

BEFORE THE MARYLAND HEALTH CARE COMMISSION

IN THE MATTER OF)
)
)
)
APPLICATION OF MEDSTAR)
FRANKLIN SQUARE MEDICAL)
CENTER FOR A KIDNEY)
TRANSPLANT SERVICE)
)
Docket No. 17-03-2405)
_____)

**MEDSTAR FRANKLIN SQUARE MEDICAL CENTER’S RESPONSE TO THE
INTERESTED PARTY COMMENTS of UMMC and JHH
Kidney 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. MFSMC’S PROPOSAL IS CONSISTENT WITH GENERAL SHP OBJECTIVES

UMMC claims that MedStar’s proposed program is inconsistent with the stated goal of SHP - to have a limited number of high volume programs. *See* UMMC Comments (“UM.Cmt.”) at 2-4. UMMC suggests as well that this type of regionalization was the result of the recent update to the SHP. *Id.* JHH echoes this viewpoint when it argues that a “small volume program” is

inconsistent with the SHP policy on regionalization (JHH Comments (“JHH.Cmt.”) at 22), and moreover that there is no need for more than two programs in the region.

First, the longstanding policy of this and other SHP chapters regarding kidney 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.

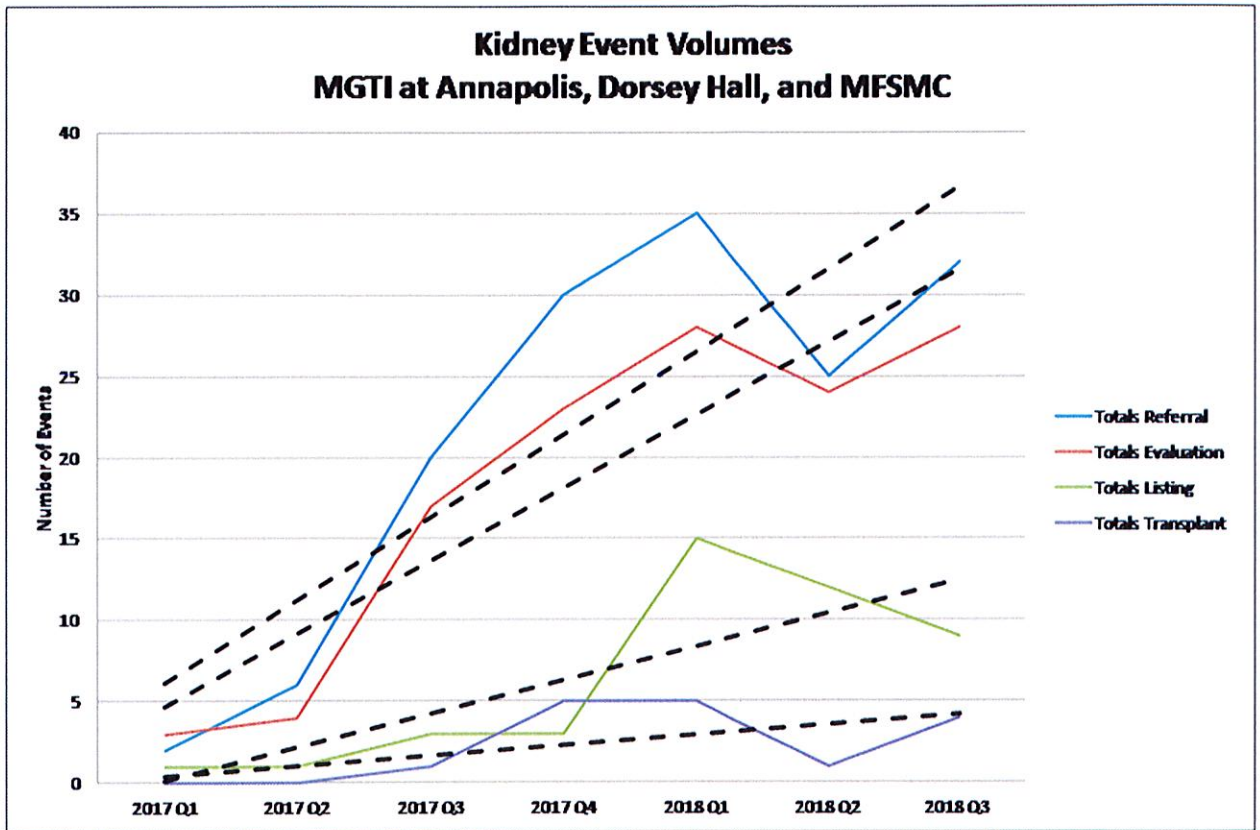
In addition, the policy goals in the SHP do not state that “two programs” is the appropriate number of transplant programs for a given region. When UMMC notes the SHP goal of a limited number of general hospital programs, it overlooks the section of the SHP that specifically provides the basis for the addition of another program in the state: the ability to enhance the supply of organs. It also ignores the SHP’s standards for the minimum volume necessary to approve a new program. This standard implicitly acknowledges that at least initially a program may perform at a lower volume. 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.

The fact is that large urban areas near this region have more than just two kidney transplant programs. New York City zip code 10023 has seven (adult kidney transplant programs within 50 miles), while Philadelphia zip code 19104 has six. In addition, both of these areas have separate, additional pediatric transplant facilities. Thus, there is no “rule” that a single region may have only two, or any other number of transplant programs. Moreover, MFSMC has demonstrated that a new program would support growth in the organ pool while maintaining an exceptional quality standard in order to contribute effectively to the region’s needs. MedStar has also explained that it has no intention of maintaining a “low volume” program but rather projects continued growth after an initial judicious start-up period.

The interested parties’ criticism of the MFSMC proposal as a low volume program is invalid. The MFSMC program will be built on the platform of the higher volume MedStar program in Washington, comprised of a very experienced team of professionals at a CMS-compliance high volume program with superior patient and graft outcome statistics. MedStar does not propose to operate a “low volume” program. Rather, MedStar’s *conservative volume* projections in the first three years outline a program initiation trajectory, *i.e.* a plan based on a combination of appropriate 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 in growth is entirely reasonable when one observes the pattern of referral/evaluation/listing/transplantation that has been demonstrated during the period following the establishment of MedStar outreach sites. See Table 1 below

Table 1. Trends in Patient Referrals, Evaluations, Listings and Transplants at MGTI from Selected Medstar Outreach Sights



Source: MedStar internal data

MedStar’s transplant program will build volume judiciously over several years. In fact, short of diverting volumes from other programs, this would be the only way, and preferred way, to expand services to the community.

III. MFSMC HAS ADEQUATELY ADDRESSED THE NEED STANDARD

Both JHH, JHH.Cmt at 8-18, and UMMC, UM.Cmt. at 5-10, assert that MFSMC has not shown the need for a new program. They claim that MFSMC relies only on generalized statements about its expertise to support its assertion that MedStar will be able to increase the

availability of organs in Maryland. They further argue that MFSMC's description of the strategies it will employ to increase the use and supply of donor organs does not quantify their impacts. And, according to the interested parties, none of these strategies will increase organ availability in Maryland. *See, e.g.*, UM.Cmt. at 5-6; JHH.Cmt. at 11-12. MFSMC addresses these points below.

A. Living Donor Transplants

UMMC argues that MFSMC's application contradicts the comments MedStar made in opposing GWUH's recent CON Application in the District of Columbia. In particular, UMMC cites MedStar's comment that a new program cannot "somehow generate a sudden spike in organ donations." UM.Cmt. at 6. MedStar stands by its comments regarding the GWU CON application. The increase in kidney transplant volume across the country, including programs in the WRTC area, was wholly attributable to changes in kidney allocation policy implemented at precisely the time that the GWU program was initiated in 2016. In fact, the temporary influx in the number of transplants performed at GWU, attributable to the policy change, has not been sustained. GWU transplant rates are essentially flat; the program has not accomplished its major purported goals of increasing minority donation and substantially augmenting the number of living donors. See chart below, Table 2, of GWU kidney transplant volume since program inception.

Table 2. Kidney Transplants by Donor Type, George Washington University Hospital

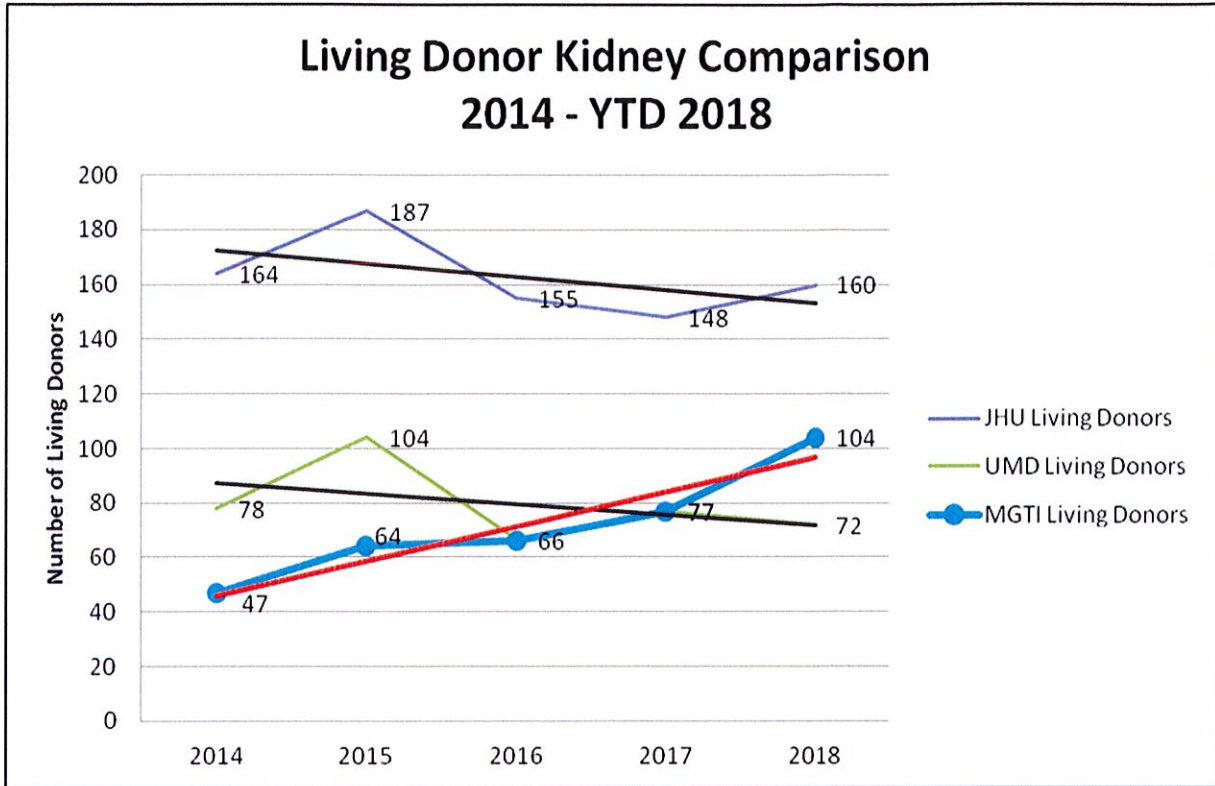
Transplants by Donor Type
US Kidney Transplants Performed
Center: DCGW- TX1 George Washington University Hospital
Based on OPTN data as of October 21, 2018

	2018 YTD	2017	2016	2015	1996	1995
All Donor Types	40	48	55	31	1	1
Deceased Donor	27	30	41	23	1	1
Living Donor	13	18	14	8	0	0

Source: MedStar internal data

Both commenters criticize MFSMC’s projections regarding the generation of living donors. See UM.Cmt. at 6-7; JHH.Cmt. at 11-12. But the trajectory of these procedures performed at MGTI – a program that will extend to MFSMC – is trending positive, versus the Baltimore programs shown in the graphic below (Table 3). Note that the trend in living donor transplants is declining at both Baltimore programs. From their highs in 2015, they are down -14.44% (JHH) and -30.77% (UMMC) respectively, while the MGTI program continues to increase – over the same time frame living donor transplants have increased by +62.5%. See graphic.

Table 3. Trends in Living Donor Kidney Transplants, 2014-2018



Source: SRTR Data

B. Active participation in, and support of, the LLF OPO.

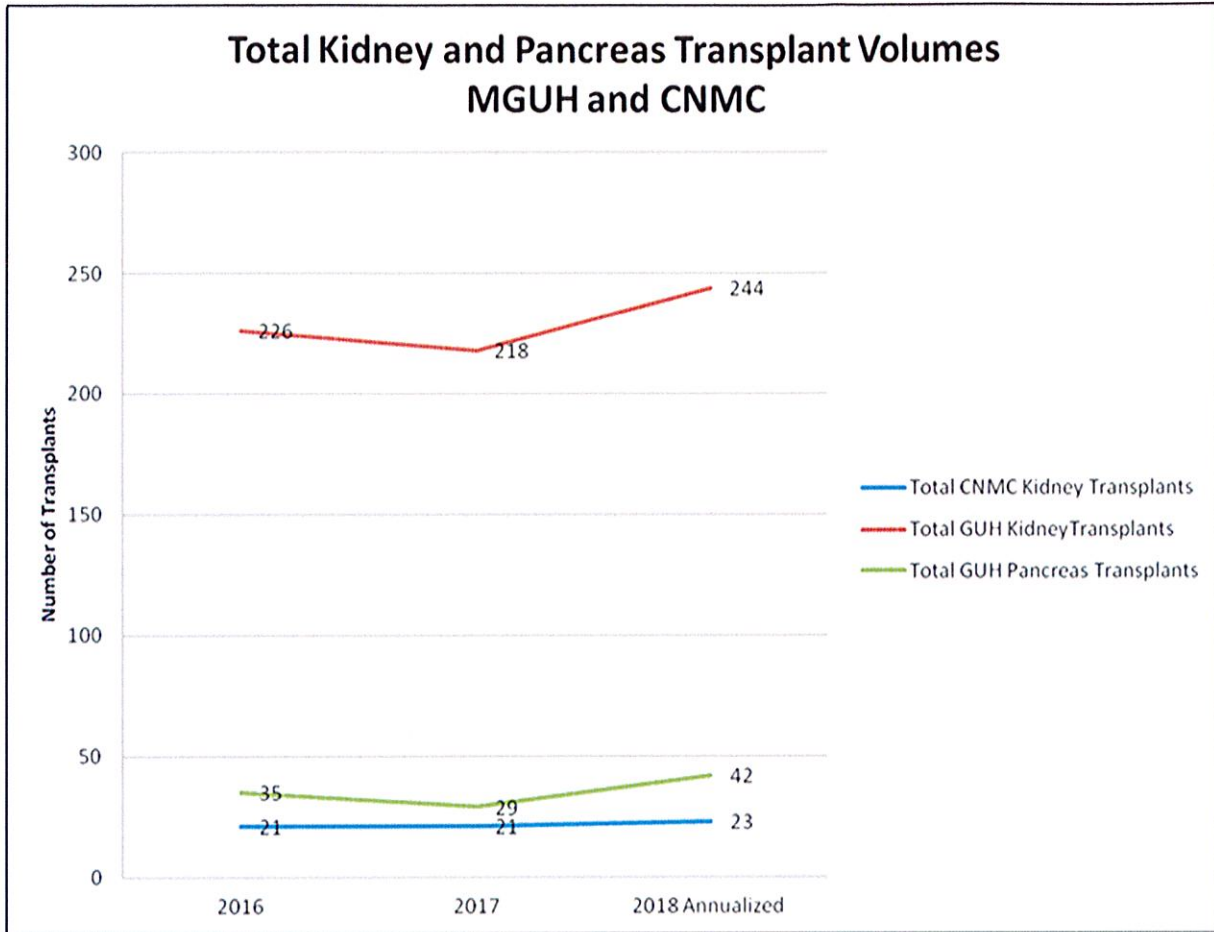
MFSMC has not linked participation with the OPO (LLF DSA) to the inception of a new organ transplant program. Rather, MFSMC has pointed out that a new program at MFSMC serves to focus greater attention on the identification and retrieval of more organs at MedStar’s four Baltimore-area hospitals -- serving the common goal of increasing organ donation across the area. MFSMC believes that more active education and promotion of donor opportunities in the hospital service area inevitably encourages organ donation, and feels strongly that the addition of a transplant program at MFSMC will further increase community awareness of the need for donor organs and, in so doing, have an impact on the available organ pool.

C. MGTI Transplants Allegedly Declining

UMMC states that MedStar’s comments in connection with the Suburban Hospital CON review indicate that MGTI kidney transplant volume has been declining since 2016. UM.Cmt. at 7. This statement is disingenuous. The chart in that document actually shows that there was a volume surge following the allocation policy change effective in 2016. (see discussion of policy change at p. 4). The two following years reflected the volume stabilization occurring subsequent to that change. In 2018, MedStar volume is significantly higher than before the change and continues to grow.

The following graphic shows the most current volumes of kidney and pancreas transplants for MGTI and Children’s National Medical Center (“CNMC”) -- where MGTI performs all transplant procedures projected through calendar year 2018. MedStar volumes continue on the rise. The increase in pancreas transplantation volume is impressive also – a near 45% increase year over year 2017-18. Pancreas transplantation is a definitive treatment for diabetes, one of the major causes of kidney disease and need for kidney transplantation. MedStar’s progress in this area, which will be expanded to MFSMC, is a huge leap forward in the management of kidney disease and a contribution to the field.

Table 4. Trends in Total Kidney and Pancreas Transplants, 2016-2018



Source: SRTR data

D. National Kidney Registry

JHH points out that both it and UMMC already participate in the National Kidney Registry (“NKR”). JHH.Cmt. at 13. Actually, because UMMC failed to pay its monetary and organ debts it was sued by and recently disenrolled from the NKR. UMMC has since repaid the monetary debt but has yet to repay the “organ debt” and as noted, performed *zero* NKR procedures over last 12 months because of the debt owed. See Table 5 below:

Table 5. Comparison of National Kidney Registry Transplants

Rank	Center Name	State	Implied Transplant Wait Time	NKPT Transplants Last 12 mo.	NKPT Total Transplants	Unmatched Pairs Enrolled	Antibody Desensitization	Non-Steroid Protocol	Donor Shield	Advanced Donation	Remote Donation Network
			sort	sort	sort	sort	sort	sort	sort	sort	sort
1	UCSF Medical Center	CA	1	56	201	3	YES	YES	--	YES	YES
2	UW Health Transplant Program	WI	3	46	168	12	YES	YES	--	YES	YES
3	MedStar Georgetown University Hospital	DC	1	43	96	5	YES	YES	YES	YES	YES
4	NewYork-Presbyterian/Weill Cornell	NY	0	37	213	1	YES	YES	YES	YES	YES
5	UCLA Medical Center	CA	2	37	271	6	YES	YES	--	YES	YES
6	University of Colorado Hospital/UCHealth	CO	0	32	56	0	YES	YES	--	YES	YES
7	University of Pennsylvania Hospital	PA	2	27	75	4	--	YES	--	YES	YES
8	University of Minnesota Medical Center	MN	0	24	67	1	YES	YES	--	YES	YES
9	Johns Hopkins Hospital	MD	3	21	72	6	YES	--	--	YES	--
10	Emory Transplant Center	GA	5	20	131	9	--	--	YES	YES	YES
11	Massachusetts General Hospital	MA	3	20	56	5	YES	YES	--	YES	YES
12	Saint Barnabas Medical Center	NJ	4	17	116	5	YES	YES	--	YES	--
13	Mayo Clinic Rochester	MIN	4	16	25	6	YES	YES	--	YES	YES
14	Legacy Good Samaritan Medical Center, T...	OR	1	15	29	1	YES	--	--	YES	YES
15	Brigham and Women's Hospital Living Don...	MA	1	12	34	0	YES	YES	--	YES	YES
Rank Continued											
60	Hartford Hospital Transplant Center	CT	--	1	16	0	YES	--	--	YES	YES
61	HIQM	HI	--	1	2	1	--	--	--	--	--
62	Medical University of South Carolina	SC	--	1	43	9	--	--	--	YES	--
63	OSF Saint Francis Medical Center	IL	--	1	4	3	--	--	--	--	--
64	Starzl Transplant Institute (UPMC)	PA	--	1	40	3	YES	YES	--	--	--
65	University of Virginia Transplant Center	VA	--	1	10	2	YES	--	--	YES	--
66	Virginia Transplant Center	VA	--	1	30	0	--	--	--	YES	YES
67	Children's Hospital of Pittsburgh	PA	--	0	1	0	--	--	--	--	--
68	Christiana Care Health System	DE	--	0	8	1	--	YES	--	YES	--
69	Crozer-Chester Medical Center	PA	--	0	1	0	YES	YES	--	--	--
70	Dartmouth-Hitchcock MC	NH	--	0	11	0	YES	YES	--	--	--
71	Lucile Packard Children's Hospital	CA	--	0	1	0	YES	YES	--	--	--
72	Mayo Clinic Arizona	AZ	--	0	2	0	--	YES	--	YES	--
73	North Shore University Hospital Transplant	NY	--	0	0	0	YES	YES	--	--	--
74	Rady Children's Hospital San Diego	CA	--	0	0	0	YES	--	--	--	--
75	Riverside Community Hospital	CA	--	0	1	0	YES	--	--	--	--
76	Seattle Childrens	WA	--	0	1	0	YES	YES	--	--	--
77	Temple University Hospital	PA	--	0	1	0	YES	YES	--	--	--
78	University Hospitals Transplant Institute	OH	--	0	0	1	--	YES	--	YES	YES
79	University North Carolina Hospitals	NC	--	0	5	2	--	YES	--	YES	--
80	University of Maryland Medical Center	MD	--	0	79	0	YES	YES	--	--	--

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E. National Consensus Conference

Regarding the conference, JHH states that “beyond the location of the conference, there is no connection to the LLF DSA, and that this conference has nothing to do with whether a third kidney transplant program is needed in the LLF DSA.” JHH.Cmt. at 15.

MFSMC finds this response curious. The conference was about increasing organ supply through scrutinizing innovative approaches to optimizing organ utilization, lessening organ discards and more. Neither existing Baltimore program was represented, despite the value that the conference represented for the transplant community at large.

F. Benefits of Future Research

JHH questions specific kidney research underway at MedStar Georgetown’s Center for Translational Transplantation Medicine (“CTTM”). JHH.Cmt. at 16. In fact, as shown in Table 6 below, CTTM has a robust portfolio of ongoing clinical research. All of the following studies are being led by MGTI faculty:

Table 6. Studies Relevant to Kidney Transplantation

IRB Number	Sponsor	Title	Principal Investigator
2015-0830	Shire	A Randomized double-blind placebo controlled study to evaluate the efficacy and safety of CINRYZE (C1 esterase inhibitor [human]) for the treatment of acute antibody-mediated rejection in kidney transplant patients	Alexander Gilbert, MD
2015-1113	Johns Hopkins	Wellness and Health Outcomes of Live Donors: A Multi-Center Longitudinal Follow-up of Living Kidney Donors (WHOLE DONOR)	Jennifer Verbesey, MD
2016-0266	NIAID through UCSF (U 01)	Impact of CCR5 Blockade in HIV+ Kidney Transplant Recipients	Matthew Cooper, MD
2015-0850	Angion Biomedica corp	A Multicenter, Prospective, Double-Blind, Randomized, Placebo-Controlled, Phase 3 Study of BB3 to Reduce the Severity of Delayed Graft Function in Recipients of a Deceased Donor Kidney	Matthew Cooper, MD
2018-0057	NIAID through Johns Hopkins	HOPE in Action Prospective Multicenter, clinical trial of HIV+ deceased donor kidney transplants for HIV+ recipients	Alexander Gilbert, MD
2017-1362	Medeor Therapeutics, Inc	A Phase 3 Prospective, Randomized, Multi-Center, Open-Label, Controlled Trial to Assess the Efficacy and Safety of Cellular Immunotherapy with MDR-101 for Induction of Immune Tolerance in Recipients of HLA-Matched, Living Donor Kidney Transplants	Matthew Cooper, MD
2018-0010	CareDx, Inc.	Evaluation of Patient Outcomes from the Kidney Allograft Outcomes AlloSure Registry (KOAR)	Matthew Cooper, MD
2014-0244	Bristol-Myers Squibb	Evaluation of Acute Rejection Rates in de novo Renal Transplant Recipients Following Thymoglobulin Induction, CNI-free, Nulojix (belatacept) - based Immunosuppression	Alexander Gilbert, MD
2016-0161	Quark Pharmaceuticals	A Phase 3, Randomized, Double-blind, Placebo Controlled Study to Evaluate the Efficacy and Safety of QPI-1002 for Prevention of Delayed Graft Function in Recipients of a Donation After Brain Death Older Donor Kidney Transplant	Matthew Cooper, MD
2016-0654	Johns Hopkins	A Pilot Prospective Clinical Trial of HIV+ Recipients of HIV+ Deceased Donor Kidney Transplants	Alexander Gilbert, MD
2016-0722	Astellas	Astagraf XL® to Understand the Impact of Immunosuppression (Astound)	Matthew Cooper, MD
2018-0064	Qiagen, Inc.	Development of the QuantiFERON®-Cytomegalovirus and QuantiFERON®-Monitor assays using blood from solid organ transplant recipients (Pilot)	Matthew Cooper, MD
2018-1125	Qiagen, Inc.	Clinical Evaluation of the QuantiFERON CMV Assay (Multicenter)	Matthew Cooper, MD
2018-0681	Hookipa Biotech AG	A Randomized, Placebo-Controlled, Phase 2 Study of HB-101, a Bivalent Cytomegalovirus (CMV) Vaccine, in CMV-Negative Recipient (R-) Patients Awaiting Kidney Transplantation from CMV-Positive Donors (D+)	Matthew Cooper, MD
2018-1127	NIH	Apo11 Long-Term Kidney Transplantation Outcomes Network (APOLLO)	Alexander Gilbert, MD

Source: CTTM

G. Simultaneous Liver Kidney Transplantation (“SLK”)

JHH complains that MFSMC has failed to explain whether it will perform SLK transplantation at MFSMC, and that it failed to quantify the procedures being performed at JHH and UMMC. JHH.Cmt. at 7. Actually, MedStar explained in detail the clinical advantages of combined liver kidney transplantation as a primary basis for why application was made for both kidney and liver transplant programs at MFSMC. See Application at 6-7, First Responses to Completeness Questions at 3-6. MedStar performs an equivalent number of these procedures relative to the individual Baltimore programs and does not deem them particularly “high risk”. MedStar certainly anticipates performing simultaneous liver/kidney transplantation procedures at MFSMC (see Table 7 below):

Table 7. Simultaneous Liver/Kidney Transplant Volume Comparison, 2013-2018

Simultaneous Liver/Kidney Volume							
Center / Calendar Year	2013	2014	2015	2016	2017	2018*	CY Avg 2013-2017
DCGU-TX1 Georgetown Univ Med Ctr	6	8	8	11	18	8	10.2
MDJH-TX1 Johns Hopkins Hospital	13	12	15	18	15	10	14.6
MDUM-TX1 Univ of Maryland Med System	10	5	10	12	14	9	10.2
*2018 as of 9/30/2018							
From UNOS.org/data accessed 11/6/2018							

H. Expanding Donor Criteria/Acceptance of Marginal Organs

JHH states that it is already making the most of local organ availability, and that it is meeting

the need of the local population by consistently importing a significant number of kidneys from other parts of the country and making optimal use of marginal organs. JHH.Cmt. at 11.

The fact is that organs presented for transplantation may be declined by a program for a variety of clinical reasons related to their suitability for the recipient. MedStar's policy is to match the donor and recipient characteristics as closely as possible, *i.e.*, MedStar is careful to balance its use of higher risk donors with successful 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. Both existing Baltimore programs have had outcomes problems in a context of volume growth; it is essential that strict attention be paid to ensuring long-term favorable outcome in the recipient. Otherwise, the transplant is a failure – for the patient and the program.

I. MFSMC's Application Is Consistent with Review Standard 10.24.15.04B(5) – Impact

JHH complains that MFSMC's impact analysis "falls short." *See* JHH.Cmt. at 21-22. MFSMC disagrees. Assessment of UMMC and JHH volumes over the last two years (provided in their comments) shows that there's been no decrement – rather a growth in volume - despite the entry of the MFSMC program for liver diseases – and 20 transplants from the Baltimore area performed at MGTI 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 to maintain volumes above the SHP's threshold volumes, that it will not have an unwarranted adverse impact on the financial viability of JHH's liver transplant service, 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.

IV. BARRIERS TO ACCESS

UMMC seems to understand that compliance with this standard is not required.

UM.Cmt. at 8. However, UMMC creates an argument that because MFSMC *mentions* access issues in the application, this must mean that the application should satisfy the access standard.

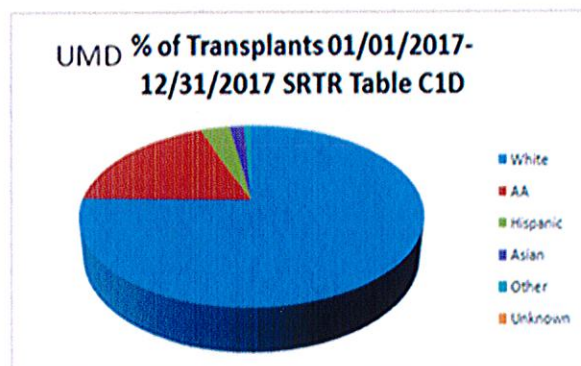
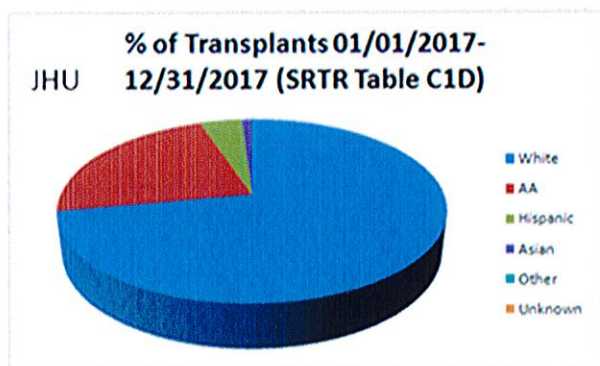
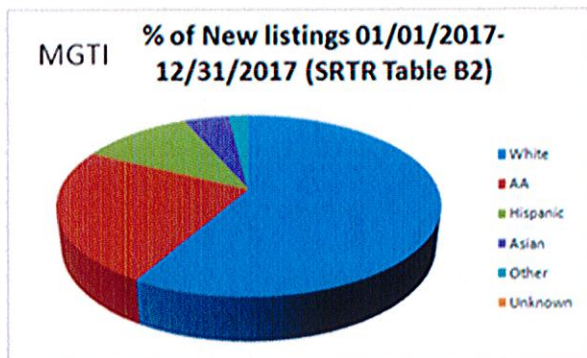
JHH likewise claims that MFSMC cannot meet this standard. JHH.Cmt. at 19 ("it is not enough for an applicant to suggest ways to improve access.").

Notwithstanding these assertions, 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). MFSMC mentioned certain issues in relation to other review criteria, *e.g.*, minority patients and MedStar-insured patients living locally, while stating . clearly that access *per se* is not applicable to its application. *See* Application at 67.

Nevertheless, MFSMC wishes to address a misleading aspect of the UMMC/JHH comments on barriers. Although UMMC states that the minority population in Maryland is "well served." MedStar actually "serves" the minority population in greater proportion than do the Baltimore programs, confirmed by SRTR data provided in the application (and again in the Completeness Question responses). MGTI has a much better record listing and transplanting minority kidney transplant candidates than either center in Baltimore. These data are indisputable. Following are the most recently updated charts published in October 2018 (Table 8):

Table 8. Percentage Minority Kidney Listings and Transplants By Center

**PERCENTAGE MINORITY LISTINGS
Comparison 2018**



SRTR October 2018 Reports

V. COST EFFECTIVENESS AND COST-EFFECTIVE ALTERNATIVES

UMMC links MedStar’s comments regarding competition in connection with the Suburban Hospital application and consolidation of its transplant programs in Washington D.C., claiming that these are in conflict with the statements made in MedStar’s application for a kidney program at MFSMC. UM.Cmt. at 12. Of course, “consolidation” and “competition” are entirely different concepts. MedStar’s consolidation of its kidney transplant programs (MWHC and MGTI) as well as its heart program years earlier, demonstrate its ability to effectively manage the available resources, reduce redundancies, streamline operations and ultimately, reduce costs.

MGTI has achieved tremendous improvement in efficiency of clinical and administrative operations by consolidating programs.

UMMC also complains generally that MFSMC's cost projections are understated. UM.Cmt. at 13-15. MFSMC stands by its staffing and cost analysis, which is based accurately on the needed incremental staffing for the proposed programs. Compliance is inherent in CMS participation; MFSMC will meet all CMS standards. All required physician and ancillary staff will be on-site at MFSMC as required.

The idea that MedStar would not comply with OPTN bylaws is unreasonable. Compliance is inherent in CMS participation; MFSMC will meet all CMS standards. The support of other functions that are not required to be on-site (*e.g.*, data management and administrative oversight) will be provided by the program at MGTI. Staff at MFSMC will be trained as needed to support the program and will be supplemented timely, based on volume growth. This approach is not only practical, it is judicious and cost-effective.

Lastly, MFSMC properly compares its charges to the existing Baltimore programs because this is the valid comparison for a program that is to be operationalized at MFSMC. As stated originally, MFSMC's costs are lower than either academic center in Baltimore. MGTI charges are irrelevant in the context of the State of Maryland.

VI. 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.

Respectfully submitted,



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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

Anne P. Weiland
Vice President - Surgery, Orthopaedics
and Neurosciences

(date)

CERTIFICATE OF SERVICE

I hereby certify that on November 20, 2018, a copy of the foregoing Response was served

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