Commission's request for additional information regarding the above-referenced application (the "Application").

PROJECT DESCRIPTION – Part III. NEED FOR NEW TRANSPLANT SERVICE AT SUBURBAN

1. The data provided in most of the tables, charts, and graphs contained in this section are not sourced. This is true for other sections of the application as well. In addition, as mentioned above the tables and graphs are not labeled. Please remedy those issues.

Applicant Response:

Please see separate binder for complete response to Question 1.

2. Please show in an organizational chart where (a) the transplant program falls within the structure of Suburban Hospital and (b) the relationship with the Johns Hopkins Comprehensive Transplant Center ("CTC").

Applicant Response:

Please see Exhibit CQ2.

3. Submit copies of the articles by Nino Dzebisashvili; Jeffrey B. Halldorson (2013); Joel T. Adler (2015); and Joel T. Adler (2016) for the record.

Applicant Response:

Please see Exhibit CQ3.

PROJECT BUDGET

4. The application represents that there is no project cost. Is it accurate that there are no costs – other than operating costs that would be reflected in the R & E projections – associated with project implementation?

Applicant Response:

Yes, it is accurate—there are no project costs.

Charity Care Policy¹

5. Please address each of the following:
- a) The link to the charity care policy provided in the application did not work.
 - b) For each subpart of this policy (e.g., two-day determination of probable eligibility, minimum required notice of the policy), staff requests applicant to quote the actual language (with a citation to the part of the policy where it can be found), as requested in the *Guidance for Applicants and CON Review Staff*. Please do so.

Applicant Response:

a)
http://www.hopkinsmedicine.org/patient_care/billing-insurance/docs/FIN034H.pdf

b)
From the Johns Hopkins Health System Policy and Procedure, Financial Assistance, Policy Number FIN034H, effective 04-01-16 (the policy that applies to Suburban Hospital, included in the original Application as Exhibit 12 and again here as Exhibit CQ5):

Page 3 of 21: “All hospital applications will be processed within two business days and a determination will be made as to probable eligibility. To facilitate this process each applicant must provide information about family size and income, as defined by Medicaid regulations.”

Page 8 of 21: “2. A preliminary application stating family size and family income (as defined by Medicaid regulations) will be accepted and a determination of probable eligibility will be made within two business days of receipt.”

Page 1 of 21 “Purpose,” third paragraph: “JHHS hospitals will publish the availability of Financial Assistance on a yearly basis in their local newspapers, and will post notices of availability at patient registration sites, Admissions/Business Office, the Billing Office, and at the emergency department within each facility. Notice of availability will be posted on each hospital website, will be mentioned during oral communications, and will also be sent to patients on patient bills. A Patient Billing and Financial Assistance Information Sheet will be provided to inpatients before discharge and will be available to all patients upon request.”

¹ Applicants should provide the policy as an exhibit, and provide the actual quotes from the policy that address each of the standard's subparts, along with a citation stating where that passage is to be found within the policy.

Quality of Care.

6. Section (a) (1) of this standard asks for documentation that the applicant is in good standing with the (Maryland Department of Health) MDH. Please provide a letter from the Office of Health Care Quality stating that Suburban hospital is currently in good standing.

Applicant Response:

Please see Exhibit CQ6 for letter from Office of Health Care Quality stating that Suburban hospital is currently in good standing.

7. With regard to section (a) (iii), the documentation provided was outdated. The letter from CMS providing documentation that Suburban hospital is in compliance with the conditions of participation of the Medicare and Medicaid programs (Exhibit 10) was dated March 14, 2013.

Applicant Response:

See Exhibit CQ7.

8. Staff notes that subpart (b) of this standard has become outdated, as currently written; however, quality is still of great import to the MHCC, so we will ask the applicant to adapt its response to MHCC's current reporting. There is still a Maryland Hospital Performance Evaluation Guide ("HPEG"), in the hospital consumer guide component of the MHCC web site, and a set of "quality measures" are included as a component of that guide. Currently, there are 37 "quality measures" listed in the HPEG derived from the CMS Process Measures file for the fiscal year that ended on March 31, 2016 and the CMS Outcome Measures file for Mortality and Readmission for the fiscal year that ended June 30, 2014. Performance for most of these measures (32 of the 37) is now reported comparatively – i.e., "Below Average," "Average," or "Better than Average." Please identify any "below average" rating for Suburban, and discuss any actions taken to upgrade that item.

Applicant Response:

Please see Exhibit CQ8.

Access and Need

9. On pages 23 and 24, the growing difference in the volume of liver transplants in the LLF compared to the WRTC between 2013 and 2016 relative to the population residing in each of these DSAs is cited as evidence of the need for a new transplant service at Suburban Hospital. Why is the volume of transplants performed in the LLF and WRTC DSAs expected to be correlated with the population of each DSA region, given the proximity of many other transplant centers for residents of the WRTC, including those located in the LLF DSA?

Applicant Response:

1. Relative Need: Need is a function of disease burden. There are data which suggest that the liver disease burden in the WRTC is coextensive with liver disease burden in the LLF:

- SRTR registry data shows that between 2012 and 2014, there were 448 liver transplant listings (throughout the country) from residents of the WRTC, compared to 577 listings of LLF residents². These comparable numbers of people seeking transplants confirm a coextensive liver disease burden.
- Because liver deaths correlate to liver disease, a proxy for liver disease burden is age-adjusted death rate due to chronic liver disease. There are no studies comparing DSA death rates. The death rates due to chronic liver disease for D.C. (7.7 per one hundred thousand), Virginia (8.7), and Maryland (6.9) are nearly equivalent (although slightly higher in D.C. and Virginia).³ See Exhibit CQ9 for age-adjusted death rate data.

Given similar disease burdens, we would expect transplant volume between the two DSAs to be far more similar than it has been in recent years. Instead, there is a consistent and growing disparity between the two DSAs.

2. Travel Burden: The fact that WRTC residents can, in theory, receive transplants in other DSAs does not mean that they have equal access to transplant services. Travel imposes a significant burden, which falls disproportionately on patients with lower socioeconomic status.

²SRTR registry data analyzed by the Epidemiology Research Group in Organ Transplantation

³Kochanek KD, Murphy SL, Xu JQ, Tehada-Vera B. Deaths: Final data for 2014, National vital statistics reports: vol. 65 no 4. Hyattsville, MD; National Center for Health Statistics, 2016, p 91, available at https://www.cdc.gov/nchs/data/nvsr/nvsr65/nvsr65_04.pdf (included as Exhibit CQ9, pages 1, 91, and 122 of the report)

The burden imposed by travel is amplified in the case of liver transplant because of the need for frequent pre- and post-transplant follow-up care. Using the experience of Suburban-eligible patients at The Johns Hopkins Hospital, Suburban-eligible patients are projected to have an average of 3.73 inpatient visits (including admission for the transplant surgery) and 13.32 outpatient visits (including the evaluation) at Suburban within a year of the transplant. If patients cannot adhere to this type of pre- and post-transplant monitoring, it makes transplant candidacy unfeasible. Thus, patients with fewer resources may never be evaluated for transplant nor have their candidacy deemed feasible, because the center is too far from where they live, preventing them from complying with pre- and post-transplant care requirements. When patients are rejected by a center because of the burdens of travel, access is reduced. Proximity to a transplant center is a critical component of access.

10. What factors contributed to the growth in liver transplants by transplant centers in the LLF for the period CY 2013- CY 2016?

Applicant Response:

Factors that led to the growth in liver transplants in the LLF include:

- An increase in deceased organs procured in the LLF (App. 40)
- An increase in the LLF centers' willingness to use marginal organs (see response to question 28)
- An increase in the number of donors (see App. 49-51)
- A reduction in patients leaving the LLF for transplants (see response to question 34)
- An increase in patients on the LLF waitlist (App. 45-48)
- Implementation of Share 35, which led to an increase in organs imported into the LLF for transplant for patients with MELD > 35

11. How did the change in national policies for liver transplant distribution (Share 35) in June 2013 affect the allocation of deceased livers in the DSAs for LLF and WRTC?

Applicant Response:

Nationally, in the first year of Share 35 the proportion of deceased donor liver transplants (“DDLT”) allocated to recipients with a MELD of 35 or greater increased from 23.1% to 30.1%. The proportion of regional liver shares increased from 18.9% to 30.4%. This means that sicker patients were accessing liver transplants at a higher rate and more livers were being shared between DSAs within a given Region.⁴

The data provided on page 44 of the Application reflects the experience of Share 35 for patients in the LLF DSA and WRTC DSA (reproduced here):

	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

Due to regional sharing, the LLF DSA began exporting more organs from FY2013 to CY2015, growing from 5 to 24 per year. Imports during this period also drastically increased, from 41 to 126. This resulted in a net increase in 85 livers for the LLF DSA, **an increase of 61.6%**.

Regional sharing also resulted in an increase in organs exported by the WRTC in FY2013 to CY2015, from 18 to 53 per year. Unlike the LLF DSA, however, imports were relatively flat, from 30 in FY2013 to 33 in CY2015. This net outflow of organs from the WRTC DSA correlated with a 33.7% decrease in liver transplants within that time period.

⁴ Massie, A. B., et al. "Early changes in liver distribution following implementation of Share 35." *American Journal of Transplantation* 15.3 (2015): 659-667.

12. On pages 28, 32, 35, and 177 of the application, Suburban Hospital appears to be assuming that the rate of liver transplants should be the same for residents of the WRTC and residents of the LLF. What evidence exists that the demand for liver transplants by residents in the WRTC DSA is higher, lower, or the same as the demand by residents in the LLF DSA?

Applicant Response:

A proxy for liver disease burden is age-adjusted death rate due to chronic liver disease. As set forth in response to question 9, the death rate due to chronic liver disease was roughly the same in D.C. (7.7), Virginia (8.7) and Maryland (6.9) in 2014. See Exhibit CQ9. This data suggests that the demand for liver transplants in the two DSAs should be roughly equivalent.

WRTC DSA residents would therefore benefit from a higher rate of transplant, which will increase the quality and length of life for additional WRTC residents suffering from chronic severe liver disease. A higher rate of transplant is possible in the WRTC DSA based on the rate achieved in the LLF DSA and the other evidence cited from peer-reviewed literature, namely the lack of intra-DSA competition.

13. What specific factors are potentially driving the difference in transplant rates for DSA residents in the WRTC and LLF DSAs at local transplant centers?

Applicant Response:

The disparity in access reflected in different DSA transplant rates is driven by several factors. The biggest factor is *capacity*. Because there are twice as many liver transplant centers in the LLF DSA, the residents have more access to beds and options for transplant. Patients with MELD scores of 35 or higher often require ICU care and are therefore dependent on ICU availability. The liver transplant centers within the LLF DSA have 382 ICU beds.⁵ In contrast, the sole liver transplant center in the WRTC DSA has 57 ICU beds.⁶ See Exhibit CQ13 for LLF DSA ICU Beds.

Another significant factor is intra-DSA competition. The positive effects of competition have been confirmed by previously cited research (App. 49-50) and experience (App. 51). Competition between kidney transplant programs in the WRTC DSA, for instance, has resulted in greater access, more transplants, and an increased supply.

⁵ 2015 Annual Report on Selected Maryland Acute Care and Special Hospital Services, Maryland Health Care Commission.

⁶ An exact number of ICU beds is not publicly reported—this value is an approximation derived from the hospital's website: <https://www.medstargeorgetown.org/for-healthcare-professionals/nursing/our-service-lines/explore-our-units/#q={>

14. Please provide the transplant rate per million population in the LLF and WRTC DSAs for all transplant centers based on only adult deceased organ transplants. As MHCC staff understands it, the figures shown on page 28 and 30 include both living donor and deceased donor transplants, and Suburban only proposes to serve adults who receive a deceased donor organ.

Applicant Response:

The LLF DSA and WRTC DSA liver transplant rates, per million adult population per year, for adult, deceased donor, liver-only cases are detailed below.

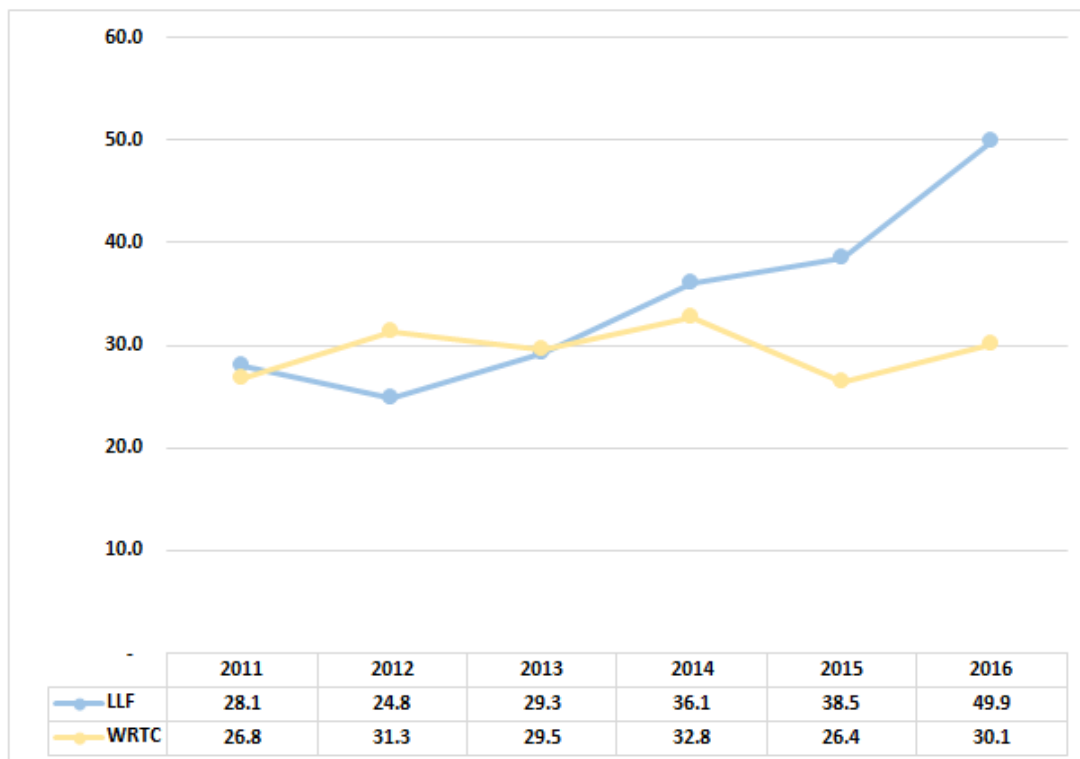
Metrics are displayed both for residents' Overall Access (any center), as well as residents' Local Access (local centers).

Methodology:

Johns Hopkins Medicine ("JHM") requested a dataset from UNOS quantifying all liver transplant patients residing in the LLF DSA, WRTC DSA, or Other DSA that were transplanted at JHH, UMMS, MGUH, or some Other Center. These statistics were requested for 2010-2016. JHM asked UNOS to exclude pediatric, live donor, and multi-organ cases. The results are:

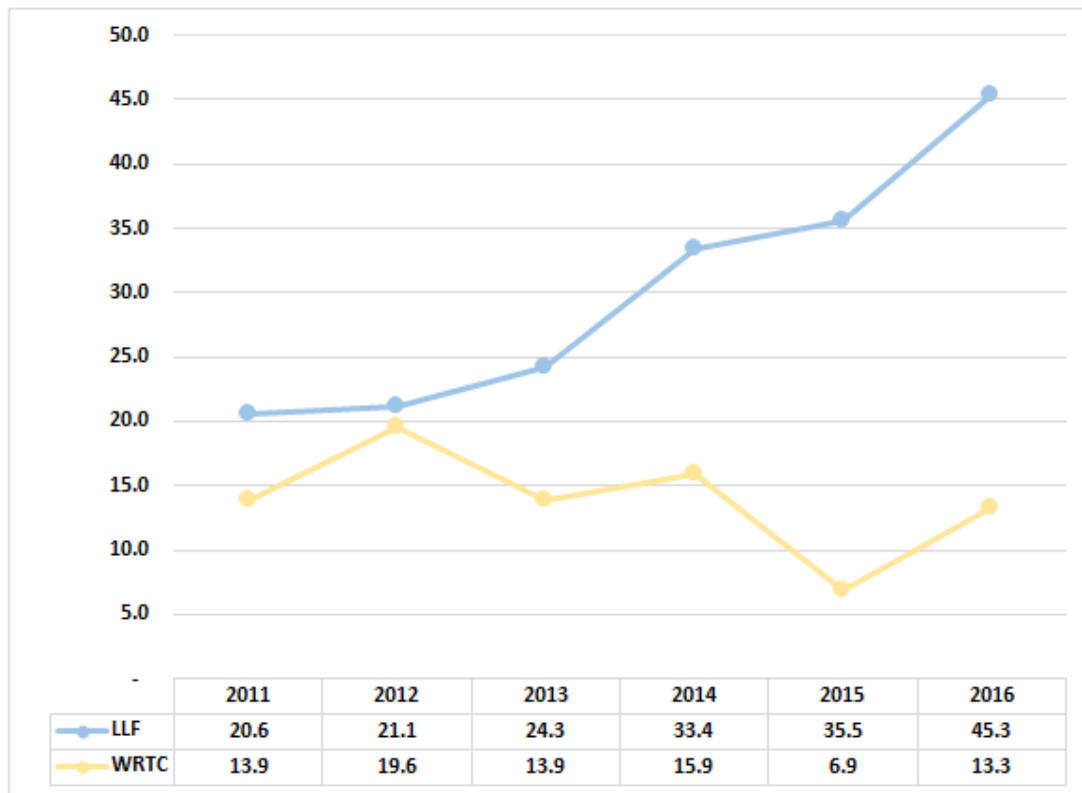
Adult, Deceased Donor, Liver-Only Cases (Overall Access)								
Year	DSA	JHH	UMMS	MGUH	Other Centers	Total	DSA Adult Population	Transplant Rate PMAP
2011	LLF	14	47	13	9	83	2,956,132	28.1
2011	WRTC	10	10	55	31	106	3,958,426	26.8
2012	LLF	22	41	8	3	74	2,982,818	24.8
2012	WRTC	4	17	79	26	126	4,031,532	31.3
2013	LLF	27	46	8	7	88	3,006,283	29.3
2013	WRTC	21	15	57	28	121	4,102,061	29.5
2014	LLF	36	65	4	4	109	3,022,937	36.1
2014	WRTC	18	25	66	27	136	4,152,146	32.8
2015	LLF	36	72	6	3	117	3,038,536	38.5
2015	WRTC	22	33	29	27	111	4,203,350	26.4
2016	LLF	45	93	8	6	152	3,044,923	49.9
2016	WRTC	30	26	56	15	127	4,225,282	30.1

DSA	2011	2012	2013	2014	2015	2016
LLF	28.1	24.8	29.3	36.1	38.5	49.9
WRTC	26.8	31.3	29.5	32.8	26.4	30.1



Adult, Deceased Donor, Liver-Only Cases (Local Access)								
Year	DSA	JHH	UMMS	MGUH	Other Centers	Total	DSA Adult Population	Transplant Rate PMAP
2011	LLF	14	47			61	2,956,132	20.6
2011	WRTC			55		55	3,958,426	13.9
2012	LLF	22	41			63	2,982,818	21.1
2012	WRTC			79		79	4,031,532	19.6
2013	LLF	27	46			73	3,006,283	24.3
2013	WRTC			57		57	4,102,061	13.9
2014	LLF	36	65			101	3,022,937	33.4
2014	WRTC			66		66	4,152,146	15.9
2015	LLF	36	72			108	3,038,536	35.5
2015	WRTC			29		29	4,203,350	6.9
2016	LLF	45	93			138	3,044,923	45.3
2016	WRTC			56		56	4,225,282	13.3

DSA	2011	2012	2013	2014	2015	2016
LLF	20.6	21.1	24.3	33.4	35.5	45.3
WRTC	13.9	19.6	13.9	15.9	6.9	13.3



15. On pages 33 and 34 and pages 117-119, Suburban states that the migration patterns for liver transplants by residents of the WRTC DSA and LLF DSA indicate that an access barrier exists for residents of the WRTC. However, the travel time to JHH or UMMS for residents of the Maryland counties located in the WRTC DSA is likely much less than it is for many residents located in the LLF DSA already, such as those residing in the Eastern Shore or in Western Maryland. Why is it considered evidence of unmet need when a resident travels for a liver transplant at a center located in another DSA?

Applicant Response:

The migration of a resident from one DSA to another to receive a transplant is not by itself evidence of an unmet need. However, if we assume ease of travel between the two DSAs, then travel would also not be a burden from areas of the LLF DSA to the existing WRTC DSA center. Yet, travel is weighted heavily from the WRTC DSA to the two LLF DSA centers. In fact, in 2015 only *seven* LLF DSA residents traveled to the WRTC DSA center for transplant. Yet 47 WRTC DSA residents traveled to an LLF DSA center for transplant. The exodus of WRTC DSA residents to the LLF DSA for liver transplant is potent evidence of a need that is not being met in the WRTC.

16. Please explain the following quoted text from page 35 of the application. “If access to transplant service were equivalent between the WRTC and LLF, one would expect equivalent cross-over migration rates.” What evidence supports this conclusion? What factors have been shown to affect organ transplant candidates’ decisions on which transplant center they choose?

Applicant Response:

1. Access and migration: Access to transplant services between the two DSAs is not equivalent. This is borne out by historical transplant rates per million and a consistent—and worsening—rate of residents leaving the WRTC DSA for transplants (App. 28). The data also show other indicia of an access disparity:

- LLF DSA residents access liver transplant services locally within their DSA far more than WRTC DSA residents.
- LLF DSA residents are less likely to leave their DSA than WRTC DSA residents.
- WRTC DSA residents travel more frequently than LLF DSA residents to access liver transplant services, yet still have a lower rate of access.

The disparity in migration patterns between the two DSAs is consistent with a lack of access to liver transplant in the WRTC DSA. If other migration factors were dominant (e.g., patient preference), one might expect the LLF DSA and WRTC DSA to change their relative position to each other over time in transplants per million, as patients and preferences change. Instead, the migration observed for WRTC DSA residents is consistently one-sided: patients leave the WRTC DSA for transplants; they do not come to the WRTC DSA for transplants. Lack of access is the most likely cause of this gap.

2. Factors affecting transplant center choice: Based on the CTC’s experience, transplant candidates choose a transplant center based on: (a) ease of travel to the candidate’s home and the candidate’s support system (e.g., family); (b) capacity of the center to conduct the candidate evaluation; (c) the availability of a donor organ (i.e., supply); (d) the patient’s insurance network for transplant; (e) referral patterns; (f) the center’s transplant experience; and (g) the reputation of the transplant center.

17. The study cited on page 37 in footnote 29 found that the increased likelihood of liver transplantation was primarily driven by travel to a DSA with improved access to organs. What evidence exists that access to livers will be better for the population that Suburban proposes to serve, as a result of Suburban establishing a liver transplant program?

Applicant Response:

A new liver transplant service at Suburban will primarily serve the population of the WRTC and result in:

- Injecting competition for performing liver transplants into the WRTC, which the data and literature have shown to correlate with increased access to transplant services;
- Increasing the number of transplant evaluations performed and patients added to the waitlist every year;
- Increasing the number of ICU beds available to liver transplant patients in the WRTC by approximately 73.7% (from approximately 57 to approximately 99, see response to question 13);
- Decreasing the need for WRTC residents to travel outside their DSA for liver transplants, as shown by migration data for competitive and non-competitive DSAs (App. 33-38); and
- Increasing supply through outreach to all regional hospitals to educate staff about approaching the families of potential deceased donors.

18. The OPTN/SRTR 2015 Annual Data Report for Livers includes comparative information across DSAs in the percentage of adults who underwent a deceased donor liver transplant within 5 years of listing in 2010 (p.15, Figure LI 12) and shows that the liver transplant rate for the WRTC was higher than the transplant rate for the LLF. This report also notes that a lower median MELD score is reported in DSAs with the highest transplant rates. Please explain why Suburban concludes that the difference in acuity among liver transplant patients in the LLF and WRTC, described on page 39 of the application, is regarded as indicative of a lack of access to transplants for residents of the WRTC DSA.

Applicant Response:

1. Transplant Rate: The “transplant rate” used in the referenced report represents the ratio of patients on a DSA’s waiting list who received a transplant, and is more accurately described as a “waitlist rate.” A waitlist rate is not the same as the rate of transplant in the population of a DSA because waitlist rate excludes DSA residents who, for whatever reason, never list. In addition, the smaller the waitlist, the higher the waitlist rate. (for example, if there are only two patients on the waitlist and one receives a transplant, the waitlist rate appears to be high).⁷ But that rate tells us nothing about access.

The better metric for the percentage of a given DSA’s population who actually received a transplant is transplants per million population (App. 28). This metric does not depend on whether or where a patient was waitlisted and demonstrates the widening gap between the WRTC DSA and the LLF DSA. This gap is indicative of a lack of access to transplants for residents of the WRTC DSA (App. 116-17).

2. MELD Scores: DSAs with higher transplant rates report higher median MELD scores (see Adler papers discussed at App. 49-50).

3. Acuity: The two programs in the LLF perform more transplants per capita than the lone program in the WRTC DSA, and the programs in the LLF DSA perform transplants on patients with higher median MELD scores. Competition leads programs to prioritize sicker patients,⁸ an outcome consistent with the prioritization policy expressed through Share 35. Conversely, the non-competitive WRTC DSA center performs transplants on relatively healthier patients (App. 39). This indicates that WRTC DSA residents with higher MELD scores have insufficient access to transplant services, contrary to national policy.

⁷ The data suggest that the WRTC waitlist is smaller than it should be (App. 121-22).

⁸ See Exhibit 17 (statement by CEO of GWUH that competition in WRTC for kidney transplants “forced [MGUH] to ‘up its game’”).

19. Although the number of livers procured in the LLF DSA is higher than in the WRTC DSA, and Suburban cites this as evidence of the shortcomings of the WRTC DSA on page 40 of its application, many factors affect the potential number of deceased liver donors. SRTR's recent evaluation reports for the WRTC indicate that it is procuring the expected number of liver donations. In addition, these reports note that the number of deaths per 1,000 population in the WRTC is almost the lowest among all 58 DSAs. (The January 2017 report indicates a death rate of 5.54 per 1,000 population for the WRTC DSA compared to 8.89 for the LLF DSA.) Please explain why the difference in livers procured is used to conclude that there is an unmet need for residents in the WRTC DSA.

Applicant Response:

We do not conclude that the difference in livers procured between the two DSAs is evidence of an unmet need. The heading at the top of page 40 of the Application is "The Increasing Supply Imbalance." The supply of deceased donor livers in a DSA has three components: livers procured, livers exported, and livers imported. After comparing these three components between the two DSAs, at the bottom of page 44 we make two conclusions: (1) centers in the LLF DSA transplanted more than three times as many livers as the one center in the WRTC DSA in 2015; and (2) the WRTC DSA's single center total net supply of deceased donor organs has decreased 33.7% since 2013 while the two LLF DSA centers had a 61.6% increase over the same time period. It is these conclusions which suggest an unmet need for residents of the WRTC DSA.

Increasing overall supply is a critical component to addressing this need. While the LLF DSA has managed to grow its supply significantly in recent years, the WRTC DSA's supply has decreased. We conclude that this growing discrepancy can be explained at least in part by the behavior of the OPO or the centers within the DSA, and suggest that the establishment of a competitive center at Suburban would address this and other discrepancies.

20. Please update the information presented on pages 41, 43, and 44 to include CY 2016.

Applicant Response:

Deceased Donor Liver Procured in CY 2016 (page 40 of Application)

LLF = 174
WRTC = 101

Livers Exported in CY2016 (page 41 of Application)

LLF = 22 (12.6%)
WRTC = 35 (34.7%)

Livers Imported in CY2016 (page 43 of Application)

JHH

- Total = 119 DDLT
- Local = 77 (64.7%)
- Imported = 42 (35.3%),

UMMS

- Total = 157 DDLT
- Local = 75 (47.8%)
- Imported = 82 (52.2%),

MGUH

- Total = 111 DDLT
- Local = 66 (59.5%)
- Imported = 45 (40.5)%,

LLF DSA Imports = 124 (42+82)
WRTC DSA Imports = 45

Total Supply (page 44 of Application)

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

LLF DSA Supply = (174) – (22) + (124) = **276**
WRTC DSA Supply = (101) – (35) + (45) = **111**

For Sourcing, See Exhibit CQ20.

21. Please explain why the addition of a liver transplant program will allow Johns Hopkins physicians and staff to expand their outreach and education efforts to identify more liver donors. To what extent is there already outreach to patients receiving care at Suburban hospital who are candidates for a liver transplant and to residents of Montgomery, Prince George's and Calvert Counties? Please explain the new outreach methods that will be used and quantify the expansion of outreach efforts.

Applicant Response:

Through the hepatology practice of Drs. Shetty and Laurin at Sibley Memorial Hospital, JHM is already engaged in outreach efforts in the WRTC DSA (App. 71). The effect of those efforts is limited because patients expect to be treated locally and there is currently only one local transplant center. The approval of a second liver transplant program at Suburban would allow the CTC to double the scope and effectiveness of these outreach efforts by:

- (a) consolidating that practice with the existing Johns Hopkins Community Physicians facility in Bethesda as part of a new hepatology center at Suburban;
- (b) integrating the new center with Suburban's existing ICU and interventional radiology capabilities, which will develop transplant expertise;
- (c) using that consolidated and integrated center to expand the footprint of Drs. Shetty and Laurin's practice within the WRTC DSA to reach more potential donors;
- (d) deploying outreach staff (nurse coordinators and educators) in the WRTC DSA where CTC does not presently operate; and
- (e) collaborating with liver disease advocacy and education organizations in the WRTC (e.g., MOTTEP) where no such collaboration currently exists.

Experience has shown that increased outreach results in increased donations--please also see our response to question 25.

22. Are the policies for adding patients to the liver transplant waitlist at any of the following liver transplant centers: MGUH, UVA-C, JHH, and UMMS affecting access to a liver transplant for residents of the WRTC? Will the policies of Suburban address any of the barriers noted?

Applicant Response:

We are unable to compare wait-listing policies between the listed centers. No such written policies are publically available. But because listing determinations are made using hundreds of clinical and social data points, there is no question that there are differences.

There is also no question that the different policies are generating markedly different results, to the detriment of residents of the WRTC DSA. There are three times as many names on the LLF DSA waitlist than on the WRTC DSA waitlist. Because Suburban will apply the same wait-listing policies as JHH and the CTC that contributed to the superior listing performance of the LLF DSA, we anticipate a corresponding increase in the WRTC DSA waitlist. That increase will alleviate the barriers to access described in the Application.

23. Please explain why Suburban has limited its analysis of access to transplant program waitlists for WRTC residents to programs in the WRTC DSA and LLF DSA. The patient migration pattern on page 118 of the application indicates that in CY 2015 approximately 19% of the WRTC DSA residents who received a liver transplant traveled to a transplant center other than those in the WRTC and LLF DSAs.

Applicant Response:

Transplant data for the three centers in the WRTC and LLF DSAs were used as a reasonable proxy for residents of the two DSAs because 109/134 (81%) of WRTC residents and 168/173 (97%) of LLF residents were transplanted at those three centers. Even if available, data concerning residents who transplanted elsewhere (19% and 3%, respectively) would not materially affect the analysis.

24. Please explain why the conclusions regarding competition from the studies cited on pages 49, 50, 123, 131, 155, and 156 of the application are still relevant, given these studies were conducted before the national change in policy regarding the allocation of livers. What do studies of competition and transplant center practices following the change in national allocation policies conclude?

Applicant Response:

The change in allocation policies brought about by Share 35 does not effect the conclusions of the cited studies. Those studies (App. 49-50) indicate that intra-DSA competition has positive effects on both the supply and demand sides of the transplant equation. Share 35 was designed to address the supply side of that equation by increasing the availability of organs for the sickest patients. A post-Share 35 study (Massie, et al.) (App. 41 n. 33) shows that Share 35 has resulted in greater supply for patients with higher MELD scores and has resulted in fewer discarded organs. Competition and Share 35 are complementary strategies for expanding the supply of available organs.

There are no post-Share 35 studies that examine the impact of Share 35 on the demand-side benefits of competition (e.g., greater access and additional waitlistings). But there should be little impact on demand because allocation policies do not drive demand. Rather, allocation policies influence the manner in which the supply of organs is used to satisfy demand. The cited studies remain relevant for showing that intra-DSA competition has positive effects on demand.

There is another important benefit to having more than one center in a DSA, i.e., competition reduces the vulnerability of transplant candidates to issues affecting a single center's service. If a single center experiences a catastrophic event, loses a surgeon, experiences a decrease in outcomes, or simply has conservative policies, operations may slow down or candidates may be excluded. A second center provides a safety net and gives candidates more options under alternative policies. Two examples below illustrate these issues.

Example 1

Transplant Center 1 loses key surgeons, necessitating a period of "conservatism" while the center works on rehiring key personnel. During this time, patients either listed at Center 1 or seeking local care will have very limited access to transplantation. The addition of a second center (Center 2) would give residents in that DSA the option to transfer their listing or seek listing at Center 2. This would benefit patients in that DSA irrespective of Share 35.

Example 2

Transplant Center 1 has a policy that excludes DCD donors (donation after cardiac death) who are over the age of 45. Livers from a DCD donor over the age of 45 that became available within the DSA would either not be harvested, or would be procured

by a transplant center from another DSA. If Center 2 is added and has a policy that only excludes DCDs over the age of 55, then not only would that DSA increase its organ utilization, but patients listed within that DSA would have a higher chance of receiving a transplant.

25. To what extent do physicians at Suburban Hospital and residents in the WRTC DSA already connect to the resources available through the CTC?

Applicant Response:

1. Physicians: Suburban physicians currently do not interact with the CTC, except to refer patients as needed for transplant or other specialized care at JHH. As previously explained (App. 69-71 and response to question 21), that will change if the Commission approves the Application.

2. WRTC Residents: Residents of the WRTC currently interact with the CTC because (in 2015) 22 WRTC residents out of the 134 who received liver transplants (or 16.4%) received their transplant at JHH (App. 35). Otherwise, residents in the WRTC DSA do not connect with the resources available through the CTC. But again, that will change if the Commission approves the Application.

26. Please explain whether the establishment of a liver transplant program at Suburban will affect the resources Johns Hopkins devotes to identifying potential living donors for residents in the WRTC and quantify the change in resources, if applicable. The description on page 62 of the application requires clarification.

Applicant Response:

The establishment of a liver transplant center at Suburban will lead to an increase in resources that support education, identification, and recruitment of live donors in the WRTC DSA. A liver transplant program at Suburban will bring an entirely new team focused on liver care and liver transplant to the WRTC.

While Suburban will not initially perform live donor transplants, there will be an increased presence in the WRTC DSA of hepatologists, nurse coordinators, educators, and other members of the Comprehensive Transplant Center team. Education and awareness concerning live donation will be a part of the overall outreach and education efforts that are an integral part of any liver transplant program. At a minimum, transplant program outreach activities include connecting with gastroenterologists in the region, educating providers on which patients may be eligible for liver transplant, educating providers and the community about the prevention of end stage liver failure, and sharing information about resources available for treating patients. Education about live liver donation will be included in all of these activities as appropriate. Because the team in the WRTC DSA will be affiliated with both Suburban and JHH, referrals of any potential live donors to JHH will be facilitated.

27. Which patients will be eligible to multi-list for a liver transplant at both Johns Hopkins Hospital and Suburban hospital (page 62 of application)? Are some or all patients on the liver transplant waiting list for Johns Hopkins allowed to multi-list currently? Can the wait time be transferred for patients initially listed at another transplant center? Have these policies changed over time? Please explain. How do Johns Hopkins' current policies compare to other transplant programs located in the WRTC DSA and LLF DSA?

Applicant Response:

1. Multi-listing at JHH and Suburban: Adult patients listed at JHH that not have a live donor, have a MELD score of less than 35, and are liver-only candidates will be eligible to list also at Suburban Hospital. Similarly, all patients listed at Suburban will be given the option of listing at JHH. Because evaluation efforts will not have to be duplicated, double-listing in the two DSAs will be achieved at a fraction of the usual cost. Eventually, patients with MELD scores greater than 35 or dual organ candidates would be given the option to list at either or both centers.

2. Current multi-listing: Any patient on the JHH waiting list has the option be evaluated and then, if accepted, to list in another DSA.

3. Wait time transfer: Wait time is not transferable or relevant for liver transplant patients. Organ allocation is prioritized by patient acuity, i.e., MELD score, not wait time.

4. Johns Hopkins' policies: We do not have access to policies at other institutions, but UNOS mandates that patients be educated about and have the opportunity to consider the option of listing at multiple centers. JHH adheres to this requirement. If permitted to operate a liver transplant center at Suburban, we will offer patients the opportunity to multi-list in the two DSAs in which Johns Hopkins operates.

28. What evidence exists that MedStar Georgetown University Hospital's liver transplant program is less willing to use higher risk organs than either of the existing programs in the LLF DSA?

Applicant Response:

The evidence exists in export data. There are two principal reasons why a transplant center exports an organ: (a) Share 35, and (b) rejection of the organ by the center(s) for various reasons. Export data for both before and after Share 35 shows that the WRTC consistently exports more organs (App. 41). Before Share 35, in FY2013, 5% of organs were exported from the LLF DSA, while nearly 20% of the organs from the WRTC were exported. After implementation of Share 35, 19% of LLF DSA organs and 39% of WRTC DSA organs were exported in CY2014, while in CY2015 20% were exported from the LLF DSA versus 60% exported from the WRTC DSA. This is a striking difference.

In addition, the data provided below in response to question 29 shows that from 2014-2016, 21 organs were exported from the WRTC DSA and accepted and transplanted in the LLF DSA. Of these, six were exported as a result of Share 35, and the remaining 15 were exported because they were rejected at MGUH but accepted at JHH. This is direct evidence that the WRTC DSA is rejecting usable organs.

The difference between the willingness of the centers in the two DSAs to use marginal organs is consistent with research findings. As described in our Application (at 49-51), published research has demonstrated that the less competitive a DSA, the less willing the programs in that DSA are to using marginal organs. In particular, Adler (2016) showed that the Liver Donor Risk Index ("LDRI") (which characterizes organ quality and the risk of graft failure) was higher in competitive DSAs, and that the increase in transplant volumes associated with competition was "driven largely by the use of higher LDRI organs."⁹ In short, competition increases the use of marginal organs.

Please also see response to question 43.

⁹ Adler, Joel T., et al. "Is Donor Service Area Market Competition Associated With Organ Procurement Organization Performance?" *Transplantation* 100.6 (2016): 1349-1355, at 1353.

29. Please quantify the number of deceased livers turned down by MedStar Georgetown University Hospital between CY 2014 and CY 2016 that were then transplanted by Johns Hopkins Hospital.

Applicant Response:

Livers Imported from WRTC OPO to JHH					
Year	Total	Imported for Share 35 Recipient (Count)		Imported for Share 35 Recipient (Percentage)	
		Yes	No	Yes	No
2014	5	1	4	20%	80%
2015	13	4	9	31%	69%
2016	3	1	2	33%	67%
Total	21	6	15	29%	71%

Source: Living Legacy Foundation OPO

From CY2014 to CY2016, Johns Hopkins Hospital imported and transplanted 21 deceased donor livers procured in the WRTC. Six (29%) of the livers imported were via Share 35. Fifteen (71%) of the livers were imported for a non-Share 35 recipient. This means that during this three-year period, Georgetown turned down 15 livers which Johns Hopkins Hospital was able to transplant. That is an average of five livers per year that MGUH rejected, but Johns Hopkins used.

30. Please note that much of the information presented on pages 92-101 was discussed earlier, and the information in these pages, particularly the information in tables and figures should be updated to reflect responses to staff questions pertaining to this information.

Applicant Response:

Information provided on pages 92-95 is the same as the information provided on pages 40-44.

Information provided on pages 95-101 is the same as pages 60-65.

Information on page 101 is the same as page 45.

The applicant's responses to update relevant tables and figures are included as requested.

31. On page 20 of the application, the number of liver transplant centers per capita is cited as evidence of disparities in access. Why is this metric used, when it is noted in the application on page 19 that DSAs “reflect historical working relationships, not the supply and demand of organs in that geographic area.” What evidence exists that the supply of deceased donor livers available to residents of the WRTC is lower? What evidence exists that the demand for liver transplants is higher, lower, or the same as the demand by residents in the LLF DSA?

Applicant Response:

1. Centers Per Capita: Whatever the history behind the formation of DSAs, it remains an anomaly at best—and a glaring disparity at worst—that a single transplant center services a population of more than 5.4 million people, a multiple of the per capita rate of the four other DSAs in this region. This metric sticks out as an indicator of lack of access.

2. Organ supply in the WRTC DSA: The SRTR data discussed on page 44 of the Application shows that when all impacts on supply are considered (livers procured – livers exported + livers imported), the supply of organs is greater in the LLF DSA than in the WRTC DSA. And that gap has been growing since 2013. The greater supply in the LLF DSA may benefit those WRTC DSA residents who are able to travel to the LLF DSA centers for a transplant, but (a) those migrating patients must endure the cost and inconvenience of travel, including for all required pre- and post- transplant encounters; and (b) as discussed in response to question 9, that greater supply in the LLF DSA does not benefit WRTC DSA residents for whom the burden of travel is an obstacle to transplantation. If organ supply is increased in the WRTC DSA as a result of the new center at Suburban, WRTC DSA residents—especially those for whom travel is a burden—will benefit.

3. Organ demand in the WRTC: The incidence of chronic liver disease is similar in Maryland, D.C., and Virginia (see response in question 9). This data implies that the demand for liver transplants is similar between the respective DSAs.

32. On page 114 of the application, the number of transplants performed in each DSA relative to the population is cited as evidence of an access barrier. Why is this metric used, when it is noted in the application on page 19 that DSAs “reflect historical working relationships, not the supply and demand of organs in that geographic area.”

Applicant Response:

Whatever the history behind the formation of DSAs, there are vast disparities in organs procured and access to liver transplants between the LLF DSA and WRTC DSA. However, measures can be taken to improve access where disparities are observed. As our Application explains, introducing competition into the single-center WRTC DSA is an effective strategy for increasing the supply of organs and meeting the demands for transplant services.

33. On page 114, responding to standard B.(3)(b) (i), the statement is made that: “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.” The applicant comments on each of those factors as evidence of there being access barriers, but does not state what the barriers are. Responding to the next part of that standard, B.(3)(b) (ii), which asks for a “credible plan to address those barriers,” the only ‘plan’ the applicant presents is “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.” Please present a clearer identification of the barriers you believe exist, and how they would be overcome. Indeed competition might be one tactic, but present a plan that also matches other solutions to each identified barrier.

Applicant Response:

The barriers to access in the WRTC, and our plans to address them, are as follows:

Barrier	Overcoming the barrier
<u>Capacity</u> : A single transplant center serving a population of 5.5 million	Doubling the number of liver transplant centers in the DSA
<u>Capacity</u> : Insufficient ICU beds	Increasing the number of ICU beds from approximately 57 to approximately 99 (see response to question 13)
<u>Vulnerability</u> : Disruptions that occur with the existing single transplant center (e.g., loss of surgeons or staff, oversight restrictions)	An alternative transplant center in the DSA to list when these disruptions limit access
<u>Waitlist limitations (capacity)</u> : The limited capacity of the single center in the DSA to evaluate potential transplant candidates for inclusion on the DSA waitlist	An additional center which will be able to evaluate and double-list additional patients in a cost-effective way
<u>Waitlist limitations (policies)</u> : Restrictions in the waitlist policies of the single WRTC transplant center	An additional center with different acceptance policies will increase options and effectively the number of patients being waitlisted.

<u>Demand</u>: Insufficient identification of transplant candidates	1. Outreach and community involvement (App. 64-65) 2. Experience and expertise of the CTC (App. 54-58) 3. Expanding the existing hepatology practice at Sibley Hospital and consolidating and integrating it with Suburban's existing clinical resources
<u>Supply</u>: Insufficient supply of donated organs	1. Additional patient and donor education (App. 59) 2. Continued collaboration with the Minority Organ Tissue Transplant Education Program (App. 59) 3. Innovative donor recruitment techniques (App. 60) 4. Continued work of the Epidemiology Research Group in Organ Transplantation (App. 60-61) 5. Increasing the number of live donors, which frees up deceased organs for other transplant candidates (App. 61-62) 6. Multi-listing (App. 62-63) 7. Development with the LLF of the Organ Donation Culture (App. 63) 8. Deployment of a Donor Advocate Program (App. 63-64) 9. Outreach and education for minority and indigent patients (App. 64) 10. Physician outreach and increasing referral patterns (App. 64)

	11. Partnerships with community organizations (App. 65) 12. Using riskier and HIV-positive organs (App. 65-66)
<u>Acuity</u> : Insufficient access by sicker patients to transplant services	1. Double the number of available ICU beds within the WRTC region 2. Competition will incentivize the current WRTC center to perform transplants on sicker patients. 3. Over time, the additional center at Suburban will serve patients with higher MELD scores.
Travel (this barrier disproportionately impacts WRTC residents of a lower socioeconomic status)	Locating the additional transplant center at Suburban Hospital in Bethesda, a facility easily reachable by WRTC residents via highways and public transportation.

34. What factors may have contributed to the reduction of out migration for residents of the LLF between 2011 and 2015? How did the policies and practices of the transplant centers in the LLF DSA change over this period of time?

Applicant Response:

1. Reduction of out-migration: Factors which led to a reduction in out-migration from the LLF DSA between 2011 and 2015 include (a) increased access afforded by two competing services within the LLF DSA which reduced the need for LLF DSA residents to seek transplants outside the DSA; (b) intra-DSA competition which encouraged further patient outreach and more robust referral practices, resulting in greater retention of LLF DSA transplant patients; (c) intra-DSA competition which led to an increase in the number of donors in the LLF DSA, thus making more organs available; (d) Share 35, which allowed the LLF DSA to use organs from outside the DSA; and (e) enhanced experience, outcomes, and reputations of the two LLF DSA centers.

2. LLF Policies and Practices: The competitive forces at work in the LLF DSA have energized the policies and practices of JHH and UMMS. These programs are now transplanting more patients, transplanting sicker patients, and making use of marginal organs, while maintaining excellent outcomes. These results are consistent with research on inter-DSA competition (App. 49-51). This competition directly reduces migration out of the LLF DSA. LLF DSA residents with the ability to travel elsewhere for a transplant are not doing so, but are instead staying home for that service.

In a competitive environment, centers adapt to changing policies in order to provide the highest level of care for the population.

35. What might account for the much higher preference for a liver transplant at UMMS compared to JHH for residents of the LLF and WRTC DSAs, as shown in the table on page 119? For residents of each DSA, almost twice as many transplants are performed at UMMS compared to JHH.

Applicant Response:

UMMS performed significantly more liver transplants than Johns Hopkins Hospital in 2016. A significant factor for this difference is that UMMS performed 30 more transplants on patients with MELD scores ≥ 35 and was thus able to take advantage of organs available through Share 35. UMMS has 266 ICU beds, compared with 116 at JHH. UMMS is able to accommodate more high MELD patients that attract regional livers. Additional possible reasons for this difference include access to insurance contracts, existing referral patterns, aggressive outreach and marketing, and more aggressive decisions about accepting organs as a result of competitive forces. Patient preference could also be a factor.

36. Please explain why Suburban concludes that the difference in acuity among liver transplant patients in the LLF and WRTC, described on page 120 of the application, is regarded as indicative of a lack of access to transplants for residents of the WRTC DSA.

Applicant Response:

As discussed in our response to question 9, the data indicate that the liver disease burden in the WRTC DSA is at least commensurate with the liver disease burden in the LLF DSA. . If the disease burden is commensurate but the programs in the LLF DSA are performing transplants on sicker patients, it follows that access to transplants is lacking by sicker patients who reside in the WRTC DSA.

This lack of access for sicker WRTC DSA residents is demonstrated by the average MELD scores of transplanted patients in the two DSAs in 2016:

DSA	Adult Liver Transplants	MELD 30-34	% MELD 30-34	MELD ≥ 35	% MELD ≥ 35
LLF	291	45	15.5%	75	25.8%
WRTC	84	11	13.1%	8	9.5%

Source: See Exhibit CQ36

Only 22.6% of transplants by the single WRTC DSA center were for patients with MELD scores ≥ 30 (19 out of 84), compared with 41.2% of transplants in the LLF DSA. That is because a single transplant center without competition will operate conservatively. The literature (App. 49-41) and experience (App. 52) indicate that intra-DSA competition will relieve this disparity and result in a greater number of transplants of sicker patients in the WRTC DSA.

37. Please address how the policies for adding patients to the liver transplant waitlist at JHH, UMMS, and MMGUH affect access to a liver transplant for residents of the WRTC.

Applicant Response:

The listing policies of UMMS and Georgetown are not publicly available. Further, the decision to list a patient is ultimately at the discretion of the center's multidisciplinary team. That said, variations in policy may be found in:

1. Age
2. HIV status
3. Certain disease states such as hypercoagulable disorders
4. Alcohol abstinence
5. Tobacco use
6. Social support
7. Pre-existing conditions such as cardiac disease.
8. Re-transplants

A center's capacity for conducting comprehensive evaluations is also a limiting factor which affects access because not being on a wait list is a barrier to access. A liver transplant nearly always requires first being evaluated and placed on the waitlist. The evaluation process is complex, iterative, and time consuming, with multiple consultations, lab tests, procedures and other diagnostic tests, depending on the patient's clinical situation and co-morbidities. An additional transplant center in the WRTC will increase access to this evaluative process, leading to more patients added to the waitlist.

Access can also be affected by patient-specific factors because evaluation requires demonstration of adequate insurance for transplant, transportation, and a capable adult caregiver to assist the potential recipient in the evaluation process and through the transplant process. When patients do not have all of these resources, they may not be considered candidates for transplant, or even be referred for evaluation. The need for these resources is an access barrier, especially for minority patients, low-income patients, and patients without a social support system.

38. Please provide a copy of the decision by the State Health Planning and Development Agency for the District of Columbia (SHPSA) cited on page 125 of the application, and a specific page citation that supports the statement that “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.”

Applicant Response:

1. Copy of decision: A copy of the decision (“Dec.”) was attached as Exhibit 4 to the Application.

2. Competition citation: SHPDA issued its CON for a kidney transplant service to GWUH on April 11, 2014. In October 2016, the Court of Appeals for the District of Columbia directed SHPDA to decide “whether to uphold its previous decision, modify the CON or allow the CON to remain in place ‘in light of current circumstances.’” Dec. 1. The “current circumstances” were “that a substantial time has passed” since the CON was issued, and that “DHP is currently operating the transplant facility.” Dec. 2.

On March 30, 2017, SHPDA reaffirmed its decision authorizing a kidney transplant service at GWUH, citing five “changed circumstances.” Dec. 13-14. One of the five changes that supported continuation of GWUH’s transplant service was that “the number of transplants performed at MedStar Georgetown Hospital has not been negatively affected. In fact, the number of transplants performed at MedStar over the last two years has increased and not decreased.” Dec. 14. The SHPDA based its conclusion on statistics which showed that “during the two years GWUH’s program has been operational, the number of transplants at MedStar ha[d] grown from 163 transplants in 2013 and 150 transplants in 2014 to 201 transplants in 2015 and a projected 206 transplants in 2016.” Dec. 5. Thus, SHPDA found that, despite MedStar’s contrary prediction, the addition of a second transplant service to compete with MedStar resulted in an increase in transplants at both facilities. Dec. 14.

This finding by SHPDA of positive, competitive effect was confirmed by the CEO of GWUH in that institution’s letter supporting Suburban’s Application:

Because the sole existing kidney transplant program (i.e., adult, nonmilitary) in the District [i.e., MedStar] 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.”

Exhibit 17 at 1 (quoted at App. 161).

39. Please explain why the proximity of existing adult liver transplant centers within approximately 100 miles of Bethesda, where Suburban Hospital is located, do not provide sufficient competition and access for residents in the WRTC DSA?

Applicant Response:

The benefits of competition are specific to intra-DSA competition. Two transplantation programs could be located within one mile of each other. But if the programs are in different DSAs, their proximity alone will not cause them to compete with one another.

For liver transplant, the LLF DSA is an example of a competitive DSA, and the WRTC DSA is an example of a non-competitive DSA. The development of a program at Suburban would introduce this sorely needed intra-DSA competition.

See Exhibit CQ39 for map and list of 5 transplant programs within 100 miles of Bethesda.

40. Given that Suburban will not be offering transplants to sicker patients, those with MELD scores over 35, how will the presence of Suburban result in sicker patients getting transplants at a higher rate than is currently experienced?

Applicant Response:

Suburban does expect to transplant patients with MELD scores 35 and above after its program matures. In the meantime, a liver transplant program at Suburban will increase overall capacity for liver transplants in the WRTC DSA. While Suburban's sickest patients (MELD scores 35 and higher) will initially receive transplants at other centers, some patients with MELD scores 34 and lower will shift from the three existing centers in the LLF DSA and WRTC DSA to Suburban. This will create more capacity at the other centers to serve additional liver transplant patients of any MELD score.

41. What evidence exists that the patients Suburban proposes to serve would not be on the waitlist of an existing transplant center if Suburban does not develop its proposed transplant center?

Applicant Response:

The LLF waitlist is more than three times the size of the WRTC waitlist. Yet there is no evidence to suggest that the patient population in the WRTC DSA is three times as healthy. This indicates that there are patients in the WRTC DSA who are not being waitlisted.

42. Are mortality rates higher for WRTC residents with liver disease? Is there evidence that WRTC DSA residents are disadvantaged by being slower to get on a waitlist?

Applicant Response:

The age-adjusted death rate due to chronic liver disease is roughly equal for residents of the jurisdictions comprising the two DSAs (though slightly higher for residents of D.C. and Virginia than Maryland). See response to question 9 and Exhibit CQ 9. Note again, the LLF DSA waitlist is three times as long as the WRTC DSA's waitlist.

43. The study cited on page 17 of the application concludes that liver transplant center variability in accepting organ offers has a significant impact on patient survival among those who receive the first offer of a donor liver. Is there any evidence that surgeons' donor liver acceptance rates create an access barrier for the residents that Suburban proposes to serve? For example, how do the first offer acceptance rates compare among transplant centers within approximately 100 miles of Bethesda, where Suburban Hospital is located?

Applicant Response:

There is no available data about organ acceptance rates for the WRTC DSA or other DSAs in this region. What is available is export data presented in question 29. Between 2014 and 2016, 21 livers were imported from WRTC and 71% were for non-Share 35 patients, meaning they were rejected by MGUH first. This indicates that the WRTC DSA center is less willing to use marginal organs than the LLF DSA centers. Furthermore, research presented in response to question 28 shows that competitive DSAs are less likely to squander marginal organs.

44. What is the estimated travel cost for people that Suburban expects to provide a liver transplant who currently go out of state? How many people fall in this group, and in which states do they reside?

Applicant Response:

The projected volume for 2018-2022 of WRTC DSA residents who would have received a transplant at a center other than JHH, UMMS, and MGUH, and will shift to Suburban, is 23.5 (App. 134).

Transplant patients experience inpatient and outpatient utilization of hospital services before and after the actual transplant. When patients are accepted and placed on the waitlist, they commit to receiving care at the transplant hospital (except in medical emergencies). Using the actual experience of JHH transplant patients that meet the Suburban eligibility criteria, here are the expected number of visits to Suburban for a transplant patient:

Pre-transplant Clinic Evaluation (outpatient)	1.00 visit
Pre-transplant Admissions (inpatient)	1.35 admissions (one year)
Transplant Admission (inpatient)	1.00 admission
Post-transplant Admissions (inpatient)	1.38 admissions (one year)
Pre-/Post-transplant Clinic Visits*	12.32 visits (one year)
Total	17.05 visits
*Pre-transplant and post-transplant outpatient visits are combined into one category.	

Patients are projected to travel to Suburban for care, on average, 17.05 times within the year before transplant and one year after. Of the 17.05 trips to Suburban, 3.37 trips will be for an inpatient stay.

The 23.5 patients who will shift to Suburban from other centers could be traveling from as close as Pennsylvania or from as far away as California. The costs associated with travel for these patients will vary tremendously depending on many factors, including distance, whether air travel will be necessary, and whether family or friends live in the area of the transplant center. At some points during the course of treatment, it will be unwise for the patient to travel other than by private car due to the immune-suppressing drug regimen and overall health. Expenses may therefore include one or more extended stays in another city.

45. Please explain how access to an experienced liver specialist will be improved, as noted on page 158 of application.

Applicant Response:

The experienced liver specialists referenced at page 158 of the Application are Johns Hopkins hepatologists Dr. Kirti Shetty and Dr. Jacqueline Laurin (App. 71). Drs. Shetty and Laurin are currently practicing at several sites in the region, including Sibley Memorial Hospital, Johns Hopkins Community Physicians in Bethesda and Frederick Memorial Hospital. If the Application is approved, their practice will be consolidated and focused at Suburban, where they will build relationships and expertise in multiple areas necessary to a highly functioning transplant program, including interventional endoscopy, interventional radiology, intensive care, addiction treatment, transplant pharmacy, psychiatry, etc.

As the program grows, the size and scope of the hepatology program will be synchronized with the needs of the patient population managed at Suburban and associated outreach sites for pre- and post-transplant care.

Impact

46. What is the average annual growth per year by transplant center location and region of residence or sub-region of residence, if only cases with MELD<31 (or less than 35) are considered? This group would be more consistent with the population Suburban proposes to serve. Has Suburban tried to request this information from UNOS?

Applicant Response:

The average annual growth per year by transplant center location for Suburban-eligible patients (adult, deceased donor, liver-only, MELD <35) is as follows:

Suburban-Eligible Volume							
	2010	2011	2012	2013	2014	2015	2016
JHH	27	29	26	47	50	51	78
UMMS	38	54	46	34	40	79	91
MGUH	54	65	85	54	49	32	59
Total	119	148	157	135	139	162	228
Annual Growth	-	29	9	-22	4	23	66
Average Annual Growth Rate 2010-2015						8.6	
Average Annual Growth Rate 2010-2016							18.2

(Source: UNOS Data Request 2 - 10012017)

The Average Annual Growth Rate for 2010-2015 was 8.6 cases.

The Average Annual Growth Rate for 2010-2016 was 18.2 cases.

JHM requested data from UNOS with this unique "Suburban-eligible" description on September 26, 2017, and it was received on October 3, 2017.

47. Please update projections and analysis to incorporate CY 2016 data from UNOS and other available updated information, as appropriate.

Applicant Response:

Suburban-Eligible Center Volumes

In its application, JHM estimated the percentage of total liver transplant patients at JHH, UMMS, and MGUH that were Suburban-Eligible. It combined these percentages with patient-residency data to quantify the Suburban-Eligible market and project future volumes for Suburban, JHH, UMMS, and MGUH by patient residence.

Since submitting the Application, JHM obtained an additional dataset from UNOS, which directly provides the number of Suburban-Eligible patients transplanted at JHH, UMMS, and MGUH from 2010 to 2016, as shown here:

	UNOS: Suburban-Eligible - Actual Cases							Projection	
	2010	2011	2012	2013	2014	2015	2016	2017	2018
JHH	27	29	26	47	50	51	78	84.1	90.1
UMMS	38	54	46	34	40	79	91	97.1	103.1
MGUH	54	65	85	54	49	32	59	65.1	71.1
Total	119	148	157	135	139	162	228	246.2	264.3
Annual Growth	-	29	9	-22	4	23	66	18.2	18.2
Average Annual Growth Rate 2010-2015						8.6			
Average Annual Growth Rate 2010-2016							18.2		
Average Annual Growth Rate 2010-2016, distributed evenly 3 ways							6.1		

(Source: UNOS Data Request 2 - 10012017)

The average annual growth rate for 2010-2015 was 8.6. Updating to include data for 2016, the average annual growth rate for 2010-2016 was 18.2.

2018 Patient Residency Projection – Application (data for 2010-2015)

In the Application, to project center volumes and patient residency volumes for 2018, JHM produced the following table (copied from page 172 of the Application):

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

(Source: UNOS Data Request 1 – 04112016)

As described in the Application, this table was created using the first UNOS data request:

- (1) based on 2015 patient residency data for All Patients
- (2) based on estimated 2015 Suburban-Eligible Percentages by center

JHM's new dataset from UNOS allows it to redo this projection with more current and precise information.

2018 Patient Residency Projection – Updated (data for 2010-2016)

UNOS: 2016 Suburban-Eligible Patients (Counts)						
Year	DSA	JHH	UMMS	MGUH	Other Centers	TOTAL
2016	LLF	38	60	8	6	112
2016	WRTC	24	17	50	13	104
2016	Other	16	14	1	-	31
2016	TOTAL	78	91	59	19	247

(Source: UNOS Data Request 2 - 10012017)

The table above reports actual Suburban-Eligible cases, by center and DSA of residence, for 2016.

JHM then calculated the percentage of cases from the three residency categories for each center:

UNOS: 2016 Suburban-Eligible Patients (Percent of Center Total)						
Year	DSA	JHH	UMMS	MGUH	Other Centers	TOTAL
2016	LLF	49%	66%	14%	-	-
2016	WRTC	31%	19%	85%	-	-
2016	Other	21%	15%	2%	-	-
2016	TOTAL	100%	100%	100%	-	-

As an example, in 2016, 38 Suburban-Eligible cases were done at JHH for residents of the LLF DSA, out of 78 total Suburban-Eligible cases at JHH that year. $38/78 = 49\%$ of Suburban-Eligible cases performed at JHH in 2016 were for LLF DSA residents. $24/79 = 31\%$ were for WRTC DSA residents, and $16/78 = 21\%$ were for residents of Other DSAs.

Next, center growth projections were made using the Average Annual Growth Rate for 2010-2016 (18.2 cases per year) distributed evenly across the three centers:

Center	Projected Growth Per Year	
	2017	2018
JHH	6.1	6.1
UMMS	6.1	6.1
MGUH	6.1	6.1

Center	Projected Volume By Year	
	2017	2018
JHH	84.1	90.1
UMMS	97.1	103.1
MGUH	65.1	71.1

The new center totals were then distributed across the three residency areas according to the percentages shown in the table at the top of the page:

Projected: 2018 Suburban-Eligible Patients (Counts)						
Year	DSA	JHH	UMMS	MGUH	Other Centers	TOTAL
2018	LLF	43.9	68.0	9.6	6	127.5
2018	WRTC	27.7	19.3	60.3	13	120.3
2018	Other	18.5	15.9	1.2	-	35.6
2018	TOTAL	90.1	103.1	71.1	19.0	283.3

The 2018 volume projections, revised to include 2016 actual volumes, are higher than the projections in the Application due to the higher-than-usual growth in total cases in 2016.

The volume projections in the Application were purposely made using a conservative methodology. Projected 2018 volumes specifically for the new Suburban center remain unchanged. Given the increased size of the market as shown in the 2016 data, the entrance of a new program at Suburban will have even less of an impact on the other area centers than Suburban initially estimated in the Application.

48. Given Suburban will not be performing living donor transplants, at least initially, why was the trend for all liver donor types used to determine projected overall growth in cases?

Applicant Response:

The trend for all liver donor types was used to determine projected overall growth in cases in the market, not to project cases at Suburban.

The Suburban Volume Projection Methodology presented in the Application does the following:

- Reports annual volumes for centers in the market
- Quantifies the market's growth trend
- Projects that trend into the future, distributing growth evenly to the 3 area centers (Status Quo)
- Calculates what percentage of the market is Suburban-Eligible (adult, deceased donor, MELD <35, liver-only)
- Projects Suburban volumes using only the Suburban-Eligible market, quantifying shifts in the market, growth in the market, and new volume in the market resulting from increased access

49. If only about half of the liver transplants performed at JHH are expected to be Suburban-eligible and only 34% of the volume at Georgetown, and 54% of the volume at UMMS, then it seems questionable to assume a migration pattern based on all liver transplants at each location. Is it possible to obtain analysis of the categories used in the tables on page 170 from UNOS that more closely aligns with the pool of Suburban-eligible cases?

Applicant Response:

JHM requested a new data set from UNOS allowing JHM to produce an analysis of the categories used in the tables on page 170 for patients transplanted in 2015 that fit the Suburban-Eligible definition (adult, deceased donor, MELD <35, liver-only). That dataset, received on October 3, 2017, shows the following:

UNOS: Actual 2015 Counts - Suburban-Eligible Patients					
DSA	JHH	UMMS	MGUH	Other Centers	TOTAL
LLF	26	52	4	3	85
WRTC	14	20	27	20	81
Other	11	7	1	-	19
TOTAL	51	79	32	23	185

See Application page 170 chart 1 of 3 to see “Actual 2015 Counts – All Patients.”

50. On pages 136 and 142, it is stated that 40 new cases over five years are projected as a result of competition. However, it appears the basis for this projection is not explained until page 177 of the application. It would be helpful to have that clarifying information included on pages 136 and 142.

Applicant Response:

The projection methodology was developed and explained in response to COMAR 10.24.01.08G(3)(f) (“Impact on Existing Providers and the Health Care Delivery System”) beginning at App. 164. The resulting projection of 40 new cases over five years appears at App. 136 in response to the Cost Effectiveness standard; and at App. 142 in response to the Impact standard. In these instances, Suburban was responding to specific standards, which are not concerned with the projection methodology but do require the actual number of cases projected for a complete answer.

The methodology resulting in a projection of 40 New Cases is described on page 177 of the Application and is copied here:

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

51. On page 173, please explain why residents of the LLF will seek services at Suburban hospital rather than JHH and UMMS, rather than remaining in the LLF DSA and why the number of liver transplant patient will be the same as the number estimated for MGTU.

Applicant Response:

Residents of the LLF DSA will seek services at Suburban for the following reasons:

- They will take the opportunity to multilist locally, at either JHH or UMMS (LLF DSA), and at Suburban (WRTC DSA). This increases their chances of matching with an available deceased donor organ.
- As staff has pointed out, for many LLF DSA residents the travel burden to Suburban will not be much different from traveling to JHH or UMMS.
- At Suburban, patients will receive care from Johns Hopkins faculty and have the benefit of the extensive experience, expertise, clinical trials, and research of the Johns Hopkins Comprehensive Transplant Center.

The number of LLF DSA residents projected to receive a transplant at Suburban in 2018 is the same as the number projected at MGUH because the number at MGUH was used as a guide for what to expect at Suburban. Very few LLF DSA residents travel to MGUH for a transplant each year. The 2018 projection for MGUH is based on historical patterns reduced to reflect the proportion expected to be Suburban-Eligible. We assume that LLF DSA residents will be at least as likely to travel to Suburban as they are to MGUH for a liver transplant. We chose 3.3, the same number as projected for MGUH, as a conservative volume projection.

52. Please explain why the number of residents from Maryland who reside in the LLF DSA and receive transplants at MGTU will not be affected at all by the proposed addition of Suburban in 2018, as shown in the table at the bottom of page 173.

Applicant Response:

The number of cases expected to shift from each of the three area centers is in proportion to the cases currently going from the LLF DSA to each center. Because so few people currently go from the LLF DSA to MGUH—3.3 projected for 2018 in the table cited in the question—that calculation results in a projected shift of only one-tenth of one case from MGUH to Suburban. This small of a shift is immaterial. For purposes of projecting future volumes at Suburban, the projection of LLF DSA residents receiving a transplant at MGUH was not changed.

53. Please explain why there will be no increase in case volume attributed to competition in the first year of operation of the liver transplant program at Suburban, as shown on pages 173 and 174.

Applicant Response:

JHM projects that there will be a ramp-up period in Year 1, as Suburban initiates operations, conducts outreach to referring physicians, other providers, and others, and builds a waitlist.

For any service, it is reasonable to expect there to be a time lag between an increase in capacity in a given area and an observable, measurable increase in patient access. While the increase in capacity should quickly increase the number of patients evaluated and waitlisted in the WRTC DSA, additional time will be necessary for patients to progress through the UNOS waitlist, match with a donor, and receive a liver transplant.

54. How does the proportion of Suburban-eligible cases at transplant programs in the LLF and WRTC DSAs in CY 2015 shown in the table on page 171 compare to the proportion for CY 2016 and CY 2014? Is there consistency over time?

Applicant Response:

The proportion of Suburban-Eligible cases at transplant programs in the LLF DSA and WRTC DSA in CY2015 shown in the table on page 171 of the Application (copied below) were estimates based on the methodology outlined on pages 166 and 167.

	Suburban-Eligible Patients			
	JHH	UMMS	G'town	Total
% of Total Volume	49%	54%	34%	47%

JHM requested a new data set from UNOS allowing it report on the exact number of patients transplanted at the three centers listed above that fit the Suburban-Eligible definition (adult, deceased donor, MELD <35, liver-only). That dataset was received on October 3, 2017 and shows the following values for CY2014, CY2015, and CY2016:

- All patients
- Suburban-Eligible patients
- Proportion of All patient that are Suburban-Eligible

All Patients			
Year	JHH	UMMS	MGUH
2014	86	115	102
2015	100	147	81
2016	126	169	117

Suburban-Eligible			
Year	JHH	UMMS	MGUH
2014	50	40	49
2015	51	79	32
2016	78	91	59

% of Patients Suburban-Eligible			
Year	JHH	UMMS	MGUH
2014	58%	35%	48%
2015	51%	54%	40%
2016	62%	54%	50%

55. On page 177, Suburban states that an additional 108 transplants should have been given to WRTC DSA residents to meet their needs in CY 2015, based on an assumption that the rate of liver transplants should be the same for residents of the LLF and WRTC DSAs. Please note that MHCC staff has requested additional information to support this conclusion.

Applicant Response:

See response to Question 12, duplicated here:

A proxy for liver disease burden is age-adjusted death rate due to chronic liver disease. As set forth in response to question 9, the death rate due to chronic liver disease was roughly the same in D.C. (7.7), Virginia (8.7) and Maryland (6.9) in 2014. See Exhibit CQ9. This data suggests that the demand for liver transplants in the two DSAs should be roughly equivalent.

WRTC DSA residents would therefore benefit from a higher rate of transplant, which will increase the quality and length of life for additional WRTC residents suffering from chronic severe liver disease. A higher rate of transplant is possible in the WRTC DSA based on the rate achieved in the LLF DSA and the other evidence cited from peer-reviewed literature, namely the lack of intra-DSA competition.

56. Please address how the budget at JHH will change as a result of shifting cases away from it to Suburban. Please address the budget impact at JHH and UMMS that is expected as a result of market shifts for liver transplants (response should be based on consultation with the Health Services Cost Review Commission (HSCRC)).

Applicant Response:

JHM anticipates no immediate impact on the budget at JHH or UMMS. Currently, organ transplants are excluded from market shift adjustment calculations.

JHM has had preliminary conversations with HSCRC staff about the need for this program and the additional resources Suburban would need to make it possible. The HSCRC was receptive to the idea, but would like to discuss further. JHM proposes an arrangement that would treat these cases as a pass-through, allowing Suburban to operate the program in a budget-neutral fashion for a three-year-period until rates could be set appropriately based experience.

57. How do costs for the patients that Suburban proposes to serve compare to those at MGUH and other liver transplant centers where the patients are already served? If necessary please request this information from those centers.

Applicant Response:

We estimate that the charge for a liver transplant case at Suburban will be \$148,208. This was derived using the actual 2015 JHH charge for Suburban-Eligible patients (\$172,955), and then applying lower Suburban rates.

The charges for liver transplant cases are highly variable, and the criteria distinguishing Suburban-Eligible cases—lower MELD score, Liver-only, Adult, deceased donor—impact the costs charges significantly. Comparable charge information from other centers cannot be calculated without access to those centers' internal data, which was not available. Suburban can only surmise that the charges at Georgetown MGUH and University of Maryland are more like the charges at JHH than the estimated charges at Suburban, as Georgetown MGUH and the University of Maryland are academic medical centers, as is JHH.

58. Please list and explain the assumptions used to generate the information in the table on page 135 showing the annual cost of services at Suburban.

Applicant Response:

The table from page 135 of the Application shows the projected annual costs of services associated with the new program and is included here for reference:

	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: Contingency, Outpatient Activity, Organ Acquisition	\$890,934	\$1,953,179	\$2,254,507	\$2,557,425	\$2,805,117
TOTAL OPERATING EXPENSES	\$4,754,424	\$8,174,353	\$9,251,720	\$10,647,857	\$11,571,946

(Also appears in Table K, Section 2, Expenses)

These costs include all utilization expected to result from the new program, as reflected in Table I of the Application, including Transplant, Pre-Transplant, Post-Transplant, and Outpatient hospital activities associated with transplant patients. The costs were derived as follows:

1. Salaries & Wages (including benefits). Using a cohort of JHH liver transplant patients, average utilization per transplant was calculated. A Suburban Variable Direct Charge per Case was developed by applying JHH utilization by rate center to Suburban FY16 rates. Then the HSCRC Variable Direct Cost to Charge ratio (from Suburban's HSCRC FY15 annual filing) was applied, resulting in a Suburban Variable Direct Cost per Case. This was multiplied by the number of transplants projected each year.
2. Contractual Services. These include personnel salaried and benefits, physician support, and misc. operating support all supplied through JHH. The costs reflected in the table above are quotes from JHH.
3. Supplies and Drugs. These costs are based directly on costs at JHH, as they will not vary by hospital.
4. Other Expenses. These include organ procurement (variable direct costs as derived above), direct costs for Outpatient Activities, and a yearly contingency.

59. Have anticipated market shift reductions in budget been accounted for in the projections? Please address based on consultation with HSCRC.

Applicant Response:

As stated in response to question 56, currently organ transplants are excluded from market shift adjustment calculations, so no reductions in budget will result.

60. How will the budget at JHH change as a result of the shifting of liver transplant cases from other Maryland hospitals to Suburban?

Applicant Response:

The only other Maryland transplant hospital is UMMS. No change in the budget at JHH is anticipated as a result of the shifting of liver transplant cases from UMMS.

61. On page 155 of the application, it is stated that the existing LLF centers would find it difficult to increase their volume of liver transplants further. What information was obtained regarding the capacity of the liver transplant programs at UMMS and Johns Hopkins Hospital? What is regarded as the liver transplant capacity for each program estimated to be? What are the factors driving the volume limits?

Applicant Response:

Here is the exact language from page 155 of the Application: "Further, the two LLF centers are already functioning at a high level, making it difficult for them to increase their volume further."

Capacity is one of many factors that might limit a center's ability to increase volume, but we were referencing utilization and efficiency, not capacity, at page 155. The centers in the LLF have grown their programs significantly in the last several years through evaluating and listing patients, maximizing the use of organs, and expanding outreach, education, and donor advocacy. From 2010 to 2016, the volume at the two LLF centers grew from 94 to 295 cases, or 263%. While both centers will continue to serve as many patients as possible, it is unlikely that they will be able to sustain that level of growth given the limitations in organ availability and clinical resources.

62. Please explain why increasing the volume of existing transplant centers in the LLF and other transplant centers where WRTC DSA residents currently obtain liver transplants could not meet the need for liver transplants by residents of the WRTC DSA. The explanation provided is inadequate. As indicated by other questions of MHCC staff, insufficient information has been provided regarding the demand for liver transplants by residents of the WRTC DSA and the role of barriers to access.

Applicant Response:

As explained above in response to question 61, the volume of transplants performed in the LLF DSA has grown significantly over the last few years, increasing 263% from 2010 to 2016. While the two centers in the LLF DSA will continue to strive to serve as many patients in need as possible, it is unlikely that they will be able to sustain that level of growth given the limitations in organ availability and clinical resources. The volume performed in the WRTC DSA, on the other hand, has been flat in that same timeframe. The growth achieved in the LLF DSA suggests equivalent growth would be achieved in the WRTC DSA, which is our principal argument in support of adding a program at Suburban.

About 20% of the WRTC DSA residents who received a liver transplant in 2015 went to "Other Centers," meaning they obtained a transplant somewhere other than in the LLF DSA or the WRTC DSA. The potential for increasing volume in any of these other centers is not known. Given the substantial travel burden associated with leaving a resident's local area to access a transplant, increasing the number of WRTC DSA residents who must travel to receive a transplant would only increase that burden.

Finally, as we noted in response to questions 24, 34, and 39, intra-DSA competition is the key. Increasing volume in a neighboring DSA does not alleviate the problems associated with a single-center DSA.

63. On page 156 of the application, please address what evidence exists that socioeconomic status is limiting residents of the WRTC DSA from obtaining transplants.

Applicant Response:

As discussed on page 36 of the Application, a study by Dzebisashvili confirms the association between socioeconomic status and the ability to travel to other DSAs. The lower the socioeconomic status of a patient, the less means and less inclination that patient has to travel. This means that patients are more likely to opt out of transplantation (this phenomenon was explained in detail in response to question 9). Census data shows that the lowest tier of socioeconomic status—those living below the poverty line—is equivalent in the core metropolitan areas within the LLF DSA and the WRTC DSA. See <https://censusreporter.org/profiles>.

	Jurisdiction	Population	% Below the Poverty Line
WRTC	Washington, D.C.	681,170	18.6%
	Prince George's County	908,049	9.1%
	Charles County	157,705	6.8%
	Montgomery County	1,043,863	6.7%
LLF	Baltimore City	614,664	21.9%
	Baltimore County	831,026	9.0%
	Anne Arundel County	568,346	6.9%
	Howard County	317,233	4.7%

These statistics show that in Washington, D.C. and the Maryland counties within the WRTC DSA, 289,992 residents live below the poverty line, compared with 263,529 people who live below the poverty line in Baltimore City and the three most populous counties in the LLF DSA. This demographic similarity makes the disparities in total number of transplants, livers imported, livers exported, and the length of the waitlists in the two DSAs all the more striking. This data, combined with Dzebisashvili's findings about travel, are powerful evidence that socioeconomic status is limiting residents of the WRTC DSA from obtaining transplants.

64. On page 158, please clarify whether the establishment of a regional Center of Excellence for Liver Disease is dependent on approval of a new transplant program at Suburban Hospital.

Applicant Response:

JHM intends to continue expanding its services to meet the growing needs of liver disease patients in the WRTC DSA. JHM's recruitment of hepatologists Dr. Shetty and Dr. Laurin was the first step of this process. A Center of Excellence for Liver Disease would aim to treat liver disease patients across the entire spectrum of treatment modalities. The inability to perform liver transplants excludes a significant part of the spectrum and will make it difficult for Suburban to achieve true Center of Excellence status with the program and resources available.

65. On page 158, please quantify the likely impact of efforts to reduce progression of liver disease. Over what timeframe will the results of this effort be realized?

Applicant Response:

With specialized hepatology care, the progression of liver disease can in some cases be slowed or halted, and some patients will never actually get sick enough to require listing for a transplant. Some conditions, such as alcohol-related and bariatric-related liver diseases, can be reversed if appropriate treatment and education are initiated before sudden liver failure. Patients with hepatitis C, if treated while their liver disease is still in its early stages, will never progress. Without specialized hepatology care, though, more patients will succumb to liver disease and more will require a transplant to survive.

Quantifying impact, in the context of the progression of liver disease, is impossible at this time. One way to measure impact over time would be to monitor the Age-adjusted Death Rate due to Chronic Liver Disease/Cirrhosis in the two regions.

66. On page 158, please explain to what extent the population health initiatives listed or similar ones are already in place and serving residents of the WRTC DSA and the LLF DSA.

Applicant Response:

Suburban hospital has a robust Community Health and Wellness division and engages in an array of population health initiatives with the goal of improving the health of the community. Suburban currently targets five health priorities, including diabetes, obesity, and substance use disorders (under behavioral health), all risk factors for liver disease. The population health efforts currently underway to address these priorities are described in Suburban's FY 2016 Community Benefit Report:

http://www.hscrc.state.md.us/Documents/HSCRC_Initiatives/CommunityBenefits/CBR-FY16/Suburban-CBR16.PDF

Liver disease and its precursors are included in Suburban's population and community health strategy, but the addition of a transplant program would bring significantly more, targeted resources to address liver disease. Initiatives that would be enabled by a transplant program include trained nurse educators to engage in community education and outreach specific to liver disease and transplant, a donor advocacy program, enhanced clinical capabilities, expansion of hepatology and related wraparound services, and the establishment of a Center of Excellence for treating and managing liver disease. JHH partners with the LLF in establishing and deploying these kinds of services, sharing the costs and coordinating efforts. Suburban hopes to have a similar synergistic partnership with the WRTC.

67. Table I. Please explain the relationship between projected discharges for the new service and the projected liver transplant volumes.

Applicant Response:

Projected liver transplant volume at Suburban:

	FY2019	FY2020	FY2021	FY2022	FY2023
Transplants	17	32	37	42	46

Table I asks for all utilization projected to result from the new program. For every patient that receives a liver transplant, there is significant utilization beyond the transplant surgery and hospital stay itself. Total admissions and outpatient visit volume projected:

	FY2019	FY2020	FY2021	FY2022	FY2023
Transplants	17	32	37	42	46
Total Admissions	140	268	314	362	402
Total Outpatient Visits	226	452	567	688	805

*Transplants are included in Total Admissions

To project the number of Total Admissions and Total Outpatient Visits expected as a result of the program at Suburban, JHM analyzed utilization for patients that have been transplanted at JHH that met the Suburban eligibility criteria. For inpatient admissions, utilization was divided into four types. For every transplant performed, the following additional utilization is expected:

Pre-transplant Admissions	1.35 per transplant
Readmissions (within one year)	1.38 per transplant
Readmissions (after one year)	0.17 per transplant
Hepatology-Related Admissions (Not Transplanted)	4.55 per transplant

Two categories of outpatient visits were identified, and utilization was projected:

Evaluations and Clinic Visits For Patients Transplanted (within 1 year)	13.32 per transplant
Post-Transplant Clinic Visits (greater than 1 year post-transplant)	1.5 per transplant

The tables below show the application of these ratios to projected Suburban transplant volumes to calculate total utilization related to the program. The results tie to Table I.

Inpatient Admissions	Transplant: Admission Ratio	Aggregate Transplant: Admission Ratio	FY2019	FY2020	FY2021	FY2022	FY2023
Transplants	-	-	17	32	37	42	46
Aggregate Transplants Post FY2019 (Year 1)	-	-	0	17	49	86	128
Pre-Transplant Admissions	1.35	-	23	43	50	57	62
Readmissions (within 1 year)	1.38	-	23	44	51	58	63
Readmissions (after 1 year)	-	0.17	0	3	8	14	21
Hepatology-Related Admissions (Not Transplanted)	4.55	-	77	146	168	191	209
Total Discharges			140	268	314	362	402

Outpatient Visits	Transplant: Visit Ratio	Aggregate Transplant: Visit Ratio	FY2019	FY2020	FY2021	FY2022	FY2023
Transplants	-	-	17	32	37	42	46
Aggregate Transplants Post FY2019 (Year 1)	-	-	0	17	49	86	128
Evaluations And Clinic Visits For Patients Transplanted (within 1 year)	13.32	-	226	426	493	559	613
Post-Transplant Clinic Visits (greater than 1 year post-transplant)	-	1.50	0	26	74	129	192
Total Outpatient Visits			226	452	567	688	805

68. Please provide the assumptions associated with the Revenue and Expense statements for Exhibits 1G, 1H, 1J, and 1K.

Applicant Response:

Revenue and Expense Statements for Exhibits 1G and 1H:

The Exhibit G and H Financial Statements incorporate Suburban's 10-Year Plan and the liver transplant program. The Revenues and Expenses reflect projected discharge volume and patient days.

Revenue and Expense Statements for Exhibits 1J and 1K:

1. Program Revenue – Based on Charge/Case of each transplant episode and the respective discharge volume.
2. Allowance for Bad Debt – Bad debt refers to the first 10 transplant cases in Year 1, which will be unreimbursed 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 expected to be reimbursed.
3. Contractual Allowance – An 85% collection rate is applied to both Inpatient and Outpatient services revenue.
4. No GBR constraints have been considered in the revenue statement of the Liver Program.
5. Please refer to our response to Question 58 for the algorithm for Suburban's Charge per Case and Variable Direct Expense per Case. Expense inflation assumes the average historical inflation rate of 2.5% for all expenses.

69. Tables G,H,J,K (Revenue and Expense, entire facility and new service/inflated and uninflated): In each pair of these tables, the projected revenue for the “inflated” table is the same as it is for the “uninflated.” Is that correct?

Applicant Response:

Initially we did not apply a rate of inflation to the Revenue because the Suburban GBR approved rate is determined by the HSCRC. In order to be consistent with the Expense Inflation Rate, a 2.5% inflation rate has now been applied to Revenue as well. Revised tables are included showing the change. See Exhibit CQ69.

70. Table L shows that the program will add 50.1 FTEs to Suburban's staff.

- a) That is more personnel additions than projected number of transplants. Is this accurate?
- b) Describe how the program will be staffed. That is, what positions will be recruited for, and will some be shared with JHH and/or be CTC employees?

Applicant Response:

- a. As shown in Table I, in FY 2023, 402 incremental discharges and 3,337 patient days are projected as a result of the new liver transplant program. We project that 50.1 FTEs will be necessary to care for these patients. That estimate is based on (i) existing staffing on nursing floors and in the OR at Suburban, and (ii) experience at JHH with liver transplant patients. Adding these staff will be a gradual process as the program slowly ramps up. The staffing plan will be adjusted as we observe the actual impact of these new patients on the floors.
- b. Table L shows the job titles for the positions to be added. Of the 50.1 projected FTEs, 45.18 are direct care providers (nursing, OR, pharmacy, Social Work, Dietician, etc.) (39.42 regular employees and 5.76 contractual) Some of the FTEs included as contractual employees will be shared with the JHH program. Table L reflects the financial support Suburban will provide.

Services that will be provided through contractual agreements with JHH:

- Medical Direction
- Surgical Direction
- Surgical coverage
- Organ procurement coverage
- Administrative Director (overall administrative leadership, strategic planning, communications and marketing, and patient centered care)
- Assistant Administrative Director (clinical operations and activation, onboarding of new staff, clinical metrics, financial metrics and outcomes)
- Regulatory Oversight and Quality Programming (UNOS, CMI, TJC, QAPI, policies and procedures, quality auditing)
- Nurse onboarding, management and training
- Social work onboarding, oversight and training
- Nutrition training
- Pharmacy training
- Information technology and training on the Epic module for transplant (Phoenix)
- Data collection and submission to regulatory bodies

Thank you for the opportunity to provide additional information regarding our application for a Certificate of Need to develop a liver transplant program at Suburban Hospital. We look forward to continuing to work with you and your staff during the review process.

Sincerely,

Anne Langley

cc: Travis A. Gayles, MD, PhD, Acting Health Officer, Montgomery County