

**MARYLAND
HEALTH
CARE
COMMISSION**

MATTER/DOCKET NO.

DATE DOCKETED

**HOSPITAL
APPLICATION FOR CERTIFICATE OF NEED**

PART I - PROJECT IDENTIFICATION AND GENERAL INFORMATION

1. FACILITY

Name of Facility: Franklin Square Hospital Center d/b/a MedStar Franklin Square Medical Center

Address:

<u>9000 Franklin Square Drive</u>	<u>Rosedale</u>	<u>21237</u>	<u>Baltimore</u>
Street	City	Zip	County

Name of Owner (if differs from applicant):
MedStar Health, Inc.

2. OWNER

Name of owner: MedStar Health, Inc.

3. APPLICANT. *If the application has co-applicants, provide the detail regarding each co-applicant in sections 3, 4, and 5 as an attachment.*

Legal Name of Project Applicant

Franklin Square Hospital Center d/b/a MedStar Franklin Square Medical Center

Address:

<u>9000 Franklin Square Drive</u>	<u>Rosedale</u>	<u>21237</u>	<u>MD</u>	<u>Baltimore</u>
Street	City	Zip	State	County

Telephone: 443-777-7000

Name of Owner/Chief Executive Samuel E. Moskowitz, FACHE

4. NAME OF LICENSEE OR PROPOSED LICENSEE, if different from applicant:

N/A

MedStar Franklin Square Medical Center Liver Transplant Service

5. LEGAL STRUCTURE OF APPLICANT (and LICENSEE, if different from applicant).

Check or fill in applicable information below and attach an organizational chart showing the owners of applicant (and licensee, if different).

- A. Governmental
- B. Corporation
- (1) Non-profit
- (2) For-profit
- (3) Close
- State & date of incorporation
State of Maryland, 1898;
amended State of Maryland,
1901
- C. Partnership
- General
- Limited
- Limited liability partnership
- Limited liability limited partnership
- Other (Specify): _____
- D. Limited Liability Company
- E. Other (Specify): _____
- To be formed:
- Existing:

6. PERSON(S) TO WHOM QUESTIONS REGARDING THIS APPLICATION SHOULD BE DIRECTED

A. Lead or primary contact:

Name and Title: Patricia G. Cameron, Director, Regulatory Affairs - Maryland

Mailing Address:

10980 Grantchester Way Columbia 21044 MD
Street City Zip State

Telephone: 410-772-6689

E-mail Address (required): patricia.cameron@medstar.net

Fax: _____

B. Additional or alternate contact:

MedStar Franklin Square Medical Center Liver Transplant Service

Name and Title: Anne P. Weiland – Vice President – MedStar Health

Mailing Address:

100 Irving Street NW Suite 3125	Washington	20010	DC
Street	City	Zip	State

Telephone: 202-877-3524

E-mail Address (required): anne.p.weiland@medstar.net

Fax: 202-877-3852

Name and Title: Eric Slechter – Director, Strategic & Business Planning, MFSSMC and MHHH

Mailing Address:

9000 Franklin Square Drive	Baltimore	21237	MD
Street	City	Zip	State

Telephone: 443-777-7525

E-mail Address (required): Eric.Slechter@medstar.net

Fax:

7. TYPE OF PROJECT

The following list includes all project categories that require a CON under Maryland law. Please mark all that apply.

If approved, this CON would result in:

- (1) A new health care facility built, developed, or established
- (2) An existing health care facility moved to another site
- (3) A change in the bed capacity of a health care facility
- (4) A change in the type or scope of any health care service offered by a health care facility
- (5) A health care facility making a capital expenditure that exceeds the current threshold for capital expenditures found at:
http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_con/documents/con_capital_threshold_20140301.pdf

8. PROJECT DESCRIPTION

A. Executive Summary of the Project: The purpose of this BRIEF executive summary is to convey to the reader a holistic understanding of the proposed project: what it is; why you need/want to do it; and what it will cost. A one-page response will suffice. Please include:

- (1) Brief description of the project – what the applicant proposes to do;
- (2) Rationale for the project – the need and/or business case for the proposed project;
- (3) Cost – the total cost of implementing the proposed project; and
- (4) Master Facility Plans – how the proposed project fits in long term plans.

Response:

MedStar Franklin Square Medical Center (MFSMC), in partnership with the MedStar Georgetown Transplant Institute (MGTI), seeks to establish liver and kidney transplantation programs at MFSMC's campus in Rosedale, Maryland.

The new transplant programs at MFSMC will afford the Baltimore metropolitan area the same outstanding level of clinical expertise, superior clinical outcomes and exceptional patient experience that characterizes MGTI. As described in detail in this document, MFSMC and MGTI expect to effect improvement in both demand and supply sides of the organ acquisition equation in the Baltimore region. MGTI's expertise in the effective medical management of liver disease patients, including viral hepatitis screening and treatment, has resulted in decreases in the demand for organs. As well, through the application of innovative surgical techniques, targeted toward optimizing utilization of organs, and successful efforts in expanding living donor options, MGTI is further expanding the available donor organ supply. These effective approaches to care will be mirrored at MFSMC.

MGTI's level of achievement in evaluating and transplanting minority populations exceeds both local and national benchmarks. A highly advanced clinical research platform underlies all of these clinical activities and these efforts will continue to be

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applied and expanded to support and benefit Maryland transplant patients. Finally, importantly, the cost structure at MFSMC is significantly lower than either existing transplant center in Baltimore. Hence, MFSMC provides a more cost-effective option for transplantation in Maryland, serving ultimately to lower costs across the health care system.

This project does not require facility renovations or new construction, and accords with MFSMC's existing Master Facility Plan.

In summary, establishing liver and kidney transplantation programs at MFSMC advances the goals of the *State Health Plan for Facilities and Services: Specialized Health Care Services – Organ Transplant Services* and the Maryland Health Care Commission.

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B. Comprehensive Project Description: The description must include details, as applicable, regarding:

- (1) Construction, renovation, and demolition plans;
- (2) Changes in square footage of departments and units;
- (3) Physical plant or location changes;
- (4) Changes to affected services following completion of the project; and
- (5) If the project is a multi-phase project, describe the work that will be done in each phase. If the phases will be constructed under more than one construction contract, describe the phases and work that will be done under each contract.

Response:

MedStar Franklin Square Medical Center, Transplant Center Comprehensive Project Description

Introduction

The evolution of solid organ transplantation over the last five decades has markedly altered the outcome of end-stage organ failure, in particular the most commonly affected organs - the liver and kidney. The incidence of viral hepatitis and liver cancer is growing exponentially in our country. End-stage renal failure is among the leading causes of death and disability in the nation, in large part attributable to the growing incidence and prevalence of diabetes mellitus. In this context, 200,000 people die from these diseases annually and the number of patients awaiting transplant increases every year.

Driving the rationale for MFSMC's combined liver and kidney organ transplant services through integration with MGTI is the fact that many patients requiring a liver transplant also require a kidney transplant as several disease processes affect both organs. Advanced liver disease can lead to *hepato-renal syndrome*, a life-threatening medical condition that consists of rapid deterioration in kidney function in patients with cirrhosis or fulminant liver failure. Up to 50% of hospitalized cirrhotic patients have acute kidney

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injury. The yearly incidence of *hepato-renal syndrome* in patients with decompensated cirrhosis and ascites is 12%.¹

Organ allocation policy favors patients who require both organs, and patients with this condition rise to the top of the waiting list; typically, these combined transplants are accomplished with organs from the same deceased donor. Nationally and in Region 2 (which includes the State of Maryland), ten to fifteen percent of liver recipients receive both organs concurrently.² Accordingly, most liver transplant programs exist in association with a kidney program, since a stand-alone liver transplant program is not able to manage this population of patients, who require transfer to another center.

By integrating with MGTI's multi-organ transplant program and research enterprise located in Washington, DC, patients will be afforded additional access and specialized expertise. As well, the addition of kidney and liver transplant services at MFSMC is important to addressing the MHCC's goal to increase the available organ supply and utilization for transplant recipients. To achieve this, MFSMC is requesting approval for two separate certificates of need for kidney and liver transplantation, as required by the State of Maryland.

MedStar Health

MedStar Health is a \$5.3 billion not-for-profit healthcare system based in Columbia, Maryland serving residents across the Baltimore-Washington, DC corridor. MedStar

1 Garcia-Tsao G, Parikh CR, Viola A. Acute kidney injury in cirrhosis. *Hepatology* 2008;**48**:2064–77; Buccsics T, Krones E. Renal dysfunction in cirrhosis: acute kidney injury and the hepato-renal syndrome. *Gastroenterology Report*. 2017;5(2):127-137. doi:10.1093/gastro/gox009.

2 Fagundes C, Barreto R, Guevara M, Garcia E, Solà E, Rodríguez E, Graupera I, Ariza X, Pereira G, Alfaro I, et al. A modified acute kidney injury classification for diagnosis and risk stratification of impairment of kidney function in cirrhosis. *J Hepatol*. 2013;59:474–481; Gines A, Escorsell A, Gines P, et. al. Incidence, predictive factors and prognosis of the hepatorenal syndrome in cirrhosis with ascites. *Gastroenterology* 1993; 105(1):229-36.

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Health is comprised of tertiary care academic medical centers, community hospitals, an acute care rehabilitation hospital and an extensive delivery system that includes a primary and specialty care physician network, a comprehensive configuration of outpatient rehabilitation sites, home health services and ambulatory care venues that offer physician consultation, urgent care and surgery.

MFSMC offers a full range of clinical services with sophisticated capabilities in critical care, cancer treatment and gastroenterology with broad-based primary care physician training programs and one of the busiest emergency departments in the state. MFSMC is an ideal site for the location of a new transplant center for kidney and liver diseases. In addition to serving as a center for digestive disease diagnosis and treatment, it is surrounded by 10 dialysis centers that are situated within a two-mile radius. Patients and physicians in the local vicinity and beyond are enthusiastic about the potential of improved access - and convenience - to a top tier transplant center. See letters of support.

Commitment to Population Health

MedStar Health's strategy to manage the population's health is based on its continued development of a distributed care delivery network (DCDN) through providing broad access for the patients MedStar serves. In addition to the build out of the DCDN, MedStar has continued to increase the number of covered lives it is responsible for through a variety of insurance products. MedStar Family Choice, MedStar's Medicaid managed care organization, has participated in the state's HealthChoice program since its inception in 1997. It has consistently provided high quality cost effective care to its enrollees. Today, MedStar Family Choice is at risk for providing the care necessary for over 85,000 Medicaid recipients. The MedStar Medicare Choice program has over 11,000 covered lives. MedStar Accountable Care LLC is a Track 3 Medicare Shared Savings Program with nearly 50,000 attributed Medicare lives. And, MedStar Select is an insurance product available to MedStar associates. All of these programs require significant attention to utilization management, effective transitions in care, risk and illness stratification, and

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care coordination for the populations served. All are critical to improving population health.

MedStar's plan to locate kidney and liver transplant services at MFSMC furthers its commitment to managing population health, as it assures better access to needed services for the nearly 250,000 covered lives MedStar manages.

Integration between the MedStar Georgetown Transplant Institute and MedStar Franklin Square Medical Center

The integration between MGTI and MFSMC enables extension of the expertise and efficiency of one of the largest and most sophisticated transplant programs in the United States, to MFSMC and the Baltimore region. MGTI is committed to advancing the field of transplantation, which it accomplishes through its strict attention to maintaining excellence in clinical care and an active research enterprise through the Center for Translational Transplant Medicine (CTTM), a multi-disciplinary approach to transplantation research which was founded in collaboration with Georgetown University in 2013. CTTM has long-served as a valuable resource for individuals experiencing all categories of organ compromise and failure, including those affecting the kidney, pancreas, liver and small bowel.

MGTI's transplant programs are high-volume, experienced programs that are among the top centers in the nation as demonstrated in the figure below.

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Figure 1

US Transplant Center Rankings by Volume		2016
Rank	Center	Abdominal Organs
0	All Centers	28,856
1	FLJM-TX1 Jackson Memorial Hospital	536
2	CAUC-TX1 UCLA Medical Center	527
3	WIUW-TX1 Univ of Wisconsin Hosp and Clinics	527
4	CASF-TX1 Univ of CA San Francisco Med Ctr	520
5	AZMC-TX1 Mayo Clinic Hospital	477
6	GAEM-TX1 Emory University Hospital	444
7	INIM-TX1 Indiana University Health	442
8	TXHS-TX1 Methodist Specialty & Transplant Hosp	440
9	MDUM-TX1 Univ of Maryland Med System	407
10	CASM-TX1 UC Davis Medical Center	403
11	DCGU-TX1 Georgetown Univ Med Ctr	398
12	NYMS-TX1 Mount Sinai Med Center	373
13	LAOF-TX1 Ochsner Foundation Hospital	373
14	ALUA-TX1 Univ of Alabama Hospital	366
15	MNMC-TX1 Rochester Methodist Hosp- Mayo Clinic	359
16	TXMH-TX1 Houston Methodist Hospital	358
17	FLTG-TX1 Tampa General Hospital	355
18	TNVU-TX1 Vanderbilt Univ Med Ctr	353
19	ILNM-TX1 Northwestern Memorial Hospital	347
20	OHCC-TX1 Cleveland Clinic Foundation	342
21	MDJH-TX1 Johns Hopkins Hospital	342

MGTI programs have grown substantially (almost 30% overall) over the past five years while maintaining the highest levels of excellence in patient and graft survival, operational effectiveness and patient satisfaction. Using calendar year 2016 data and based on the total number of transplants completed, MGTI is the 11th largest transplant center in the United States and the second largest transplant center in the Baltimore-Washington, DC region behind only the University of Maryland Medical System. Nationally, the University of Maryland is 9th, MGTI is 11th and Johns Hopkins is ranked 21st.

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MGTI is under the clinical and administrative direction of Dr. Thomas M. Fishbein, an international leader in the field of liver and small bowel transplantation. Trained at Mt. Sinai Medical Center in New York City, Dr. Fishbein has overseen an 85% percent expansion in transplant cases at MGTI since his arrival in late 2003. The intestinal transplant program is the largest and most clinically successful in the United States and the only program in the region. Patients seek care for this type of transplantation from many states across the nation and from outside the United States. MGTI's pediatric liver transplant program is consistently one of the two largest in the United States. Both adult and pediatric liver transplant programs boast patient and graft survival that are superior to national averages as reported by the Scientific Registry of Transplant Recipients (SRTR).

Dr. Fishbein has recruited an extraordinary team of physicians and ancillary providers to lead these efforts in all aspects of solid organ transplantation as noted below.

MGTI Liver Transplant Program

Through a team of five fellowship-trained, highly experienced hepatologists led by Dr. Rohit Satoskar, who trained at the University of Chicago Hospitals, patients can be evaluated for transplant within two weeks of referral at a variety of MedStar sites across the State of Maryland.

As discussed at greater length below, MGTI's liver transplant program provides greater access to minority populations (more than 51% are minorities), than any program in the region or nation. In addition, MGTI transplants the highest number of the most critically ill patients awaiting transplant relative to other centers in the State of Maryland, regionally and nationally. The most recent data show that 16% of liver transplant candidates were "Status I," the most gravely ill category, relative to regional and national averages in the 5-6% range and that overall severity scores are comparable with local program averages.

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MGTI's patient wait times for liver transplant average 7.4 months as compared to the Living Legacy Foundation Donor Service Area (LLF DSA) average of 22.8 months. The regional average (UNOS region 2 including DC, Maryland, Pennsylvania, New Jersey, Delaware and West Virginia) is 18.3 months, while the national average is 14.4 months. The table below shows the waiting times for liver transplant candidates at area centers.

TIME TO TRANSPLANT (Months waiting on list)

SRTR April 2017	MGTI	JHH	UMMS
25 th percentile	1.7	5.9	1.5
50 th percentile	7.8	Not observed *	14.0

* "Not observed" means that less than that percentile of patients had received a transplant, e.g., more than 50% of patients waiting have not received a transplant during the follow up period or were removed because of death or other reasons.
(Source: SRTR April 2017)

Dr. Fishbein's experience with *partial and split liver transplantation* has substantially augmented the number of organs available for recipients in need as will be explained in more detail later in this application. In addition, the liver transplant service continues to expand its active living donor liver program in order to address the shortage of available cadaveric organs. Collectively, these programs expand the pool of transplantable organs more than live donor liver transplantation at other programs currently available in Maryland.

MGTI's Rate of Transplantation is Higher Than Other Maryland Transplant Centers

Transplant rate is a measure of how frequently patients undergo transplant at a program per every 100 patients per year waiting. Both living and deceased donor transplants are counted. The percentage of MGTI liver transplant candidates from the waiting list receiving transplants is double the national average at 45.4 while centers in the LLF DSA have an average transplant rate of 36.6. These numbers reflect an MGTI strategy that differs from other regional programs. Rather than boast the largest wait list, MGTI patients are evaluated and listed for transplant in a timely manner that enables a short interval to organ availability and excellent outcome.

MGTI's Minority Transplantation Rates for Liver Are the Highest in Local OPOs and Higher Than the U.S. Average

MGTI is a leader in transplantation to minorities, a subject of intense debate not only in the media but in the academic literature. In both contexts it has been noted that these candidates do not receive transplants as quickly as do non-minority candidates. Transplant registry data show that MGTI has both wait-listed and transplanted minority (African-American, Hispanic/Latino, Asian, Other) liver candidates that exceed regional and national averages (see figure below). By contrast, both current programs in Baltimore transplant minorities at significantly lower rates than the MGTI program. MGTI takes its commitment to providing access to these populations in the Washington metropolitan area very seriously and will do the same in the Baltimore region.

Figure 2. LIVER Transplant Wait List by Ethnicity

	SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS	Georgetown University Medical Center Center Code: DCGU Transplant Program (Organ): Liver Release Date: July 6, 2017 Based on Data Available: April 30, 2017	SRTR Program-Specific Report Feedback?: SRTR@SRTR.org 1.877.970.SRTR (7787) http://www.srtr.org
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B. Waiting List Information

Table B2. Demographic characteristics of waiting list candidates
 Candidates registered on the waiting list between 01/01/2016 and 12/31/2016

Demographic Characteristic	New Waiting List Registrations 01/01/2016 to 12/31/2016 (%)			All Waiting List Registrations on 12/31/2016 (%)		
	This Center (N=209)	OPTN Region (N=1,630)	U.S. (N=12,734)	This Center (N=269)	OPTN Region (N=2,072)	U.S. (N=14,723)
All (%)	100.0	100.0	100.0	100.0	100.0	100.0
Ethnicity/Race (%)*						
White	52.2	72.7	68.6	61.3	74.4	68.1
African-American	29.2	15.6	8.7	22.7	14.6	7.8
Hispanic/Latino	12.9	7.7	16.4	7.4	6.7	17.3
Asian	4.3	3.4	4.8	7.8	4.1	5.5
Other	1.4	0.6	1.5	0.7	0.2	1.3
Unknown	0.0	0.0	0.0	0.0	0.0	0.0

NOTE: The column labeled “This Center” refers to MGTI.

MFSMC’s Program Will Be Lower Cost Through Integration of Resources with MGTI

MedStar’s goal is to manage the Liver and Kidney Transplant Programs at MFSMC with needed resources, while keeping the overhead of the operation as “lean” as possible through sharing resources with the MGTI transplant programs in Washington, DC. MFSMC and MGTI will achieve this while making quality of care and patient experience paramount. For example, all data coordination and reporting, and mature Quality Assessment Performance Improvement (QAPI) indicator tracking will remain centralized under MGTI’s seasoned leadership. Because of the strong leadership of MGTI, and the excellent resources integral to MFSMC, MedStar is confident that that this integration

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will enhance MedStar's ability to deliver superior quality, comprehensive, accessible care in Baltimore at a lower cost.

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 MFSMC. MGTI has also extended follow up services required for the long-term maintenance of patient and organ health after transplantation. Building on MGTI's existing platform of highly effective clinical care, excellent graft and patient outcomes and efficient operations, we expect to provide patients seeking transplantation at MFSMC with greater availability and access at the same level of quality available in Washington but at a lesser cost relative to the two transplant programs in Baltimore.

MFSMC's lower cost position can be measured by both the HSCRC's equivalent case mix adjusted discharge (ECMAD) data showing the average charge per ECMAD as well as actual discharge data for transplants conducted at Johns Hopkins and the University of Maryland. The ECMAD data for the nine-month period from July 2016 through March 2017 using HSCRC Abstract Tapes are as follows:

Figure 3. Average Charge per ECMAD Comparison

Provider	Charge Per ECMAD	% Higher Than MFSMC
UMMS	\$19,544	49.2%
Johns Hopkins	\$16,640	27.0%
State Average	\$14,196	8.4%
MFSMC	\$13,099	--

Source: HSCRC Abstract Tapes for 6-month period from October 2015 to March 2016.

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With MFSMC proposed pricing at 25% below the lowest charge Baltimore academic medical center, MFSMC is able to provide the following pricing differential to Medicare, Medicaid and commercial insurers, as shown below:

Figure 4. Average Charge per Case Comparison

Provider	Average Charge per Liver Transplant	% Higher Than MFSMC
Johns Hopkins	\$230,871	55.1%
UMMS	\$198,464	33.3%
MFSMC	\$148,848	--

Source: HSCRC Abstract Tapes for 9-month period from July 2016 to March 2017.

Integrated resources, well-suited facilities and applied technology enable MFSMC to extend the expertise of MGTI to the Baltimore region. At present, MFSMC maintains 40 critical care beds directed by Dr. Stephen Selinger, an experienced, board-certified specialist in pulmonary and critical care medicine. MFSMC plans to dedicate a portion of the critical care unit as an intermediate care unit for liver and kidney transplant patients. MFSMC staff will be fully trained by MGTI staff, who will serve as a consistent available resource. MGTI's Quality Assurance and Performance Improvement (QAPI) function will bring aboard personnel and systems and provide optimal training and maintenance of competencies for all MFSMC staff. MGTI and MFSMC will recognize cost savings because the MFSMC programs can leverage MGTI's existing regulatory infrastructure. At the same time, many of the administrative and data collection and reporting functions will be based at MGTI for greater efficiency in operations.

Current operating room capabilities have been assessed and are adequate to sustain the case complexity anticipated; new operating rooms planned in the near future will provide an enhanced environment of care for patients and staff. Medical consultants in all subspecialty areas are available as needed. MGTI and MFSMC see no clinical resource

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gap at this time and as noted earlier, little capital investment is required. See Table E: Project Budget for capital requirements.

Summary

MFSMC's full clinical integration with MGTI enables MedStar Health to deliver the expertise of MGTI to the Baltimore region in a substantially lower cost setting than is available currently. In particular, the efficiency gained through integration of resources, minor capital equipment additions and greater application of technology assures that MedStar can meet its obligations in managing costs of care for its patients and the healthcare system. Through its partnership with MGTI, the MFSMC transplant programs will enhance clinical innovation and advanced research in the Baltimore metropolitan area. New approaches to medical management, and surgical techniques that have been perfected at MGTI, will be applied at MFSMC to increase the organs available for Maryland transplant recipients and reduce the gap between the supply and demand for organs in Maryland. The program will also clearly serve to reduce the disparity in transplantation rates among minorities, particularly African-Americans, as MGTI has accomplished in Washington.

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- C. Complete the DEPARTMENTAL GROSS SQUARE FEET WORKSHEET (Table B) in the CON TABLE PACKAGE for the departments and functional areas to be affected.**

Response:

The addition of this service does not involve a specific department or functional area. Therefore, this question is not applicable.

9. CURRENT PHYSICAL CAPACITY AND PROPOSED CHANGES

Complete the Bed Capacity (Table A) worksheet in the CON Table Package if the proposed project impacts any nursing units.

Response:

This project does not impact any nursing unit. Therefore, this question is not applicable.

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10. REQUIRED APPROVALS AND SITE CONTROL

- A. Site size: _____ acres
- B. Have all necessary State and local land use approvals, including zoning, for the project as proposed been obtained? YES _____ NO _____ (If NO, describe below the current status and timetable for receiving necessary approvals.)

- C. Form of Site Control (Respond to the one that applies. If more than one, explain.):

- (1) Owned by: _____
Please provide a copy of the deed.
- (2) Options to purchase held by: _____
Please provide a copy of the purchase option as an attachment.
- (3) Land Lease held by: _____
Please provide a copy of the land lease as an attachment.
- (4) Option to lease held by: _____
Please provide a copy of the option to lease as an attachment.
- (5) Other: _____
Explain and provide legal documents as an attachment.

Response:

Question 10 is not applicable because the project does not involve a new site or changes to the existing site.

MedStar Franklin Square Medical Center Liver Transplant Service

11. PROJECT SCHEDULE

In completing this section, please note applicable performance requirement time frames set forth at COMAR 10.24.01.12B & C. Ensure that the information presented in the following table reflects information presented in Application Item 7 (Project Description).

	Proposed Project Timeline	
<u>Single Phase Project</u>		
Obligation of 51% of capital expenditure from CON approval date		months
Initiation of Construction within 4 months of the effective date of a binding construction contract, if construction project		months
Completion of project from capital obligation or purchase order, as applicable		months
<u>Multi-Phase Project</u> for an existing health care facility (Add rows as needed under this section)		
<u>One Construction Contract</u>		
Obligation of not less than 51% of capital expenditure up to 12 months from CON approval, as documented by a binding construction contract.		months
Initiation of Construction within 4 months of the effective date of the binding construction contract.		months
Completion of 1 st Phase of Construction within 24 months of the effective date of the binding construction contract		months
<u>Fill out the following section for each phase.</u> (Add rows as needed)		
Completion of each subsequent phase within 24 months of completion of each previous phase		months
<u>Multiple Construction Contracts</u> for an existing health care facility (Add rows as needed under this section)		
Obligation of not less than 51% of capital expenditure for the 1 st Phase within 12 months of the CON approval date		months
Initiation of Construction on Phase 1 within 4 months of the effective date of the binding construction contract for Phase 1		months
Completion of Phase 1 within 24 months of the effective date of the binding construction contract.		months
<u>To Be Completed for each subsequent Phase of Construction</u>		
Obligation of not less than 51% of each subsequent phase of construction within 12 months after completion of immediately preceding phase		months
Initiation of Construction on each phase within 4 months of the effective date of binding construction contract for that phase		months

MedStar Franklin Square Medical Center Liver Transplant Service

Completion of each phase within 24 months of the effective date of binding construction contract for that phase		months
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Response:

Because this project does not involve construction contracts or construction or renovation, this question does not apply.

12. PROJECT DRAWINGS

A project involving new construction and/or renovations must include scalable schematic drawings of the facility at least a 1/16" scale. Drawings should be completely legible and include dates.

Project drawings must include the following before (existing) and after (proposed) components, as applicable:

- A. Floor plans for each floor affected with all rooms labeled by purpose or function, room sizes, number of beds, location of bathrooms, nursing stations, and any proposed space for future expansion to be constructed, but not finished at the completion of the project, labeled as "shell space".
- B. For a project involving new construction and/or site work a Plot Plan, showing the "footprint" and location of the facility before and after the project.
- C. For a project involving site work schematic drawings showing entrances, roads, parking, sidewalks and other significant site structures before and after the proposed project.
- D. Exterior elevation drawings and stacking diagrams that show the location and relationship of functions for each floor affected.

Response:

Because this project does not involve construction or renovation, this question does not apply.

13. FEATURES OF PROJECT CONSTRUCTION

- A. If the project involves new construction or renovation, complete the Construction Characteristics (Table C) and Onsite and Offsite Costs (Table D) worksheets in the CON Table Package.
- B. Discuss the availability and adequacy of utilities (water, electricity, sewage, natural gas, etc.) for the proposed project, and the steps necessary to obtain utilities. Please either provide documentation that adequate utilities are available or explain the plan(s) or anticipated timeframe(s) to obtain them.

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Response:

Because this project does not involve construction or renovation, this question does not apply.

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PART II - PROJECT BUDGET

Complete the Project Budget (Table E) worksheet in the CON Table Package.

Note: Applicant must include a list of all assumptions and specify what is included in all costs, as well the source of cost estimates and the manner in which all cost estimates are derived.

Response:

See Attachment 1 for Table E. The only capital expenditures required for the liver transplant project are equipment as shown below. The equipment includes:

Sorin Brat Cell Saver	2@	\$20,400	=	\$40,800
TEG ³	1@	\$18,000	=	\$18,000
GEMStat ⁴	2@	\$ 8,500	=	\$17,000

MFSMC owns several pieces of equipment. The liver transplant program will need to augment these so that both OR and ICU are served and back-up is available.

³ The TEG is a Thromboplast Hemostasis Analysis System. It is a diagnostic instrument used in the OR and ICU that helps assess bleeding/blood clotting risk.

⁴ GEMStat is another system used to assist with treating bleeding/coagulation issues.

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TABLE E. PROJECT BUDGET				
INSTRUCTION: Estimates for Capital Costs (1.a-e), Financing Costs and Other Cash Requirements (2.a-g), and Working Capital Startup Costs (3) must reflect current costs as of the date of application and include all costs for construction and renovation. Explain the basis for construction cost estimates, renovation cost estimates, contingencies, interest during construction period, and inflation in an attachment to the application. See additional instruction in the column to the right of the table.				
NOTE: Inflation should only be included in the Inflation allowance line A.1.e. The value of donated land for the project should be included on Line A.1.a as a use of funds and on line B.8 as a source of funds				
		Hospital Building	Other Structure	Total
A. USE OF FUNDS				
1. CAPITAL COSTS				
a. New Construction				
(1)	Building			\$0
(2)	Fixed Equipment			\$0
(3)	Site and Infrastructure			\$0
(4)	Architect/Engineering Fees			\$0
(5)	Permits (Building, Utilities, Etc.)			\$0
SUBTOTAL		\$0	\$0	\$0
b. Renovations				
(1)	Building			\$0
(2)	Fixed Equipment (not included in construction)			\$0
(3)	Architect/Engineering Fees			\$0
(4)	Permits (Building, Utilities, Etc.)			\$0
SUBTOTAL		\$0	\$0	\$0
c. Other Capital Costs				
(1)	Movable Equipment	\$75,800		\$75,800
(2)	Contingency Allowance			\$0
(3)	Gross interest during construction period			\$0
(4)	Other (Specify/add rows if needed)			\$0
SUBTOTAL		\$75,800	\$0	\$75,800
TOTAL CURRENT CAPITAL COSTS		\$75,800	\$0	\$75,800
d. Land Purchase				
e. Inflation Allowance				
TOTAL CAPITAL COSTS		\$75,800	\$0	\$75,800
2. Financing Cost and Other Cash Requirements				
a. Loan Placement Fees				
b. Bond Discount				
c. Legal Fees (CON)				
d. Legal Fees (Other)				
e. Non-Legal Consultant Fees (CON application related - specify what it is and why it is needed for the CON)				
f. Non-Legal Consultant Fees (Other)				
g. Liquidation of Existing Debt				
H. Debt Service Reserve Fund				
i. Other (Specify/add rows if needed)				
SUBTOTAL		\$0	\$0	\$0
3. Working Capital Startup Costs				
TOTAL USES OF FUNDS		\$75,800	\$0	\$75,800
B. Sources of Funds				
1. Cash				
2. Philanthropy (to date and expected)				
3. Authorized Bonds				
4. Interest Income from bond proceeds listed in #3				
5. Mortgage				
6. Working Capital Loans				
7. Grants or Appropriations				
a. Federal				
b. State				
c. Local				
8. Other (Specify/add rows if needed)				
TOTAL SOURCES OF FUNDS		\$0	\$0	\$0
		Hospital Building	Other Structure	Total
Annual Lease Costs (if applicable)				
1. Land				
2. Building				
3. Major Movable Equipment				
4. Minor Movable Equipment				
5. Other (Specify/add rows if needed)				

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PART III - APPLICANT HISTORY, STATEMENT OF RESPONSIBILITY, AUTHORIZATION AND RELEASE OF INFORMATION, AND SIGNATURE

1. *List names and addresses of all owners and individuals responsible for the proposed project.*

Kenneth A. Samet, FACHE
President and CEO
MedStar Health, Inc.
10980 Grantchester Way
Columbia, Maryland 21044

Samuel E. Moskowitz, FACHE
President
MedStar Franklin Square Medical Center
9000 Franklin Square Drive
Rosedale, Maryland 21237

2. *Is any applicant, owner, or responsible person listed above now involved, or has any such person ever been involved, in the ownership, development, or management of another health care facility? If yes, provide a listing of each such facility, including facility name, address, the relationship(s), and dates of involvement.*

Samuel E. Moskowitz, FACHE
Executive Vice President and Chief Operating Officer
Mercy Medical Center
345 St Paul Place
Baltimore, Maryland 21202
February 1993 – May 2012

Samuel E. Moskowitz, FACHE
Director, Strategic Program Development
University of Maryland Medical Center
22 S. Greene Street
Baltimore, MD 21201
October 1986 – February 1993

3. *In the last 5 years, has the Maryland license or certification of the applicant facility, or the license or certification from any state or the District of Columbia of any of the facilities listed in response to Question 2, above, ever been suspended or revoked, or been subject to any disciplinary action (such as a ban on admissions) ? If yes, provide a written explanation of the circumstances, including the date(s) of the actions and the disposition. If the applicant(s), owners, or individuals responsible for implementation of the Project were not*

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involved with the facility at the time a suspension, revocation, or disciplinary action took place, indicate in the explanation.

No

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4. *Other than the licensure or certification actions described in the response to Question 3, above, has any facility with which any applicant is involved, or has any facility with which any applicant has in the past been involved (listed in response to Question 2, above) ever received inquiries from a federal or any state authority, the Joint Commission, or other regulatory body regarding possible non-compliance with Maryland, another state, federal, or Joint Commission requirements for the provision of, the quality of, or the payment for health care services that have resulted in actions leading to the possibility of penalties, admission bans, probationary status, or other sanctions at the applicant facility or at any facility listed in response to Question 2? If yes, provide, for each such instance, copies of any settlement reached, proposed findings or final findings of non-compliance and related documentation including reports of non-compliance, responses of the facility, and any final disposition or conclusions reached by the applicable authority.*

The hospital's compliance with State and Federal regulations and accreditation requirements is subject to periodic governmental inquiries, and the hospital has responded appropriately to any such inquiries. From time to time, the hospital may make a business decision to resolve a matter, but there is nothing material to the hospital or to this project and the hospital has not been subject to any additional compliance terms or scrutiny as a result.

-
5. *Has any applicant, owner, or responsible individual listed in response to Question 1, above, ever pled guilty to, received any type of diversionary disposition, or been convicted of a criminal offense in any way connected with the ownership, development, or management of the applicant facility or any of the health care facilities listed in response to Question 2, above? If yes, provide a written explanation of the circumstances, including as applicable the court, the date(s) of conviction(s), diversionary disposition(s) of any type, or guilty plea(s).*

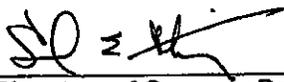
No

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One or more persons shall be officially authorized in writing by the applicant to sign for and act for the applicant for the project which is the subject of this application. Copies of this authorization shall be attached to the application. The undersigned is the owner(s), or Board-designated official of the applicant regarding the project proposed in the application.

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

August 10, 2017
Date


Signature of Owner or Board-designated Official

President,
MedStar Franklin Square Medical Center
Position/Title

Samuel E. Moskowitz
Printed Name

PART IV - CONSISTENCY WITH GENERAL REVIEW CRITERIA AT COMAR 10.24.01.08G (3):

INSTRUCTION: Each applicant must respond to all criteria included in COMAR 0.24.01.08G (3), listed below.

An application for a Certificate of Need shall be evaluated according to all relevant State Health Plan standards and other review criteria.

If a particular standard or criteria is covered in the response to a previous standard or criteria, the applicant may cite the specific location of those discussions in order to avoid duplication. When doing so, the applicant should ensure that the previous material directly pertains to the requirement and the directions included in this application form. Incomplete responses to any requirement will result in an information request from Commission Staff to ensure adequacy of the response, which will prolong the application's review period.

10.24.01.08G (3) (a). The State Health Plan.

COMAR 10.24.10: Acute Care Hospital Services

.04 Standards.

A. General Standards.

(1) Information Regarding Charges.

Information regarding hospital charges shall be available to the public. After July 1, 2010, each hospital shall have a written policy for the provision of information to the public concerning charges for its services. At a minimum, this policy shall include:

- (a) Maintenance of a Representative List of Services and Charges that is readily available to the public in written form at the hospital and on the hospital's internet web site;*
- (b) Procedures for promptly responding to individual requests for current charges for specific services/procedures; and*
- (c) Requirements for staff training to ensure that inquiries regarding charges for its services are appropriately handled.*

Response:

Regarding part (a) of the standard, MFSMC maintains a representative list of services and charges that is readily available to the public in written form on the hospital's web site at: <https://www.medstarfranklinsquare.org/our-hospital/estimated-average-charges-for-common-procedures>.

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See Attachment 2 for a copy of the hospital's policy related to Information Regarding Charges, which addresses the requirement for the provision of information to the public concerning charges for its services (parts (b) and (c)).

For services not included on the hospital's list of representative services, MFSMC's Financial Counseling Department and Finance Department provide information concerning charges upon request. Each request for information is addressed individually depending on the nature of the patient's inquiry. Patient financial service representatives utilize a pricing tool to provide an estimated cost of care, help patients understand their insurance coverage, assist eligible patients to enroll in the Medical Assistance program, and evaluate patient eligibility for MedStar Health's financial assistance program.

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(2) Charity Care Policy.

Each hospital shall have a written policy for the provision of charity care for indigent patients to ensure access to services regardless of an individual's ability to pay.

(a) The policy shall provide:

(i) Determination of Probable Eligibility. Within two business days following a patient's request for charity care services, application for medical assistance, or both, the hospital must make a determination of probable eligibility.

(ii) Minimum Required Notice of Charity Care Policy.

1. Public notice of information regarding the hospital's charity care policy shall be distributed through methods designed to best reach the target population and in a format understandable by the target population on an annual basis;

2. Notices regarding the hospital's charity care policy shall be posted in the admissions office, business office, and emergency department areas within the hospital

3. Individual notice regarding the hospital's charity care policy shall be provided at the time of preadmission or admission to each person who seeks services in the hospital.

(b) A hospital with a level of charity care, defined as the percentage of total operating expenses that falls within the bottom quartile of all hospitals, as reported in the most recent Health Service Cost Review Commission Community Benefit Report, shall demonstrate that its level of charity care is appropriate to the needs of its service area population.

Response:

Regarding part (a), MFSMC provides medical services to all patients regardless of their ability to pay. Please refer to Attachment 3 for MedStar Health's written policy regarding the provision of complete and partial charity care for indigent and Medicaid patients and the Federal Poverty Guidelines for MFSMC's determination of charity allowance based on the Federal Poverty Level standards. MFSMC also posts formal notices in both English and Spanish at primary access points, including the main patient entrance, the Woman's Pavilion entrance, the ambulatory services entrance, the emergency department entrance and all admitting/ registration areas, that it complies with the Omnibus Budget Reconciliation Act of 1989 (OBRA) and affirms MFSMC's obligation and commitment to treat emergent and acute patients regardless of the patient's ability to pay (see Attachment 3 for examples). The hospital also provides a one-page summary of its

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financial assistance policy to all patients who receive medical care. See Attachment 3 for a copy of the document.

The hospital maintains a staff of easily accessible financial counselors and social workers who proactively assess potential patients and assist eligible patients on an individual basis in the process of procuring financial assistance to pay for needed healthcare services upon admission and/or discharge.

MFSMC makes a determination of eligibility for charity care within two (2) days of the patient's completion of an application form for such a determination. However, it should be noted that this process does not affect the delivery of services. Services are provided regardless of the status of a patient's charity care application. See Attachment 3 for a copy of the hospital's Financial Assistance Application.

Regarding part (b), as one of the region's leading not-for-profit healthcare systems, MedStar Health is committed to ensuring that uninsured patients and underinsured patients meeting medical hardship criteria within the communities we serve who lack financial resources have access to emergency and medically necessary hospital services. Over the past five fiscal years, MedStar Franklin Square Medical Center has provided an average of \$10.5 million in free and reduced-cost health care services.

In the most recent HSCRC Charity Care Report (FY15), MFSMC was ranked in the bottom quartile of the ratio of charity care dollars to total expenses among Maryland Acute Care Hospitals. The table below, compiled from Maryland Hospitals' Community Benefits Reports posted on the Health Services Cost Review Commission website, details the amount of charity care MFSMC provided in the FY11-FY15 period as well as its quartile ranking of charity care as a percentage of total operating expenses compared to other Maryland acute hospitals.

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A Figure 5.
MFSMC Charity Care
Dollars of Care Provided & Ranking Among Maryland Hospitals FY11-FY15

	FY11	FY12	FY13	FY14	FY15
Charity Care \$	\$10,808,600	\$12,654,205	14,943,857	\$13,581,700	\$6,028,378
% Charity Care of TE*	2.63%	2.90%	3.30%	2.90%	1.24%
Maryland Quartile Rank	3 rd	3 rd	3 rd	3 rd	4 th

Source: http://hscrc.maryland.gov/init_cb.cfm

*TE = Total Operating Expenses

As the figure indicates, the amount of charity care MFSMC provided to its community in the FY11-FY13 period grew each year, both in absolute dollars of charity care and as a percentage of total MFSMC operating expenses. Charity care dollars grew by \$4M in the period, a nearly 40% increase. This level of charity care as a percentage of total operating expenses placed the hospital in the third quartile compared to other Maryland hospitals during the period. This year by year growth trend ended in FY14, when charity care declined by \$1.4M or about 9% below FY13, and again in FY15, when charity care declined \$7.6M or about 56%, below FY14. The FY14-FY15 level of charity care as a percentage of total operating expenses placed MFSMC in the third quartile among Maryland Hospitals in FY14 and the fourth quartile in FY15.

The primary reason for the decline in MFSMC charity care expense as a percentage of total operating expenses is the expansion of the Maryland Medicaid program that began in January 2014. In 2013, the U.S. Congress passed the Affordable Care Act (ACA), which included provisions for the expansion of state Medicaid programs. Maryland then expanded its Medicaid program in January of 2014 with the goal of reducing the number of Marylanders without health insurance. The Maryland Department of Health and Mental Hygiene, together with the Maryland Department of Legislative Services, reported that in FY13, prior to the passage of the ACA, there were just over 1 million Marylanders enrolled in Medicaid, the Maryland Children's Health Program, and the Primary Adult Care Program, which ended on January 1, 2014. By FY14, there were just over 1.1 million

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enrollees in these programs, and by FY15 there were about 1.25 million enrollees.⁵ This represents an increase of over 200,000 enrollees in the eighteen months after the expansion of the Maryland program.

As the table below indicates, comparing the pre-Medicaid expansion data of FY13 with the post-expansion data of FY15, Maryland hospitals experienced a 22.6% increase in gross hospital revenue from patients covered by Medicaid⁶.

Figure 6.
Maryland Hospital Gross Acute Inpatient Revenue by Selected Payer
& Charity Care Expense
FY13-GY15

Payor Category	FY13	FY14	FY15	%Var. FY13-FY15
Medicaid HMO (All)	942,838,890	1,123,614,999	1,331,002,978	41.2%
Medicaid	572,441,693	573,727,712	526,812,320	-8.0%
Total	\$1,515,280,583	\$1,697,342,711	\$1,857,815,298	22.6%
Self-Pay	293,270,116	171,419,807	77,639,101	-73.5%
Charity/No Charge	518,504,648	483,833,107	362,585,727	-30.1%
Total	\$811,774,764	\$655,252,914	\$440,224,828	-45.8%

Source: Medicaid, Medicaid HMO and Self-Pay: HSCRC Discharge Abstract Data, Jul 2012 - Jun 2015

Charity Care: HSCRC Website, Maryland Community Benefits Data, http://hscrc.maryland.gov/init_cb.cfm

Excludes Newborns and Neonates

MFSMC believes this statewide shift is the expected outcome of the expansion of the Maryland Medicaid program. As noted above, the purpose of the expansion was to reduce the number of Marylanders without health insurance. The expansion of the Medicaid program was successful in this regard, adding over 200,000 previously uninsured Marylanders to the program in the FY13-FY15 period. This resulted in an increase in Medicaid revenue to hospitals, as many who were previously uninsured (and

⁵ http://dls.state.md.us/data/polanasubare/polanasubare_das/HHS_MDMedicaidProgramEnrollment.pdf

⁶ Unless otherwise noted, "Medicaid" in the narrative sections of this response refers to Medicaid and Medicaid HMO.

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who would have qualified for charity care or who would have paid a highly discounted fee out-of-pocket) became insured through Medicaid. This shift, then, had the corresponding impact of decreasing self-pay revenue and charity care expense among Maryland hospitals. In short, the increase in the number of insured Marylanders resulted in a decrease in the number who paid for care out-of-pocket or who were provided charity care in FY15 compared to FY13.

These changes did not impact all hospitals equally. In fact, the expansion of the Maryland Medicaid program in the period had greater impact on MFSMC than was typical among Maryland hospitals. As the table below indicates, MFSMC experienced a 53.6% increase in gross hospital revenue from patients covered by Medicaid, much greater than the 22.6% state average; it also experienced a decline of 59.7% in charity care expense, which was significantly larger than the 30.0% average decline in charity care in the state (the impact on self-pay at MFSMC was very close to the state average). The table below details the large increase in Medicaid revenue at MFSMC in the period and the similarly large decrease in self-pay revenue and charity care expense.

Figure 7.

MFSMC Gross Acute Inpatient Revenue by Selected Payer
& Charity Care Expense
FY13-GY15

Payor Category	FY13	FY14	FY15	%Var. FY13-FY15
Medicaid HMO (All)	35,078,724	46,047,926	61,755,366	76.0%
Medicaid	14,645,119	15,754,831	14,619,624	-0.2%
Total	\$49,723,843	\$61,802,757	\$76,374,990	53.6%
Self-Pay	10,011,060	6,485,159	2,592,947	-74.1%
Charity/No Charge	14,943,857	13,581,700	6,028,378	-59.7%
Total	\$24,954,917	\$20,066,859	\$8,621,325	-65.5%

Source: Medicaid, Medicaid HMO and Self-Pay: HSCRC Discharge Abstract Data, , Jul 2012 - Jun 2015
Charity Care: HSCRC Website, Maryland Community Benefits Data, http://hscrc.maryland.gov/init_cb.cfm
Excludes Newborns and Neonates

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There are three factors that help explain why MFSMC's payer shifts were greater than the state average in the period. First, MFSMC's PSA is comprised of communities which skew to the low end of median income among Baltimore County Census Designated Places. Three of the four lowest median income communities in Baltimore County are in MFSMC's PSA, while the fourth is in MFSMC's secondary service area.⁷ As a result, the expansion of the Medicaid program would be expected to result in an increase in Medicaid enrollees in these communities that is above the state average.

Second, eastern Baltimore County has a very active coalition of organizations called the Baltimore County Southeast Area Network (BCSAN). This network, of which MFSMC is a member and active participant, has as its focus improving the quality of life and health status of eastern Baltimore County residents. Since the expansion of the Medicaid program, one element of the network's efforts in concert with the MFSMC Board Community Health Improvement Committee has been to inform residents of the change in the eligibility requirements of the Maryland Medicaid program and support members of the community with the application process for program enrollment. This effort seems to have been very successful. The four zip codes which comprise MFSMC's primary service area, 21220, 21221, 21222 and 21237 form the heart of the community targeted by the BCSAN. Medicaid discharges from these four zip codes grew at over twice the rate of the state average. And because this growth occurred in MFSMC's PSA, it helps to explain the growth in Medicaid utilization experienced by MFSMC in the period.

Finally, in addition to the work of the Board Community Health Improvement Committee, MFSMC remains committed to identifying uninsured patients who may qualify for insurance under the expanded Maryland Medicaid program and facilitating the enrollment process. This supports the program's goal of reducing the number of uninsured Marylanders. Enrollment in the program also provides insurance for these patients to comply with their post-discharge care (prescriptions, follow-up doctor's visits, etc.), and

⁷ http://planning.maryland.gov/msdc/hhinc_median&mean.shtml (Dundalk, Essex, Parkville, Middle River)

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also enables these patients to have regular access to primary and preventive care in the future. In this way, MFSMC is supporting both the Medicaid program's goal and Maryland's population health goals.

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 residents with Medicaid insurance. The hospital is convinced that this factor alone accounts for the decline in charity care provided by the hospital in FY15 and the hospital's FY15 rank in the bottom quartile for charity care expense as a percentage of total operating expenses among Maryland hospitals. To say it another way, MFSMC believes 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. For this reason, MFSMC believes that it met the need for charity care in its community in FY15.

Notwithstanding the influence that this dynamic has had on the hospital's charity care expenditures, MFSMC is committed to providing charity care and is currently developing a plan of action to verify that it is meeting the needs of the uninsured or under-insured members of its community, and will make adjustments to its charity care processes and practices based on the results of this evaluation. One example of MFSMC's efforts is through collaboration with Baltimore County on the newly expanded Eastern Family Resource Center (EFRC) that will open in November 2017. The EFRC serves as a resource to homeless individuals (principally women and children) in Eastern Baltimore County. The expanded EFRC, which includes a primary care center staffed by MFSMC physicians, a shelter and transitional housing facility, was funded by grants from MedStar Health and the State of Maryland (in addition to funding provided by Baltimore County).

(3) Quality of Care.

An acute care hospital shall provide high quality care.

(a) Each hospital shall document that it is:

(i) Licensed, in good standing, by the Maryland Department of Health and Mental Hygiene;

(ii) Accredited by the Joint Commission; and

(iii) In compliance with the conditions of participation of the Medicare and Medicaid programs.

(b) A hospital with a measure value for a Quality Measure included in the most recent update of the Maryland Hospital Performance Evaluation Guide that falls within the bottom quartile of all hospitals' reported performance measured for that Quality Measure and also falls below a 90% level of compliance with the Quality Measure, shall document each action it is taking to improve performance for that Quality Measure.

Response:

MFSMC collects and reviews its quality performance data monthly to monitor and improve its performance. These measures include Serious Safety Events, Acute Care Core Measures, and Patient and Employee Safety Measures. See Attachment 4 for a fuller description of MFSMC's approach to Quality and Safety. MFSMC was granted accreditation by The Joint Commission on July 18, 2016, and is licensed through the Department of Health and Mental Hygiene through August 6, 2019.

COMAR 10.24.15: Organ Transplant Services

A. General Standards

(1) An applicant for a certificate of need to establish an organ transplantation service shall address and meet the general standards in COMAR 10.24.10.04A.

Response:

MFSSMC complies with this standard.

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(2) Each Maryland transplant program shall agree to comply and maintain compliance with all requirements of CMS and UNOS certification and, if applicable, accreditation by the Foundation for the Accreditation of Cellular Therapy.

(a) Each organ transplant service shall be certified by UNOS within the first year of operation.

(b) Each hematopoietic stem cell bone marrow transplant service shall be accredited by the Foundation for the Accreditation of Cellular Therapy within the first two years of operation.

Response:

Regarding part (a), MFSHC agrees to comply and maintain compliance with all requirements of CMS and UNOS certification for its proposed transplant program and to be certified by UNOS within the first year of operations.

Part (b) does not apply to this project.

B. Project Review Standards

(1) Need

An applicant shall demonstrate that a new or relocated organ transplant center is needed. Closure of an existing service, in and of itself, is not sufficient to demonstrate the need to establish a new organ transplant center. An applicant shall address:

(a) The ability of the general hospital to increase the supply or use of donor organs for patients served in Maryland through technology innovations, living donation initiatives, and other efforts.

(b) Projected volume shifts from programs in the two OPOs that serve Maryland residents, detailing the underlying assumptions upon which each projection is based.

(c) The utilization trends for the health planning region in which the proposed organ transplant service will be located and the jurisdictions in which the population to be served resides. If the proposed service will be located in a jurisdiction that shares a border with another health planning region, then the utilization trends in each health planning region shall be addressed.

Response

As noted in the Project Description, MFSMC proposes to partner with the MGTI, one of the largest and highest quality transplant programs in the United States (see Comprehensive Project Description). MGTI has exceptional knowledge and experience in providing candidates for transplantation with the most appropriate option regarding organ availability, helping to ensure a successful outcome and optimal long-term survival.

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(a) The ability of the general hospital to increase the supply or use of donor organs for patients served in Maryland through technology innovations, living donor initiatives, and other efforts.

The proposed project will increase the availability of donor livers for patients served in Maryland. MGTI's liver transplant program has a two-fold mission that underpins the proposed program at MFSMC: 1) to reduce the need for liver transplant through the expert medical management of patients with viral hepatitis, liver tumors, genetic disorders and other complex conditions, and 2) to apply surgical expertise, research initiatives and community outreach activities to increase the availability of organs suitable for transplant. Each of these factors is discussed in greater detail below:

(1) Reducing the demand for donor organs through:

- a. Medical management with intervention where appropriate;
- b. Advancements in clinical research related to cellular therapy/bio-artificial liver.

(2) Increasing the supply of donor organs through:

- a. Active participation in, and support of, the LLF OPO;
- b. Application of expanded donor criteria;
- c. Broader application of advanced surgical techniques;
- d. Expansion of living donor transplant options.

Each of these areas is addressed further in the detail that follows.

(1) Reducing the need for donor organs through improved medical management of patients with advanced liver disease

Medical treatment of patients with Hepatitis C viral infection (HCV) and other advanced liver disease can reduce the need for liver transplantation, thus increasing the supply of donor organs for other transplant candidates. The development of all-oral, interferon-free regimens for the treatment of HCV in 2013 was a breakthrough in the treatment of this liver disease, affecting both aspects of the program's equation. HCV has historically been the

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single leading indication for liver transplant and the cause of more deaths in the United States today than HIV. Viral infection with HCV can lead to cirrhosis and hepato-cellular carcinoma but is curable with all-oral, well-tolerated medications. The FDA approved medications now include pangenotypic regimens which will cure the majority of those who are treated.

These therapies can stop the progression of liver disease caused by HCV and in many instances improve liver function over time. The treatment and cure of HCV leads to a diminished need for liver transplant in those patients. Though it is difficult to quantify the decrease in the need for donor livers as a result of these interventions, it is clear that this medical treatment frees up donor organs for patients whose liver disease cannot be treated medically and whose only recourse is transplantation. MGTI's early adoption of these new pharmaco-therapy alternatives, combined with its medical expertise and community outreach, serves to reduce the demand for liver transplants.

As part of its efforts to reduce the need for liver transplantation, MGTI has worked to greatly expand community outreach through a *Liver Screening Program* to detect Hepatitis B virus (HBV) infection and HCV infection, as well as non-alcoholic fatty liver disease (NAFLD). It is the first of its type in the mid-Atlantic region, and MGTI and MFSSMC have already begun offering this community outreach in the MFSSMC area. The program aims to identify "at risk" individuals and get them into treatment early. The program provides free screening for individuals who live in areas with an expected high prevalence of liver disease (e.g., those of Asian descent) and others that also have a higher prevalence of viral hepatitis but are generally under-diagnosed. Lack of awareness remains a major barrier to screening that MGTI is trying to change. The program also offers social and financial screening services aimed at enrolling underserved patients into health insurance programs for which they may qualify, but about which they may lack awareness. Because Fairfax and Loudoun Counties in Virginia and Montgomery County in Maryland have high percentages of Asians (almost 400,000 collectively), these areas were targeted for outreach to primary audiences, community gatherings, faith-based organizations - as well as primary care physicians and

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clinics in the DC Metropolitan Area. The Baltimore region, with an Asian population projected at almost 172,000 by 2020, will be targeted similarly.⁸ The strategy also includes one-on-one outreach by a dedicated Liver Screening Program coordinator hired within the last year. Finally, the program also targets individuals who exhibit behaviors that may place them at a higher risk. HCV is a major public health issue, and screening programs such as that sponsored by MGTI have been recommended by the US Preventive Services Task Force.

At present, MGTI provides free testing both in its clinic settings and at community fairs. Testing includes evaluation of HBV, HCV and abnormal ALT which may be a marker of fatty liver disease. If testing is reactive, patients are offered a free consultation followed by linkage to care either within MedStar or in the community. More than 650 individuals were screened in the first year of the program with a goal of more than 1,000 for year two.

These medical interventions, enhanced by significant community outreach, have become and will continue to be central to MFSMC's proposed program, thus extending these important benefits from Maryland's DC suburbs to the residents of the Central Maryland region. This program is one way in which MedStar Health is working to decrease the demand for the scarce donor liver resource.

(2) Increasing the supply of donor organs

- a. Active participation in the Living Legacy Foundation (LLF) Organ Procurement Organization

MedStar Health is cognizant of the critical role that community hospitals play in the supply of life-saving deceased donor organs; its four Baltimore region hospitals all have systems in place to ensure support of the donor identification and retrieval efforts of the Living Legacy Foundation of Maryland (LLF), the statewide Organ Procurement Organization

⁸ Buxton Demographic Summary Report for Central Maryland.

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(OPO) for the Designated Service Area (DSA). The same can be said for MedStar Health's six hospitals operating in the jurisdiction of the Washington Regional Transplant Community (WRTC) organ bank, including MedStar Washington Hospital Center, a trauma center and the largest contributor of donor organs to the WRTC OPO. MedStar Health supports both the LLF and WRTC OPOs by ensuring that candidates for transplantation have access to as many organs from deceased donors as possible from its own hospitals.

As a system, MedStar Health is very invested in, and supportive of, its organ donation committees and seeks regular input from the leadership of those groups which are comprised of critical care medicine specialists, nursing managers, social workers and other interested parties. MGTI leadership sits on the WRTC Board and Executive Committee of WRTC and is involved also with working to advance and support the objectives of that organization in any way possible. MedStar Health believes that the creation of a liver transplant program at MFSMC serves to focus greater attention on organ donation at its Baltimore-area hospitals and in the identification and retrieval of more organs.

b. Expanded donor criteria (EDC) for transplantation

Due to the ongoing problem of donor organ supply, national attention over the last decade has been given to whether or not the established criteria for determining deceased donor suitability are appropriate. After much debate, experts from around the country have reached agreement that certain criteria previously considered exclusionary, including older donors, those with certain systemic illnesses, exposure to infectious diseases, etc., should be reconsidered in a manner that is compatible with recipient clinical characteristics. Matching donor risk to recipient risk factors is critical to the success of this approach, and MGTI clinical expertise enables it to make full use of EDC protocols for patients. These same protocols will be applied as part of the MFSMC program, with the same anticipated success.

c. Advanced transplantation techniques

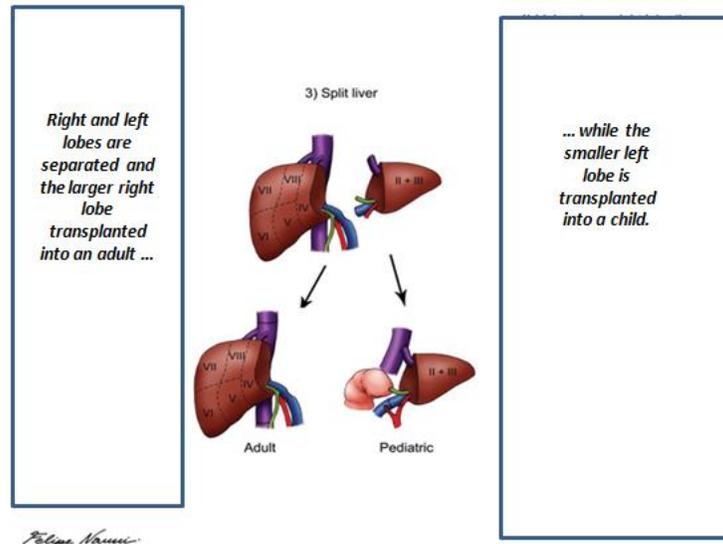
Split liver and domino liver transplants are innovative techniques pioneered at MGTI that offer access to both children and adults in need. MGTI is a national leader in this field.

Split Liver Transplantation

A particularly innovative method of expanding the use of deceased donor organs, perfected by Dr. Thomas Fishbein, Executive Director of MGTI, and now routinely used by MGTI liver transplant specialists, is to divide the available organ into segments that can be transplanted into more than one recipient. In this procedure, the largest segments of the liver are separated and the segmented lobes are then transplanted into two individual recipients (see diagram below).

Figure 8.

Split Liver Transplant



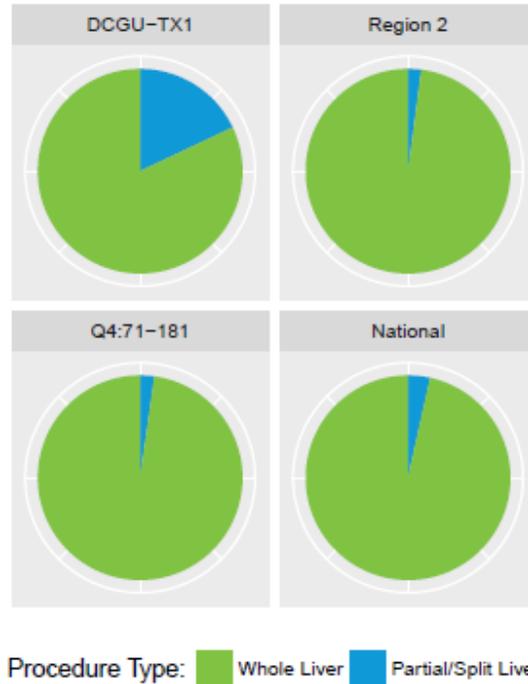
The operation has the effect of creating two transplantable donor organs out of one donor organ. The rate of split liver transplants at MGTI far outstrips the national average among liver transplant programs as depicted in the graphic below that shows the percentage of all liver transplant procedures that were split liver procedures performed at MGTI versus Region 2 and nationally. As Figure 9 below indicates, in CY2016 17.98% of liver transplants at MGTI were split liver transplants compared to only 2.09% in our Region 2 and 3.49% nationally.

Figure 9. (SRTR Figure 11). Liver Benchmark Report

Benchmark Report | Liver

DCGU-TX1 April 2017

Figure 11. Procedure Type as of April 7, 2017



	Procedure Type (%)			
	DCGU-TX1	Region 2	Q4:71-181	National
Whole Liver	82.02	97.91	97.76	96.51
Partial/Split Liver	17.98	2.09	2.24	3.49
Total	100.00	100.00	100.00	100.00

Figure 11 shows the distribution of procedure type for deceased donor liver transplants between January 1, 2016 and December 31, 2016. Nationally, most procedures were Whole Liver (96.51%).

Note: In Figure 9, “DCGU-TX1” refers to the MedStar Georgetown Transplant Institute.

MGTI’s expertise in split-liver transplants enables it to make a significant contribution to the supply of donor organs and will be available immediately at MFSMC.

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One area where the split liver technique will make an immediate difference is with pediatric patients. MGTI currently operates the second largest pediatric transplant program in the country with volumes and outcomes superior to those available in the Baltimore region (LLF DSA).

Figure 10: Pediatric Liver Transplantation Comparison
WRTC and LLF DSAs

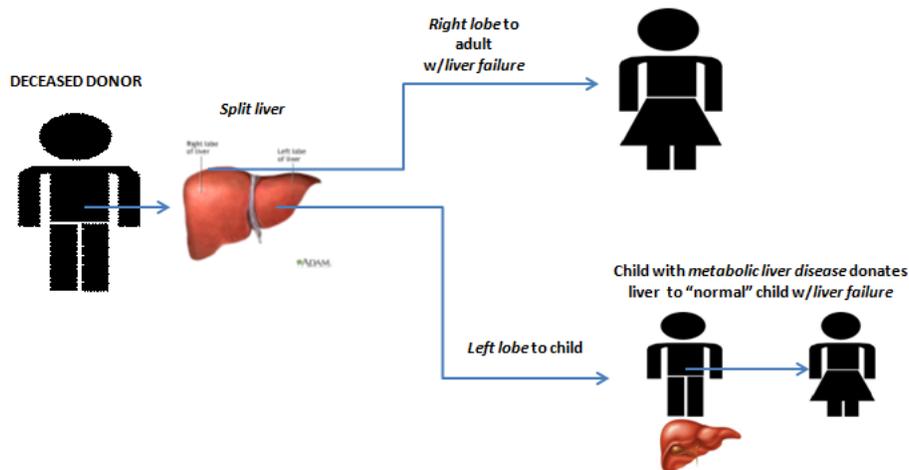
Pediatric Liver Transplantation			
WRTC DSA			
	2015	2016	2017 YTD
<1 years	6	11	8
1-5 years	18	17	5
6-10 years	5	3	1
11-17 years	3	2	1
Total Peds	32	33	15
LLF DSA			
	2015	2016	2017 YTD
<1 years	1	0	1
1-5 years	3	2	0
6-10 years	1	0	1
11-17 years	1	2	2
Total Peds	6	4	4

Domino Liver Transplantation

MFSMC would also offer Domino Liver Transplantation, pioneered at MGTI and another original approach for expanding available organs to more individuals in need. In this

procedure, a single organ from a deceased donor is segmented; the larger right lobe is transplanted into an adult recipient with liver failure while the smaller left lobe is placed in a child who needs a transplant because of genetic metabolic disease. The affected child's liver is then transplanted into a patient without the abnormal genetic defect with a successful outcome. This domino effect enables one donor liver to provide life saving organ access to three people.

Figure 11.
Domino Liver Transplant



MGTI has successful experience with this technique and together with split liver procedures will enable the program at MFSMC to increase the supply of deceased donor organs in the region.

d. Living Donor Transplantation

MFSMC will offer living donor transplantation, initially through MGTI, and over time, on site. MGTI, through its considerable research and experience, is at the forefront of living donor liver transplantation, a clinical practice available to selected patients at most sophisticated transplant Centers. Because the liver has the unique ability to regenerate

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to full size over time after removal of a segment, living donor transplantation has become a viable option for individuals who have a relative or friend who is a suitable match and is willing to donate part of his or her organ.

MGTI's Living Donor Program will work to continuously to enhance community awareness of the need for liver transplantation and the life-giving solution that is offered through living donation in the Baltimore region. Importantly, the program offers donor and recipient "navigation" services by a registered nurse who helps guide patients through all phases of the donation process from initial interest in donation to the decision point of making a living donation.

Pediatric patients are relatively far more complicated as a subset population – and MGTI leads the country (second largest pediatric liver and largest small bowel program in the country) in the number of pediatric liver transplant procedures performed – including from living donors. In terms of expertise in managing complex patients (combined organ transplants and innovative split liver procedures), MGTI outperforms the Baltimore area Regional and National norms. MGTI has 100% patient and graft survival for its living donor transplant procedures in a context of an "expected probability of survival" in the Baltimore region of 89.41%, and a national average of 87.75% (SRTR April 2017).

See survival data related to living donor transplantation for the three centers in the Baltimore-Washington area pictured below.

Figure 12
Living Donor Transplantation Survival Among Area Centers

 SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS		University of Maryland Medical System Center Code: MDUM Transplant Program (Organ): Liver Release Date: July 6, 2017 Based on Data Available: April 30, 2017	SRTR Program-Specific Report Feedback?: SRTR@SRTR.org 1.877.970.SRTR (7787) http://www.srtr.org
C. Transplant Information			
Table C6L. Adult (18+) 1-year survival with a functioning living donor graft Single organ transplants performed between 01/01/2014 and 06/30/2016 Deaths and retransplants are considered graft failures			
		MDUM	U.S.
Number of transplants evaluated		27	648
Estimated probability of surviving with a functioning graft at 1 year (unadjusted for patient and donor characteristics)		92.59%	87.75%
Expected probability of surviving with a functioning graft at 1 year (adjusted for patient and donor characteristics)		88.13%	--
Number of observed graft failures (including deaths) during the first year after transplant		2	76
Number of expected graft failures (including deaths) during the first year after transplant		3.11	76
Estimated hazard ratio*		0.78	1.00
SRTR SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS			
		Johns Hopkins Hospital Center Code: MDJH Transplant Program (Organ): Liver Release Date: July 6, 2017 Based on Data Available: April 30, 2017	SRTR Program-Specific Report Feedback?: SRTR@SRTR.org 1.877.970.SRTR (7787) http://www.srtr.org
C. Transplant Information			
Table C6L. Adult (18+) 1-year survival with a functioning living donor graft Single organ transplants performed between 01/01/2014 and 06/30/2016 Deaths and retransplants are considered graft failures			
		MDJH	U.S.
Number of transplants evaluated		19	648
Estimated probability of surviving with a functioning graft at 1 year (unadjusted for patient and donor characteristics)		78.60%	87.75%
Expected probability of surviving with a functioning graft at 1 year (adjusted for patient and donor characteristics)		87.07%	--
Number of observed graft failures (including deaths) during the first year after transplant		4	76
Number of expected graft failures (including deaths) during the first year after transplant		2.42	76
Estimated hazard ratio*		1.36	1.00
95% credible interval for the hazard ratio**		[0.50, 2.64]	--
SRTR SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS			
		Georgetown University Medical Center Center Code: DCGU Transplant Program (Organ): Liver Release Date: July 6, 2017 Based on Data Available: April 30, 2017	SRTR Program-Specific Report Feedback?: SRTR@SRTR.org 1.877.970.SRTR (7787) http://www.srtr.org
C. Transplant Information			
Table C6L. Adult (18+) 1-year survival with a functioning living donor graft Single organ transplants performed between 01/01/2014 and 06/30/2016 Deaths and retransplants are considered graft failures			
		DCGU	U.S.
Number of transplants evaluated		6	648
Estimated probability of surviving with a functioning graft at 1 year (unadjusted for patient and donor characteristics)		100.00%	87.75%
Expected probability of surviving with a functioning graft at 1 year (adjusted for patient and donor characteristics)		89.41%	--
Number of observed graft failures (including deaths) during the first year after transplant		0	76
Number of expected graft failures (including deaths) during the first year after transplant		0.64	76
Estimated hazard ratio*		0.76	1.00
95% credible interval for the hazard ratio**		[0.09, 2.11]	--

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MGTI has employed a new surgeon, arriving in January 2018, who will be charged with further building the living donor program at MFSMC under the leadership of Dr. Fishbein. He is a well-trained and experienced physician leader who has performed numerous living donor procedures with superior outcomes at another institution.

Overall, MFSMC will increase the supply of livers for transplantation through offering these living donor options to Baltimore region patients.

e. MGTI Clinical Developments Advancing the Field of Liver Transplantation

MFSMC will participate in clinical research that is advancing the Field of Liver Transplantation through the Center for Translational Transplant Medicine (CTTM). Formed in 2013, within Georgetown University Medical Center (GUMC) under the leadership of Dr. Thomas Fishbein, Professor of Medicine at Georgetown University Medical School, the CTTM promotes an interdisciplinary approach toward research in transplantation by permitting various specialties to conduct research within one academic center. As such, CTTM is comprised of transplant surgeons, hepatologists, nephrologists, pathologists, interventional radiologists, pediatricians, gastroenterologists, and other internal medicine specialties that clinically support the needs of patients under the care of MGTI.

Since its inception, CTTM has managed the following portfolio of 83 research studies; the figure below summarizes these studies.

Figure 13. Sponsored Studies

Specialty	Number of Studies	Sponsorship	Number of Studies
Transplant Surgery	58	Industry	66
Transplant Imaging	18	Federal	9
Transplant GI	7	Foundation	8
TOTAL	83		83

Source: MGTI

The annual budget for the research center is in the range of \$5-8M annually including federally funded trials, industry and foundation sponsored studies. This research involves the following areas of investigation:

- Reducing delayed graft function, rejection and organ failure. Current clinical and basic research activities aimed at prolonging graft function and survival by finding:
 - Strategies to minimize post-transplant CMV infections
 - Novel immunosuppressive strategies to avoid organ injury and increase graft survival times
- Increased opportunities for transplant for patients with Hepatitis C and HIV
- Increasing the use of marginal organs through understanding pathways of inflammation that lead to failure of fatty donor livers
- Limiting Ischemic Reperfusion Injury (IRI) through immunotherapy – the ultimate goal of this project – would enlarge the pool of organs that result in successful transplantation in three ways:
 - Organs that are currently being *discarded* – for fear of triggering IRI – could actually be used

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- Organs that are being transplanted – despite being sub-optimal – would be less likely to result in IRI/preservation injury and associated short- or long-term sequelae that limit graft survival
- Organs that had been excluded as split candidates could now be split – benefitting children who need liver transplant.

As the innovative breakthroughs in split liver and domino liver transplantation demonstrate, participation in CTTM's research increases the supply of donor organs. MFSMC and MGTI expect ongoing research to produce future innovations that will further increase the supply of donor organs in the Baltimore region.

(b) Projected volume shifts from programs in the two OPOs that serve Maryland residents, detailing the underlying assumptions upon which each projection is based.

Response:

The goal of the MFSMC program is not to draw patients away from the area's existing transplant Centers, but rather to provide more Maryland citizens in need of liver transplantation with the opportunity to have this life-saving procedure.

MedStar has existing patients who can benefit from the MFSMC program. MGTI currently provides an unparalleled quality of care for liver transplant services, but its distance from Baltimore is a geographical challenge for many. MGTI currently has 40 patients wait-listed for liver transplant (and 129 for kidney transplant) from Maryland counties that orient to Baltimore (i.e., excluding Montgomery County). Those transplant operations could take place at MFSMC, within their home state and closer to their local community.

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The table below details liver transplant volume for the area's two current transplant centers in the CY12-CY16 period. As the data indicate, the volume of liver transplants at both centers far exceeds the minimum transplant volume requirement per COMAR 10.24.15.

Figure 14
Liver Transplants
Univeristy of Maryland/Johns Hopkins
Actual Adult Volume to Minimum Annual Case Volume Standard

Metric	Minumum Volume	UMMS					JHH				
		CY12	CY13	CY14	CY15	CY16	CY12	CY13	CY14	CY15	CY16
Liver	12	86	90	115	146	169	41	79	84	95	122
Variance from Min.	-	74	78	103	134	157	29	67	72	83	110
% Variance from Min.	-	617%	650%	858%	1117%	1308%	242%	558%	600%	692%	917%

Source: <https://optn.transplant.hrsa.gov/data/view-data-reports/state-data/>

The addition of a third program at MFSMC will not impact the ability of the current LLF DSA programs to meet threshold volume requirements and are in fact expected to result in very modest volume shifts from the two transplant centers that serve Maryland residents. MedStar Health believes that its center at MFSMC will improve utilization and allocation overall by augmenting service offerings in the region as well as encourage exploration of more advances in the field through clinical research.

MFSMC has estimated the shift in volume from the current centers based on the number of MedStar patients referred either to JHH or UMMS for advanced liver disease evaluation. These FY15 and FY16 referrals to JHH and UMMS are estimates since referrals outside the MedStar System for these procedures were not part of the data maintained by MFSMC.

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Figure 15
 Projected Liver Transplant Volume Shift
 MedStar Health & JHH/UMMS
 FY15-FY21 Projected

Metric	Actual ¹	Actual ¹	Annualized	Proj.	Program Years		
	FY15	FY16	FY17	FY18	FY19	FY20	FY21
Referrals to JHH and UMMS	9	10	5	2	0	0	0
Referrals to MGTI (Washington, DC)	3	3	6	12	5	2	2

¹FY15-FY16 referral to JHH and UMMS are estimates
 Source: MGTI Internal Data, MFSMC estimates for referrals to JHH/UMMS for FY15 and FY16
 Note: Data compiled before full-year FY17 actual data available

(c) The utilization trends for the health planning region in which the proposed organ transplant service are discussed below.

The proposed MFSMC transplant program will be located on the MFSMC campus in Rosedale, Maryland. This location falls into the region served by the LLF OPO, which serves western and central Maryland, the Eastern Shore, Calvert, and St. Mary's Counties in southern Maryland. The adult liver transplant utilization trends for this region are detailed below.

Figure 16
 Adult Liver Transplants
 Living Legacy Foundation OPO Transplant Centers
 Calendar Year 2006-2016

Transplant Center	CY06	CY07	CY08	CY09	CY10	CY11	CY12	CY13	CY14	CY15	CY16	% Var. CY06-CY16
Johns Hopkins	67	58	50	60	36	34	41	79	84	95	122	82%
University of Maryland	40	44	55	48	55	78	86	90	115	146	169	323%
Total	107	102	105	108	91	112	127	169	199	241	291	172%

Source: <https://optn.transplant.hrsa.gov/data/>

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After stable volume levels in the CY06-CY11 period, there was significant growth in the number of adult liver transplants performed by these two centers, with notable single deviation occurring in the 2010-2011 period in which the Johns Hopkins program experienced a volume decline.

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(2) Minimum Volume Requirements

(a) An applicant shall demonstrate that a proposed organ transplantation service can generate the minimum annual case volume required by this Chapter within the first three years of operation and will likely maintain at least the minimum annual case volume in subsequent years.

(b) An applicant shall acknowledge that, if its application for a Certificate of Need is approved, any approval is conditioned on the applicant's agreement to close its organ transplant service under the following circumstances:

(i) A service that meets the minimal annual case volume required for a new service is unable to sustain the minimum annual case volume for any two consecutive years, and is unable:

1. to provide an explanation acceptable to the Commission as to why it failed to maintain the minimum annual case volume; and

2. to develop a credible plan for achieving the minimum annual threshold case volume that is approved by the Commission; or

(ii) The program fails to achieve the minimum annual case volume by a deadline established by the Commission as a result of the program's failure to achieve the minimum annual case volume requirements.

Table 2: Minimum Annual Case Volume Requirements by Organ Type

Organ Type	Minimum Annual Case Volume
<i>Kidney</i>	
<i>Adult</i>	30
<i>Pediatric</i>	10
<i>Liver</i>	12
<i>Pancreas, Heart/Lung, Intestine (small bowel)</i>	<i>No Volume Requirement</i>
<i>Heart</i>	12
<i>Lung</i>	12
<i>Hematopoietic Stem Cell:</i>	
<i>Autologous</i>	10
<i>Allogeneic</i>	10
<i>Other Transplantable Cells</i>	
<i>Islet Cells</i>	<i>No Volume Requirement</i>
<i>Hepatocytes</i>	<i>No Volume Requirement</i>
<i>Vascular Allograft</i>	<i>No Volume Requirement</i>

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Response:

The gastroenterologists associated with the MedStar Health Baltimore hospitals (MedStar Franklin Square Medical Center, MedStar Good Samaritan Hospital, MedStar Harbor Hospital and MedStar Union Memorial Hospital) maintain large and diverse medical practices and this fact, together with the amount of liver disease in the MedStar patient population, prompted MGTI to establish an Advanced Liver Disease Center at MFSSMC in July 2015. Over the last year, the Advanced Liver Disease center saw 240 patient visits, a 104% increase over the previous year. Growing demand for this service at MFSSMC resulted in MedStar expanding clinic hours to three half-day sessions weekly begin in February 2017. An inpatient consultation service for liver diseases is active, increasing the level of care for high acuity liver patients in the hospital. This service is staffed by a full-time hepatologist with advanced practice clinician support.

Volume at MedStar's other centers for advanced liver disease has been growing steadily. MGTI's Frederick site has shown year-over year growth of 92% in patients seen with advanced liver disease. MGTI's Annapolis site, established a few months ago, has seen more than 100 patients to date. In September 2017, the newest site, located in Ellicott City, will open.

Since Frederick, Annapolis and the Ellicott City locations lie approximately equidistant from Baltimore and Washington, DC, MedStar patients identified as candidates for liver transplant will have the option to have the procedure at MGTI in Washington, DC or MFSSMC in Baltimore, through dual listing in both DSAs.

The data and assumptions noted above yield the projected transplant volume at MFSSMC that is summarized in the figure below.

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Figure 17
MFSMC Liver Transplant Program
Transplant Volume Projection
Fiscal Year 2018-2021

Organ	Projected Years			
	FY18	FY19 ¹	FY20	FY21
Liver	0	10	14	30

¹Year 1 of transplant program

Innovation in medical management of liver disease and surgical approaches as described earlier, combined with the ongoing collaboration between MedStar hospitals' donation committees and the LLF OPO, position MFSMC for a substantial increase the supply of transplantable organs available for patients in the Maryland DSA. Together with the opening of four MedStar Advanced Liver Disease Centers over the last two years MFSMC is confident in the assumption that it will easily exceed the 10-case minimum annual case volume requirements of COMAR 10.24.15B(2) in both year 2 (FY20) and year 3 (FY21) of the program, and will grow beyond that volume thereafter.

Summary

MedStar is committed to caring for patients with advanced liver disease - particularly those populations that we serve directly - across the continuum of care from diagnosis through long-term follow up and for patients from birth through advanced age. Building on the advanced liver disease center that was initiated two years ago at MFSMC through the addition of on-site transplantation services is a natural – and needed – extension of services to the community based on the following facts:

- A large number of individual candidates for transplantation have been listed with MGTI and they will be offered the advantage of dual-listing with two DSAs.

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- These patients are being served currently through the variety of Advanced Liver Disease Centers and other sites of care, medical and ancillary providers and services, tele-health communication and community resources.
- The provision of additional services and resources closer to patients' homes and families advantages them greatly.
- MFSMC will offer the same level of innovative medical management, pharmacotherapy and advanced surgical techniques that have extended organ access to patients transplanted at MGTI.
- Gaps in access for candidates requiring multi-organ transplant not available locally, those appropriate for split or domino transplant, children and minority populations will be narrowed.
- The local physician and patient communities have expressed enthusiastic support for the new program, evidenced by the many attached letters.
- MFSMC is a lower cost environment than the academic medical center, advantageous financially to both MedStar and state budgets.
- The advantages of managing MedStar's own population's health through quality, continuity and efficiency cannot be understated. MedStar should be able to offer its patients full access, closer to home, for all of their health care needs, including transplantation.

MedStar is committed to serving its Maryland population in the most comprehensive, clinically effective and cost-efficient manner possible over the long term.

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(3) Access

(a) Each type of organ transplant service should be accessible within a three-hour one-way drive time for at least 95 percent of Maryland residents.

(b) An applicant that seeks to justify the need for additional organ transplantation services on the basis of barriers to access shall:

(i) Present evidence to demonstrate that barriers to access exist, based on studies or validated sources of information, and

(ii) Present a credible plan to address those barriers. The credibility of the applicant's plan will be evaluated on whether research studies or empirical evidence from comparable projects support the proposed plan as a mechanism for addressing each barrier identified, whether the plan is feasible, and whether members of the communities affected by the project support the plan.

(c) Closure of an existing service, in and of itself, is not sufficient to demonstrate an access issue or the need to establish a new or replacement organ transplantation service.

(d) 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 is less than three hours one-way.

Response:

Regarding part (a), MFSMC's proposed program complies with this element of the Standard.

Regarding part (b), this item is not applicable because MFSMC is not seeking to justify the need for an additional transplant program on the basis of barriers to access. However, we note that substantial detail has been provided in this document relative to the additional access to organs that will be provided through the entry of an MGTI-affiliated program.

Regarding part (c), see response to *COMAR 10.24.15.04B: Organ Transplant Services, Project Review Standard, (1) Need*.

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(4) Cost Effectiveness

An applicant shall demonstrate that the proposed establishment or relocation of an organ transplant service is cost-effective by providing:

(a) A demonstration that analyzes why existing programs cannot meet the need for the organ transplant service for the proposed population to be served.

(b) An analysis of how the establishment or relocation of the proposed organ transplant service will benefit the population to be served, quantifying these benefits to the extent feasible and documenting the projected annual costs of the proposed service over a period of at least five years.

(c) Estimates of the costs to the health care system as a whole and the benefits of the proposed program, quantifying the benefits to the extent feasible over a period of five years.

Response:

(a) As discussed in the Comprehensive Project Description, above, MedStar Health's innovative surgical approaches offer additional options to patients that existing programs cannot serve. In addition, MedStar has demonstrated the ability to serve a much greater percentage of minority patients than either of the existing programs in the LLF DSA.

(b) In both the *Comprehensive Program Description* and the *Need* section, COMAR 10.24.15.04(B) (1) of this application (see also *Table H, Revenues & Expenses, Inflated.*), MFSMC has demonstrated the added benefit that its proposed transplant program will bring to Maryland residents.

(c) See the application section *Table H, Revenues & Expenses, Inflated.* As already noted, MFSMC is a community teaching hospital. MFSMC has a lower cost structure and charge per case than the area's two academic medical centers which currently provide transplant services in the LLF OPO (Figures 3 and 4 from the Comprehensive Program Description, are repeated below). By integrating with the existing MGTI infrastructure, MFSMC can deliver the service in a highly cost-effective manner.

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Figure 18. Average Charge per ECMAD Comparison

Provider	Charge Per ECMAD	% Higher Than MFSMC
UMMS	\$19,544	49.2%
Johns Hopkins	\$16,640	27.0%
State Average	\$14,196	8.4%
MFSMC	\$13,099	--

Source: HSCRC Abstract Tapes for 9 month period from July 2016 to March 2017.

With MFSMC proposed pricing at 25% below the lowest charge Baltimore academic medical center, MFSMC is able to provide the following pricing differential to Medicare, Medicaid and commercial insurers, as shown below:

Figure 19. Average Charge per Case Comparison

Provider	Average Charge per Liver Transplant	% Higher Than MFSMC
Johns Hopkins	\$230,871	55.1%
UMMS	\$198,464	33.3%
MFSMC	\$148,848	--

Source: HSCRC Abstract Tapes for 6 month period from October 2015 to March 2016.

From this perspective, performing liver transplant procedures at MFSMC will bring greater cost efficiency to the Maryland health care system. The overall savings to the health care system can be quantified by multiplying the projected number of liver transplant procedures by the cost savings per case as compared to JHH and UMMS.

Although transplant surgery is a clinically resource-intensive, high-cost process, patients with advanced liver disease who do not receive transplants will require intense medical management including periodic intervention. Processes of care may involve ED visits, multiple hospital admissions inclusive of ICU days, and repeated diagnostic and

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therapeutic procedures. These alternative costs must be considered in the assessment of the cost effectiveness of the MFSMC transplant program initiation. Considering all these factors, MedStar Health believes its proposed program will result in a net reduction in health care expenditures for patients with advanced liver disease.

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(5) Impact

(a) A new organ transplant service or relocation of an organ transplant service shall not interfere with the ability of existing transplant services of the same organ type to maintain at least the three-year average annual threshold case volumes required by this Chapter, as measured by the most recent data available through UNOS; and

(b) A new organ transplant service shall not have an unwarranted adverse impact on the financial viability of another hospital's organ transplant service of the same type; and

(c) A new organ transplant service shall not have an unwarranted adverse impact on patient access to the same type of organ transplant services at another hospital, the quality of services provided, or patient outcomes following organ transplantation.

(d) An applicant shall provide documentation and analysis that supports:

(i) Its estimate of the impact of the proposed organ transplant service on patient volume at other organ transplant services of the same type in the same health planning region and in other health planning regions that may be impacted. The applicant shall quantify the shifts in case volume for each location; and

(ii) Describe the anticipated impact on access to transplant services for the population residing within a three-hour drive time of the proposed location, including financial and geographic access; and

(iii) Describe the anticipated impact on the quality of care for the population residing within a three-hour drive time of the proposed location.

(e) If a transplant service of the same organ type has been designated as a member not in good standing by the Organ Transplant and Procurement Network, then the potential adverse impacts of the proposed new or relocated organ transplant service on such a program may be disregarded, at the discretion of the Commission.

**Table 3: Three-Year Average Annual
Threshold Case Volume Requirements by Type of Organ**

<i>Type of Organ</i>	<i>Threshold Case Volume Requirement</i>
<i>Kidney</i>	
<i>Adult</i>	50
<i>Pediatric</i>	10
<i>Liver</i>	20
<i>Pancreas /Heart Lung</i>	<i>No requirement</i>
<i>Heart</i>	20
<i>Lung</i>	20
<i>Hematopoietic Stem Cell:</i>	
<i>Autologous</i>	10
<i>Allogeneic</i>	40
<i>Intestine/Small Bowel, Islet Cells, Hepatocytes.</i>	<i>No requirement</i>
<i>Vascular Composite Allograft</i>	<i>No requirement</i>

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Response:

(a-d) MedStar Health has demonstrated in its response to *COMAR 10.24.15B: Organ Transplant Services, Project Review Standards (1) and (2)* above, that its proposed program will have no significant volume impact on the two current providers of transplant service in the LLF DSA. Volume shifts were calculated based on MedStar's estimate of its current number of patient referrals for liver transplant to these programs and equate only to approximately 3.3% of their total volume. As both current programs far exceed the three year average annual liver transplant volume threshold of 20 transplants/year (see response to *COMAR 10.24.15.04B: Organ Transplant Services, Project Review Standard (1)(b)* above), the volume shift projected from these programs will have no material effect on their volumes.

MedStar Franklin Square Medical Center Liver Transplant Service

(6) Certification and Accreditation

(a) A general hospital awarded a Certificate of Need to establish an organ transplant service shall be certified by United Network for Organ Sharing within the first year of operation.

(b) A general hospital awarded a Certificate of Need to establish a hematopoietic stem cell transplant program shall meet accreditation requirements of the Foundation for the Accreditation of Cellular Therapy (FACT) within the first two years of operation. An applicant shall apply and be FACT-accredited within 12 months of becoming eligible to apply for accreditation and shall maintain its accreditation thereafter.

(c) A general hospital seeking to establish an organ transplant service must be accredited by the Joint Commission.

Response:

MGTI has been a member in good standing with the United Network for Organ Sharing (UNOS) since 1986 and the original program at MedStar Washington Hospital Center became CMS-certified in 1974; the combined program through MGTI has had no interruption in certification nor any sanctions imposed over the full term. With this expertise readily available, MedStar Health is confident that the new program at MFSMC will be UNOS certified within the first year of operation. MFSMC is accredited by The Joint Commission (TJC).

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(7) *Health Promotion and Disease Prevention*

An organ transplant program shall actively and continuously engage in health promotion and disease prevention activities aimed at reducing the prevalence of end stage organ disease and increasing the availability of donor organs. An applicant must describe the relevant preventive services designed to address those at greatest risk for end stage organ failure.

Response:

By October 1, 2017, MedStar will have seven (7) transplant outreach clinics focused on the clinical management of advanced liver disease, across the Baltimore-Washington, DC area. Viral hepatitis screening is ongoing in the DC area and will soon be expanded to the Baltimore region. Please refer to discussion of outreach and screening above in the Comprehensive Project Description and in response to transplant standard.15.04B (1).

(8) Comparative Reviews

In a comparative review of applications to establish a transplant service for the same type of organ in which all applicants have met all policies and standards, the Commission will give preference to the applicant that:

(a) Has established effective community education and outreach programs that focus on prevention, early detection, and treatment of diseases and conditions that may lead to end-stage organ disease, such as diabetes, coronary artery disease, alcohol and substance abuse, and hypertension, with particular outreach to minority and indigent patients in the hospital's regional service area; and

(b) That is most likely to establish a proposed organ transplant service that will reach minority and indigent patients, as demonstrated by:

(i) The applicant's record of serving minority and indigent patients; and

(ii) The applicant's record of establishing programs for outreach to the minority and indigent populations; and

(c) That shows improved outcomes or improved health status of the populations that it serves based on an evaluation of the effectiveness and efficiency of the applicant's disease prevention and intervention programs.

Response: Not applicable.

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10.24.01.08G (3) (b). Need.

The Commission shall consider the applicable need analysis in the State Health Plan. If no State Health Plan need analysis is applicable, the Commission shall consider whether the applicant has demonstrated unmet needs of the population to be served, and established that the proposed project meets those needs.

INSTRUCTIONS: Please identify the need that will be addressed by the proposed project, quantifying the need, to the extent possible, for each facility and service capacity proposed for development, relocation, or renovation in the project. The analysis of need for the project should be population-based, applying utilization rates based on historic trends and expected future changes to those trends. This need analysis should be aimed at demonstrating needs of the population served or to be served by the hospital. The existing and/or intended service area population of the applicant should be clearly defined.

Fully address the way in which the proposed project is consistent with each applicable need standard or need projection methodology in the State Health Plan.

If the project involves modernization of an existing facility through renovation and/or expansion, provide a detailed explanation of why such modernization is needed by the service area population of the hospital. Identify and discuss relevant building or life safety code issues, age of physical plant issues, or standard of care issues that support the need for the proposed modernization.

Please assure that all sources of information used in the need analysis are identified. Fully explain all assumptions made in the need analysis with respect to demand for services, the projected utilization rate(s), the relevant population considered in the analysis, and the service capacity of buildings and equipment included in the project, with information that supports the validity of these assumptions.

Explain how the applicant considered the unmet needs of the population to be served in arriving at a determination that the proposed project is needed. Detail the applicant's consideration of the provision of services in non-hospital settings and/or through population-based health activities in determining the need for the project.

Complete the Statistical Projections (Tables F and I, as applicable) worksheets in the CON Table Package, as required. Instructions are provided in the cover sheet of the CON package.

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RESPONSE:

As discussed in detail earlier, MedStar Health demonstrates the need for another transplant center, located at MFSMC, on the following bases:

- The introduction of a new program that offers additional innovation in clinical care, medical therapy, surgical approaches and clinical research effectively increases the supply of available donor organs and benefits every patient and resident of the state of Maryland needing a transplant.
- MedStar's successful record in transplanting minority populations at MGTI provides evidence that it can improve access for this population in Baltimore.
- By integrating the services at MFSMC with MGTI, and providing transplant services at MFSMC, a lower cost community teaching hospital, MedStar can minimize program overhead and streamline care based on evidence-based best practices. This approach will result in a high-quality, lower-cost program that benefits the system and the State of Maryland ultimately.
- MedStar Health has a "population health" focus that involves caring for its patients through the continuum – from prevention through diagnosis, treatment and aftercare. MedStar manages approximately 250,000 covered lives, the majority of which are Maryland residents. Ensuring that needed transplant services and programs are a part of the system of care, convenient to patients' homes and families is integral to the successful management of the population's health.

See also State Health Plan Review Standards .05B(1) and B(2) for details regarding need analysis and assumptions for the utilization projections are described in the financial viability section below. See Attachment 1 for Tables F and I.

10.24.01.08G (3) (c). Availability of More Cost-Effective Alternatives.

The Commission shall compare the cost effectiveness of the proposed project with the cost effectiveness of providing the service through alternative existing facilities, or through an alternative facility that has submitted a competitive application as part of a comparative review.

INSTRUCTIONS: Please describe the planning process that was used to develop the proposed project. This should include a full explanation of the primary goals or objectives of the project or the problem(s) being addressed by the proposed project. The applicant should identify the alternative approaches to achieving those goals or objectives or solving those problem(s) that were considered during the project planning process, including:

- a) the alternative of the services being provided through existing facilities;
- b) or through population-health initiatives that would avoid or lessen hospital admissions.

Describe the hospital's population health initiatives and explain how the projections and proposed capacities take these initiatives into account.

For all alternative approaches, provide information on the level of effectiveness in goal or objective achievement or problem resolution that each alternative would be likely to achieve and the costs of each alternative. The cost analysis should go beyond development costs to consider life cycle costs of project alternatives. This narrative should clearly convey the analytical findings and reasoning that supported the project choices made. It should demonstrate why the proposed project provides the most effective method to reach stated goal(s) and objective(s) or the most effective solution to the identified problem(s) for the level of costs required to implement the project, when compared to the effectiveness and costs of alternatives, including the alternative of providing the service through existing facilities, including outpatient facilities or population-based planning activities or resources that may lessen hospital admissions, or through an alternative facility that has submitted a competitive application as part of a comparative review.

Response:

Planning Process, Goals and Objectives

As noted above in the *Comprehensive Project Description*, MedStar Health has developed, and continues to develop, a substantial Distributed Care Delivery Network to expand access to its health care services in the communities it serves (see Attachment 5 for map of DCDN sites). The goals of MedStar's approach to the delivery of health care services are to provide the appropriate level of care close to the patients' homes, as cost effectively as possible.

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MedStar Health leadership meets regularly to evaluate the effectiveness of its existing DCDN and to identify clinical and geographic gaps in the network. Through this process, gaps in access to innovative, timely liver (and kidney) transplant services (in particular, better organ utilization, advanced techniques in surgery and community outreach) were identified as gaps for MedStar Health patients residing in the Central Maryland area.

Alternative Approaches

MedStar Health evaluated three alternative approaches to meeting the needs for high quality liver and kidney transplant services for MedStar Health patients in Central Maryland. These approaches are detailed below.

(1) Utilize the two existing programs in Baltimore to provide these services

Although MedStar Health offers a sophisticated transplant enterprise in Washington, DC, some patients have historically elected to undergo these procedures at one of the two Baltimore transplant centers. However, as MedStar Health has matured and refined its population health strategy, built upon a platform of continuity of care for the population that it serves, the importance of providing a full continuum of services has become increasingly obvious. When the continuum of care is broken by referring patients outside the MedStar Health System, critical components in the delivery of high quality care are compromised or lost altogether, and costs for these patients increase. For these reasons, MedStar Health rejected this approach.

It should be noted also that the costs of care are higher at the currently available Centers, since both are academic medical centers, known to operate within a higher cost structure. MedStar wishes to introduce a more efficient care model at MFSMC in the region, at lower cost.

(2) Refer patients to MGTI in Washington DC

MGTI currently provides an unparalleled quality of care for liver and kidney transplant

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services and patients are referred there preferentially in order to maintain the continuum of care for MedStar's Central Maryland transplant patients. However, MGTI's location in Washington, DC creates a geographic challenge for many MedStar Health transplant patients who live in the Baltimore area that can have an impact on the continuity of their care. Moreover, this alternative does not achieve MedStar's goal of providing care to its patients in their own communities and the lowest cost environment whenever possible. For these reasons, this alternative was also rejected.

(3) Establish a program at MFSMC

The third alternative, establishing organ transplant services at MFSMC is the ideal solution. The program will be fully integrated with the nationally recognized MGTI, and will achieve MedStar Health's strategic goals and objectives in the following ways:

1. It maintains the continuity of care that supports the highest quality outcomes by providing MedStar Health patients with this important service within the MedStar Health System.
2. It locates this much need service in a convenient and accessible location for MedStar's Central Maryland patients (MFSMC is located in the center of this region, and is conveniently accessed via Interstate 95 and Interstate 695).

Over the past two years, MGTI has laid the groundwork to provide the full range of transplantation-related services to MedStar's Central Maryland population. To date, in anticipation of expanded services, MGTI has extended all services required for referral, triage, evaluation, and listing of transplant candidates to MFSMC (and three other outreach sites in Central Maryland). MGTI has also extended follow up services required for the long-term maintenance of patient and organ health after transplantation. The establishment of these services creates

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easy access to the full continuum of transplant care for all MedStar Health Central Maryland transplant patients.

3. It locates the program at a community teaching hospital, which has a lower cost structure and a lower average charge per case. The cost savings achieved through this alternative benefit the state health care system overall.

Integrating the established MGTI program with MFSSMC offers a clear cost advantage in that the fixed costs already associated with core services in Washington can be spread across a larger case volume, while variable start-up costs accrue in line with service growth and expansion. Surgical services will be provided initially by existing experienced MGTI surgeons, eliminating the need for a long, costly recruitment process or extended program ramp-up. No construction or renovation costs are anticipated.

Moreover, MFSSMC is the favored site within MedStar Health to provide transplant services since it has a well-developed, busy digestive disease center and associated network of supportive gastroenterologists. Its 40-bed state-of-the-art critical care service in a patient tower that is only six years old is managed by a superior team of physicians and other staff. The hospital has been approved to replace its operating rooms, a project that will begin soon, further enhancing the environment of care and patient experience.

For these reasons, establishing a liver and kidney transplant program fully integrated with MGTI, achieves all of the objectives associated with meeting the transplant needs of MedStar Health patients residing in Central Maryland.

Population Health Initiatives

MedStar Health continues to build upon its existing network of a full range of physician and facility services to care for the populations that it serves.

MedStar Accountable Care LLC, a Medicare Shared Savings program, is an example of MedStar Health's commitment to managing care for the communities it serves, in this

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case, investing in population management of Medicare fee-for-service (FFS) seniors, the vast majority of whom reside in Maryland. While Medicare ACO members have the right to go to any provider of choice, MedStar is using its system of care as effectively as possible to ensure high quality, comprehensive care for this vulnerable population at lower cost to the healthcare system, a CMS (and a Maryland) priority. Other programs described earlier include MedStar's Medicaid managed care organization, MedStar Family Choice, MedStar Medicare Choice and the MedStar Select product for MedStar Health Associates. As a result, MedStar continues to grow its population health management capabilities and to invest in quality and safety initiatives.

Managing these populations involves strict attention to the social and physical environments of care as well as to elements of individual behavior that affect preference, access and compliance. Health risk assessment through guided data analysis and comprehensive care coordination are central to MedStar's mission. The provision of a geographically distributed, high quality provider network in partnership with MedStar's provider entities promotes the best of all patient/member outcomes through a fully integrated system of care, a "Distributed Care Delivery Network." It is a fact that this approach obviates duplication of services, redundant hospital admissions and reduces costs.

MedStar's outpatient rehabilitation network has 57 sites located within communities across the Baltimore-Washington corridor. MedStar Health owns 15 urgent care sites, nine of which are co-located with MedStar Medical Group primary care physicians. Telemedicine is available at sites that are not co-located. MedStar also has seven multi-specialty outpatient ambulatory centers located in Maryland and the District of Columbia.

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10.24.01.08G (3) (d). Viability of the Proposal.

The Commission shall consider the availability of financial and nonfinancial resources, including community support, necessary to implement the project within the time frames set forth in the Commission's performance requirements, as well as the availability of resources necessary to sustain the project.

INSTRUCTIONS: Please provide a complete description of the funding plan for the project, documenting the availability of equity, grant(s), or philanthropic sources of funds and demonstrating, to the extent possible, the ability of the applicant to obtain the debt financing proposed. Describe the alternative financing mechanisms considered in project planning and provide an explanation of why the proposed mix of funding sources was chosen.

- Complete applicable Revenues & Expenses (Tables G, H, J and K as applicable), and the Work Force information (Table L) worksheets in the CON Table Package, as required. Instructions are provided in the cover sheet of the CON package. Explain how these tables demonstrate that the proposed project is sustainable and provide a description of the sources and methods for recruitment of needed staff resources for the proposed project, if applicable.
- Describe and document relevant community support for the proposed project.
- Identify the performance requirements applicable to the proposed project and explain how the applicant will be able to implement the project in compliance with those performance requirements. Explain the process for completing the project design, contracting and obtaining and obligating the funds within the prescribed time frame. Describe the construction process or refer to a description elsewhere in the application that demonstrates that the project can be completed within the applicable time frame.
- Audited financial statements for the past two years should be provided by all applicant entities and parent companies.

Response

Please note that financial and work force schedules reflect combined kidney and liver transplant programs at MFSMC that are fully integrated with clinical and administrative systems at the well-established and experienced MedStar Georgetown Transplantation Institute (MGTI), currently operating at MedStar Georgetown University Hospital (MGUH) in Washington, DC. The integration described permits program variable costs to align with program growth while limiting allocation of fixed overhead costs as appropriate to the size of the operation. This rational approach means that the new MFSMC program will provide

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kidney and liver transplant services to Marylanders at a lower cost than the other transplant programs in Maryland in a context of maintaining excellence in clinical care and patient outcomes.

Revenue & Expense (Tables G, H, J and K), and the Work Force information (Table L) are included in Attachment 1.

MFSMC has received significant support among private physicians, MedStar physicians and private members of the community. These letters are included as Attachment 6.

See Attachment 7 for MedStar Health FY15-FY16 Audited Financial Statements.

Volume Assumptions

- A. Liver transplant volumes were based on the current experience of the MGTI clinic at MFSMC and in discussions with community gastroenterologists (see letters of support).
- B. Kidney transplant volumes were estimated based on patients under dialysis treatment in MFSMC immediate vicinity as well as discussions with community nephrologists (see letters of support).
- C. Volumes for both organs are lower in the initial years recognizing that MFSMC will not receive CMS certification until year two and the Centers of Excellence designation until year three.
- D. Volumes for both organs also assume that a large proportion of patients in MedStar Health's Managed Care Programs (e.g., MedStar Family Choice) would undergo transplantation at MFSMC.

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Financial Projection Assumptions

MedStar Franklin Square Entire Facility Assumptions:

*FY17 is based on the expected performance for the Fiscal Year Ended June 30, 2017
Revenues (FY18-21)*

- A. *In addition to annual inflation adjustments for facility and professional service charges, the revenue projections assume incremental facility revenue to cover capital costs (depreciation and interest) related to a recently issued certificate of need for a surgical facility modernization project.*
- B. Contractual, bad debt, and charity care relatively constant as a % of gross revenues.
- C. Other operating revenue: FY18-FY19 includes a reduction of 6.4% in FY18 and a reduction of 2.9% in FY19 due to the decline in meaningful use revenue.

Expenses (FY18-21)

- D. Expense growth based on varying levels of expense inflation with management initiatives meant to ensure MFSMC is ability to maintain a level of profitability.

Transplant Program:

Program is expected to “go live” by the start of FY2019

Revenues

- A. Volume Assumptions:

Liver transplant volumes were based on the current experience of the MedStar Georgetown Transplant Clinic at MFSMC and in discussions with community gastroenterologists (see letters of support). Kidney transplant volumes were estimated based on patients under dialysis treatment in MFSMC immediate vicinity as well as discussions with community nephrologists (see letters of support). Volumes for both organs are lower in the initial years recognizing that MFSMC will not receive CMS or Centers of Excellence designations from managed care plans until volume threshold are met. Volumes for both organs also assume that patients

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in MedStar Health's managed care programs would undergo transplantation at MFSMC.

- B. Transplant Program Revenues: Beginning in FY19, kidney and liver revenue projections assumed \$148,848 Per Liver Transplant and \$87,203 per Kidney Transplant, approximately 75% of the lowest cost facility in the Baltimore Region.
- C. Ancillary Transplant Program Revenues: Ancillary outpatient volumes are based on patient activity expected to occur in MFSMC as a direct result of the transplant programs and are derived from MGTI experience and procedural pre- and post operation testing.
- D. Professional Fee Transplant Program Revenues: Professional fee revenue driven off the expectation of employed physician and actual MGUH experience for entire transplant program to arrive at a per transplant estimate of professional revenues.

Expenses

- A. FTE Requirements: Please see Workforce Tab L for specific FTE requirements related to the program.
- B. Transplant project variable expenses relate to organ acquisition, supplies, purchased services, drugs, and variable salary and wages based on current experience at MGTI.

Expense reductions and savings initiatives

Savings will result from a MedStar Health-wide performance and operational excellence initiative that will enable and accelerate MFSMC's ability to optimally deliver efficient and effective, high quality patient care at a high value to our patients and the Maryland's Healthcare System. The initiative is focused on the following:

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- A. Improved performance through enhanced clinical productivity;
- B. Reduction in 20 FTEs, about \$2M in salary expenses resulting from the consolidation of the current two separate OR suites into one facility;
- C. Creation of greater enterprise-wide synergy related to the oversight of our employed provider network; and
- D. Improvement in the process of care as it relates to length-of-stay management across the continuum of care and management of observation status patients.

Staffing Assumptions

- A. Variable staffing is modeled on MGTI staff to case volume ratios in the context of a new, start-up operation, with attention to ensuring coverage by medical and surgical physician specialists and patient safety. Support personnel are allocated based on initial volume projections with capacity to expand with volume growth. See Comprehensive Project Description for more information.
- B. In general fixed staffing will be maintained through MGTI including quality/data management, regulatory compliance, and senior level oversight functions.

Recruitment

MedStar recruits through various means. Physician recruitment is generally accomplished through placing notices in professional journals, word of mouth and recommendations from faculty at other transplant training programs. Other staff is recruited through human resources (HR) activities at each hospital that are customized to the type of staff being recruited. HR uses various on-line recruitment tools as well as advertising venues. All positions are posted on-line. Word of mouth is also an important tool, and promotional opportunities from within our own institutions are important for

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recruitment, i.e., staff has opportunities to seek employment at any location in the MedStar Health system.

10.24.01.08G (3) (e). Compliance with Conditions of Previous Certificates of Need.

An applicant shall demonstrate compliance with all terms and conditions of each previous Certificate of Need granted to the applicant, and with all commitments made that earned preferences in obtaining each previous Certificate of Need, or provide the Commission with a written notice and explanation as to why the conditions or commitments were not met.

INSTRUCTIONS: List all of the Certificates of Need that have been issued to the applicant or related entities, affiliates, or subsidiaries since 2000, including their terms and conditions, and any changes to approved CONs that were approved. Document that these projects were or are being implemented in compliance with all of their terms and conditions or explain why this was not the case.

Response:

MFSMC has applied for two CONs since 2000. Docket No. 05-03-2173 was approved on July 26, 2006. A modification to the CON was filed by letter on January 26, 2007. This project was implemented in compliance with the terms and conditions of the CON.

The second CON, Docket No. 16-03-2380, was approved on June 15, 2017. This project is entering the design phase.

See Attachment 8.

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10.24.01.08G (3) (f). Impact on Existing Providers and the Health Care Delivery System.

An applicant shall provide information and analysis with respect to the impact of the proposed project on existing health care providers in the health planning region, including the impact on geographic and demographic access to services, on occupancy, on costs and charges of other providers, and on costs to the health care delivery system.

INSTRUCTIONS: Please provide an analysis of the impact of the proposed project:

- a) On the volume of service provided by all other existing health care providers that are likely to experience some impact as a result of this project;
- b) On access to health care services for the service area population that will be served by the project. (state and support the assumptions used in this analysis of the impact on access);
- c) On costs to the health care delivery system.

If the applicant is an existing hospital, 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 Project Budget, the projections of revenues and expenses, and the work force information.

Response:

Regarding part (a), see response to Project Review Standard.15.04B (1) b, Need

(b) The primary goal of the program is to increase the total number of Marylanders who receive liver or kidney transplants. By making transplant evaluation more convenient for the widely dispersed population, consolidating their continuity of care, and obviating the prohibitive expenses of travel, more patients will be afforded geographic and financial access. These issues are particularly important for disadvantaged and minority populations.

Secondly, MedStar has shown that minorities in Baltimore receive transplants at lower rates than non-minorities. MGTI's successful experience with transplanting minority populations is expected to translate positively at MFSMC, expanding the rate of liver transplant to this vulnerable population of Marylanders.

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Finally, the proposed MFSMC program will complete the continuum of care for MedStar Health patients in their local community. Importantly, MedStar Health patients can remain engaged in their own system and the resources provided through its distributed care delivery network.

Regarding part (c), as a community teaching hospital, MFSMC has a lower cost structure and charge per case than the area's two existing academic medical centers. MFSMC's average charge per case will be significantly lower than the charge per case of either Hopkins or Maryland (see Figure 19, Page 65). From this perspective, performing transplant procedures at MFSMC will bring greater cost efficiency to local and state health care systems.

List of Attachments

1. Tables Package
2. Information Regarding Charges
3. Charity Care and Financial Assistance
4. Quality
5. Distributed Care Delivery Network Maps
6. Letters of Support
7. MedStar Audited Financial Statements
8. Compliance With Conditions on Previous CONs