BEFORE THE MARYLAND HEALTH CARE COMMISSION

IN THE MATTER OF	)
APPLICATION OF MEDSTAR FRANKLIN SQUARE MEDICAL CENTER FOR A LIVER TRANSPLANT SERVICE	)
Docket No. 17-03-2406	)

MEDSTAR FRANKLIN SQUARE MEDICAL CENTER'S RESPONSE TO THE INTERESTED PARTY COMMENTS of UMMC and JHH Liver Transplant Program

I. INTRODUCTION

MedStar Franklin Square Medical Center ("MFSMC"), through undersigned counsel and pursuant to COMAR § 10.24.01.01 *et seq.,* hereby offers its response to comments of University of Maryland Medical Center ("UMMC") and Johns Hopkins Hospital ("JHH") as to MFSMC's application for a liver transplantation service. MFSMC submits that the comments fail to establish any appropriate basis to deny the issuance of a Certificate of Need ("CON") for a liver transplant service at MFSMC.

II. THE PROPOSED PROGRAM AND ANALYSIS COMPORT WITH GENERAL OBJECTIVES OF THE STATE HEALTH PLAN

UMMC suggests that MFSMC's proposed service is inconsistent with the State Health Plan ("SHP") goal of having a limited number of high volume programs. *See* UMMC Comments ("UM.Cmt.") at 2-4. UMMC also suggests that this type of regionalization plan was the result of the 2017 update to the SHP. *See* UM.Cmt at 2. These comments are not persuasive.

First, the longstanding policy of this and other SHP chapters regarding liver transplant programs has not changed. In fact, the recent changes to the SHP chapter on transplantation eliminated the then existing need methodology and provided for an alternative approach to establish need for a new transplant program – a sign of a significant moderation to the policy. Regarding the inference that this policy derives from changes made by the workgroup, the policy about specialized services is not new to the 2017 update of the transplant plan chapter. The section of the SHP discussing specialized services on page 8 is comprised of two paragraphs, less than the previous version of the transplant plan chapter that discussed specialized services over four pages. New additions to the 2017 Plan chapter include sections about cost effectiveness, quality of care, and access. In fact, MHCC changed the emphasis of the regionalization policies in the 2017 update. The need methodology was among the items deleted from the Plan, along with related policies.

Furthermore, the policy goals in the SHP do not state that "two programs" is the correct number to serve a given population. As quoted from that document: "the public is best served if a *limited* number of general hospitals provide specialized services to a substantial population base." COMAR § 10.24.15.03, p. 8 (emphasis supplied). The reality is that urban areas near our own have a number of liver transplant programs in operation. New York City zip code 10023 has seven adult liver transplant programs within 50 miles, while Philadelphia zip code 19104 has six. In addition, both of these areas have additional, separate pediatric liver transplant programs. MedStar has argued that a new program should support growth in the organ pool, while maintaining an exceptional quality standard, in order to contribute effectively; *i.e.*, the focus should be on these elements regardless of number.

Also to be noted, when UMMC emphasizes the SHP goal of a limited number of general hospital programs, it overlooks the section of the SHP which specifically provides the basis for the addition of another program in the state: the ability to enhance the availability of organs. COMAR § 10.24.15.04B(1)(a). It also ignores the SHP's standards for the minimum volume necessary to approve a new program. COMAR § 10.24.15.04B(2).

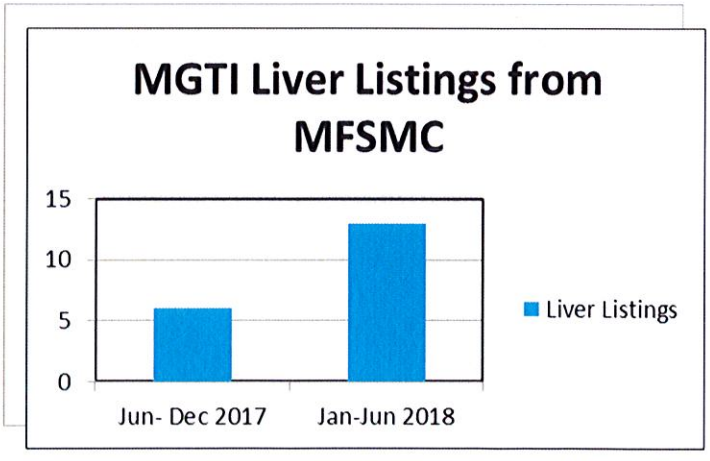
UMMC characterizes the MFSMC program as "low volume," focusing principally on the predicted number of cases in the start-up years. *See* UM.Cmt. at 3. Although MedStar agrees that chronically low volume programs are not in the long-term interest of the transplant community, MedStar has explained that it has no intention of maintaining a low volume program but rather to grow the program at MFSMC. See the evidence of growth in referral and listing volume in Tables 1 and 2.

From this perspective, the SHP's own standard acknowledges that a program may perform at a lower volume level *initially*. COMAR § 10.24.15.03(B)(2)(a) (requirement to meet minimum volumes within the first three years). UMMC would have the MHCC define the SHP's general goal of having a limited number of high-volume programs in contradiction to the SHP's specific review standard for the introduction of an additional program in Maryland. The general goal of the SHP cannot be used to nullify the SHPs specific standard which serves as the grounds for approval of an additional program.

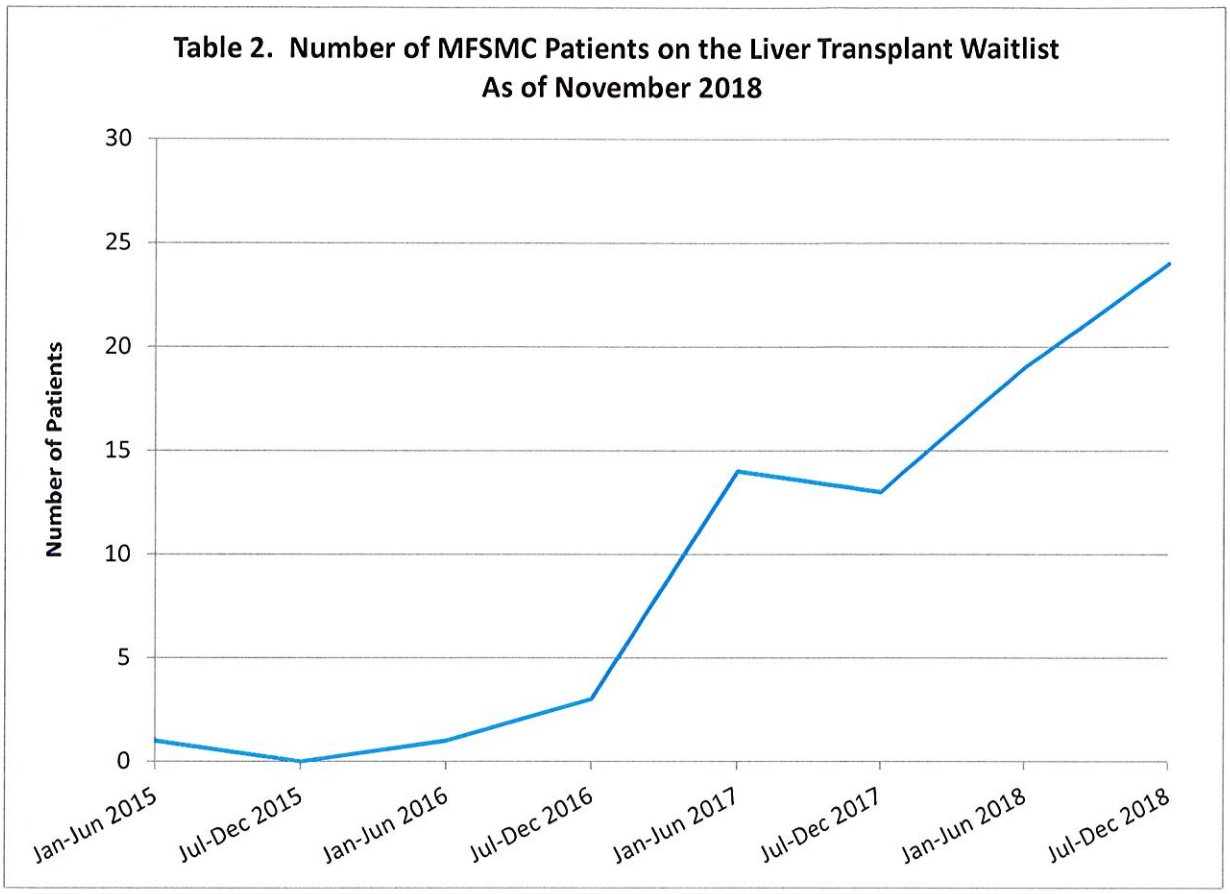
Since the proposed program at MFSMC will be built on the platform of the MGTI program, it is not accurate to depict it as a long term, low volume program. The high volume MGTI program (a very experienced team of professionals at a CMS-compliant high-volume program with superior patient and graft outcome statistics) will serve as ongoing support to the new program. MFSMC's conservative volume projections in the first three years outline a

planned "start-up" trajectory, *i.e.,* a combination of clinical judiciousness and attention to insurance coverage issues. Once the program has obtained CMS and managed care contract approvals, volume will continue to rise. This forecast is entirely reasonable when one observes the pattern of referral/evaluation/listing and transplantation that has been demonstrated over the time frame since MedStar outreach sites have been established and, importantly, since MedStar deployed a full-time hepatologist on-site at MFSMC. Since application was made in August 2017, MGTI transplants referred from MFSMC are on a trajectory to exceed the thresholds set by the MHCC. A comparative snapshot of patients wait-listed for transplantation, provided in tables below, shows that listings more than doubled in a recent six-month period. The subsequent graphic, Table 2, shows the progressive upward trend over time in those patients evaluated for transplant at MFSMC, listed for liver transplant over time.

Table 1. MGTI Listings for Liver Transplant from MFSMC More Than Doubled in a Six-Month Period.



Source: Internal MedStar Health data



UMMC unfairly dismisses the role of the successful MGTI program when it states that MFSMC's ability to increase organ availability "is based on generalized statements about MedStar's supposed expertise, and lacks meaningful support." UM.Cmt. at 3. To the contrary, the most recent SRTR data reveal MGTI to be the superior program in the Baltimore-Washington area, demonstrating better outcomes than either Maryland program. Recent SRTR reports from October 2018 regarding patient survival and waiting time for liver transplant, shown below, Tables 3, 4A and 4B, unequivocally demonstrate the point. The same level of clinical expertise underlying the superior position of MGTI will underlie the new site at MFSMC.

Table 3. Comparison of Liver Transplant One-Year Patient Survival

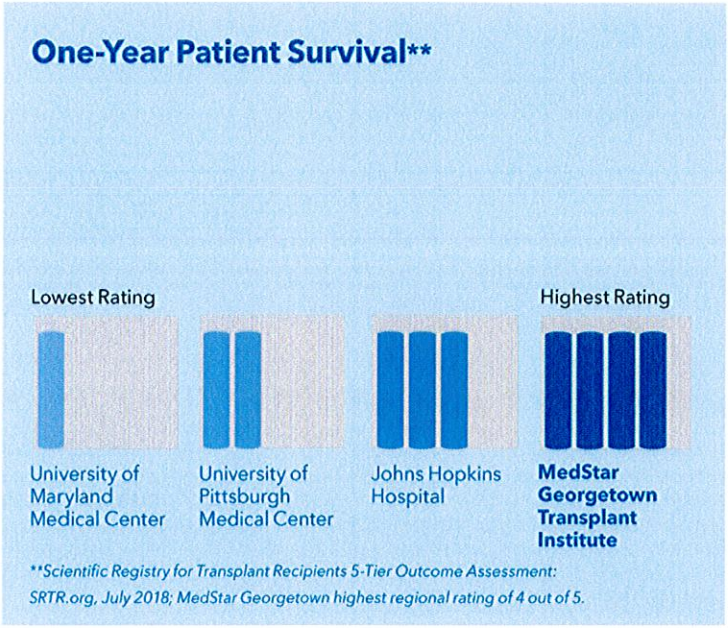


Table 4(A). Comparison of Liver Transplant Median Wait Time

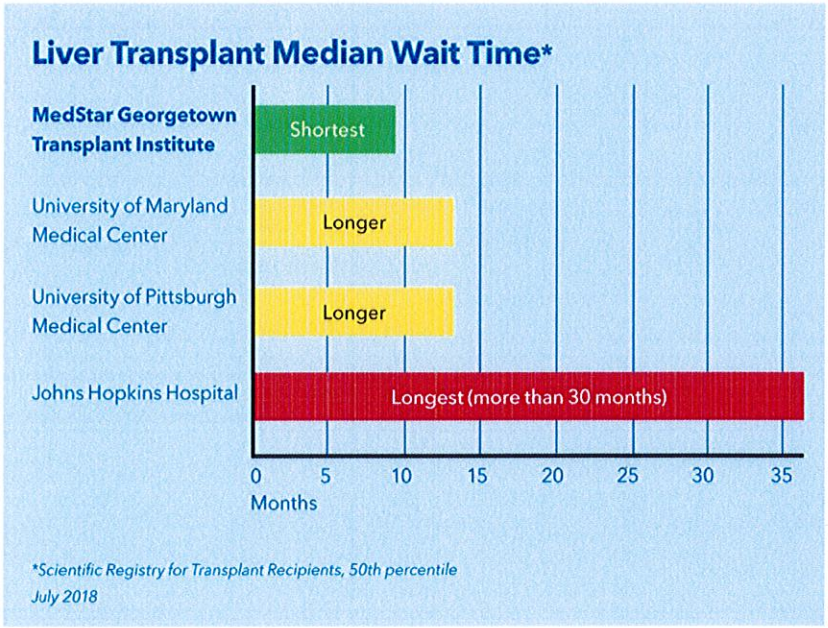
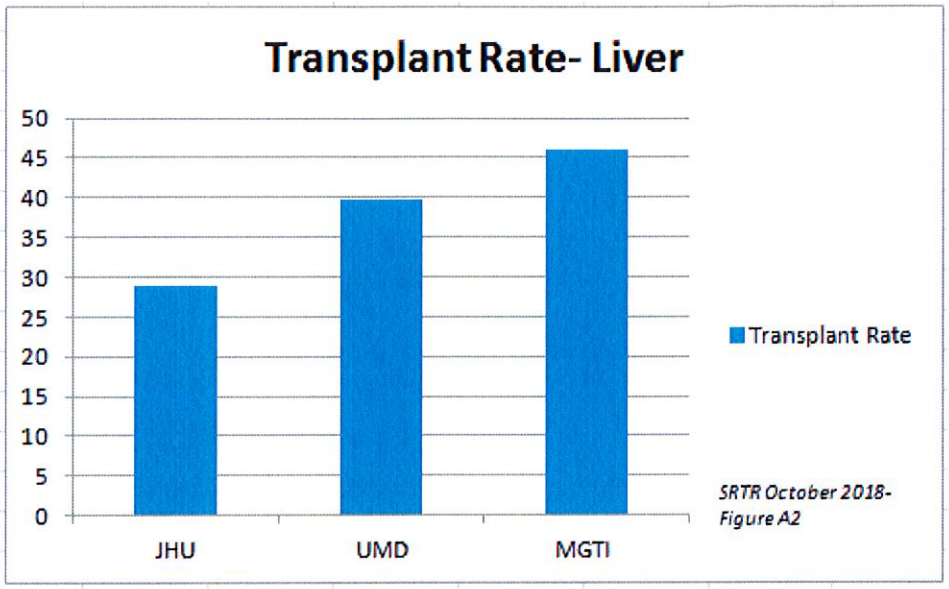


Table 4(B)



Note: Transplant rate in the above table is a metric that indicates movement of patients form the waiting list to transplantation

III. MFSMC'S NEEDS ANALYSIS IS SOUND

UMMC, UM.Cmt. at 5-10, and JHH, Johns Hopkins Hospital comments ("JHH.Cmt.") at 8-17, both claim that MFMSC has not shown the need for a new program and the ability to increase the availability of organs. Both commenters express skepticism regarding the validity of the strategies MedStar will pursue to increase organ availability. Notwithstanding these comments, MFSMC has gone into great detail, including providing data, regarding how it will apply innovative strategies, currently in use in Washington, at a new program in Baltimore. *See* MFSMC Responses to Completeness Questions 2 at 42-55.

A. Active Participation and Support of LLF OPO

UMMC criticizes MFSMC's active participation in and support of the LLF OPO. *See* UM.Cmt. at 6. First, and contrary to UMMC's assertion, MedStar has in no way linked participation with the OPO (LLF DSA) to the existence of an organ transplant program. Rather, MedStar has pointed out that the creation of transplant programs at MFSMC serves to focus greater attention on the identification and retrieval of more organs at MedStar's four Baltimore-area hospitals toward the common goal of increasing organ donation across the area. MedStar believes that more active education and promotion of donor opportunities in the hospital service areas inevitably lead to greater potential for organ donation and that the addition of a transplant program at MFSMC will further increase community awareness of the need for donor organs, with a consequential impact on the available organ pool.

B. Application of Expanded Donor Criteria/Advanced Transplantation Techniques

UMMC emphasizes its utilization of "marginal" organs as being greater than MGTI. *See* UM.Cmt at 6-7. Indeed, the graphics provided by UMMC show that its donor acceptance practices are disproportionate relative to the norm. However, it must be considered that in order to assure the most favorable outcomes possible, it is critical that donor and recipient clinical characteristics be matched carefully. Failing to do so will lead to unsatisfactory recipient outcomes, perhaps the reason behind UMMC's declining outcomes in a context of growing volumes built on a large ratio of marginal donor organs.

MedStar's philosophy of care is to match the donor and recipient characteristics as closely as possible, *i.e.*, MedStar is careful to balance any use of higher risk donors with an expected outcome. For example, an older donor is not suitable for a decades-younger recipient because the healthy younger patient has, potentially, many life-years ahead. Conversely, a less-

than-perfect organ from an older donor might be acceptable for a similarly older recipient who will benefit from an extended life expectancy through liver transplantation. Importantly, a singular focus on volume can affect patient outcome negatively. Both Baltimore programs have had outcomes problems in a context of volume growth:

- As noted in earlier documents, and available as public information, JHH was sanctioned for poor outcomes by CMS and on probation for 3 years; patients were mandated by CMS to be directed to UMMC and MGTI for listing.
- UMMC data in most recent reporting period shows their survival rates at 4th lowest position in the country. UMMC outcomes have deteriorated substantially as volume has increased.

MedStar believes strongly that strict attention must be paid to ensuring long-term favorable outcome in the recipient. Otherwise, the transplant is a failure – for the patient and the program. MGTI outcomes surpass both UMMC and JHH as shown in Table 3.

C. Split Liver and Domino Techniques

Again, both commenters strenuously criticize MFSMC's intended utilization of split liver and domino techniques to increase availability. *See, e.g.* UM.Cmt at 8-9, JHH.Cmt. at 10-12. First, MFMSC disagrees that these procedures are any more "rare" than living donor transplants (LDL). The volumes of split liver transplants performed at MGTI are comparable to those LDL volumes for UMMC, *i.e.,* they are no more rare.

Moreover, the MGTI experience with adult split liver transplants exceeds the regional and national experience as demonstrated by SRTR data below, Table 5. MedStar did not

propose to split livers between two adults, but rather between a child and an adult.[1] Pediatric patients are involved frequently, given their high placement on waiting lists (pediatric patients have highest priority). Because MGTI has a far more robust pediatric program than either JHH or UMMC (a majority of the high MELD pediatric patients in the region are listed at MGTI), it has access to organs for these patients who are highest priority on waiting lists; *i.e.* MGTI will receive organs for pediatric patients that can then be split. With an additional program at MFSMC, MedStar will make efficient and effective use of the larger segment of liver in an adult; these larger segments may otherwise be declined by another program – or discarded.

In other words, when offered a liver for a pediatric patient, MGTI has the opportunity to use the larger lobe in an adult – and this operation is performed most facilely when the surgeons for both pediatric and adult recipients are part of the same program.

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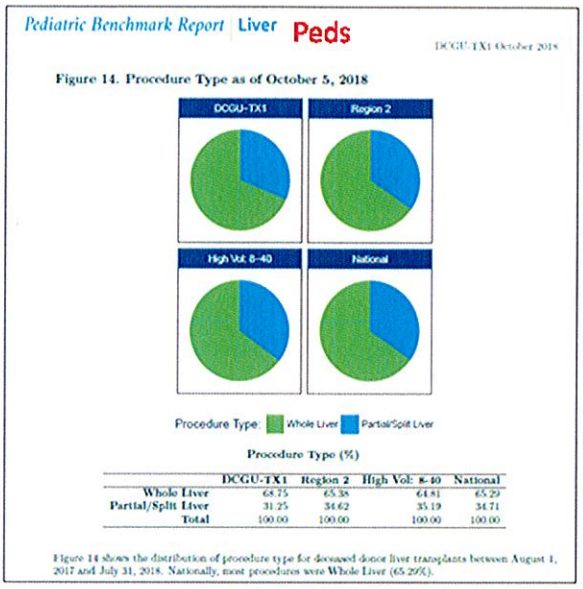
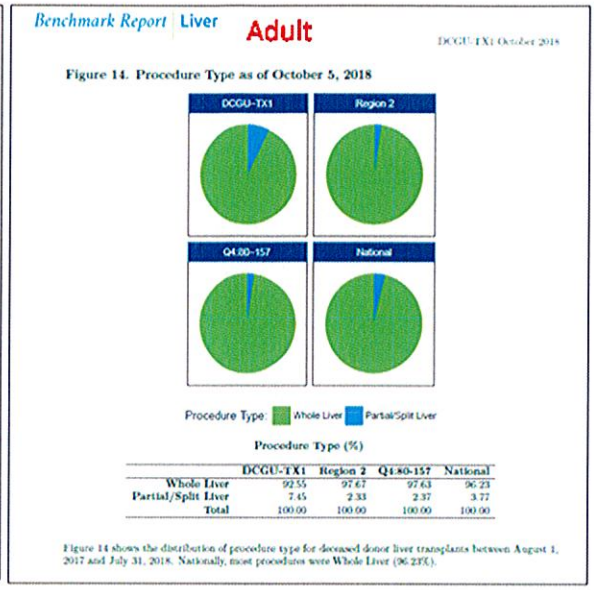
[1] This is another curious argument made by both commenters. *See* UM.Cmt. at 8; JHH.Cmt. at 11. MFSMC never suggested that it would be performing split liver transplants on two adults. Rather, MFSMC's responses to the Commission's first set of completeness questions, MFSMC made the unremarkable observation that the smaller lobe of a split liver typically goes to a "smaller recipient (a child or small adult)." *See* MFSMC Responses to First Set of Completeness Questions at 38. This argument is a classic straw man.

Table 5. Pediatric and Adult Split Liver Transplantation at MGTI

MGTI Split Livers →

Group/ CY	2013	2014	2015	2016	2017	2018 thru 9/30
Adult Whole	72	75	44	78	93	68
Adult Split	4	3	2	4	4	3
Ped Whole	10	17	18	17	19	10
Ped Split	3	5	5	12	7	2
Total DD Livers	89	100	69	111	123	83





Source: *Secure release UNOS Benchmark Report for DCGU-TX1 October 2018.*

D. Offering Living Donor Transplants

MedStar stated that it would not perform living donor surgery initially - not that it would *never* perform these procedures (JHH likewise stated that initially it would not perform living donor liver transplants in its Suburban application). *See* JHH Suburban Hospital Application at 45, 99. Given the known higher risk of these operations (frequently to the donor), this amounts to prudent judgment on the part of MedStar.

According to UMMC, "UMMC has the second best outcomes nationally among moderate to high volume programs for living donor patient and graft survival." UM.Cmt. at 9. With that said, and as shown below in Table 6, MGTI's survival during the most recent comparable period

when both programs were performing living donor procedures was *perfect,* albeit with smaller numbers, again emphasizing MedStar's thoughtful approach to donor and recipient selection in every category of transplant procedure performed. MedStar intends to resume living donor transplantation at MGTI in calendar year 2019.

Table 6. Comparison of Living Donor Transplant Survival

SRTR SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

University of Maryland Medical System
Center Code: MDUM
Transplant Program (Organ): Liver
Release Date: July 6, 2017
Based on Data Available: April 30, 2017

SRTR Program-Specific Report
Feedback?: SRTR@SRTR.org
1.877.970.SRTR (7787)
http://www.srtr.org

C. Transplant Information

Table C6L. Adult (18+) 1-year survival with a functioning living donor graft
Single organ transplants performed between 01/01/2014 and 06/30/2016
Deaths and retransplants are considered graft failures

	MDUM	U.S.
Number of transplants evaluated	27	648
Estimated probability of surviving with a functioning graft at 1 year (unadjusted for patient and donor characteristics)	92.59%	87.75%
Expected probability of surviving with a functioning graft at 1 year (adjusted for patient and donor characteristics)	88.13%	--
Number of observed graft failures (including deaths) during the first year after transplant	2	76
Number of expected graft failures (including deaths) during the first year after transplant	3.11	76
Estimated hazard ratio*	0.78	1.00

SRTR SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

Johns Hopkins Hospital
Center Code: MDJH
Transplant Program (Organ): Liver
Release Date: July 6, 2017
Based on Data Available: April 30, 2017

SRTR Program-Specific Rep
Feedback?: SRTR@SRTR.o
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C. Transplant Information

Table C6L. Adult (18+) 1-year survival with a functioning living donor graft
Single organ transplants performed between 01/01/2014 and 06/30/2016
Deaths and retransplants are considered graft failures

	MDJH	U.S.
Number of transplants evaluated	19	648
Estimated probability of surviving with a functioning graft at 1 year (unadjusted for patient and donor characteristics)	78.60%	87.75%
Expected probability of surviving with a functioning graft at 1 year (adjusted for patient and donor characteristics)	87.07%	--
Number of observed graft failures (including deaths) during the first year after transplant	4	76
Number of expected graft failures (including deaths) during the first year after transplant	2.42	76
Estimated hazard ratio*	1.36	1.00
95% credible interval for the hazard ratio**	[0.50, 2.64]	--

SRTR SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

Georgetown University Medical Center
Center Code: DCGU
Transplant Program (Organ): Liver
Release Date: July 6, 2017
Based on Data Available: April 30, 2017

SRTR Program-Specific Repo
Feedback?: SRTR@SRTR.or
1.877.970.SRTR (7787)
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Single organ transplants performed between 01/01/2014 and 06/30/2016
Deaths and retransplants are considered graft failures

	DCGU	U.S.
Number of transplants evaluated	6	648
Estimated probability of surviving with a functioning graft at 1 year (unadjusted for patient and donor characteristics)	100.00%	87.75%
Expected probability of surviving with a functioning graft at 1 year (adjusted for patient and donor characteristics)	89.41%	--
Number of observed graft failures (including deaths) during the first year after transplant	0	76
Number of expected graft failures (including deaths) during the first year after transplant	0.64	76
Estimated hazard ratio*	0.76	1.00
95% credible interval for the hazard ratio**	[0.09, 2.11]	--

E. Strategies To Increase Organ Supply

The application and completeness responses indeed quantify the projected increase in the supply of organs and provide a solid basis for such a projection. *See, e.g.,* MFSMC's Responses to Second Set of Completeness Questions at 16-17 (estimating the addition to the supply of organs in year 1 of program based on MGTI's experience). The commenters may disagree with the projection or question MFSMC's ability to achieve this volume, but it cannot be said that it is based on "general statements" or that MFSMC makes no effort to predict the impact of these various factors. Also, UMMC cannot demonstrate that there is a potential for erosion of quality care or other risks of adding a new program, UM.Cmt at 5, given MGTI's outcomes data and in view of the fact that MGTI clinicians will be providing on-site clinical expertise at MFSMC. Again, this is not a "net-new start-up" program in that it leverages the clinical proficiency and operational knowledge from the existing, high-quality, highly efficient MedStar program in Washington, D.C.[2]

In summary, MedStar has adequately and comprehensively responded to the SHP review standard regarding need. Finally, historic utilization cannot portend the future definitively because of the organ availability issue that is inherent in the nature of transplantation services.

IV. MFSMC's APPLICATION IS CONSISTENT WITH REVIEW STANDARD 10.24.15.04B(5)-- IMPACT

JHH complains that MFMSC's impact analysis "falls short." *See* JHH.Cmt. at 23-24. MFSMC disagrees.

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[2] UMMC' footnote on p. 5 is not persuasive. That an increase in competition **may** have both positive and negative consequences is a heavily qualified statement that does not lend support to UMMC' argument. Again, one study found a greater number of transplant centers was associated with a greater number of transplants, but greater competition was associated with higher patient mortality and worse graft outcomes. The argument also runs counter to the Hopkins arguments in its Suburban Hospital application.

Assessment of UMMC and JHH volumes over the last two years (provided in their comments) shows that there has been no decrement – rather a growth in volume over the time frame of the entry of the MFSMC program for liver diseases. Twenty transplant procedures have been performed at MGTI imported from the Baltimore region since the inception of the Center for Digestive Diseases at MFSMC.

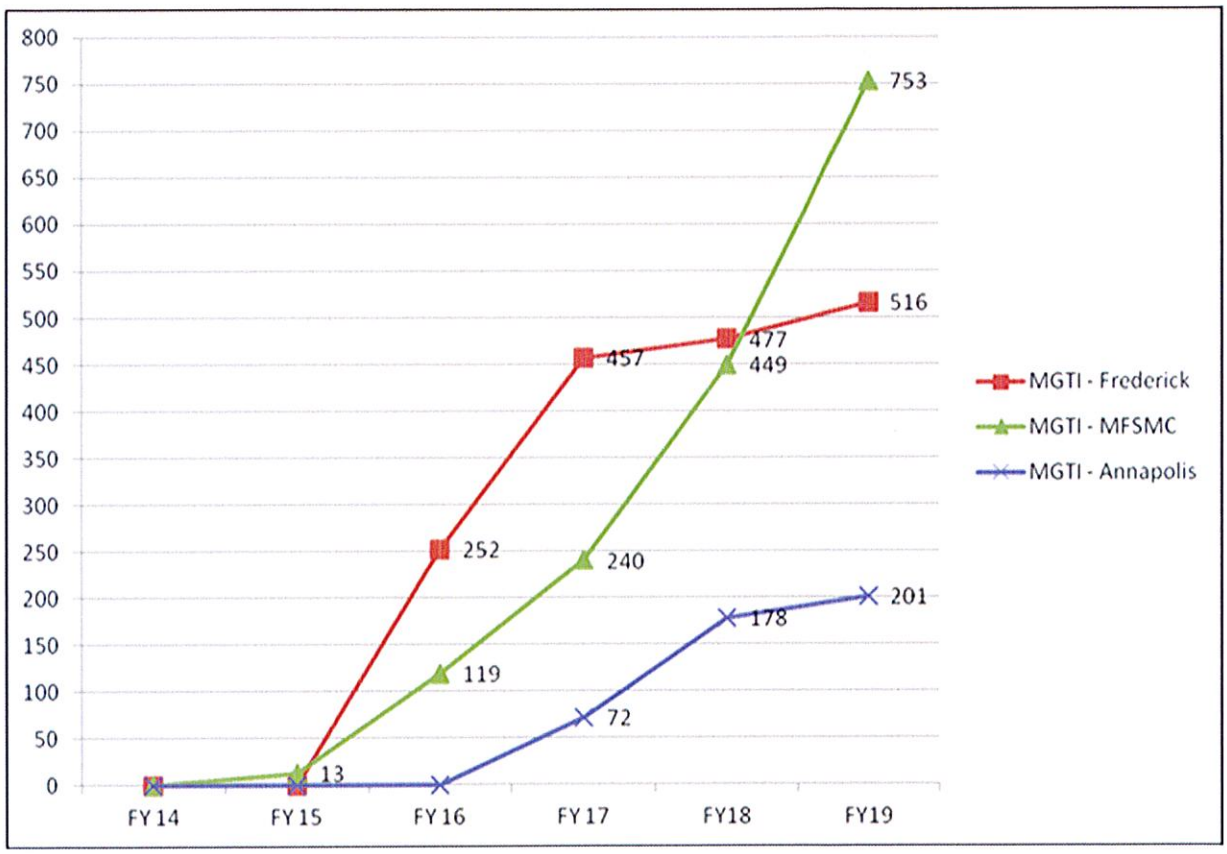
MFSMC has provided sufficient information to satisfy the MHCC that the proposed program will not interfere with the ability of JHH or UMMC to maintain volumes above the SHP's threshold volumes, that it will not have an unwarranted adverse impact on the financial viability of JHH or UMMC's liver transplant services, and that it will not have an unwarranted adverse impact on patient access to liver transplant services. The MHCC has been given no information suggesting that MFSMC's application is not consistent with the requirements of this standard.

V. MFSMC WILL MEET MINIMUM VOLUME REQUIREMENTS

UMMC suggests that MFSMC's referral volume from the Baltimore area for liver transplant cannot support the proposed program. UMMC specifically asserts that MFSMC's ability to comply with the minimum volume standard is 'undermined' by MFSMC's volume assumptions and by the expected new liver allocation policy. UM.Cmt. at 10. First, UMMC has said nothing about how the proposed new allocation policy will affect volume assumptions. Second, MFSMC's application has clearly shown how the proposed program will be consistent with the requirements of this standard; MFSMC has shown a pattern of growth in referral visit volume, transplant evaluation volume and transplant waitlist volume, all of which continue to result in an increase in transplant activity from patients presenting to the MFSMC program. Hence, MFSMC is confident it will meet and continue to meet the minimum volume standards.

The following graph, Table 7, illustrates the existing trend in new patient referrals, evaluations, listings and transplants. Clearly, the referral community and patients are supportive of the entry of the MedStar program expertise to the Baltimore area.

Table 7. Trends in Patient Referrals, Evaluations, Listings and Transplants at MGTI from Selected MedStar Outreach Sights Located in the Baltimore Region



Source: Internal MGTI volume. FY 19 is projected

MedStar is reaching out to the population in the Baltimore area in ways that UMMC and JHH have failed to do, through seven outreach sites, four of which are located in the Baltimore region. Graphical data already provided (*see* Tables 1 and 2) show a dramatic increase in patients referred to these sites and listed for transplantation services.

Again, MFSMC does not propose to maintain a "low volume" program. MFSMC's conservative volume projections were structured based on a "start-up" trajectory in order to ensure clinical program integrity until such time as Medicare approval is obtained and managed care contracts can be negotiated for center of excellence participation.

VI. BARRIERS TO ACCESS

UMMC seems to understand that compliance with this standard is not required. UM.Cmt. at 14. However, UMMC constructs the argument that because MFSMC *mentions* access issues in the application, this means that the application must satisfy the access standard. *Id.* JHH likewise claims that MFSMC cannot meet the standard. *See* JHH.Cmt. at 18 ("it is not enough for an applicant to suggest ways to improve access."). JHH goes on to claim that there is no travel barrier for residents of the DSA, no barrier to access for multi-organ transplant patients, no way to resolve any national organ availability barrier, and no limitations to access for minority patients in the DSA. *Id.* at 18-22.

MFSMC did not claim barriers to access as a justification for the need for additional services. MFSMC did, however, address need under review standard B(1). Although MFSMC mentioned some specific issues in relation to other review criteria, *e.g.,* minority patients and MedStar-insured patients living locally, MFSMC stated clearly that access *per se* is not applicable to its application.

That said, MFSMC wishes to address two misleading aspects of the comments on barriers. First, with respect to minorities, data from the established acceptable source, the SRTR database, that were provided in the application (and again in the Completeness Question responses) show clearly that MGTI evaluates, lists and transplants more minority patients - as a percentage - than either center in Baltimore. These data, (see Tables 8-10) are indisputable.

Table 8. Percentage of Minority Liver Patients Listed and Transplanted by Center

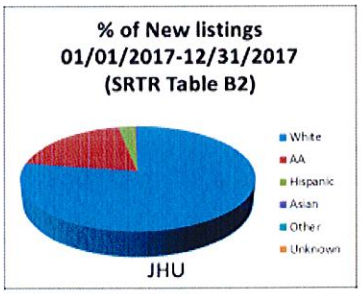
PERCENTAGE MINORITY TRANSPLANTS: Comparison 2018

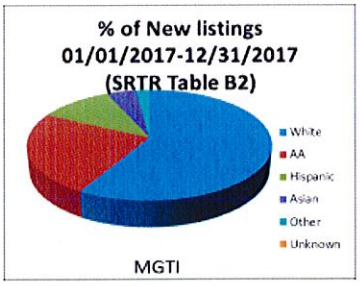
	MGTI- Liver	
	% of New listings 01/01/2017-12/31/2017 (SRTR Table B2)	% of Transplants 01/01/2017-12/31/2017 (SRTR Table C1D)
White	58.3	57.7
AA	24.1	21.1
Hispanic	11.1	14.6
Asian	4.6	3.3
Other	1.9	3.3
Unknown	0	0

	JHU- Liver	
	% of New listings 01/01/2017-12/31/2017 (SRTR Table B2)	% of Transplants 01/01/2017-12/31/2017 (SRTR Table C1D)
White	77.1	72.2
AA	19.3	22.7
Hispanic	2.8	4.1
Asian	0.3	1
Other	0	0
Unknown	0	0

	UMD- Liver	
	% of New listings 01/01/2017-12/31/2017 (SRTR Table B2)	% of Transplants 01/01/2017-12/31/2017 SRTR Table C1D
White	76.9	76.2
AA	16.5	19.2
Hispanic	4.3	3.3
Asian	2	1.7
Other	0.4	0.7
Unknown	0	0

Table 9. Percentage of Minority Liver Patients Listed by Center





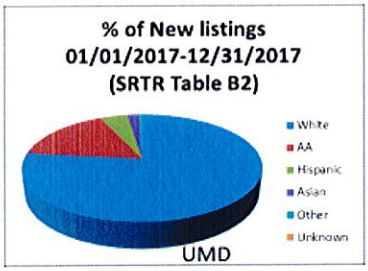


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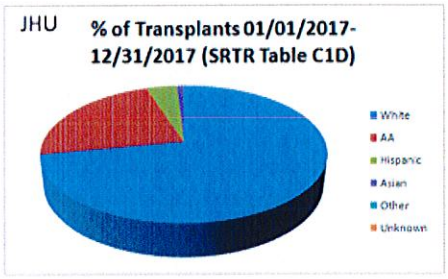
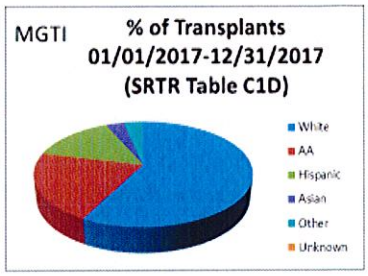
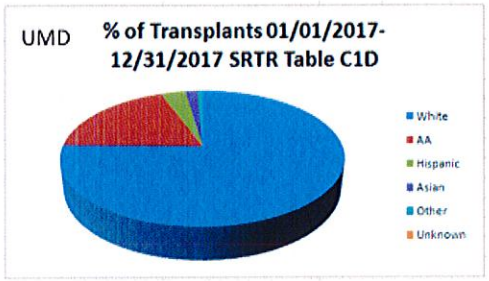
Table 10. Percentage of Minority Liver Patients Transplanted by Center







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Second, with respect to travel times and geographical access, MFSMC does not dispute claims that Baltimore area patients have geographical access to transplantation services in Baltimore City. However, repeated suggestions that these programs' performances are superior to MGTI's program is misleading. Recent SRTR data demonstrate that Baltimore program outcomes are deteriorating overall. *See* Tables 3, 4A and 4B. While UMMC offers a rating from CareChex, one of the many marketed rating systems that sell their products to healthcare systems, the SRTR is the standard, governmentally mandated database that is utilized nationally to rate and rank transplantation programs.

VII. COST EFFECTIVENESS

Although UMMC claims that MFSMC underestimates the cost of its program, and that staffing projections are insufficient to meet requirements, UM.Cmt. at 20-22, MedStar stands by its staffing and cost analysis, accurately based on the needed incremental staffing for the

proposed programs. MedStar will certainly meet UNOS requirements, but will use central functions already in place at MGTI in order to avoid duplication, *e.g.*, data management and reporting, administrative management functions until such time as incremental volume growth demands that additional staff and other resources supplement the initial configuration. All required physician and ancillary staff will be on-site at MFSMC.

UMMC also claims that MedStar improperly compares the cost effectiveness of its program to UMMC and JHH rather than to MGTI. MedStar compares the charges at MFSMC to the existing Baltimore programs because this is the valid comparison if a program is to be operationalized at MFSMC. MGTI charges are irrelevant in the context of the State of Maryland Cost Review Commission. By establishing a new transplantation program in Baltimore for those Maryland patients now being referred to MedStar, the MHCC maintains those patients in the State – and at lower cost than if either (1) they travelled to Washington, or (2) they were transplanted at one of the Baltimore academic centers. As reported earlier, MFSMC's costs are lower than either academic center in Baltimore.

VIII. PROPOSED CHANGES TO ALLOCATION POLICY

UMMC's comments repeat the arguments raised in its previously filed motion to stay. MFSMC believes its position on this issue was adequately stated in its response to the UMMC motion: the policy has not been finalized, reviewed or implemented, and any statements regarding its impact are conjecture, at best, and cannot be validated.

IX. CONCLUSION

For all the reasons stated herein, as well as those in its Application and prior responses to the Commission, MFSMC respectfully requests that the CON be issued.

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November 20, 2018

Affirmation

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

11.19.18

(date)

Anne P. Weiland
Vice President - Surgery, Orthopaedics
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CERTIFICATE OF SERVICE

I hereby certify that on November 20, 2018, a copy of the foregoing Response was served by e-mail and first class mail on:

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