MedStar Health

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June 1, 2018

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

Re: MedStar Franklin Square Liver Transplant Service- Matter # 17-03-2406

Dear Mr. McDonald:

Attached please find our response to your letter dated May 3, 2018. Should you have any questions regarding this matter, feel free to contact me at (410) 772-6689.

Sincerely,

Patricia G. Cameron
Director, Regulatory Affairs - Maryland

cc: Paul Parker
Gregory Branch, MD, Health Officer, Baltimore County

PART I – PROJECT IDENTIFICATION AND GENERAL INFORMATION

1. Regarding your response to Question #2, please quantify the cost savings that will be passed on with the establishment of the liver and kidney transplant programs to MedStar Health's enrollees in such programs as MedStar Family Choice, MedStar Medicare Choice, MedStar Accountable Care, LLC, and MedStar Select.

MFSMC Response:

Our application, on pages 8 and 9, described MedStar Health's commitment to population health and the need for significant attention to utilization management for the enrollees in our managed care plans. Our previous response to question #2 attempted to describe how the proposed transplant services would be consistent with the concept of a distributed care delivery network, for all of our patients, not just those enrolled in our own managed care plans. Cost savings will accrue to the health care system overall from delivering transplantation services more conveniently in a lower cost community hospital setting, without duplication and redundancies that can be avoided by providing a MedStar Health transplant program in the Baltimore region for MedStar patients, regardless of their insurance coverage.

The table below shows that the liver transplant program at MFSMC would save the health care system between $1.5 million and $2.5 million in the third year of operation, based on a comparison of average charges shown in the discharge abstract. The kidney transplant program would save the system between $1.3 and $2.7 million, for a total savings in Year 3 of between $2.8 and $5.1 million.

Table 1. Estimated Net Charges and System Savings – Liver and Kidney Transplant Services at MFSMC

	MFSMC	JHH	UMMS
Average Charge - Liver	$148,848	$230,871	$198,464
Projected Cases	30		
Total Charges	$4,465,440	$6,926,130	$5,953,920
Savings compared to JHH		-$2,460,690	
Saving compared to UMMS			-$1,488,480
Average Charge - Kidney	$87,203	$148,500	$116,270
Projected Cases	44		
Total Charges	$3,836,932	$6,534,000	$5,115,880
Savings compared to JHH		-$2,697,068	
Saving compared to UMMS			-$1,278,948
Total Savings compared to JHH		-$5,157,758	
Total Saving compared to UMMS			-$2,767,428

Charity Care Policy

2. Regarding MFSMC's charity care policy, specifically to the section relating to determination of probable eligibility, please provide a copy of the "initial financial assistance application."

MFSMC Response:

See Attachment A for the requested financial assistance application.

3. Your response to completeness question 9, requiring a demonstration that MFSMC's level of charity care is appropriate to the needs of its service area residents (because it was in the 4th quartile), stated that "MFSMC is currently developing a plan of action…and will make adjustments to its charity care processes and practices." Please note that your response is still required.

MFSMC Response:

MFSMC refers to the Staff Report and Recommendation of June 15, 2017, Docket No. 16-03- 2380, regarding MFSMC's charity care expense, repeated below:

> MFSMC believes that "these measures have reduced the need for charity care in its community by decreasing the number of uninsured residents and increasing the number of residents with Medicaid insurance" and "...that this factor alone accounts for the decline in charity care provided by the hospital in FY15 and {its} FY15 rank in the bottom quartile for charity care expense as a percentage of total operating expenses among Maryland hospitals...{i.e., that} the decline in charity care it provided to its community in FY15 is the result of a decline in the need for charity care in its community attributable to the factors detailed above." MFSMC presented data showing that its inpatient Medicaid discharges increased by 40% in FY2015 over FY2013, while they increased by 12% statewide. [MHCC] Staff concurs with the applicant's view that its charity care ranking in the bottom quartile is explainable by what appears to be a disproportionate gain in insured patients attributable to the ACA Medicaid expansion undertaken by Maryland and the demographics of its service area, and recommends that the Commission find that this standard has been satisfied.

MFSMC believes that its charity care position is still explainable by these factors. Hospital leadership continues to review its charity care policies and practices, and will report to MHCC staff when its process is complete. The table below, a comparison of charity care metrics for the same July-April period across fiscal years, demonstrates an

improved trend in performance - a 21% growth in applications and a 32% growth in expense - over the 3-year time frame, FY 16 -18.

Table 2. Charity Care Trends

Charity Care Indicators	Jul-Apr FY16	Jul-Apr FY17	Jul-Apr FY18
Charity Care Applications	7,773	8,541	9,400
Charity Care Expense	$4,347,467	$4,293,717	$5,733,595

Quality of Care

4. Staff notes that the review of MFSMC's Quality of Measures on April 3, 2018 indicates that a number of quality of care measure were reported as "Below Average." Please provide details on how the applicant will correct the following quality measure:[1]

Results of Care	Rating	Risk-Adjusted Rates
How often did nurses always communicate well with patients?	Below Average	74%
How often did doctors always communicate well with patients?	Below Average	76%
How often did staff always explain about medicines before giving them to patients?	Below Average	58%
Were patients always given information about what to do during their recovery at home?	Below Average	86%
How well do patients understand their care when they leave the hospital?	Below Average	41%
How often were the patients' rooms and bathrooms always kept clean?	Below Average	58%
How often did patients always receive help quickly from hospital staff?	Below Average	55%
How often was patients' pain always well-controlled?	Below Average	62%
How often was the area around patients' rooms always kept quiet at night?	Below Average	54%
How do patients rate the hospital overall?	Below Average	63%
How long patients spent in the emergency department before leaving for their hospital room	Below Average	452 minutes
How long patients spent in the emergency department before being sent home	Below Average	291 minutes
How long patients spent in the emergency department before they were seen by a healthcare professional	Below Average	55 minutes

[1] Note: CMS provides an update on these quality measures on a quarterly basis (last update was April 1, 2018), though not all of the measures are updated at the same time. Staff requests that the applicant review the status of its quality of care measures during the course of the project's CON review and provide any updates with the course of correction if the status of these measures should change and receive a rating of "below average."

How long patients who came to the emergency department with broken bones had to wait before receiving pain medication	Below Average	71 minutes
Patients who left the emergency department without being seen	Below Average	4%
How long patients who come to the hospital with chest pain or possible heart attack waited to get a test that detects heart damage after a heart attack	Below Average	12 minutes
Patients who had a low-risk surgery and received a heart-related test, such as an MRI, at least 30 days prior to their surgery though they do not have a heart condition	Below Average	6%

MFSMC Response:

Results of Care	Rating	Risk-Adjusted Rates	Corrective Action
How often did nurses always communicate well with patients?	Below Average	74%	bedside shift report and inviting patient and families to attend daily IMOC (interdisciplinary Model of Care) Rounds
How often did doctors always communicate well with patients?	Below Average	76%	5-minute Physician sit-down at bedside
How often did staff always explain about medicines before giving them to patients?	Below Average	58%	information sheets for nursing with common medication indication information and Pharmacy rounding on select patients
Were patients always given information about what to do during their recovery at home?	Below Average	86%	pilot discharge folder on 1T to address info such as discharge medications, follow-up appointments, etc.
How well do patients understand their care when they leave the hospital?	Below Average	41%	pilot discharge folder on 1T to address info such as discharge medications, follow-up appointments, etc.
How often were the patients' rooms and bathrooms always kept clean?	Below Average	58%	EVS leaving high-touch area cards in patient rooms of the areas that have been cleaned, such as the bathroom and bedside table, with a contact number if additional housekeeping was needed
How often did patients always	Below	55%	a "No pass zone" to respond to call bells

receive help quickly from hospital staff?	Average		in a more timely manner and purposeful hourly rounding to proactively address patient needs
How often was patients' pain always well-controlled?	Below Average	62%	Dimension discontinued in Jan 2018, focus on new Communication about Pain questions
Results of Care	**Rating**	**Risk-Adjusted Rates**	**Corrective Action**
How often was patients' pain always well-controlled?	Below Average	62%	Dimension discontinued in Jan 2018, focus on new Communication about Pain questions
How often was the area around patients' rooms always kept quiet at night?	Below Average	54%	using white noise machines on specific units at night to promote sleep and silence ambient noise on the unit
How do patients rate the hospital overall?	Below Average	63%	Key drivers are Communication with Doctors and Communication with Nurses, continue to monitor efforts being made to improve those dimension scores. Efforts are focused on daily meetings with patient, physician and nurse (and family member if desired) to discuss daily treatment plans, etc.
How long patients spent in the emergency department before leaving for their hospital room	Below Average	452 minutes	full-capacity protocol in place when criteria met and patients meeting criteria are transferred to the floors in a hallway location to begin their inpatient care
How long patients spent in the emergency department before being sent home	Below Average	291 minutes	FastER which focuses on evaluating patients in FlexCare locations or transferring appropriate post-MSE patients to appropriate care setting
How long patients spent in the emergency department before they were seen by a healthcare professional	Below Average	55 minutes	FastER which focuses on evaluating patients in FlexCare locations or transferring appropriate post-MSE patients to appropriate care setting
How long patients who came to the emergency department with broken bones had to wait before receiving pain medication	Below Average	71 minutes	FastER which focuses on evaluating patients in FlexCare locations
Patients who left the emergency department without being seen	Below Average	4%	Evaluating reasons why patients leave the ED and when during their ED visit they leave (pre-triage, between triage and evaluation, post-eval pre-treatment etc.). Focus is on shorter wait-times to treatment and patient triage at time of check in.

How long patients who come to the hospital with chest pain or possible heart attack waited to get a test that detects heart damage after a heart attack	Below Average	12 minutes	FastER which focuses on evaluating patients in FlexCare locations with the intention of reserving the main ER for more acute patients with lower ESI scores
Results of Care	**Rating**	**Risk-Adjusted Rates**	**Corrective Action**
Patients who had a low-risk surgery and received a heart-related test, such as an MRI, at least 30 days prior to their surgery though they do not have a heart condition	Below Average	6%	Cardiac CT angiography service for patients presenting to the ED with chest pain. This exam can rule out coronary artery stenosis as cause of chest pain much faster than traditional stress testing. 3 hours vs. 8 – 12 hours

Project Review Standards – State Health Plan

Need and Access

5. Regarding your response to Question #14, please provide details that address "creating transportation alternatives" and focusing on social support for these patients. How will the applicant fund this program, and will the program also provide room and board for family and friends to accompany the patient for the various examinations and tests both before and follow-up after the organ transplantation procedure?

MFSMC Response:

The response to question #14 described the challenges of travel to the transplant center at MGTI for populations (especially minorities) that may have less access to transportation funding or family resources, and social support. The proposed program at MFSMC will provide transportation for patients for emergent and urgent clinical conditions and in more routine instances as appropriate to maintaining continuity of care. For emergent urgent cases, MFSMC is fully integrated with the MedSTAR Transport system and is able to provide timely critical care transportation 24/7. For routine needs when a sedan or wheelchair van service is acceptable, we work with local health departments to facilitate round trip transportation for medical assistance patients. For other patients in need of routine transportation, we have contracted vendors that will support us on an as needed basis. Payment for this service is either from the patient or family. For those individuals that qualify based on income, the transplant institute has a philanthropically-supported funding for small dollar needs.

Social support will be provided - both pre and post transplantation - to patients and their families by our team of licensed Social Workers. MGTI social workers collaborate with other allied health professionals such as pharmacists, dieticians, pastoral care, and financial counselors as individual patient needs dictate.

Minimum Volume Requirements

6. Regarding your response to Question #19, please state the minimum volume thresholds needed for (1) CMS certification and (2) managed care organizations' Centers of Excellence (COE) certification.

MFSMC Response:

The CMS volume requirement for participation is ten liver transplants per year (and three per year for kidney transplants). See: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/downloads/Transplantfinal.pdf

Managed care Centers of Excellence requirements are shown below.

Table 3. Volume Requirements, Managed Care

	Kidney	Liver
Aetna	40	30
Cigna	30	12
LifeTrac	50	40
Optum	50	35

Cost Effectiveness

7. Regarding your response to Question #21, please provide details as to when the applicant expects to start performing living donor liver transplantations at MFSMC.

MFSMC Response:

MFSMC will initially offer living donor transplantation through MGTI, as described previously. MFSMC does not plan to perform living donor liver (LDL) transplantation procedures until such time as the deceased donor and hepato-biliary resection programs are fully established, including optimization of the inpatient team, operating room nursing (to run two rooms simultaneously) and fully-capable critical care management.

Impact

8. Regarding your response to Question #26, the applicant states that "MGTI is currently performing liver transplants currently on Baltimore area residents that could be performed at MFSMC." Will the establishment of the MFSMC liver transplant program have an adverse impact on MGTI's program with respect to staff and quality of care?

MFSMC Response:

There will be no adverse impact on MGTI's program with respect to staffing or quality of care. MGTI operates a robust program in Washington, DC that has capacity to expand the clinical and managerial operation as needed, both in terms of variable staff (nurse coordinators, OR staff, nursing et al.) and core staff (data management, administration et al.) in order to support growth in program volume. We have sufficient personnel to staff both programs in the initial start-up phases, and will bring on more staff as clinical care needs are prescribed by programmatic growth.

Health Promotion and Disease Prevention

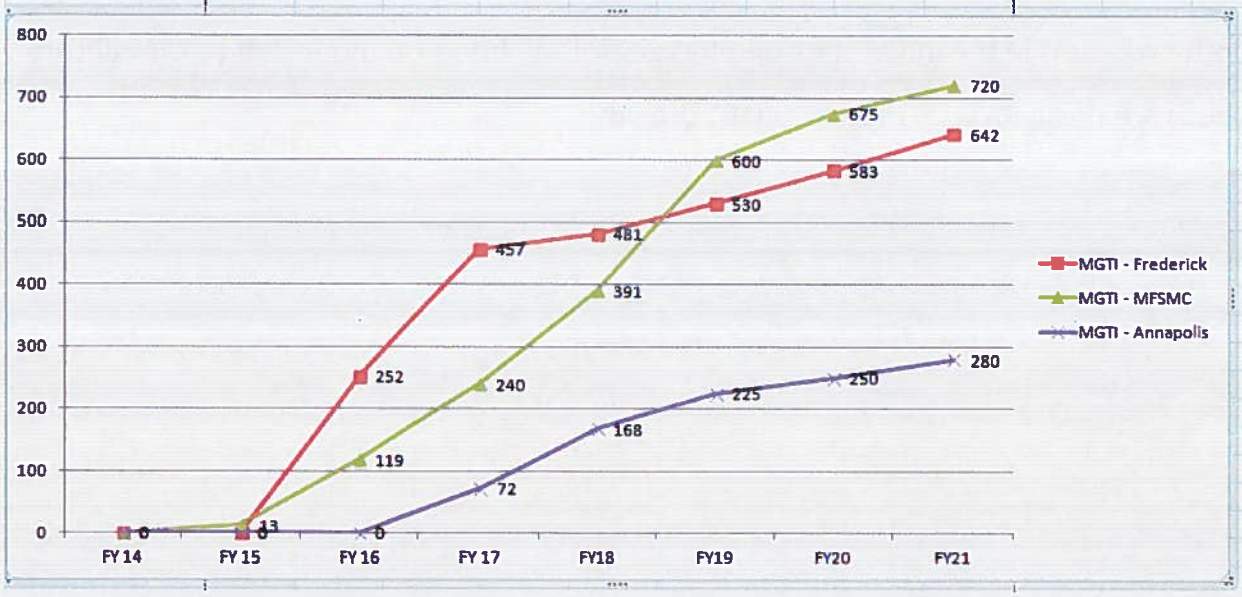
9. Regarding Figure 31 on p. 52, please provide projected MGTI Outreach Visits for FY 2018 through FY 2021.

MFSMC Response:

The projections are shown in the table below.

Table 4. Trend in MGTI Outreach Visits

	FY 14	FY 15	FY 16	FY 17	FY18	FY19	FY20	FY21
MGTI - Frederick	0	0	252	457	481	530	583	642
MGTI - MFSMC	0	13	119	240	391	600	675	720
MGTI - Annapolis	0	0	0	72	168	225	250	280



NEED

10. Regarding your response to Question #28(b), your response provides national trends in liver disease. Please provide utilization rates based on historic trends and expected future changes to those trends that are specific for the service area population indicated in your response to #28(a) of this completeness response.

MFSMC Response:

Chronic liver disease is a primary indicator of the need for liver transplantation. Using national prevalence rates of chronic liver disease applied to the LLF OPO population, and conservatively assuming that 2.0% of people with the disease will experience liver failure and need a liver transplant, MFSMC provides in the table below a historical and projected future volume of liver transplants needed in this geography.

Table 5: Liver Transplant Need in the LLF OPO Geography
Historical Trends & Projection

	Historic				Forecast	
Metric	**CY2010**	**CY2015**	**CY2016**	**CY2017**	**CY2021**	**CY2025**
Population[1]	3,791,804	3,890,944	3,914,075	3,937,205	4,031,891	4,133,066
Chronic Liver Disease/1000 Pop.[2]	0.3178	0.3178	0.3178	0.3178	0.3178	0.3178
Transplant Need	1,205	1,237	1,244	1,251	1,281	1,313

[1]Source: LLF OPO population (All Maryland excluding Charles, Montgomery and Prince Georges County): 2017 Total Population Projections for Non-Hispanic White, Non-Hispanic Black, Non-Hispanic Other and Hispanic by Age and Gender (August 2017), Prepared by the Maryland Department of Planning, Projections and State Data Center
[2]Source: U.S. Population: https://www.census.gov/quickfacts/fact/table/US/PST045216; Chronic Liver Disease Prevalence: *https://www.cdc.gove/nchs/fastats/leading-causes-of-death.htm*. For this calculation, MFSMC assumed that 2.0% of chronic liver disease cases require transplant at any time.

This level of transplant need far exceeds the number of donor organs available for transplantation in the LLF OPO. This projected shortfall of available donor organs is also in line with national and Maryland data that indicate a large gap between the supply of donor organs and the demand for donor organs. This data was previous referenced by MFSMC in its Figure 11: Organ Supply vs. Demand (National) and Figure 12: Organ

Supply vs. Demand (Maryland) in its response to staff's first set of completion questions, p.24-26.

It is this shortfall of donor organs, and MGTI's demonstrated ability to increase the supply of donor organs, that forms the basis of MFSMC's case for its proposed liver transplant program.

The table below summarizes MGTI's CY2016 success in applying innovations and initiatives that increase the supply of donor livers. It also projects the volume, by type of transplant, of the application of these innovations and initiatives at the proposed MFSMC program in CY2021.

Table 6. Liver Transplants by Type, MGTI Experience and MFSMC Projected

Innovation/Initiative	MGTI Experience[1] (CY2016 – Total n =117)		Projected MFSMC Impact (CY2021 – Total n =30)	
	Cases	% Total	Cases	% Total
Split/Partial	19	16.2%	5	16.7%
Living Donor/Partial	5	4.3%	1	3.3%
Domino Liver (pediatric)	3	2.6%	0	0%
Routine	90	76.9%	24	80.0%
Total	**117**	**100%**	**30**	**100%**

[1]Source: Internal data

AVAILABITY OF MORE COST-EFFECTIVE ALTERNATIVES

11. Question 30 asked MFSMC to "articulate very plainly [the project's] goals and objectives." The response spoke to the reputation of its transplant program at MGTI, abilities to meet needs of a minority population, and the enthusiasm of individual patients and their doctors for establishment of such a program at MFSMC. This is not a" clear articulation of goals and objectives."

MFSMC Response:

Specific goals and objectives related to the proposed combined liver/kidney transplant program are listed below:

- *Provide a combined kidney and liver transplant service, and thereby support those liver transplant patients that will require a simultaneous liver kidney (SLK) transplant, the standard of care for patients with co-existing disease, since ≈15% of individuals with advanced liver disease also develop kidney failure, and outcomes are far better when the transplants are performed simultaneously;*
- *Reduce the cost of transplantation services by developing a high quality transplant program in a community hospital setting;*
- *Increase the availability of organs through the application of advanced surgical techniques, such as split liver transplantation, where one organ is utilized for more than one recipient, paired kidney exchanges, and living donors; encouraging more living donation, judiciously matching "marginal" donors to recipients by their individual characteristics (age, coexisting disease, size etc), and desensitization protocols that permit matching donors and recipients with ostensible ABO incompatibility.*
- *Better serve referring gastroenterologists and internists in the community who have expressed a need for assistance with the long-term management of these complex patients;*
- *Offer the Baltimore community MGTI's deep experience with transplanting complicated patients – with improved clinical outcomes;*

- *Obviate redundancy and duplication through strict utilization management, effective transitions in care, risk and illness stratification and care coordination overall; and*
- *Build on MFSMC's strong teaching mission, its robust digestive disease center and strong relationship with local dialysis centers.*

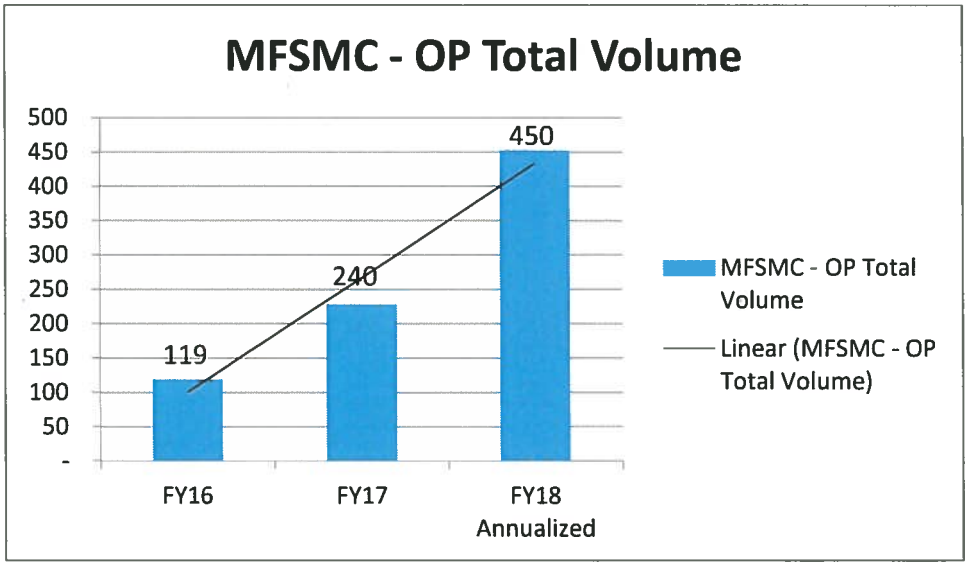
VIABILITY OF THE PROPOSAL

12. Your response to Question 33 – presented in graphical format – does not allow for extraction of actual numbers. Please restate the response with simple numbers.

MFSMC Response:

The actual volumes at the Advanced Liver Disease Center at MFSMC depicted on that graphic could be found in Figure 31 in response to question #27 of our first completeness response. These are now incorporated in the chart below.

FIGURE 34 (revised): MFSMC PATIENTS REFERRED/EVAL/LISTED/TRANSPLANTED



IMPACT

13. The applicant did not provide a response to Completeness Question #36. Please provide a response, which requested the following:

As the applicant is an existing hospital, please follow the instruction to provide a summary description of the impact of the proposed project on costs and charges of the applicant hospital, consistent with the information provided in the application's tables package.

MFSMC Response:

For the initial year, MFSMC expects operating revenues of $2.9 million with matching expenses of $3.5 million, resulting in an operating loss of $0.6 million in the first year of operation. The program is expected to be profitable by year three.

TABLES

14. Please explain the nature of the "non-transplant discharges" listed in Table I.

MFSMC Response:

Non-transplant discharges were calculated by assessing preoperative and postoperative admissions related directly to the actual transplant procedures performed at MGUH in 2016. In addition to these admissions, patients with progressive disease, who might not proceed to transplantation but were admitted for medical management and interventional procedural treatments, were incorporated; this latter group was included under the proviso that patients with advanced disease will seek the expertise of a center experienced in advanced disease management and transplantation.

15. Regarding Tables J and K, please provide:

a. The assumptions used to calculate allowance for bad debt, contractual allowance, and charity care;
b. The basis for "Other Expenses" and "Purchased Services."

MFSMC Response:

Allowances for bad debt, contractuals and charity care are based on historical trend data for MFSMC.

Purchased Services are related to payment for organ acquisition services through the OPO as well as additional organ transport services (i.e., jet transport for distantly-located organs) when indicated.

Other Expenses refers to miscellaneous costs incurred for the courier of materials between OPOs, middle-of-the-night transportation (patients who cannot get to the hospital independently), and organ "packaging" for transport. These are costs that are not included routinely in the organ cost for individual patients.

16. Regarding Table L, please clarify the discrepancy between the reduction of 22.5 FTEs at a cost of about $3.0 million in the table with the assumptions in Attachment 11 under Expense Reductions and Saving Initiatives, Item B that the project will result in the reduction of 20 FTEs at a cost of $2 million.

MFSMC Response:

The FTE changes reported in Table L are correct. Attachment 11, item B under '*Expense Reductions and Savings Initiatives*' refers to a separate project, a part of overall FTE savings to MFSMC, but not directly related to the liver or kidney transplantation proposals.

Attachment A

MedStar Health Uniform Financial Assistance Application

Patient Account Number(s):_____

Information About You

Name _____
First Middle Last

Social Security Number _____-____-_____ Marital Status: Single Married Separated
US Citizen: Yes No Permanent Resident: Yes No

Home Address _____ Phone _____

_____

_____ _____
City State Zip code Country

Employer Name _____ Phone _____

Work Address _____

_____
City State Zip code

Household members:

Name	Age	Relationship

Have you applied for Medical Assistance Yes No
If yes, what was the date you applied? _____
If yes, what was the determination? _____
Do you receive any type of state or county assistance? Yes No
Advocate that completed or mailed F/A Application:_____ Date:_____

I. Family Income

List the amount of your monthly income from all sources. You may be required to supply proof of income, assets, and expenses. If you have no income, please provide a letter of support from the person providing your housing and meals.

	Monthly Amount
Employment	
Retirement/pension benefits	
Social security benefits	
Public assistance benefits	
Disability benefits	
Unemployment benefits	
Veterans benefits	
Alimony	
Rental property income	
Strike benefits	
Military allotment	
Farm or self employment	
Other income source	
Total	

II. Liquid Assets

	Current Balance
Checking account	
Savings account	
Stocks, bonds, CD, or money market	
Other accounts	
Total	

III. Other Assets

If you own any of the following items, please list the type and approximate value.

Home	Loan Balance _____	Approximate value _____
Automobile	Make __N/A___ Year __N/A____	Approximate value _____N/A____
Additional vehicle	Make ___N/A__ Year _N/A____	Approximate value ____ N/A_____
Additional vehicle	Make ___N/A____ Year __N/A__	Approximate value _____N/A_____
Other property		Approximate value _____N/A_____
		Total _____

IV. Monthly Expenses

	Amount
Rent or Mortgage	___N/A_____
Utilities	___N/A_____
Car payment(s)	___N/A_____
Credit card(s)	___N/A_____
Car insurance	___N/A_____
Health insurance	___N/A_____
Other medical expenses	_____
Other expenses	___N/A_____
Total	_____

Do you have any other unpaid medical bills? Yes No

For what service? _____

If you have arranged a payment plan, what is the monthly payment? _____

If you request that the hospital extend additional financial assistance, the hospital may request additional information in order to make a supplemental determination. By signing this form, you certify that the information provided is true and agree to notify the hospital of any changes to the information provided within ten days of the change.

_____ _____

Applicant signature Date

_____

Relationship to Patient

Affirmations

Affirmation

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

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

June 1, 2018

Affirmation

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

Eric Slechter
Director of Planning
MedStar Franklin Square Medical Center
MedStar Harbor Hospital

6/1/18
(date)