

IN THE MATTER OF
MEDSTAR FRANKLIN SQUARE LIVER
TRANSPLANT SERVICE

Docket No. 17-03-2406

* BEFORE THE
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* MARYLAND HEALTH
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* CARE COMMISSION
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**UNIVERSITY OF MARYLAND MEDICAL CENTER’S COMMENTS
ON MEDSTAR HEALTH, INC.’S CON APPLICATION PROPOSING THE
ESTABLISHMENT OF A LIVER TRANSPLANT SERVICE
AT MEDSTAR FRANKLIN SQUARE HOSPITAL CENTER**

University of Maryland Medical Center (“UMMC”), by its undersigned counsel and pursuant to COMAR § 10.24.01.08F, submits these comments addressing the Certificate of Need (“CON”) Application and related materials filed by MedStar Health, Inc. (“MedStar”) proposing to establish a liver transplant service at Franklin Square Hospital Center d/b/a MedStar Franklin Square Medical Center (“MFSMC”). For the reasons described more fully below, UMMC respectfully asks that the Commission deny MedStar’s Application. In the alternative, and as described more fully in the accompanying Motion for Stay of CON Review, UMMC requests that the Commission defer review of MedStar’s application until the United Network for Organ Sharing finalizes its forthcoming changes to liver allocation policy in December 2018, and require MedStar to update its analyses of its compliance with the applicable State Health Plan chapter and review criteria based on that new policy.

In addition to the following comments, and in an effort to avoid the review of duplicative information by the Commission and all parties, UMMC incorporates by reference as if fully set forth below: (i) UMMC’s Motion for Stay, in full; and (ii) portions of the Interested Party Comments of The Johns Hopkins Hospital (“JHH”) concerning MedStar’s failure to demonstrate need for its proposed program or existing barriers to access for minority populations.

Statement of Interested Party Status

UMMC is an “interested party” within the meaning of COMAR § 10.24.01.01B(20) because UMMC is authorized to provide the same service as the applicant, in the same planning region used for purposes of determining need under the State Health Plan. UMMC has provided liver transplant services at its facility in downtown Baltimore since 1994. The State Health Plan Chapter for Organ Transplant Services, COMAR § 10.24.15, defines “the health planning regions for CON review of an application to establish or relocate organ transplant services in Maryland” to be “consistent with the OPO [Organ Procurement Organizations] designations.” COMAR § 10.24.15.03, p. 8. MFSMC, JHH, and UMMC all fall within the Living Legacy Foundation service area designation, serving western and central Maryland, the Eastern Shore, Calvert, and St. Mary’s Counties in southern Maryland. Id., pp. 7-8.

Introduction

The Maryland Health Care Commission (the “Commission”) convened a Workgroup in October 2014 to recommend changes to the State Health Plan for Organ Transplant Services. The Workgroup engaged in a more than two year process involving the review of current organ transplant research, policies, and data. That process resulted in the current State Health Plan Chapter for Organ Transplant Services, COMAR § 10.24.15 (the “State Health Plan Chapter”), which the Commission unanimously voted to approve in January 2017. The State Health Plan Chapter recognizes that “[o]rgan transplantation is a specialized tertiary-level health service that requires clinical expertise and a hospital setting with the most advanced diagnostic, surgical, and monitoring equipment.” COMAR § 10.24.15.03, p. 8. As a result, the Commission determined “the public is best served if a limited number of general hospitals provide specialized services to a substantial population base.” Id. The limitation of organ transplant services to high volume hospitals

offering specialized care is associated with high quality of care, efficient scale of operation, and better patient outcomes. Id., pp. 8-16.

Despite the policy goals of the State Health Plan Chapter, MedStar proposes to create a low-volume liver transplant program at a community hospital, MedStar Franklin Square Medical Center (“MFSMC”), within close proximity to two existing high volume programs and within 50 miles of MedStar’s high-volume MedStar Georgetown Transplant Institute (“MGTI”).¹

MedStar’s proposed low-volume program does not meet the policy goal of the State Health Plan Chapter to concentrate services at a limited number of high volume programs.

MedStar justifies its proposed low-volume program on the basis of several incorrect assumptions.

- MedStar’s assertion that it will be able to increase the availability of organs in Maryland is based on generalized statements about MedStar’s supposed expertise, and lacks meaningful support. MedStar relies heavily on its experience with living donor transplants and transplants involving high risk organs, both of which MedStar performs at lower volumes than UMMC and JHH, and domino and split liver transplants, which are both rare procedures that almost always involve pediatric patients, whom MedStar will not treat at MFSMC.
- Despite MedStar’s assertions in its application, the minority population in Maryland is well served by existing programs.
- MedStar underestimates the cost of its program, and improperly compares the cost effectiveness of its program to UMMC and JHH rather than to MGTI. MedStar projects

¹ Source: <https://srtr.org/transplant-centers/>, search for programs within 50 miles of MFSMC Zip Code 21237.

shifting the majority of its volume from MGTI, which has lower Medicare and Medicaid charges than the projected charges for MFSMC.

Even if MedStar had complied with the State Health Plan Chapter, the Commission should still delay review of MedStar's application because national organ allocation policy for livers is about to fundamentally change in a way that undermines much of the analysis in MedStar's application and related filings. The current organ allocation policy for livers and the forthcoming changes are described in greater detail in UMMC's Motion for Stay of CON Review. As set forth in that Motion, the result of the new liver allocation policy will be that more high-acuity adult and pediatric patients will receive livers than under the current policy, and livers will be distributed over a larger geographic area that removes the artificial boundaries of currently defined Donation Service Areas ("DSAs") for organs.

The forthcoming changes to liver allocation policy will not only render MedStar's analysis in its application out-of-date with new policy, but will also undermine the unstated purpose of MedStar's application – MedStar will not need a hospital in the current Baltimore-area DSA in order for its patients to benefit from MedStar's purported ability to increase the availability of donated organs in the Baltimore-area DSA. MedStar's efforts, under the new allocation policy, would benefit MedStar patients on MGTI and MFSMC liver transplant waiting lists equally, because any organ donated in the Baltimore area would be within the same, smallest geographic allocation area being considered under the new policy.

When stripped of unsupported assumptions and viewed in light of the forthcoming changes to liver allocation policy, MedStar's application has little support other than the desire to reduce travel time for MedStar patients through the creation of a low-volume program that will, according to MedStar, rely on the expertise and efficiency of its high-volume affiliate. The

Commission should reject this as an inadequate showing of need for a new transplant program, as such justification would open the door for every Maryland community hospital affiliate of an academic hospital with high-volume transplant programs to establish satellite organ transplant programs for patient convenience. Such a result is not only unneeded in Maryland, but is in direct contradiction with the State Health Plan Chapter's stated policy goals for these highly specialized services.

ARGUMENT

I. MEDSTAR CANNOT DEMONSTRATE THAT ITS PROPOSAL TO ESTABLISH A LIVER TRANSPLANT SERVICE COMPLIES WITH THE NEED STANDARD, COMAR § 10.24.15.04B(1).

A. MedStar has not demonstrated its ability to increase supply or use of donor organs for patients in Maryland.

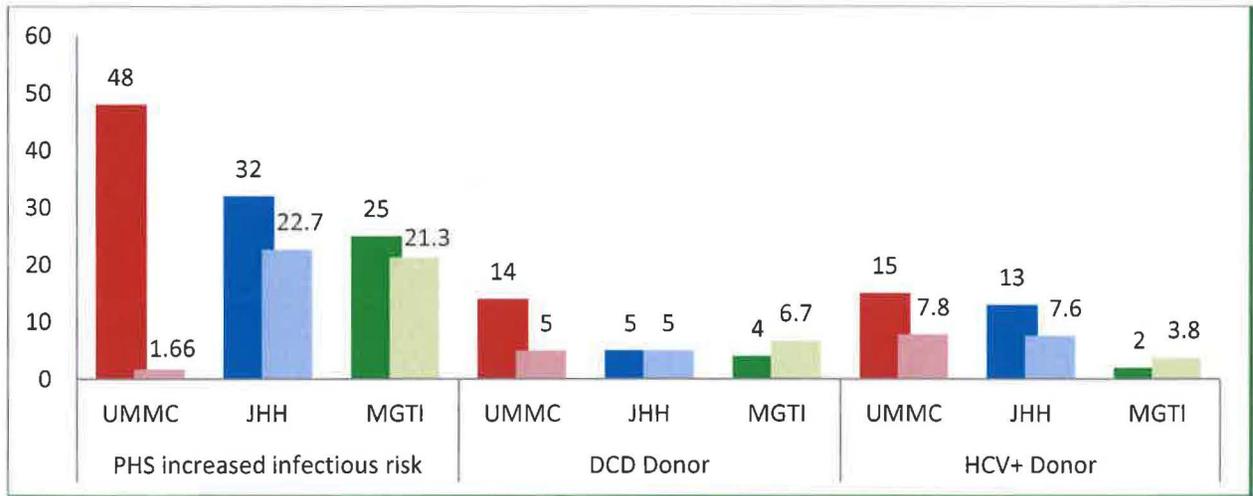
MedStar claims that it will be able to increase the use and supply of donor organs in Maryland in four ways: (a) ensuring donor support and retrieval efforts at its hospitals within the LLF (MedStar CON Appl., pp. 44-45); (b) using expanded donor criteria (*id.*, p. 45); (c) using split liver and domino techniques (*id.*, pp. 46-49); and (d) offering living donor transplantation (*id.*, pp. 50-55). MedStar makes no effort to quantify the impact these various factors might have. Without any such projection, it is impossible to determine whether the increase in supply is worth the operational costs, potential erosion of quality care, and other risks of adding a new program, or whether the volume assumption based on each effort is reasonable.²

² The State Health Plan Chapter notes that several studies examining the relationship between competition among organ transplant centers and patient outcomes “indicate that increasing competition may have both positive and negative consequences for patients.” COMAR §10.15.15.03, p. 21. One such study found that “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.” *Id.*, p. 22. (For study cited, see SHP p. 22, n.84).

Moreover, none of the four strategies MedStar relies upon are likely to increase organ use and supply in Maryland. The participation of MedStar hospitals with their DSA's OPO is not tied to the existence of an organ transplant service. It is a requirement included in CMS Conditions of Participation. 42 C.F.R. § 482.45. MedStar hospitals will continue to participate in donor programs with OPOs with or without CON approval of the proposed project, and the establishment of a transplant program at MFSMC should have no impact on the number of organs that become available at MedStar hospitals as they continue to comply with CMS regulations.

MedStar's reference to expanded donor criteria ("ECD") similarly does not point to any unique ability of MedStar to increase donor supply. MedStar cites agreement by experts on a national level to reconsider exclusionary criteria and craft ECD protocols. MedStar CON Appl., p. 45. Whatever increase the implementation of these protocols might have – and MedStar has not credibly demonstrated even what these protocol are or that they will result in any increase – the acceptance of revised protocol on "a national level" will not result in any unique ability of MedStar to increase the supply of donor organs. Moreover, while MedStar states that "MGTI clinical expertise enables it to make full use of ECD protocols for patients," *id.*, actual data on the use of high-risk organs demonstrates that UMMC and JHH make more use of high risk livers, both in raw numbers and as compared to national acceptance practices, as shown in the following figures.

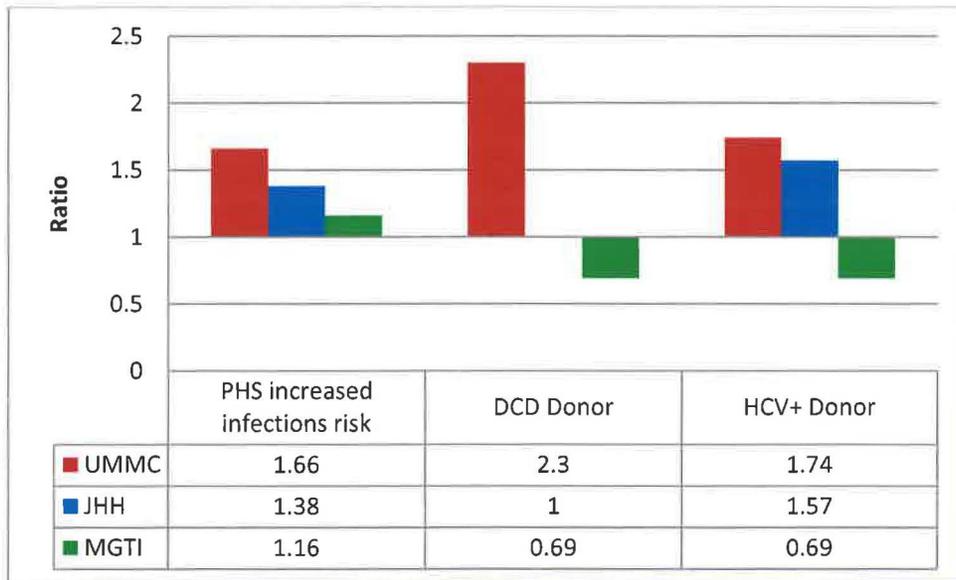
Figure 1
Offer and Acceptance Practices for High Risk Donor Livers
Acceptances and Expected Acceptances
UMMC, JHH, MGTI, CY 2017



Accepted Livers in left, dark column, Expected Accepted Livers in right, light column

PHS increase infectious risk: Donor liver within U.S. Public Health Service guidelines for increased risk of infection
DCD Donor: Donation after Cardiac Death
HCV+: Donor liver positive for Hepatitis C virus

Figure 2
Offer Acceptance Ratio¹ for High Risk Donor Livers
UMMC, JHH, MGTI, CY 2017



Note 1: "The offer acceptance ratio estimates the relative offer acceptance practice of [the Program] compared to the national offer acceptance practice. A ratio above one indicates the program is more likely to accept an offer compared to national offer acceptance practices (e.g., an offer acceptance ratio of

1.25 indicates the program is 25% more likely to accept an offer compared to the national experience), while a ratio below one indicates the program is less likely to accept an offer compared to national offer acceptance practices (e.g., an offer acceptance ratio of 0.75 indicates the program is 25% less likely to accept an offer compared to the national experience)."

Source for Figures 1,2: SRTR UMMC, JHH, MGTI Program-Specific Reports, Oct. 9, 2018, Tables B10

MedStar's reliance on domino liver transplantations and split liver transplantations also do not support its ability to create new volume. MedStar projects that 80% of its procedures (24 of 30 in CY 2021) will be routine, and it does not project performing any domino liver transplantation procedures at MFSSMC. MedStar June 1, 2018 Completeness Resp., p. 17.

MedStar's projection that 17% of the volume at MFSSMC (5 of 30 in CY 2021) will result from split/partial liver procedures lacks support. Id. As addressed more fully in JHH's Comments, split liver transplantation is a rare procedure that increases the availability of livers for children. MedStar concedes it will not perform pediatric surgeries at the proposed program at MFSSMC. MedStar March 1, 2018 Completeness Resp., p. 13. While MedStar states in its completeness responses that the smaller liver lobe can be placed in a "small adult," MedStar does not state how often it has performed this procedure for two adults rather than an adult and child. According to OPTN data on such procedures, 99.9% of split liver procedures are not performed on two adults, and no programs in the WRTC, including MGTI, have performed the procedure on two adults in the last decade. OPTN, U.S. Transplants performed January 1, 1988 - September 30, 2018.

Lastly, MedStar is not likely to increase the availability of organs through living donor transplants. Recent experience demonstrates that MGTI has performed transplants involving living liver donors on just five adults in the last 30 month period for which the Scientific Registry of Transplant Recipients ("SRTR") has data available. In comparison, UMMC has performed thirty – six times as many – in the same period.

Table 1
Adult Living Donor Transplants
Period Evaluated: 1/1/2015 to 6/30/2017

Program	Transplants
UMMC	30
JHH	18
MGTI	5

Note 1: "The hazard ratio provides an estimate of how [the Program's] results compare with what was expected based on modeling the transplant outcomes from all U.S. programs. A ratio above 1 indicates higher than expected graft failure rates (e.g., a hazard ratio of 1.5 would indicate 50% higher risk), and a ratio below 1 indicates lower than expected graft failure rates (e.g., a hazard ratio of 0.75 would indicate 25% lower risk). If [the Program's] graft failure rate were precisely the expected rate, the estimated hazard ratio would be 1.0." SRTR, Notes to PSR Table C5L.

Source: SRTR PSRs for MGTI, JHH, UMMC, Liver Program, Oct. 9, 2018, Tables C2L

UMMC has the second best outcomes nationally among moderate to high volume programs for living donor patient and graft survival. SRTR, 1year Adult Living Donor Recipient Patient Survival, 1/1/2014-6/30-2016. MedStar seemingly concedes that its efforts in this area will have little impact on the availability of organs in the service area – it projects just one liver transplant procedure at MFSMC will involve a living donor by CY 2021, obviously not a driver of volume. MedStar June 1, 2018 Completeness Resp., p. 17.

B. MedStar Does Not Need a New Program to Increase the Supply of Organs in Maryland.

MedStar's argument that it will be able to increase the use and supply of organs in Maryland is premised on the assumption that much of Maryland is in the LLF, while MedStar is in the WRTC, as whatever efforts MedStar is currently capable of should already be benefiting patients on waitlists for hospitals in WRTC. As described more fully in UMMC's Motion for Stay, OPTN will change liver allocation policy in December, 2018 to remove the geographic boundaries of DSAs. See Motion for Stay, pp. 3-10; OPTN Committee Data Analysis Request Form, attached as Exhibit F to Motion for Stay.

OPTN is considering two allocation frameworks, each of which involves allocating livers based on geographic circles surrounding the donor hospital, rather than static geographic territories. Id. Under either of the proposed allocation framework methods, new donor livers will first be offered to the highest acuity adult and pediatric patients at all hospitals within at least 500 nautical miles of the donor hospital, and if no recipient is found, will then be offered to a lower acuity level patient in a different geographic circle. Motion for Stay, pp. 7-10; OPTN Data Analysis Request Form, attached to Motion for Stay as Exhibit F, pp. 2, 5.

The smallest geographic radius OPTN is considering under either framework is 150 nautical miles. Id. Thus, if MedStar can increase the number of donor livers available in the current Baltimore-area DSA, under the forthcoming changes to the allocation policy, this increase will benefit all transplant candidates located within, at a minimum, 150 nautical miles of the donor hospital, including those on the waitlist at MGTI, regardless of whether MFSMC has a liver transplant program. Every hospital in the State of Maryland is located within 150 miles of MGTI. Simply put, MedStar need not open a program in the Baltimore-area DSA in order to increase the number of donor livers available to that DSA and benefit MedStar patients, because DSAs will soon no longer exist.

II. MEDSTAR'S VOLUME ASSUMPTIONS AND THE FORTHCOMING CHANGES TO LIVER ALLOCATION POLICY UNDERMINE MEDSTAR'S ABILITY TO COMPLY WITH THE MINIMUM VOLUME STANDARD, COMAR 10.24.15.04B(2).

A. MedStar's Volume Shift Projections Undermine its Justification for its Proposed Program.

Aside from MedStar's unsupportable assertion that it will be able to increase the use and supply of livers in the Baltimore area, MedStar's primary justification for a MFSMC liver transplant program is that it will offer a lower cost, more convenient option for Medstar patients

who reside in the Baltimore area and who would otherwise travel to MGTI or who MedStar would refer to JHH or UMMC. See, e.g., MedStar CON Appl., p. 15. MedStar does not project shifting any volume other than these referrals away from UMMC and JHH. See MedStar Aug. 23, 2018 Additional Information, p. 47; MedStar CON Appl., p. 57. MedStar's annual referral volume from the Baltimore area for liver transplant is minimal, and cannot support MedStar's proposed program.

MedStar estimates that it referred an annual average of 12 patients from "from the Baltimore region" to UMMC, JHH, and MGTI combined from FY15-FY17. MedStar Aug. 23, 2018 Additional Information, p. 47; see also MedStar CON Appl., p. 57. MedStar does not provide sufficient information about these referrals to determine whether the volume could support its proposed program. For example, MedStar does not indicate for these Baltimore-area patient referrals: (i) whether the referrals represent liver transplant surgery, or only patients placed on a waitlist; (ii) if only referrals for the waitlist, the percentage of the referrals that resulted in surgery; and (iii) whether the referrals include high-risk and pediatric patients, whom MedStar concedes MFSSMC will not treat, at least during the period for which MedStar has projected volume. MedStar March 1, 2018 Completeness Resp., pp. 13, 35.

MedStar projects that its proposed program will perform 10, 14, and 30 cases in the first three years of operation, respectively. MedStar March 1, 2018 Response to Completeness Questions, Table I. However, MedStar may not even be able to meet the minimum volume threshold requirement of 12 cases for liver transplant services. COMAR §10.24.15.04B(2).

Even if MedStar’s annual average of 12 referrals from the Baltimore region³ resulted in non-high-risk, adult transplants, if MedStar truly intends its proposed program to support only MedStar patients from the Baltimore region who otherwise would have had surgery at MGTI, UMMC, or JHH, MedStar’s ability to meet the minimum volume requirement will depend on 100% of these 12 patients opting to have surgery at a local, newly established community hospital rather than an established, high-quality, high-volume program that is just as conveniently located. This assumption is unreasonable.

If MedStar instead expects to create sufficient “new” donated organs in the Baltimore area to support its volume, that assumption is unreasonable, as described more fully under the discussion of the Need standard and criteria above. The Commission certainly cannot expect MedStar’s efforts to result in an additional 18 donated livers by its third year of operation.

If MedStar anticipates that some non-Maryland residents will also opt to have surgery at MFSSMC, MedStar should justify this assumption and quantify the impact that the shift of such patients into Maryland would have on Medicare costs and all-Maryland hospital costs so that the Commission may consider the program in conjunction with the new Total Cost of Care Model State Agreement with CMS.

Because MedStar’s referral volume is only sufficient to support its proposed program if 100% of Maryland patients whom MedStar previously would have referred elsewhere (i) are not “high-risk,” (however MedStar defines that term); (ii) are not pediatric patients; and (iii) opt to

³ Notably, MedStar had an annualized FY17 Baltimore area referral volume of just 11 patients – a slight decrease from the two prior years and insufficient to meet the Minimum Volume standard.

receive services at MFSMC, MedStar has not demonstrated that its program can generate the minimum annual case volume required by the Minimum Volume review standard.

B. The Forthcoming Changes to Liver Allocation Policy Further Undermine MedStar's Ability to Comply with the Minimum Volume Standard.

As described more fully in UMMC's Motion for Stay, the forthcoming changes to liver allocation policy will prioritize more adult and pediatric patients at the highest levels of acuity, and the result will be more organs being offered to sicker people. See Motion for Stay, pp. 7-10; see also SRTR Analysis Report, Sept. 24, 2018, attached to Motion for Stay as Exhibit H (finding that both potential new frameworks result in a national increase in the median MELD at time of transplant, referred to within the report as a MMAT score), p. 2. MedStar concedes that its proposed program at MFSMC will not treat pediatric or high-risk patients, at least in any years for which it projects volume, although MedStar does not define what MELD score will be used as a cutoff. MedStar March 1, 2018 Completeness Resp., pp. 13, 35

Under existing liver allocation policy, if MFSMC had a transplant program, patients within similar acuity ranges would be passed over only for the higher acuity adult or pediatric patients within that range at UMMC and the JHH. Under either of the proposed allocation framework methods, new donor livers will first be offered to the highest acuity adult and pediatric patients at all hospitals within at least 500 nautical miles of the donor hospital. OPTN Data Analysis Request Form, attached to Motion for Stay as Exhibit F. With this much expanded competition for organ allocation, a new program at MFSMC that does not treat high-risk or pediatric patients may be unable to perform surgeries at a the threshold minimum volume of 12 cases annually, the threshold the Commission has determined is necessary in order for staff to remain proficient and for a program to remain cost effective.

III. MEDSTAR DOES NOT DEMONSTRATE EXISTING BARRIERS TO ACCESS.

While MedStar concedes that the access standard, COMAR § 10.24.15.04B(3), does not apply because MedStar “is not seeking to justify the need for an additional transplant program on the basis of barriers to access,” (MedStar CON Appl., p. 63), MedStar makes statements throughout its application attempting to justify its program based on various access-related issues, including access for minority patients, access to a program with high quality and acceptance rate measures, and geographic access. The Commission should reject these based on MedStar’s concession that it is not seeking to justify its program based on access.

Furthermore, no access barriers exist. Patients in the LLF, including minority patients, have access to two high-quality liver transplant services. Adding a third program would contradict the Commission’s express recognition that “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.

A. Minority Patients Have Appropriate Access to Liver Transplant Services in the Baltimore Area.

MedStar’s assertion that its program “provides greater access to minority populations...than any program in the region or nation” must be rejected. As detailed in JHH’s Comments, minority populations receive transplants at a higher rate within the LLF, served by JHH and UMMC, than in the WRTC, served only by MedStar.

UMMC has a strong record of access for minority patients. UMMC has the largest population of African American patients on its liver transplant waitlist than any other program nationally. OPTN, National Transplant Demographic Data, Liver, CY 2017. Liver allocation for patients on a waitlist is determined by OPTO allocation policies, which do not include race as a

basis for allocation.⁴ Thus, placement on a program's waitlist is an appropriate marker for access. This is confirmed by UMMC's 2016-2017 actual experience in liver transplantations in calendar year 2017, which demonstrates that UMMC performed more liver transplants in African American patients than any other program in the United States. Id.

B. Baltimore Area Patients Have Access to UMMC's High-Quality, High-Volume Program.

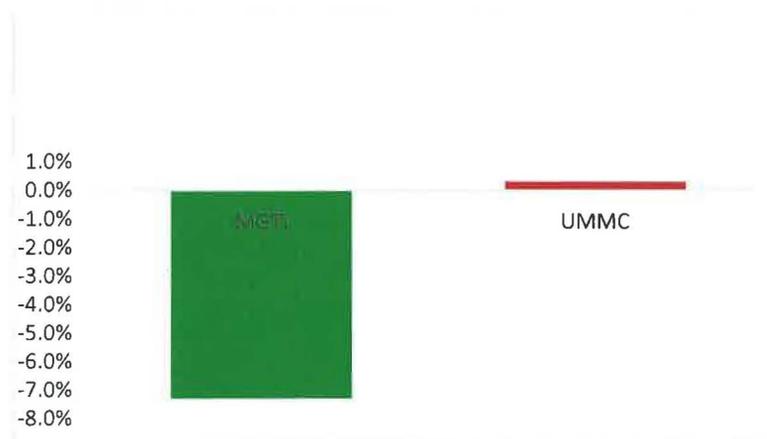
While MedStar touts MGTI's average liver transplant wait list time, UMMC has superior transplant rates to MGTI. In measuring transplant rates, SRTR calculates a program's observed rate of transplant and an expected rate of transplant. The observed transplant rates demonstrate "the number of candidates who received a transplant divided by the person-years observed at the program (person-years is a combination of how many candidates were on the waiting list along with how long each candidate was followed since some candidates are not on the waiting list for the entire year)." SRTR Program Specific Reports, User Guide, p. 1. The expected transplant rate "is an estimate of what [SRTR] would expect at this program if it were performing transplants at rates similar to other programs in the US with similar candidates on their waiting lists." Id. SRTR uses these data points to calculate a ratio of the observed to expected transplant rate. Id. "A ratio of 1 indicates that the observed transplant rate was equal to the expected transplant rate, while a ratio less than 1 indicates the observed rate was lower than expected rate and a ratio greater than 1 indicates the observed rate was higher than the expected rate." Id.

As demonstrated in the figures below, for the two year period 2016-2017, UMMC's observed transplant rate exceeded the expected transplant rate for its program, resulting in a

⁴ See, e.g., UMMC Motion for Stay, Exhibit B, OPTN *Questions and Answers for Transplant Candidates about Liver Allocation*. pp. 3-5.

transplant rate of 1.00. SRTR UMMC Program-Specific Report, Oct. 9, 2018, Figure B1. For the same period, MGTI failed to meet the expected rate, resulting in a transplant rate of 0.93. SRTR MGTI Program-Specific Report, Oct. 9, 2018, Figure B1.

Figure 3
Difference between Observed to Expected Transplants Rates
CY2016-2017 (Adult)



Source: SRTR UMMC, MGTI Program-Specific Reports, Oct. 9, 2018, Figures B1

UMMC is ranked as the third largest liver transplant program in the United States for two consecutive years. OPTN National Data, Liver Transplants by Center, CY 2016-2017. UMMC has the second best outcomes for living donor patient and graft survival for moderate to high volume programs during the same time period. OPTN National Data, Liver Transplants by Center, CY 2016-2017. CareChex, a medical quality rating system, ranked UMMC the #1 liver transplant program in US for Medical Excellence and Patient Safety in 2018.

Table 2
CareChex, America's Top Quality Hospitals, 2018
Patient Safety – Nation
Transplant of Liver

Rank	Hospital Name	City	State
1	University of Maryland Medical Center	Baltimore	MD
2	Baylor University Medical Center	Dallas	TX
3	Hospital of University of Pennsylvania	Philadelphia	PA
4	University Health System	San Antonio	TX
5	University of Alabama Hospital	Birmingham	AL
6	Vanderbilt University Medical Center	Nashville	TN
7	Duke University Hospital	Durham	NC
8	Stanford Health Care	Stanford	CA
9	University of Washington Medical Center	Seattle	WA

Source: CareChex 2018 Rankings, Data Time Period: January 2014 – June 2016

Table 3
CareChex, America's Top Quality Hospitals, 2018
Medical Excellence – Nation
Transplant of Liver

Rank	Hospital Name	City	State
1	University of Maryland Medical Center	Baltimore	MD
2	UCSF Medical Center	San Francisco	CA
3	Carolinas Medical Center/Behavioral Health	Charlotte	NC
4	Stanford Health Care	Stanford	CA
5	Baylor University Medical Center	Dallas	TX
6	Hospital of University of Pennsylvania	Philadelphia	PA
7	University Health System	San Antonio	TX
8	Loyola University Medical Center	Maywood	IL
9	Keck Hospital of USC	Los Angeles	CA

Source: CareChex 2018 Rankings, Data Time Period: January 2014 – June 2016

C. Driving Distance to MGTI is not a Barrier to Access.

MedStar proposes a new program less than ten miles away from two existing high-volume programs and within 50 miles of its existing MGTI.⁵ The State Health Plan Chapter

⁵ See Note 1, *supra*.

provides that “travel to an organ transplant center located in a health planning region other than where the organ transplant recipient resides is not, in and of itself, considered a barrier to access, if the drive time in less than three hours one-way.” COMAR § 10.24.15.04B(3). Even if improving drive time were a permissible justification, establishing a new program just ten miles away from two existing programs does nothing at all to further geographic access to organ transplant services in Maryland.

To the extent that MedStar intends to improve access based not simply on driving time, but by expansion into a new DSA, that goal will be rendered irrelevant when OPTN adopts new allocation policy in December of 2018 that removes the DSAs geographic barriers from allocation procedures. See Motion for Stay, pp. 7-10. Furthermore, as MedStar appropriately comments in the review of the Suburban Hospital’s CON Application to establish liver transplant services, Docket No. 17-15-2400, “in areas of close geographic proximity, there should not be an expectation that residents of a DSA with arbitrary borders should be transplanted within that same DSA.” MedStar April 30, 2018 Interested Party Comments on Suburban Hospital CON Application; (“MedStar Comments on Suburban CON Appl.”), p. 4.⁶

Finally, MedStar does not need a new program at MFSCMC to improve its post-surgical treatment of Baltimore area patients, and may make use of its existing network of providers. MedStar states that it has been building its infrastructure in the Baltimore area to support transplant patients:

Since 2015, MedStar has been laying the groundwork to provide the full range of transplant-related services to those patients in need in the Baltimore region. To date, in anticipation of expanded services, MGTI has extended all services required for referral, triage, evaluation, and listing of transplant candidates to

⁶ MedStar further commented that “[i]n light of the liver organ allocation policy mandated by CMS, ‘migration’ based on ‘access’ simply does not occur, and thus should be ignored.” Id.

MFSMC. MGTI has also extended follow up services required for the long-term maintenance of patient and organ health after transplantation.

MedStar CON Appl., p. 15. In its comments on the Suburban CON Application, MedStar similarly touted that it “has seven established and functioning evaluation centers at sites distributed around the Baltimore-Washington area” and that “volumes of patient visits and evaluations at [MedStar] sites have been growing steadily.” MedStar Comments on Suburban CON Appl., p. 5. To the extent that MedStar desires to achieve more accessible, local care for its Baltimore-area transplant patients, there is no reason MedStar cannot provide that care without opening a transplant program at MFSMC.

IV. MEDSTAR’S PROGRAM IS NOT COST EFFECTIVE AND THERE ARE MORE COST EFFECTIVE ALTERNATIVES THAT WOULD ACCOMPLISH MEDSTAR’S PURPOSE (COMAR § 10.24.15.04(4); COMAR 10.24.01.08G(3)(c).

A. MedStar Recognizes that Increased Competition Results in Increased Costs

As noted above, less than four months prior to submitting its Application, MedStar opposed the Suburban Hospital CON application to establish a new liver transplantation service. MedStar relied principally on three arguments, among these that “[s]cientific literature and actual experience do not support the claim that increased competition leads to increased numbers of transplants and improved patient survival.” Medstar Comments on Suburban CON Appl., Enclosure Letter, p. 2.

Of note, MedStar indicated that its own quality and costs improved when it consolidated its two programs:

MGUH consolidated the volumes of its two programs (one at MedStar Washington Hospital Center) in July 2015. Aside from the increased volume, decreasing the competition between these programs resulted in greater efficiency in operations, volume growth overall and lower costs, all of which have been sustained. In our own experience, eliminating competition between programs has resulted in greater productivity.

Medstar Comments on Suburban CON Appl., p. 22. MedStar further summarized with endorsement studies finding that increased competition led to various risks, including increased graft failure and increased costs. *Id.*, pp. 16-18.

Having just recently touted the increased efficiency and quality MedStar achieved through consolidation, MedStar should not be eager to open a new low-volume program, and thus risk both undermining its newfound cost-saving efficiency and volume gains at MGTI, and imposing greater costs and quality risks on Maryland's existing high-quality, high-volume providers.

B. MedStar's Projected Staffing Costs are Understated and do not Comply with OPTN By-laws.

MedStar's projected operational costs fail to account for the considerable staffing needs required to operate a liver transplantation program. "A general hospital awarded a Certificate of Need to establish an organ transplant service shall be certified by United Network for Organ Sharing ["OPTN"] within the first year of operation." COMAR § 10.24.15.04B(6)(a). OPTN bylaws require transplantation programs to be fully functioning as stand-alone programs. That is, MedStar may not simply run MFSSMC as a satellite of MGTI, but must meet each staffing requirement of the OPTN bylaws.

OPTN bylaws require each transplant center to have surgeons and transplant physicians available 365 days a year, 24 hours a day, 7 days a week to provide program coverage. OPTN bylaws, available at: <https://optn.transplant.hrsa.gov/governance/bylaws/> (last accessed 10/13/2018). MedStar's proposed staffing of just four total physicians is impractical, especially

at the relatively low average salary of \$385,250.⁷ MedStar March 1, 2018 Completeness Response, Table L. According to OPTN bylaws, A transplant surgeon must be readily available in a timely manner to facilitate organ acceptance, procurement, and transplantation, and a transplant surgeon or transplant physician may not be on call simultaneously for two transplant programs more than 30 miles apart unless the circumstances have been reviewed and approved. OPTN Bylaws. Without an exemption for specific reasons, the primary surgeon or primary physician cannot be designated as the primary surgeon or primary physician at more than one transplant hospital unless there are additional transplant surgeons or transplant physicians at each of those facilities. Id. Additional transplant surgeons must be credentialed by the transplant hospital to provide transplant services, and be able to independently manage the care of transplant patients, including performing the transplant operations and organ procurement procedures. Id. Additional transplant physicians must be credentialed by the transplant hospital to provide transplant services and be able to independently manage the care of transplant patients. Id.

In addition, the proper care and management of transplant recipients require both physicians and ancillary health professionals. The transplant program must show proof of collaboration with experts in anesthesia. Id. MedStar makes no mention of transplant anesthesiology in its proposed staffing plan, and does not describe its staffing plan with any sufficient detail to demonstrate that its extremely lean staffing model could meet all staffing requirements. MedStar March 1, 2018 Completeness Response, Table L. A transplant center requires, in addition to surgical and anesthesia staffing, collaboration with experts

⁷ Not only is this salary relatively low, but MedStar fails to project any amount of benefits for any staffing level. MedStar March 1, 2018 Completeness Response, Table L.

in histocompatibility and immunogenetics, immunology, infectious disease, pathology, physical therapy and rehabilitation medicine, pulmonary medicine, including respiratory therapy support, and radiology.

MedStar also fails to include any pharmacy staffing in its staffing model. MedStar March 1, 2018 Completeness Response, Table L. OPTN Bylaws require a transplant program to identify at least one Clinical Transplant Pharmacist on staff who will provide pharmaceutical expertise to transplant recipients. OPTN Bylaws. The Clinical Transplant Pharmacist should be a member of the transplant team, providing comprehensive pharmaceutical care to transplant recipients. Id. The Transplant Pharmacist must be a licensed pharmacist with experience in transplant pharmacotherapy, and must work with patients and their families, and members of the transplant team, including physicians, surgeons, nurses, clinical coordinators, social workers, financial coordinators, and administrative personnel. Id.

The Commission should require MedStar to submit additional detail regarding its staffing plan, and should evaluate the sufficiency of the staffing model in light of OPTN bylaws.

MedStar should also be required to add benefits, which often comprise significant proportion of staffing costs, to its projection.

C. The Majority of MedStar’s Proposed Patients Will Pay More, Not Less, for Transplant Services at MFSMC.

MedStar misleadingly frames its program as a more cost efficient alternative to UMMC and JHH. According to MedStar’s own assertions, however, MedStar will shift only a handful of cases from JHH and UMMC, and MedStar expects that these “existing programs would be able to replace the small number of cases with additional transplant volume” and suffer no volume losses. MedStar March 1, 2018 Completeness Resp., p. 50. As a result, the appropriate cost comparisons are not UMMC and JHH, but MGTL.

MedStar expects that, by the third year of operation, its program volume will have a payer mix that includes 41.9% Medicare patients and 25.3% Medicaid patients. March 1, 2018 Completeness Resp., Table K. Because of Maryland's Total Cost of Care Model State Agreement with CMS, Medicare and Medicaid charges are actually significantly higher in Maryland than nationally. MedStar's proposed charges exceed MGTI's CMS reimbursement rates for Medicare transplant recipients, and likely Medicaid transplant recipients as well. CMS FY 2019 IPPS Impact File, Correction Notice Tables 1A-1E for Labor, Non Labor and Capital Rates and Other Adjustments. As a result, 67.2% of MedStar's projected patients will likely pay more, not less, for liver transplant services if MedStar shifts patients who would otherwise seek services at MGTI to MFSMC.

D. There are Cost-Effective Alternatives to MedStar's Proposed Program.

As discussed throughout these Comments, MedStar may implement its proposed efforts to increase organ use and supply in the Baltimore area without establishing a new program at MFSMC. To the extent that MedStar may not have done so under the existing allocation policy because such efforts would not directly benefit patients on MedStar's MGTI waitlist, the forthcoming changes to the liver allocation policy will eliminate the DSA barrier. As a result, MedStar's efforts will benefit its patients to the same extent they would benefit patients waitlisted at MFSMC, as well as any patients waitlisted at other transplantation programs located, at a minimum, within 150 nautical miles of the hospital where the "new" donor organ becomes available.

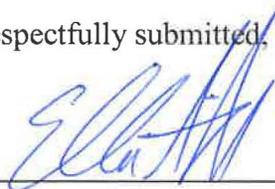
In addition, as set forth more fully in the JHH Comments, UMMC and JHH are adequately serving the needs of the MedStar's targeted service area. To the extent that a handful of patients a year may prefer to have surgery at a location closer to Baltimore, those patients are

able to join waitlists for UMMC and JHH programs as well as MGTI – and in fact may already be on those waitlists. MedStar has not supported the operation of a new program at a cost of \$10 million a year simply for one to two dozen patients annually to avoid 60 minutes of driving.⁸

Conclusion

For the reasons set forth above, UMMC respectfully asks that the Commission deny MedStar’s Application proposing to establish a liver transplant service at MedStar Franklin Square Medical Center.

Respectfully submitted,



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October 15, 2018

⁸ While MedStar projects 30 patients annually, MedStar has had an annual average of only 12 patients from the “Baltimore area.” See Section II, *supra*. Moreover, MedStar has not demonstrated that these patients are in fact close to MFSMC – MedStar defines patients that “orient to Baltimore” as any Maryland resident that resides outside of Montgomery County. MedStar CON Appl., p. 55.

CERTIFICATE OF SERVICE

I hereby certify that on the 15th day of October 2018, a copy of University of Maryland Medical Center's Comments on MedStar Health, Inc.'s CON Application Proposing the Establishment of a Liver Transplant Service at MedStar Franklin Square Hospital Center was sent via email and first-class mail to:

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Ella R. Aiken

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

October 15, 2018

Date



Scott Tinsley-Hall

Director, Strategy & Market
Intelligence

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

October 15, 2018

Date

A handwritten signature in black ink, appearing to read 'Rolf Barth', written over a horizontal line.

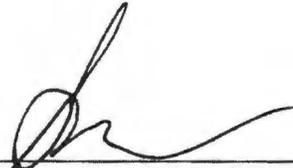
Rolf Barth, MD

Professor of Surgery

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

October 15, 2018

Date



Anahita Masoumi, DNP, MBA, RN
Director of Transplant &
VAD Programs