March 1, 2018

Via E-mail and USPS

Mr. Kevin McDonald
Chief, Certificate of Need
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

Re: MedStar Franklin Square Kidney Transplant Service- Matter # 17-03-2405

Dear Kevin:

This letter is written in response to the questions raised, on behalf of the Maryland Health Care Commission (MHCC), in your letter of December 26, 2017 regarding MedStar Health's application to initiate kidney transplantation services at MedStar Franklin Square Medical Center (MFSMC). We have undertaken substantial effort in answering the questions as factually and comprehensively as possible. While you will note redundancy in some responses, we understand that the questions likely originated from several reviewers, and in order to ensure no misunderstandings or incomplete responses, some repetition seemed necessary.

Responses are provided ***in blue*** below in the format presented originally by the MHCC.

On behalf of MedStar Health, thank you for the opportunity to respond to the MHCC. Should you have any questions regarding this matter, please feel free to contact me at (410) 772 - 6689.

Sincerely,

Patricia G. Cameron
Director, Government Affairs

cc: Paul Parker, Director, Center for Health Care Facilities Development
Gregory Branch, MD, Health Officer, Baltimore County
Samuel E. Moskowitz, President, MedStar Franklin Square Medical Center
Anne P. Weiland, Vice President, MedStar Health

LIST OF FIGURES
Kidney Transplant Completeness Question Responses

M. Joy Drass, MD, EVP and Chief Operating Officer, MedStar Health

INTRODUCTION

The State Health Plan has acknowledged the large gap between the supply and demand of donor organs that exists on national as well as state levels. MedStar Health believes that the proposed MFSMC program, a collaboration with the MedStar Georgetown Transplant Institute (MGTI), can increase the supply of donor organs for patients in the LLF OPO. A cited throughout the Certificate of Need Application and the responses to Completeness Questions below, MGTI's history of innovation, research, surgical expertise and demonstrated superior clinical outcomes is carried out in a context of offering patients all available options for transplantation.

MGTI is a national leader in specific areas of innovation that include novel surgical approaches to expand the utilization of single organs among multiple recipients and, importantly, judicious consideration of higher risk donors in appropriate recipients to improve long-term survival. MGTI is confident in its ability to increase the number of minorities served, as demonstrated in the data provided herein.

BEGINNING OF RESPONSES TO COMPLETENESS QUESTION

Note: Figures numbers have been assigned to the graphics provided in these responses. Where a specific graphic from the application is pasted into the response without a Figure number, the Figure number from the application is provided in black, underlined font, e.g. "Figure 8 (page 46 in the application) pasted below".

PART I – PROJECT IDENTIFICATION AND GENERAL INFORMATION

1. Will the proposed kidney transplant program treat adults only?

CORRECT – adults only

2. Sources are not provided for the information presented in the following charts/tables/illustrations. …Please remedy that by providing the source for each.

Figures 1, 2, 3, and 4. (Note: there are two charts labeled "Figure 3," one on p. 15 and one on p. 17.)

Figure 1 (Page 10) entitled US Transplant Center Rankings by Volume
Source: *OPTN Organ Data source. Copied into Excel and sorted from highest to lowest total abdominal volume (liver, kidney, intestine, pancreas; heart and lung volumes excluded).*

Figure 2 (Page 13) entitled "Candidate Waiting List Status (Active vs. Inactive)
Source: *UNOS Benchmark Report, published by UNOS and available to centers via secure website*

Untitled Figure (Page 14) shown as Figure B4. Observed and expected waiting list mortality rates: 07/01/2015 – 06/30/2016
Source: *Program Specific Report by SRTR report based on April 2017 data. Released July 2017.*

Figure 2 (Page 15) entitled Kidney Transplant Wait List By Ethnicity
Source*: Program Specific Report by SRTR report based on April 2017 data. Released July 2017.*

Figure 3 (Page 15) entitled Kidney Transplant List By Ethnicity
Source: *UNOS Benchmark Report, published by UNOS and available to centers via secure website*

Figure 3 (Page 17) entitled Average Charge per ECMAD Comparison
Source (as noted): *HSCRC Abstract Tapes for 6 month period from October 2015 to March 2016*

Figure 4 (Page 17) entitled Average Charge per Case Comparison
Source (as noted): *HSCRC Abstract Tapes for 9 month period from July 2016 to March 2017.*

3. Please…

a) provide the data (and sources) to back up several statements made in the opening description of the project. Specifically, do that for the underlined parts of these statements:

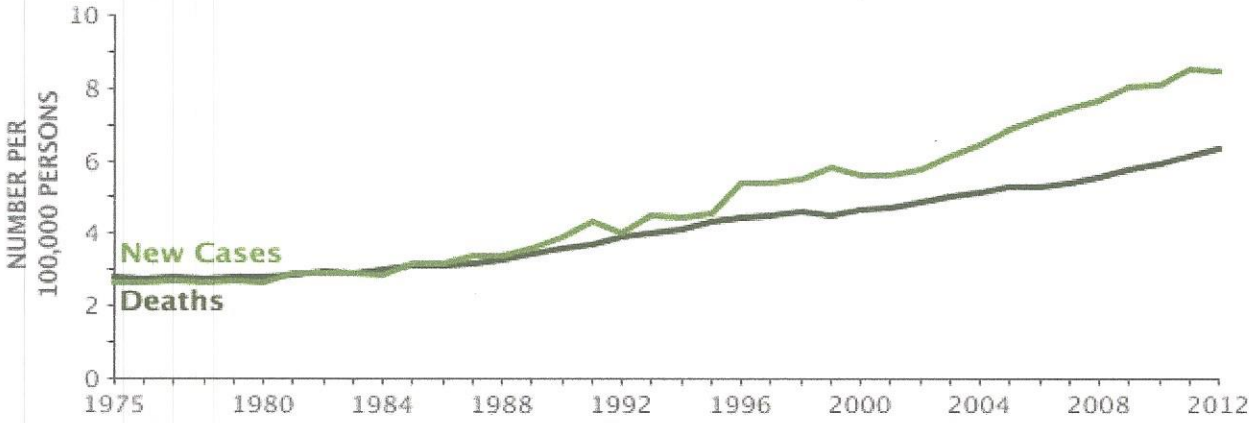
The incidence of viral hepatitis and liver cancer is growing exponentially in our country. End-stage renal failure is among the leading causes of death and disability in the nation, in large part attributable to the growing incidence and prevalence of diabetes mellitus. In this context, 200,000 people die from these diseases annually and the number of patients awaiting transplant increases every year.

Liver Disease:
It is estimated that in the US, 3.9M people have chronic Hepatitis C Virus (HCV) and 1.2M have chronic Hepatitis B Virus (HBV), disease conditions that drive the rise of liver cancer. The incidence rate for 2014 was 0.7 cases per 100,000 population, an increase from 2010-12. An estimate 30,500 new infections of HCV occurred in 2014. In 2014, nearly 20,000 deaths resulted from HCV. The incidence of liver cancer has continued to

rise. In the US, there were 35,660 new cases of liver cancer in 2015. Between 2003 and 2013, liver cancer incidence rates and deaths have increased at the highest rate of any cancer. Furthermore, rates of nonalcoholic fatty liver disease (NASH) and resultant liver cancer continue to rise exponentially. It is estimated that by 2030, incidence of decompensated cirrhosis and liver cancer due to this disease will increase by 168% and 137% respectively.

Source: These statements are sourced by the Centers for Disease Control and well as the United States Renal Data System (USRDS): https://www.cdc.gove/nchs/fastats/leading-causes-of-death.htm. See also other sources below the graphic.

FIGURE 1. INCIDENCE OF LIVER DISEASE AND DEATHS 1975-2012



https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm#section1

http://seer.cancer.gov/statfacts/html/livibd.html

Annual Report to the Nation on the Status of Cancer. March 9, 2016 DOI: 10.1002/cncr.29936

Hepatology. 2017 Aug 12. doi: 10.1002/hep.29466.

Renal Disease:

Nationally there are ~450,000 patients who are on dialysis and ~20,000 kidney transplant are performed each year. The ratio=20000/450000=0.04 or ~4%, or ~4:100

Dialysis=468,000

Transplants:

Kidney=19000

Kidney pancreas=800
Kidney liver=700
Kidney heart=150

Extrapolated from Medicare data, USRDS, UNOS data reports:

https://data.medicare.gov/Dialysis-Facility-Compare/Dialysis-Facilities-in-the-U-S-/kwkm-uxp2/data
https://www.unos.org/
https://www.usrds.org/

b) Re: the statement: *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*, document (and source) the percentage of kidney transplant patients who also require a liver transplant.

From a liver disease viewpoint: Advanced liver disease leads to a high incidence of hepato-renal syndrome and acute kidney injury, life-threatening medical conditions that consist of rapid deterioration in kidney function in patients with cirrhosis or severely advanced liver failure. Up to 50% of patients hospitalized with advanced liver disease develop acute kidney injury and annually 12% of hospitalized patients with cirrhosis develop hepato-renal syndrome. As a result of current organ allocation policy, 10-15% of patients requiring a liver transplant also require a kidney transplant, depending on the year in question, center practices and population demographics. As a result, MedStar Health concurrently requests certificates of need for both liver and kidney transplant programs within one center so as to address this critical need affecting a significant proportion of patients suffering from end stage liver disease.

Sources:

Garcia-Tsao G, Parikh CR, Viola A. Acute kidney injury in cirrhosis. Hepatology 2008; 48:2064–77.

Bucsics 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.

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 hepato-renal syndrome in cirrhosis with ascites. Gastroenterology 1993; 105(1):229-36.

From a kidney disease viewpoint: It is clear that liver and kidney dysfunction are tied together closely as the MELD score that is currently utilized to allocate deceased donor livers has recipient Creatinine (the primary lab value in assessing kidney function) as the most powerful driver in the calculation of that score. A liver patient with end-stage renal disease (ESRD) alone - with a normal Bilirubin and International Normalized Ratio (INR) - has a MELD score of 20 which is the average MELD at the time of liver transplant for several OPOs. Because of the predisposition to hepato-renal syndrome and acute kidney injury in this population, many of these

patients will benefit from Simultaneous Liver-Kidney (SLK) transplantation The data demonstrate clearly that patients with ongoing renal failure postoperatively following liver transplant have unfavorable outcomes.

Selected sources:

Al-Riyami, D et al. Decreased Survival in Liver Transplant Patients Requiring Chronic Dialysis: A Canadian Experience. Transplantation, 85:1277-80, May 15, 2008.

Zand, MS et.al. High Mortality in Orthotopic liver transplant recipients who require hemodialysis. Clinical Transplantation, 2011: 25: 213-21.

c) Document the statement that "most liver transplant programs exist in association with a kidney program".

Nationally, there are 141 centers performing liver transplant that are CMS certified and approved by UNOS,; only two (2) liver transplant centers nationally do not have a kidney transplant program. These are small liver transplant programs, averaging 23 transplant procedures annually. Since 1988, 8019 combined liver-kidney transplants have been performed nationally.
Source: https://www.unos.org/

d) Provide the data and sources for the claims: "Most recently, in calendar year 2016, MGTI kidney transplant volumes surpassed both Maryland programs (Johns Hopkins Hospital and University of Maryland) while maintaining superior outcomes in graft and patient survival..." and "While among the highest volume programs in the country, the kidney transplant program also has the lowest percentage of inactive candidates (individuals for whom the transplant procedure is on hold, usually for medical reasons), on its waiting list in the entire nation."

Sources: https://www.unos.org/; https://www.srtr.org/; www.optn.transplant.hrsa.gov

MGTI outcomes reflect an appropriate degree of aggressiveness and innovation that is rarely seen in programs with an Observed: Expected ratio (O/E) < 1.0. MGTI's additional strengths (and complements to these data) are the points made elsewhere regarding- imports, minority transplants, use of high KDPI organs and KPD. The tables in Figure 2 show the most recently reported comparative outcome data.

FIGURE 2. COMPARATIVE KIDNEY TRANSPLANT OUTCOMES (January 2018 – SRTR) *Source: http://srtr.org*

Note: since filing the CON application, more recent (CY17) data has become available as shown in the lower table.

Kidney Outcome Data SRTR Jul 2017 Release			
Center	**CY 16 Volume**	**O/E Patient Death***	**O/E Graft Failure***
MGTI	226	0.86	1.17
CNMC *	21	0.00	0.00
U Maryland	223	0.85	1.39
Hopkins	212	1.47	1.10
Source: SRTR Jan 2018 Release. A ratio > 1 indicates worse than expected outcomes			
**Note that MGTI performs all kidney transplant procedures at CNMC.*			

Kidney Outcome Data SRTR Jan 2018 Release			
Center	**CY 17 Volume**	**O/E Patient Death***	**O/E Graft Failure***
MGTI	218	0.73	1.11
CNMC *	21	0.00	0.00
U Maryland	273	1.14	1.61
Hopkins	196	1.65	1.19
Source: SRTR July 2017 Release. A ratio > 1 indicates worse than expected outcomes			
** Note that MGTI performs all kidney transplant procedures at CNMC.*			

Note that total MGTI volume is the sum of transplants performed by MGTI surgeons at Children's National Medical Center (CNMC) as well as MGTI.

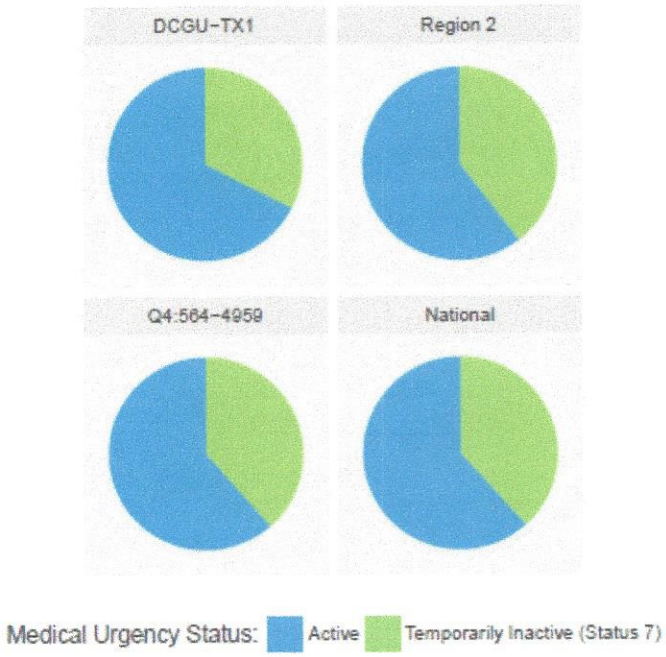
Regarding waitlist activity, see Figure 3 below.

Figure 3 shows status 7 (INACTIVE in green) waiting list volume quoted from the UNOS Benchmark report, made available to centers via secure website. MGTI has fewer inactive candidates than Region 2 or the Nation.

FIGURE 3. *ACTIVE vs. INACTIVE CANDIDATES: MGTI vs. Region 2 vs. National*

(note that "Q4" in column 3 of all SRTR reports is a subset of quarterly data)

Figure 2. Candidate Waiting List Status (Active vs. Inactive) on March 31, 2017 as of April 7, 2017



Medical Urgency Status (%)

	DCGU-TX1	Region 2	Q4:564-4959	National
Active	67.43	60.40	61.44	61.69
Temporarily Inactive (Status 7)	32.57	39.60	38.56	38.31
Total	100.00	100.00	100.00	100.00

Figure 2 shows the distribution of candidate medical urgency status for a snapshot of the kidney wait list on March 31, 2017. Active candidates accounted for 61.69% of the national wait list.

4. Please elaborate on and explain with specificity the "services required for referral, triage, evaluation, and listing of transplant candidates" and the "follow up services required for the long-term maintenance of patient and organ health after transplantation" that the application states have been extended to Franklin Square by MGTI. What are these services?

Transplant services, including referral evaluation, listing, transplantation and follow up are provided along a continuum of care by a multi-disciplinary team of professionals that includes nurse coordinators, advanced practitioners, social workers and nutritionists in addition to resident and attending physicians. In addition, patients are supported by patient navigators, nursing services, financial counseling, pharmacy services, psycho-social services, medical technology and rehabilitation. Additional consultants are made available as needed.

Each stage of the continuum of care is touched by a number of these personnel and services as follows:

Referral: the referral is taken by several individuals who handle scheduling of the candidate at one of several sites available in the community or at hospitals, based on patient convenience. Patients seen at MFSMC will be seen by a dedicated on-site team.

Formal Evaluation: at the time of evaluation for transplantation, comprehensive intake including medical history is taken by a transplant coordinator, who will follow the patient through the continuum. A transplant physician examines the patient candidate and determines whether transplantation is a feasible option. A social worker and nutritionist interview the candidate relative to family support, psychological and physical readiness to undergo the procedure and long-term follow up regimen required after transplantation. Based on the preliminary evaluation, if the patient is deemed a potential candidate, s/he moves forward to review by the Transplant Candidate Review Committee (i.e., listing committee).

Waiting List: If approved for transplant, the patient is placed on the official UNOS waiting list that is specific to each transplant program. Re-evaluation takes place periodically, according to protocol, in order to confirm candidacy and readiness for the procedure.

Transplantation: Coordination of organ matching through the UNOS registry takes place in collaboration with the local organ bank (WRTC or another depending on organ source). The patient is called for transplantation and the procedure performed.

An important caveat:

Aside from the routine Human Leukocyte Antigen (HLA) matching and allocation process demanded by policy under UNOS, a key to assuring the most successful long-term outcome possible for each recipient is the judicious appraisal of the individual characteristics of the donor (e.g., age,

co-existing disease, mechanism of death). Appropriately and cautiously matching the donor-recipient pair on this basis is a "risk-benefit" exercise that requires detailed knowledge of the recipient candidate with concurrent meticulous assessment of the donor. Simply accepting any organ that presents as an HLA match for a recipient at the top of a deceased donor waiting list, without regard to this additional level of scrutiny does not serve the recipient well. A conscientious program that approaches the process judiciously will "pass" on a donor that is not clinically complementary with the recipient, rather than accept an organ that may not achieve a best possible outcome, merely to tally an additional transplant. For these reasons, considering "donor acceptance rates" without regard to assessing outcomes measures does not appreciate the interdependency of these metrics.

Examples:

A 70 year old high KDPI donor would not be acceptable for a 40 (or 50) year old patient at the top of the waiting list whose ESRD is secondary to Polycystic Kidney Disease (PKD) simply because his/her name has risen to the top of the list.

An HCV + recipient should not accept ANY offer from an HCV + deceased donor due to the relative paucity of patients waiting for these organs and the opportunity to be discriminatory for the 'best' organ.

A patient listed for both an SPK and a solitary Kidney Transplant should NOT be offered a 'marginal' donor kidney when an offer from a much more beneficial SPK donor is expected to follow in short order.

Conversely, a program with a highly sensitized patient (cPRA of 99 and 100%) that receives regional and national offers should be counseled to be LESS restrictive on its requirements due to the infrequency in which these patients are found an offer (so called 'needle in a haystack'), Programs should assure these patients are always ready to receive an organ and must consider carefully before declining.

Follow up: Follow up begins immediately at the point of discharge with patients returning at regularly-defined intervals for evaluation and laboratory analysis as predetermined by program protocol. A majority of follow up can be done at one of MGTI's seven (7) established outreach sites located across both metropolitan areas.

Patients are followed over their lifetime by the MGTI transplant team.

5. Regarding the charge per case comparison made in Figure 4 (p. 17) please show the component costs that were aggregated into the total cost for each of the three centers.

Figure 4 below shows the component charges by cost center for MFSMC, data readily available to MedStar Health.

FIGURE 4. CHARGE PER CASE: COMPONENT COSTS

KIDNEY TRANSPLANT	MFSMC	
(1-9 LOS)		
	% Charges	Charge per Case
ROOM/BOARD	5.8%	$ 5,066
O/R	16.3%	14,209
DRUGS	3.2%	2,757
RADIOLOGY	0.6%	480
LAB	2.0%	1,731
SUPPLY	3.3%	2,898
THERAPY	0.4%	338
ORGAN	67.9%	59,189
OTHER	0.6%	535
	100.0%	$ 87,203

PART II – PROJECT BUDGET

6. The application represents that there is no project cost. Is it accurate that there are no costs – other than operating costs that would be reflected in the R & E projections – associated with project implementation?

CORRECT, no additional capital costs are anticipated as MedStar Franklin Square Medical Center currently owns all the necessary capital equipment to provide for kidney transplant services.

PART IV – CRITERIA

STATE HEALTH PLAN

General Standards

Charity Care Policy

7. For each of the following subparts of this standard, please provide the quote from the policy that meets each provision, and in what section of the policy it can be found.

The following policy quotes incorporated into Figure 5 are taken from the MedStar Health Financial Assistance Policy, which was submitted as Attachment 3 of the MedStar Franklin Square Medical Center's CON application submitted August 11, 2017.

10.24.01.04A(2) (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.

FIGURE 5. CHARITY CARE POLICY - MFSMC

	Quote from the policy	*Section citation*
(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.	*MedStar will provide a financial assistance probable and likely eligibility determination to the patient within two business days from receipt of the initial financial assistance application.*	*Responsibilities, 2.*
	Quote from the policy	*Section citation*
(ii) Minimum Required Notice of Charity Care Policy.		
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.	*MedStar Health will provide public notices yearly in local newspapers serving the hospital's target population.*	*Responsibilities, 1.5*
Notices regarding the hospital's charity care policy shall be posted in the admissions office,	*Providing notification and information about the MedStar Financial Assistance Policy by:*	*Responsibilities, 1.4.3*

business office, and emergency department areas within the hospital.	*Displaying MedStar Financial Assistance Policy information at all hospital registration points.*	
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.	*Providing notification and information about the MedStar Financial Assistance Policy by: Offering copies as part of all registration or discharges processes, and answering questions on how to apply for assistance.*	*Responsibilities, 1.4.1*

Quality of Care

8. Staff notes that subpart (b) of this standard has become outdated, as currently written; however, quality is still of great import to the MHCC, so we will ask the applicant to adapt its response to MHCC's current reporting. There is still a Maryland Hospital Performance Evaluation Guide ("HPEG"), in the hospital consumer guide component of the MHCC web site, and a set of "quality measures" are included as a component of that guide. Currently, there are 37 "quality measures" listed in the HPEG derived from the CMS Process Measures file for the fiscal year that ended on March 31, 2016 and the CMS Outcome Measures file for Mortality and Readmission for the fiscal year that ended June 30, 2014. Performance for most of these measures (32 of the 37) is now reported comparatively – i.e., "Below Average," "Average," or "Better than Average." Please identify any "below average" rating for Suburban, and discuss any actions taken to upgrade that item.

   Below are the three quality measures reported in the hospital consumer guide component of the MHCC web site in which MFSMC scored below the Maryland hospital average in CY16: 1) Emergency Department Wait Times; 2) Flu Prevention; 3) Heart Attack and Chest Pain. A brief explanation of the steps the hospital is taking to improve performance in these areas is provided.

   1) Emergency Department Wait Times:

   In April-May of 2017, MFSMC launched several new initiatives focused on reducing volume and wait times in its Emergency Department. These initiatives include:

   - ***the creation of a FastER to treat low acuity injuries and conditions, a Vertical Patient Protocol for treating patients with an Emergency Severity Index (ESI) of "3" in the ED waiting areas rather than waiting for an available bed for treatment, and a Post-Medical Screening Exam protocol for assessing and referring patients for same-day appointments with specialists and primary care physicians. The list below summarizes other***

steps the hospital has taken to improve thru-put in its ED and reduce ED wait times.

- *First Look RN – an RN stationed in the waiting room to triage patients and move those patients needing immediate care to the treatment area.*
- *ESI Training – Improved standardization of triage training and scoring, to better align patient needs to resources.*
- *Improved Coaching and Training of ED Staff– Since a high proportion of ED nurses are recent graduates with less than a one year of experience, MFSMC developed a scheduling model where experienced nurses work alongside more novice staff to coach, monitor, and help improve practice.*
- *Use of inpatient nurses to care for ED boarders (ED patients awaiting admission to the hospital's inpatient service) in order to free up ED nurses to care for ED patients, opening up more ED capacity.*
- *Work with hospitalists to expedite the admission process for ED patients who are being admitted, freeing up ED resources to more quickly move patients from waiting to treatment areas.*

2) Flu Prevention:

MFSMC has created an order set in its EMR to prompt staff at the time of admission to determine patients' flu vaccine status and to deliver the vaccine if the patient has not been vaccinated. During the hospital stay, nurse leaders review patient flu vaccine status daily. MFSMC has also implemented several checks in its EHR to remind nurses to screen and vaccinate eligible patients during their stay, including at the time of dischHeart Attack and Chest Pain:

3) Heart Attack and Chest Pain:

Heart attack patients who received aspirin at arrival in FY17 were at 100%. Chest pain patients who received aspirin at arrival in FY17 were at 98%, both above the National Average of 97%. Chest pain patients arriving by ambulance now ECG performed in the ambulance triage area. RNs stationed in the waiting room triage patients and move those patients needing ECG tests to the testing area. ED Physicians interpret the ECGs immediately and triage patients accordingly when abnormalities are found.

Project Review Standards- State Health Plan

Need and Access

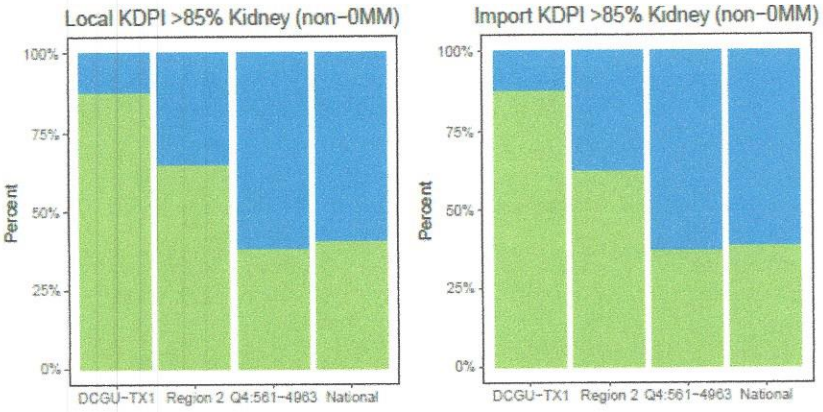
9. Please describe the story told by each of Figures 8, 9, and 10.

Figure 8 (page 46 in the application) pasted below . Kidney 'quality' is currently measured using the Kidney Donor Profile Index (KDPI) - a 10-variable formula that uses readily-available donor demographic data

ranging from 1-100%. The higher the number, the greater risk of kidney loss over time following transplant. >85% KDPI roughly corresponds to the "old" nomenclature of Expanded Criteria Donor (ECD), i.e., these are organs from donors who may be older, have viral or other disease burdens or in some way be "less than perfect". MGTI's philosophy is to provide as many opportunities for transplantation as possible by carefully matching donor and recipient characteristics that can make for compatible, successful transplantation. In the current KDPI methodology, organs are allocated in a more complex system (than standard UNOS) that differentiates into 4 categories according to the kidney donor profile index, including one for KDPI >85. In this category, donor organs are offered immediately to the region rather than via the standard UNOS allocation that offers an organ first locally and then regionally. The purpose is to distribute the higher risk organs to programs that have the skills, resources and, importantly, motivation, to adopt "expanded criteria" in transplanting organs.

In this model, in order to participate, patients are required formally to consent to high KDPI listing in the UNOS computer system as a candidate for a higher risk organ. ***Figure 8 (Page 46 in the application)*** ***pasted below provides a graphic representation of patients listed according to these criteria). There is no obligation for a patient to accept the organ when it becomes available or a penalty for a patient to decline a high KDPI organ at the time of allocation. However, preemptive listing for these high KDPI organs provides an opportunity for the patient to be considered at all otherwise they are passed over. In other words, "nothing ventured, nothing gained".***

Figure 12. Willingness to Accept >85% KDPI (non-0MM) on June 30, 2017 as of July 10, 2017



Local KDPI >85% Kidney (non-0MM) (%)

	DCGU-TX1	Region 2	Q4:561-4963	National
Unwilling	11.66	35.02	61.97	59.49
Willing	88.34	64.98	38.03	40.51
Total	100.00	100.00	100.00	100.00

Import KDPI >85% Kidney (non-0MM) (%)

	DCGU-TX1	Region 2	Q4:561-4963	National
Unwilling	11.77	37.32	62.67	61.35
Willing	88.23	62.68	37.33	38.65
Total	100.00	100.00	100.00	100.00

Nationally, 59.49% of candidates were reported as unwilling to accept a local KDPI >85% non-0 antigen mismatch kidney at the time of the snapshot. 61.35% of candidates would not accept an import KDPI >85% kidney (non-0MM).

Relative to other programs, the figure above shows that MGTI has a high percentage of patients who have willingly listed to accept a high KDPI organ. MGTI encourages listing because we want each patient to be availed of every possible opportunity for transplantation. Note that this option is neither necessary nor appropriate for every individual and programs are asked to review the recipient pool critically and consent only those who would realistically benefit from this specific opportunity.

<u>Figure 9 (page 47 in the application)</u> pasted below is a representation of the "Kidney Donor Recipient Index (KDRI)" and the correlate to the previous graphic. It shows the rates of organs offered and accepted overall and then breaks out the total by KDRI (low, medium and high) category. It shows MGTI's acceptances exceeding the local, regional and national trends, meaning the MGTI makes judicious use of every available organ presented for transplantation – another example of how the number of organs can be augmented – and a practice that will be extended to the program at MFSMC.

Table B10. Offer Acceptance Practices: 01/01/2016 - 12/31/2016

Offers Acceptance Characteristics	This Center	OPO/DSA	Region	U.S.
Overall				
Number of Offers	21,055	32,977	258,727	1,533,978
Number of Acceptances	128	266	1,565	12,467
Expected Acceptances	61.3	157.7	1,713.5	12,458.5
Offer Acceptance Ratio*	2.05	1.68	0.91	1.00
95% Credible Interval**	[1.72, 2.42]	--	--	--
Low-KDRI Donors (KDRI < 1.05)				
Number of Offers	2,292	3,887	41,219	254,475
Number of Acceptances	28	101	616	4,911
Expected Acceptances	17.8	65.4	664.1	4,909.0
Offer Acceptance Ratio*	1.52	1.53	0.93	1.00
95% Credible Interval**	[1.02, 2.11]	--	--	--
Medium-KDRI Donors (1.05 < KDRI < 1.75)				
Number of Offers	9,509	15,676	132,406	968,063
Number of Acceptances	72	133	802	6,441
Expected Acceptances	32.7	73.0	874.9	6,435.2
Offer Acceptance Ratio*	2.13	1.80	0.92	1.00
95% Credible Interval**	[1.68, 2.65]	--	--	--
High-KDRI Donors (KDRI > 1.75)				
Number of Offers	9,254	13,414	85,102	311,440
Number of Acceptances	28	32	147	1,115
Expected Acceptances	10.9	19.2	174.4	1,114.3
Offer Acceptance Ratio*	2.33	1.60	0.84	1.00
95% Credible Interval**	[1.57, 3.24]	--	--	--

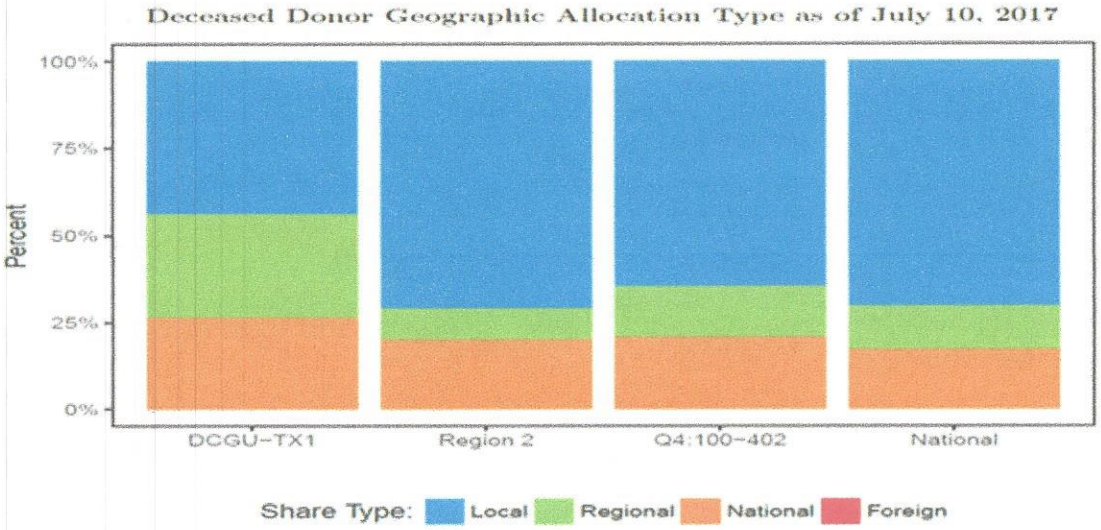
Figure 6 below (excerpted from the SRTR graphic above), shows that MGTI's use of high risk organs overall is more than two (2) times the expected for all organs (national rates being the comparator); 2.13 times for medium-risk and 2.33 times for high risk donors. One can compare these rates across the OPO/DSA and the region. Specific comparisons of MGTI to JHH and UMMS are provided below (Source: http://srtr.org).

FIGURE 6. KIDNEY DONOR RECIPIENT INDEX (KDRI) PROGRAM COMPARISON

	Medium KDPI	*High KDPI*
MGTI	***2.13***	***2.33***
UMMS	***0.73***	***1.12***
JHH	***1.05***	***1.24***

***Figure 10 (page 48 in the application) pasted below** shows the source of organs allocated for transplantation – from local, regional or national sources. The chart demonstrates that MGTI obtains organs from as many sources (local, regional, national) as present opportunities for available donor organs, i.e., not relying solely on the local OPO sources alone but affording patients every possible means of receiving a reasonable organ for transplantation. Hence, including regional allocation of organs with high KDPI (risk) as well as national sources (usually for very difficult to match patients) as well as a reputation for aggressive review of patient characteristics and attention to matching with suitable donors, one sees that over 50% of MGTI transplants come from outside the OPO. These results demand more effort in the preparation of the patients on the waitlist, critical review of every donor offer, and accommodation of less than perfect organs if they would benefit a recipient with a similar risk profile. This is another example of how the MFSMC program in collaboration with MGTI can augment the organ pool.*

The MGTI decision framework was formulated on the basis of established data-based experience that in individual patients, survival is enhanced with a high risk KDPI organ over continued long-term dialysis. The success of MGTI's approach is confirmed by its excellent patient and graph survival profile, as documented in SRTR.



Allocation Type (%)

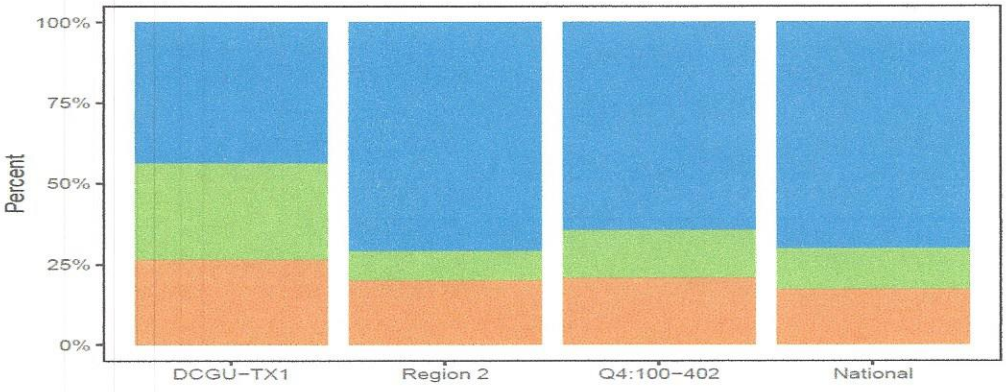
	DCGU-TX1	Region 2	Q4:100-402	National
Local	43.75	70.77	64.53	70.17
Regional	29.69	8.94	14.48	12.60
National	26.56	20.22	20.99	17.22
Foreign	0.00	0.07	0.00	0.01
Total	100.00	100.00	100.00	100.00

10. Please back up (with data and source) the statement made on p. 47 that "…MGTI has remained aggressive in the use of organs from outside the OPO and is one of the largest importers of kidneys for transplantation, far exceeding those in the region and even in the entire country. More than 50% of kidneys transplanted to MGTI wait-listed patients in the last two-year period are from either regional or national sources...

Figure 7 immediately below this statement (the same figure as shown above), provides the supporting data. As the graphic demonstrates, MGTI (DCGU) imported a total of 56.2% of organs vs. 29.23% for Region 2 and 29.82% nationally.

FIGURE 7. *ORGAN ALLOCATION FROM LOCAL, REGIONAL, NATIONAL SOURCES*

Figure 7. Deceased Donor Geographic Allocation Type as of July 10, 2017



Allocation Type (%)

	DCGU-TX1	Region 2	Q4:100-402	National
Local	43.75	70.77	64.53	70.17
Regional	29.69	8.94	14.48	12.60
National	26.56	20.22	20.99	17.22
Foreign	0.00	0.07	0.00	0.01
Total	100.00	100.00	100.00	100.00

Source: UNOS Benchmark Report, published by UNOS and available to centers via secure site.

11. Is there a downside to MGTI's "superior rate of utilization of high KDPI organs" (p. 48), e.g., greater morbidity and/or shorter survival after transplant?

A superior rate of utilization of high KDPI assumes judicious patient matching of donor and recipient characteristics so as to obviate complications and optimize patient and graft survival. In the MGTI experience, superior outcomes have been achieved in both patient and graft survival when compared with both regional and national metrics.

12. Provide the source for the data shown in Figures 13, 14 and 15. In Figure 15, what is shown on the y axis (NKR TXPs)?

The "y" axis shows participating Centers in the National Kidney Registry (NKR). These data are representative of publically-shared information regarding programs that participate in the NKR; data are updated on a quarterly basis. All of these graphs are meant to track the number of offers made to a program in the NKR and whether the program declines or accepts a particular offer due to the availability of an operating room or a surgeon to perform either the living donor or the recipient operation ("x" axis). Figure 13 from the application (pasted below) shows Georgetown in a leading position.

Figure 13 (page 51 in the application) pasted below, shows Participating Centers NKR Transplant Registry.

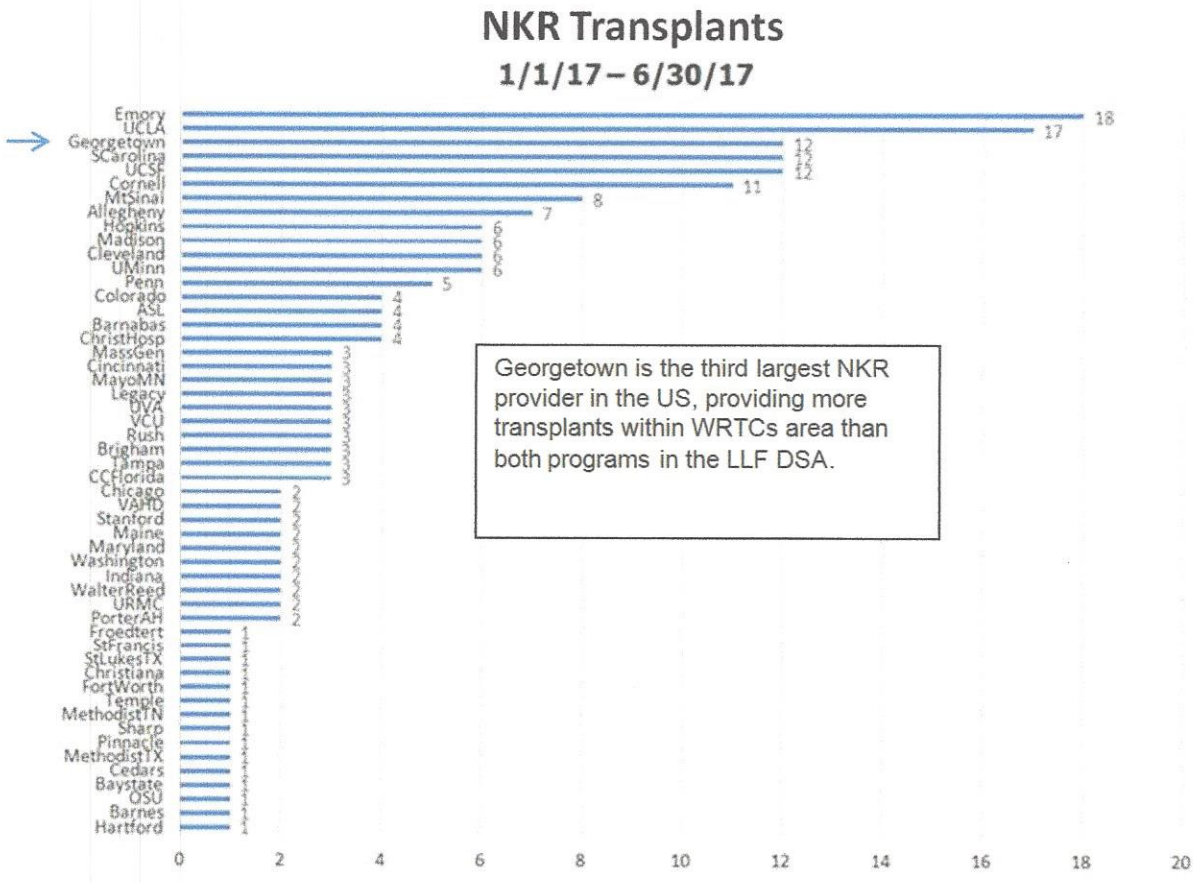


Figure 14 (page 52 in the application) pasted below this paragraph: *The Y-axis shows centers with the highest number of offers declined because of lack of surgical availability. The purpose of this graph is to highlight the number of transplants that potentially are not occurring at various centers.*

Johns Hopkins Hospital is shown in the number 2 position, having declined 5 offers and UMMS in the number 12 position, having declined two offers. Note that the Georgetown (MGTI) program does not appear on the list.

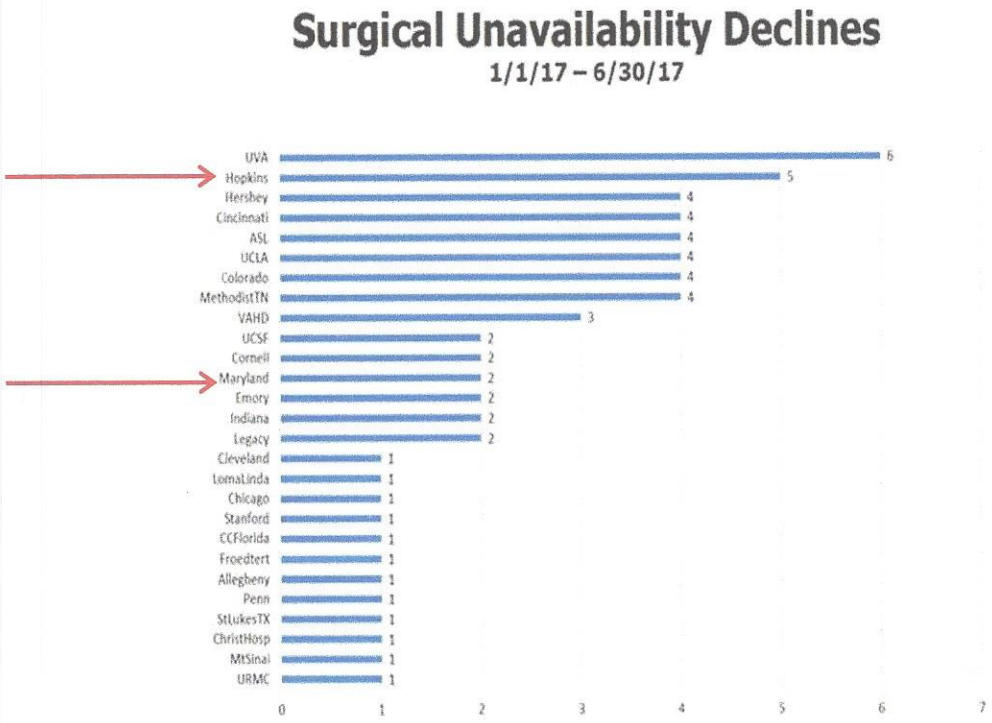
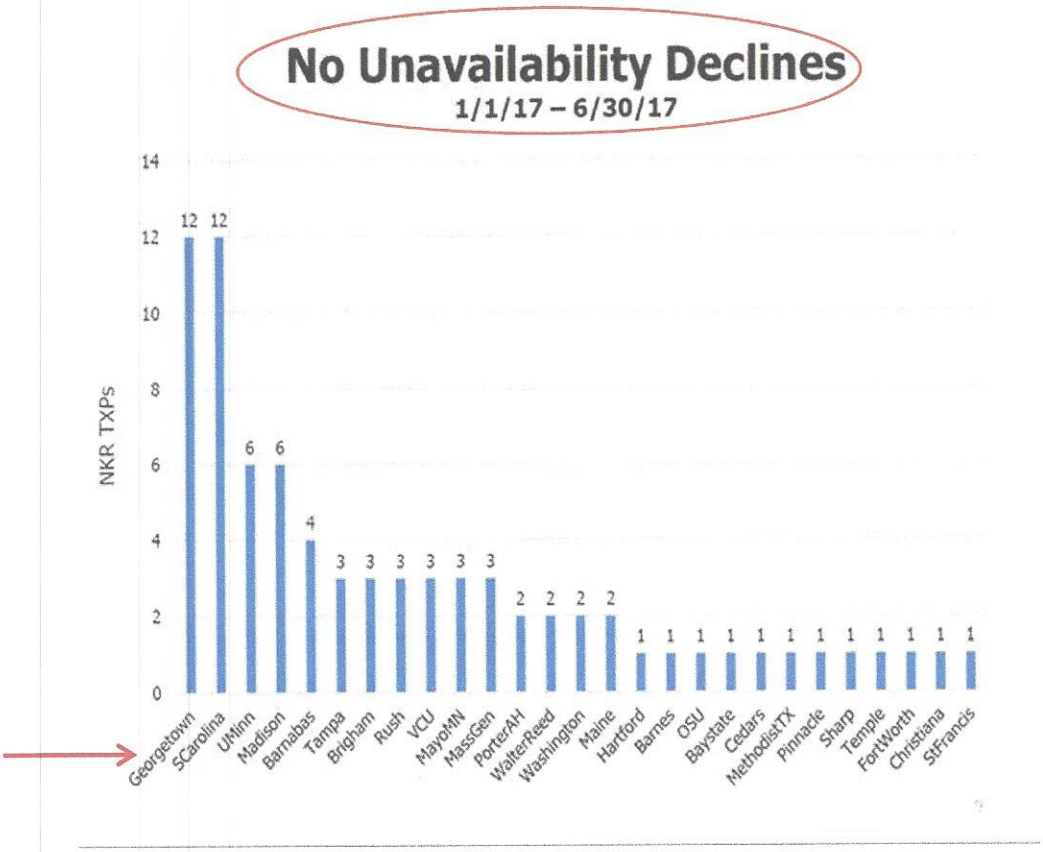


Figure 15 (page 53 in the application) pasted immediately below, shows those transplants occurring regularly because surgeons (and the operational requirements of a transplant hospital) are willing and readily-available to accept and transplant organs at all times. Georgetown (MGTI) is number one on this listing, having accepted 12 NKR offers with zero declines.



13. Part (b) of the Need standard requests that the applicant, **"detail the underlying assumptions upon which each projection is based"**. This part of the question is not addressed.

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.

(b) Detailed Underlying Assumptions:

- ***FY15-FY17 referrals are based on estimates from MedStar Health Renal Dialysis Program systems.***
- ***The MFSMC program is projected to have no impact on transfers to JHH/UMMS in program year 1 (FY19) due to the timing of its opening, historical referral patterns and potential patient preference. The primary source of patients in program year 1 will be referrals from MedStar's currently operating Advanced Kidney Disease Clinics at MFSMC, Frederick, Maryland and Annapolis, Maryland, as well as the Renal Programs at MedStar Good Samaritan Hospital and MedStar Union Memorial hospital. As the program begins to mature in year 2 (FY20), and more MedStar providers become aware of the program, MFSMC projects 40% fewer cases will be transferred to JHH/UMMS. By program year 3 (FY21), as the program begins to develop a quality reputation, another ~40% fewer cases will be transferred to JHH/UMMS.***
- ***A certain number of cases that are diagnosed in its renal dialysis programs will continue to seek transplant services at JHH/UMMS. Therefore, it projects that approximately five cases/year will continue to be referred to those centers.***

Figure 8 summarizes the projected shift in kidney transplant volume by transplant center.

FIGURE 8. TREND IN REFERRALS TO UMMS AND JHH – CURRENT AND FUTURE

	Actual			Proj.	Program Years		
Metric	FY15	FY16	FY17	FY18	FY19	FY20	FY21
Referrals UMMS	12	4	7	8	8	5	3
Referrals to Johns Hopkins	10	4	6	8	7	4	2
Total Referrals	**22**	**8**	**13**	**16**	**15**	**9**	**5**
% Variance from Prior Year					**-6%**	**-40%**	**-44%**

14. Is there a theory about the reasons behind the 19% decline in kidney transplants shown in Figure 21 between CY15 and CY16?

During CY15 and CY16 the University of Maryland and Johns Hopkins Hospital programs experienced certain regulatory issues and leadership changes respectively. These types of programmatic changes can have an impact on volume.

15. Please define the jurisdictions and zip codes the applicant considers to be its service area for this project, and enumerate by jurisdiction the 129 Maryland patients for kidney transplant that MGTI currently has wait-listed "from counties that orient to Baltimore."

MFSMC expects to primarily serve residents of Central Maryland (Baltimore City/County, Anne Arundel County, Carroll County, Harford County, and Howard County) and Frederick County. This geography includes the service areas of the four Baltimore MedStar Hospitals (MedStar Franklin Square, MedStar Good Samaritan, MedStar Harbor, and MedStar Union Memorial) and the locations of MedStar Advanced Kidney and Liver Disease Clinics (Baltimore County, Anne Arundel County, Frederick County, Prince George's, Calvert, Charles and St. Mary's counties).

The number of zip codes is lengthy so as a proxy, the following table, Figure 9, shows patients by county who are wait-listed currently (note the number fluctuates based on patients moving to transplant and those who are removed for medical reasons):

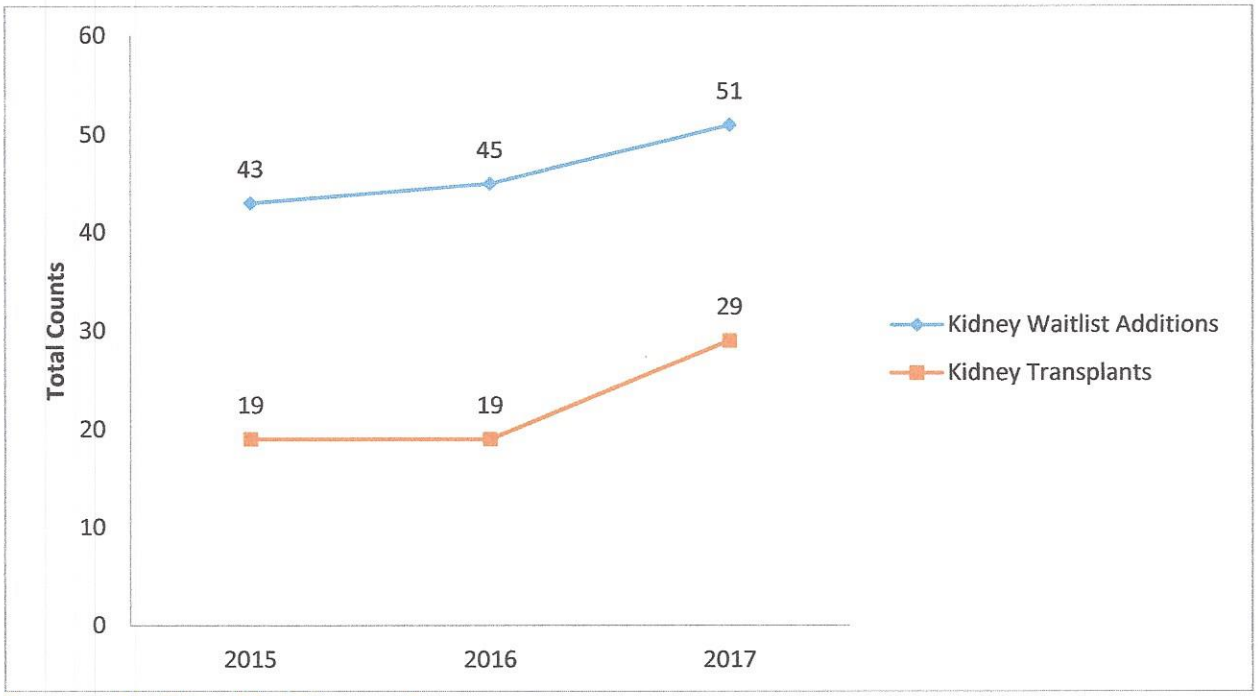
FIGURE 9. DISTRIBUTION OF PATIENTS WAIT-LISTED AND TRANSPLANTED

Kidney Transplant Program				
	Curr WL	Txps 2017	Txps 2016	Txps 2015
Anne Arundel County	9	1	3	0
Baltimore City	7	1	1	2
Baltimore County	18	4	1	0
Calvert County	6	1	3	2
Carroll County	1	0	0	2
Charles County	30	10	8	6
Frederick County	24	4	2	2
Harford County	4	1	1	0
Howard County	10	3	2	2
St. Mary's County	11	5	1	3
Unet Waitlist 1/23/2018	120			

Source: http://srtr.org

Figure 10 shows the 3-year trend in patients residing in Baltimore-oriented counties (listed in Figures 9 and 10) that were added to the MGTI waiting list or were transplanted there.

FIGURE 10. 3-YEAR TREND IN WAIT-LIST AND TRANSPLANTS AT MGTI



Source: MedStar Health records

16. Despite professing not to be making its case on barriers to access, the applicant speaks to geographical challenges among members of the target market as a project justification. This seems to ignore the basis of regionalization for such highly-specialized services[1] (note the three-hour travel benchmark in part (a) of the Access standard). To this point, the applicant neglected to respond to subpart (d) of this standard which is:

> *Travel to an organ transplant center located in a health planning region other than where the organ transplant recipient resides is not, in and of itself, considered a barrier to access, if the drive time in less than three hours one-way.*

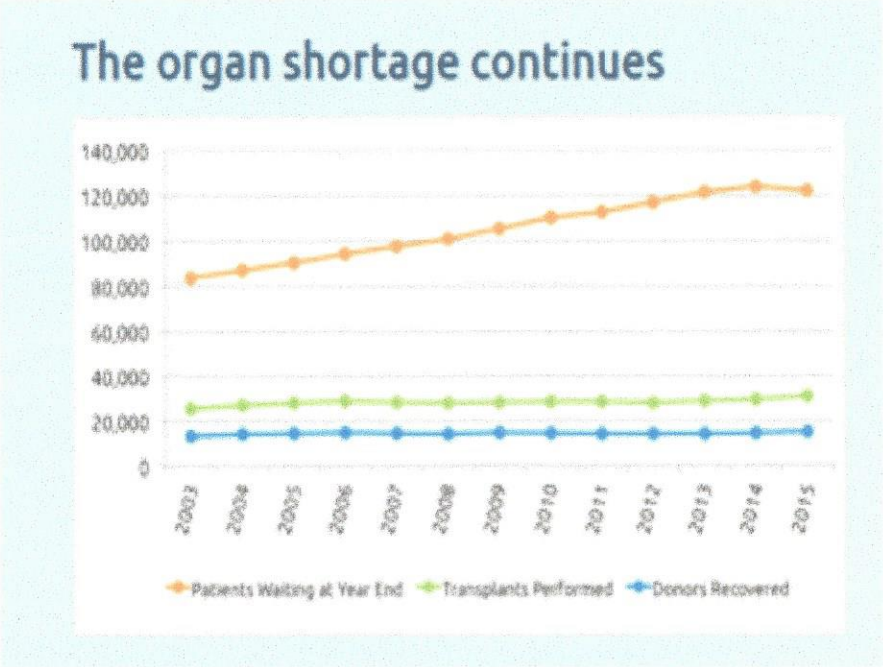
Please describe why travel from Baltimore to Washington, DC, or receiving this service at another Baltimore location is a challenge to access.

[1] Note that the State health Plan (COMAR 10.24.15) states: "For specialized services, the public is best served if a limited number of general hospitals provide specialized services to a substantial population base. This pattern promotes high quality care and an efficient scale of operation. As discussed later, higher volume organ transplant programs are often associated with better patient outcomes."

The comparison of access to kidney transplantation is variable based on a number of factors including physical access but, most importantly, organ availability, which represents the fundamental "barrier" to access. Figure 11 below demonstrates the enormous variance between patients listed for transplantation and those actually transplanted, both on national and local (Maryland) levels. The variance is due to the established fact that an inadequate number of donor organs are available relative to the many patients in need. MedStar Health believes that MGTI's collaboration with the program at MFSMC will augment the number of organs available for transplantation.

FIGURE 11: ORGAN SUPPLY vs. DEMAND (National)

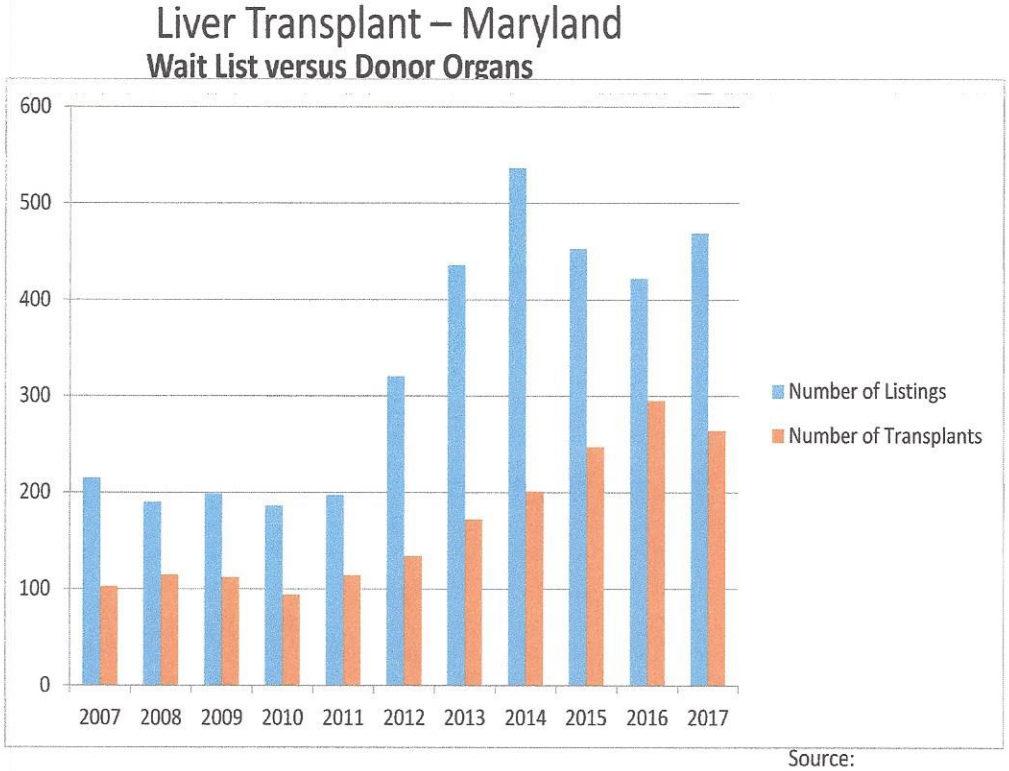
National Data on Organ Supply v. Demand by Calendar Year



Source: https://bpm.transplant.hrsa.gov/hrsa-continues-to-grow/

Clearly the growing candidate waiting list far exceeds the numbers of transplants of any kind performed in the United States. Figure 12, below, shows the same scenario relative to the state of Maryland.

FIGURE 12: ORGAN SUPPLY vs. DEMAND (Maryland)



Source:
OPTN, 2017

Because of the scarcity of the resource, access to organs largely is driven by kidney allocation policy, which is determined ultimately by UNOS. Policy changes have been made by UNOS from time to time as the organization strives to give those patients with the most acute need more immediate access to the very limited organ reserve. The most recent change in kidney allocation was finalized at the end of calendar year 2016 and implemented in 2017. This policy prioritized patients based on time on dialysis rather than time on the waiting list.

SRTR data show that MGTI makes effective use of as many available organs as possible through managing its wait-list carefully, matching recipient candidates and donors judiciously and aggressively growing the living donor program. MedStar believes that it has provided evidence that the MGTI expertise and experience can be extended to MFSMC safely and cost-effectively for the benefit of Marylanders and that MGTI's experience with the KDPI program, and other successes in augmenting the organ pool, have and will continue to benefit Maryland recipients.

17. Again, in light of the policy of regionalizing organ transplant services, and given the prevalence of electronic medical records, please explain why a kidney transplant patient's continuity of care is compromised if s/he has to leave the MedStar system.

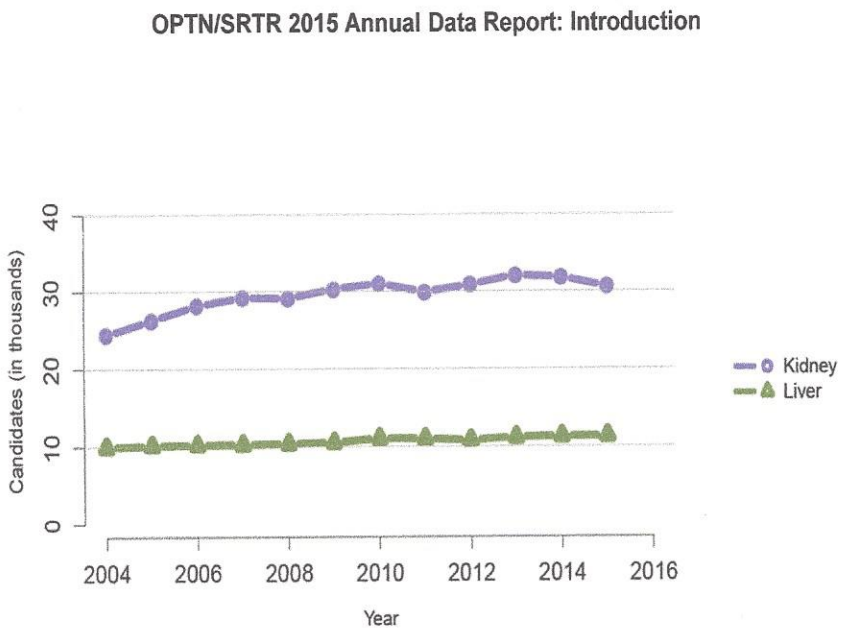
While the Chesapeake Regional Information System for Patients (CRISP) has been a successful innovation augmenting communication between providers and institutions that are under different employment and use various electronic medical records systems, its utility is still limited. The data set of information that can be communicated over the health information exchange (HIE) portal is very basic. For example, the data set includes reason for admission, medications, allergies and a few documents but not a full medical record. Hence, a patient admitted to a facility unrelated to the procedure is disadvantaged by being managed by a team that lacks familiarity with the details of the patient's medical history and ongoing clinical management strategy. For patients with complicated medical problems who have undergone complex procedures, a realm of information is needed to properly care for the patient. At this point in time, CRISP cannot provide information at that level of detail. Having "real time" access to patient data in one electronic medical record is valuable to clinicians (and their patients).

18. Please compare the access to kidney transplant services enjoyed by the target population to national benchmarks.

The comparison is variable based on a number of factors including, most importantly, organ availability. These graphics are intended to demonstrate clearly the primary issue affecting access to transplantation, that is, donor organ availability. Despite much effort on the part of many and various local and national organizations, the availability of the limited resource has not changed over time.

The following graphics (Figures 13–18) show: 1) trend of donors and recipients over time; 2) a comparison of organ donation by the LLF OPO versus national benchmarks; 3) transplants versus available organs in the State of Maryland; 4) National waitlist for all organs versus transplantation procedures by organ; 5) the growing waiting list versus transplants (from living and deceased donors) in Maryland; 6) trend in additions to the wait-list– Maryland.

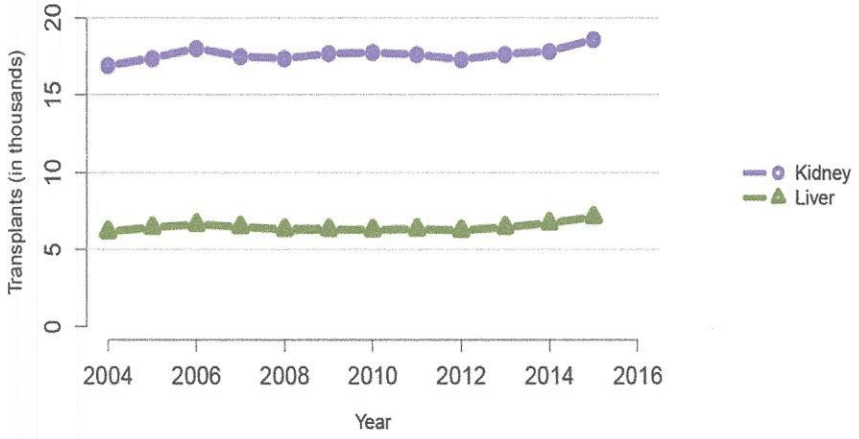
FIGURE 13. CANDIDATES FOR TRANSPLANTATION (wait list): Trend 2004-2016



American Journal of Transplantation
pages 11-20, 3 JAN 2017 DOI: 10.1111/ajt.14123
http://onlinelibrary.wiley.com/doi/10.1111/ajt.14123/full#ajt14123-fig-0003

FIGURE 14. TRANSPLANTATION PROCEDURES: Trend 2004-2016

OPTN/SRTR 2015 Annual Data Report: Introduction



American Journal of Transplantation
pages 11-20, 3 JAN 2017 DOI: 10.1111/ajt.14123
http://onlinelibrary.wiley.com/doi/10.1111/ajt.14123/full#ajt14123-fig-0005

FIGURE 15. DEATH RATES AND ORGAN DONATION TREND - LLF

SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

The Living Legacy Foundation of Maryland

OPO Code: MDPC
Public Report Release: January 05, 2018
Based on Data as of: October 31, 2017

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

B. US Population Density, Deaths, Death Rates, and Donations

Table B1. Measures of donation rate*, 07/01/2016 to 06/30/2017

		National		
	MDPC	Min.	Average	Max.
Eligible Deaths	220	43	195.17	570
Deceased Donors (All)	176	35	175.93	567
Deceased Donors Meeting Eligibility Criteria	155	29	137.71	428
Observed Donation Rate Per 100 Eligible Deaths	70.5	53.3	70.6	88.9
Expected Donation Rate Per 100 Eligible Deaths	67.2			
Standardized Donation Rate Ratio (95% CI)	1.05 (0.95,1.14)			
P Value	0.306			

*The donation rate is calculated as the number of deceased donors meeting eligibility criteria per 100 eligible deaths.

Figure B4. Standardized donation rate ratios (observed/expected), 07/01/2016 to 06/30/2017

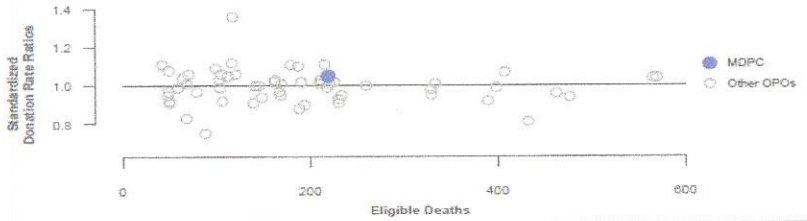
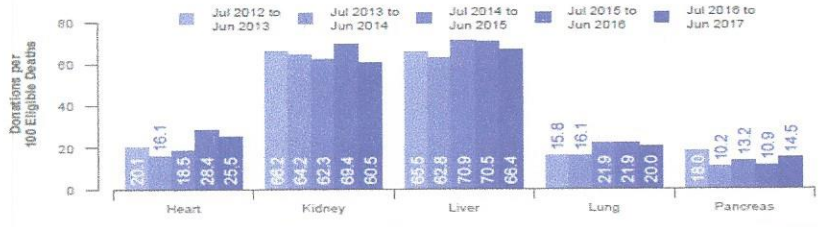


Figure B5. Donations per 100 eligible deaths, 07/01/2012 to 06/30/2017



The data reported here were prepared by the Scientific Registry of Transplant Recipients (SRTR) under contract with the Health Resources and Services Administration (HRSA).

Page: 8

FIGURE 16. *NATIONAL WAIT-LIST vs TRANSPLANTS – All organs*

Waiting list candidates as of today 9:51am

All ♦	115,257
Kidney	95,613
Pancreas	910
Kidney/Pancreas	1,692
Liver	13,898
Intestine	257
Heart	3,924
Lung	1,365
Heart/Lung	43

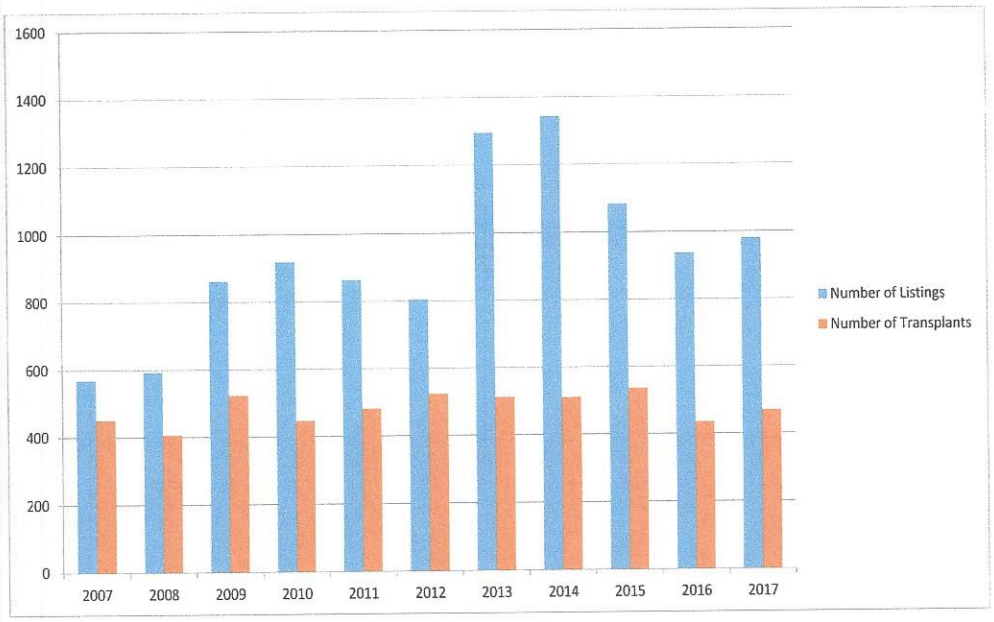
♦ *All candidates will be less than the sum due to candidates waiting for multiple organs*

Transplants performed January - December 2017

Total	34,772
Deceased Donor	28,587
Living Donor	6,185

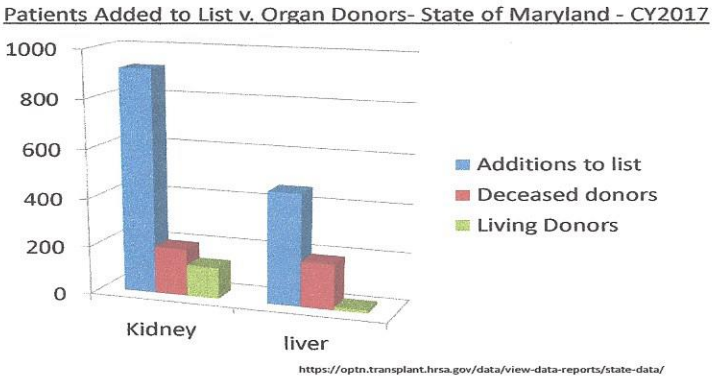
Based on OPTN data as of 01/15/2018

FIGURE 17. TREND IN WAIT-LIST vs. ORGANS - Maryland



Source: OPTN, 2017

FIGURE 18. ADDITIONS TO WAIT-LIST AND TRANSPLANTS – Maryland 2017



Organ allocation policies are constantly being reassessed by UNOS in an effort to improve access for the neediest candidates. The most recent change in kidney allocation, in the beginning of calendar year 2017, changed the algorithm from "time on the waiting list" to "time in dialysis treatment". Many patients who had accrued much time on dialysis, regardless of time on the waiting list, moved ahead of patient with longer waiting list times. Allocation policy changes have been made by UNOS periodically as the organization strives to give those patients with the most acute need more immediate access to the very limited organ resource.

There are no "national benchmarks" that cite the appropriate number of programs for any population base.

19. Figure 19 in this section represents to be the total number of kidney transplants performed by the two Baltimore programs, but the data presented therein appears to be in conflict with the data presented in Figure 21. Please correct.

Although Figures 19 and 21 (pages 60 and 62 respectively in the application) are formatted differently, we do not find a conflict with the data presented therein.

Specifically, the difference between Figure 19 (page 60 in the application) and Figure 21 (page 62 in the application) is the number of years of data reported in the tables. Figure 19 reports the number of kidney transplants for Johns Hopkins Hospital and the University of Maryland Medical Center for calendar years 2012-2016. Figure 21 reports the number of kidney transplants for Johns Hopkins Hospital and the University of Maryland Medical Center for calendar years 2006-2016. In Figure 19 and Figure 21 the counts reported in the CY2012-CY2016 period are identical.

Minimum Volume Requirements

20. Provide detailed metrics that demonstrate the "large and diverse nephrology programs" at MedStar Good Samaritan and MedStar Union Memorial Hospitals.

The nephrology programs at MedStar Good Samaritan and Union Memorial Hospitals have a large combined average monthly census of just over 400 patients representing over 53,000 dialysis treatments annually. The program cares for patients from seventy zip codes and eight jurisdictions, primarily Baltimore City and County, but also including Anne Arundel, Harford, Howard, Montgomery and St. Mary's Counties and the District of Columbia. About 85% of patients are African-American, while 12% are White and 3% are from other racial groups.

21. The applicant failed to 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 circumstances promulgated in this standard.

Applicant acknowledges that if its application for a Certificate of Need is approved, it will close the program if: (i) the service is unable to sustain the minimum annual case volume for any two consecutive years and cannot provide an acceptable explanation as to why it failed to maintain the minimum case volume; and develop a credible plan for achieving the minimum annual threshold case volume that is approved; 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.

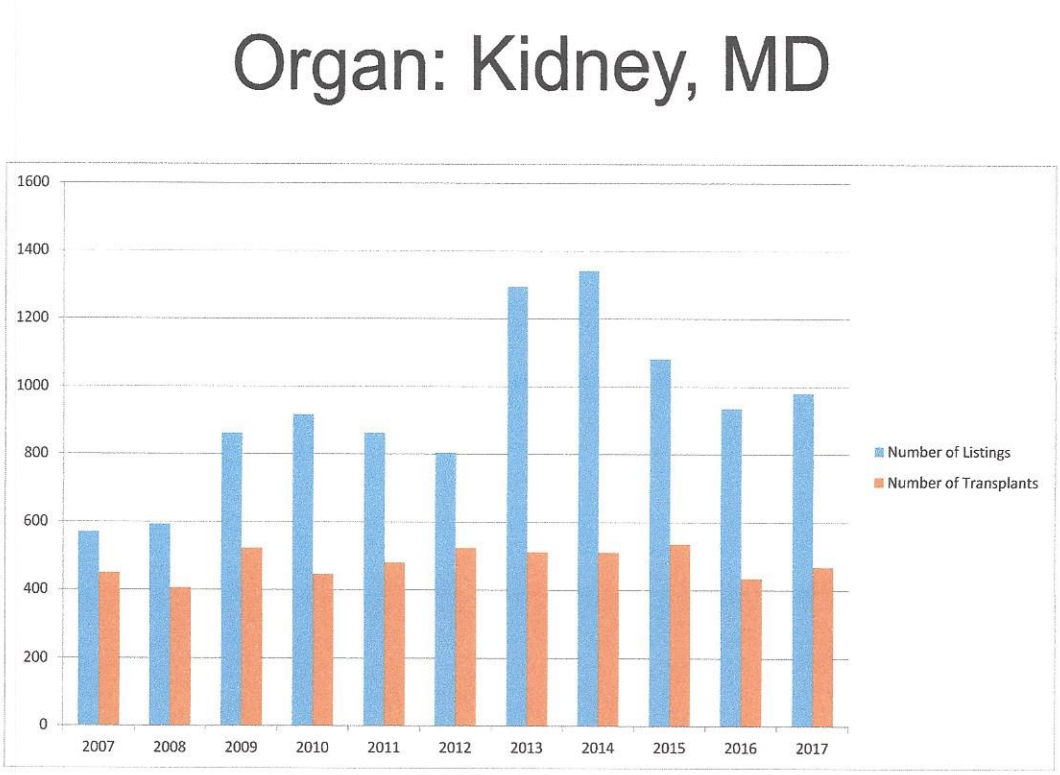
NO QUESTION 22 APPEARS IN THE ORIGINAL SET OF QUESTIONS

Cost Effectiveness

23. The applicant has not provided an analysis of whether and why existing programs cannot meet the need for the organ transplant service for the proposed population to be served, as called for in part (a) of this standard.

For the past 3 years in a row, the number of kidney transplants performed in the US has increased. Nevertheless, the waiting list continues to grow and despite this, almost 20% of deceased donor kidneys retrieved for transplant are not transplanted. The number of kidney transplants is growing due to the advancement of more living donor procedures , but has not met the demand from candidates added to the waiting list every year. This trend is likely to continue. Details behind these trends in solid organ transplantation can be found in this year's Annual Data Report organ-specific chapters (OPTN/SRTR 2015 Annual Data Report: Introduction). Figure 19 shows the variance in Maryland.

FIGURE 19. TREND IN WAIT-LIST vs. KIDNEY TRANSPLANTS Maryland 2007-2017



Source: OPTN, 2017

As noted, and shown in Figure 19 above, the demand for organs has grown rapidly over time and far exceeds the supply of organs available from deceased individuals. [2] ***As a result, closing this gap through the increase in the supply of donor organs is vital to efforts to meet the need for organ transplants, and is an important aspect of the goals of UNOS*** [3] ***and the SHP chapter on organ transplantation.*** [4] ***Through its collaboration with MGTI, MFSMC has indicated in its application*** [5] ***the means by which its proposed program will add to the supply of kidneys available to residents of the LLF OPO. As a comparison between waiting lists and transplants indicate, only about two in five patients in need of a kidney transplant in the LLF OPO undergo transplant surgery.*** [6] ***From this***

[2] State Health Plan for Facilities and Services: Specialized Health Care Services – Organ Transplant Services, COMAR 10.24.15, February 27, 2017, p. 18.

[3] UNOS Mission and Vision Statement, https://unos.org/about/mission-values/, accessed December 20, 2017.

[4] State Health Plan for Facilities and Services: Specialized Health Care Services – Organ Transplant Services, COMAR 10.24.15, February 27, 2017, B. Project Review Standards, (1)(a), p. 25.

[5] MedStar Franklin Square Medical Center Kidney Transplant Service CON Application, pp. 43-58.

[6] Organ Transplants and Waiting Lists in Maryland, 2000-2015, Michael O'Grady, PhD, Commissioner, Maryland Health Care Commission

perspective, it is an accurate assessment of the current state to say that the need for kidney transplant services in the LLF OPO is not being met. Of course, this is a national problem, as the SHP indicates.

MFSMC is not asserting that the existing programs are not able to provide transplant services to those LLF patients who are matched with a donor organ. MFSMC is asserting that too few Maryland patients needing kidney transplants receive kidney transplants. MedStar Health believes that the addition of its proposed program at MFSMC, in collaboration with MGTI's expertise, innovation (as described in response to question 24) and outreach already in place in multiple locations across both metropolitan areas, will increase the supply of donor organs available in the LLF OPO and so increase the number of Marylanders who receive kidney transplants.

24. Your response to part (a) of this standard refers to "innovative surgical approaches (that) offer additional options to patients that existing programs cannot serve." Reiterate what these "innovative surgical techniques" are, and how they create ability to meet needs others are unable to meet.

MGTI will implement the same standards and protocols that have driven its Washington site to success over many years as follows:

- *Greater utilization of High Kidney Donor Profile Index (KDPI) donors for transplantation, i.e., consideration of donors >age60+, those with certain systemic illnesses or exposure to infectious diseases– in a manner that is compatible with recipient clinical characteristics. In other words, the judicious matching donor and recipient risk factors permits less discard of potentially usable organs, hastens time to transplant for certain individuals, and decreases mortality of the waiting list. MGTI has higher donor acceptance rates (i.e. higher use of KDPI donor organs) than any regional or national program for all subsets of donated kidneys.*

- *Expansion of more unrelated, non-directed and compatible pair donations; Living Donor Transplant overall has grown 74% over the last four years due to attention to matching "difficult to match patients". Living Donor transplant procedures grew almost 19% between calendar year 2016-2017,*

- *MGTI serves as the area's "incompatibles repository", coordinating paired exchanges among transplant centers to expand the pool of locally-available organs.*

- *Implementation of Desensitization Protocols for Human Leukocyte Antigen (HLA) incompatibility. Implementation of desensitization protocols for patients who have HLA incompatibilities will have the effect of increasing the supply of donor organs for Marylanders.*

- ***The Center for Translational Transplant Medicine (CTTM) is involved with a variety of studies to advance the field, in particular, those which mediate the risk of organ rejection and graft loss:***
  - ***New treatments for antibody-mediated graft rejection***
  - ***Strategies to minimize post-transplant CMV (a herpes-related virus) infections***
  - ***Techniques to reduce post-transplant wound infections***
  - ***Novel immunosuppressive strategies to obviate organ injury and increase graft survival time***
  - ***Non-invasive methods to detect early delayed graft function (DGF)***

- ***Other MGTI Efforts***

A consensus conference aimed at improving organ utilization, with participants from CMS, UNOS, NKF and others that was chaired by Dr. Matthew Cooper, Director of Kidney/Pancreas at MGTI, in late May 2017, was mentioned in the application. This group has produced a white paper that is in publication currently. CMS has requested regular meetings to review the progress of suggested implementations with this conference and the manuscript.

25. Please respond to part (b) of this standard describing the "added benefit(s)" with specificity rather than with a broad cross-reference to other parts of the application.

The State Health Plan has acknowledged the large gap between the supply and demand of donor organs that exists on national as well as state levels. We believe that the proposed MFSMC program can increase the supply of donor organs for patients in the LLF OPO. MedStar is also confident in its ability to meet the needs of the minority population more completely, based on experience, as shown clearly in the data presented.

MedStar Health maintains the 11th largest organ transplant program in the nation. Its integration with MFSMC enables the extension of deep expertise, innovation, and refined efficiency in operations to the Baltimore region. This level of success has required strict attention to details of quality outcomes management, patient experience and active research in collaboration with Georgetown University.

Over the last two years, MedStar Health has added outpatient evaluation sites for kidney and liver transplant at Maryland sites in Frederick, Annapolis, Ellicott City and at MedStar Southern Maryland and MedStar Franklin Square Medical Centers. These locations were created expressly to offer access for patients for whom travel for preoperative evaluation and postoperative follow up proves challenging.

All of these areas represent specific benefits to Baltimore residents.

Figure 20 shows minority patients wait-listed (left side) and transplanted (right side) at MGTI (DCGU) versus the Baltimore Centers.

FIGURE 20. MINORITY LISTINGS AND TRANSPLANTS - MGTI vs. JHH vs. UMMS

26. Part (c) of this standard asks the applicant to quantify the expected benefits over a five-year period. Please do so.

A. MGTI will implement the same standards and protocols that have driven its Washington site to success over many years as follows:

- ***Greater utilization of High Kidney Donor Profile Index (KDPI) donors for transplantation, i.e., consideration of donors >age60+, those with certain systemic illnesses or exposure to infectious diseases – in a manner that is compatible with recipient clinical characteristics. In other words, the judicious matching donor and recipient risk factors permits less discard of potentially usable organs, hastens time to transplant for certain***

individuals, and decreases mortality of the waiting list. MGTI has higher donor acceptance rates (i.e. higher use of KDPI donor organs) than any regional or national program for all subsets of donated kidneys.

- *Expansion of more unrelated, non-directed and compatible pair donations; Living Donor Transplant overall has grown 74% over the last four years due to attention to matching "difficult to match patients". Living Donor transplant procedures grew almost 19% between calendar year 2016-2017.*

- *MGTI serves as the area's "incompatibles repository", coordinating paired exchanges among transplant centers to expand the pool of locally-available organs.*

- *Implementation of Desensitization Protocols for Human Leukocyte Antigen (HLA) incompatibility. Implementation of desensitization protocols for patients who have HLA incompatibilities will have the effect of increasing the supply of donor organs for Marylanders.*

- *The Center for Translational Transplant Medicine (CTTM) is involved with a variety of studies to advance the field, in particular, those which mediate the risk of organ rejection and graft loss:*
  - *New treatments for antibody-mediated graft rejection*
  - *Strategies to minimize post-transplant CMV (a herpes-related virus) infections*
  - *Techniques to reduce post-transplant wound infections*
  - *Novel immunosuppressive strategies to obviate organ injury and increase graft survival time*
  - *Non-invasive methods to detect early delayed graft function (DGF)*

- *Other MGTI Efforts*

A consensus conference aimed at improving organ utilization, with participants from CMS, UNOS, NKF and others that was chaired by Dr. Matthew Cooper, Director of Kidney/Pancreas at MGTI, in late May 2017, was mentioned in the application. This group has produced a white paper that is in publication currently. CMS has requested regular meetings to review the progress of suggested implementations with this conference and the manuscript.

B. Relative to actual cost savings, MFSMC believes that its lower cost environment of care, collaboration with MGTI toward keeping fixed costs at a minimum and judicious patient selection, particularly at program initiation, will result in substantial savings to the system that will accrue over time as volume builds.

Moreover, the sole alternative therapy to transplantation is long-term renal dialysis the average annual cost of which is $89,000/year[7]. Given the

[7] *United States Renal Data System,* https://www.usrds.org/2013/view/v2_11.aspx

average five year mortality of end stage renal patients undergoing long-term renal dialysis[8], the cost per patient for this therapy is estimated at $445,000. There are potential savings of $356,000 to the health system for every patient who receives a transplant when compared to the alternative therapy of renal dialysis. Although it is impossible to project how many of MFSMC's patients will receive transplants as a result of MGTI's ability to increase the supply of organs through living donor activities, clinical innovations, dual listings and the other means detailed in its application, the potential comparative cost benefit to the health system is significant.

Impact

27. Given the applicant's estimate that only a small number of its prospective cases will be drawn from existing providers, please discuss whether the patients projected to be served patients who are currently leaving the area, patients who are not currently receiving transplants, etc.?

MGTI is performing kidney transplants currently on Baltimore area residents that could be performed at MFSMC. Moreover, MGTI is seeing a growth in patients wait-listed and transplanted since its initiation of seven outreach sites including those in Frederick, Annapolis and Ellicott City as well as its hospital outreach sites at MedStar Southern Maryland Hospital Center in Clinton and MFSMC.

By expanding the donor pool through the methods described in the response to Question 24, the new program will make a positive impact on the community, moving more patients from dialysis to transplant. MedStar has also heard directly from nephrologists in the community that they support and welcome MedStar Health as a provider of these services locally. Nephrologists have told us that they are often burdened with the long-term management of these patients, a responsibility which they do feel is neither appropriate nor comfortable since they do not have advanced training in transplantation or immuno-suppression management.

MGTI takes very seriously its long-term commitment to the patients that it transplants and although welcomes participation in care by community nephrologists, never wishes to abrogate ultimate responsibility for the long-term success of both the patient and his/her graft. MFSMC looks forward to greater participation.

Health Promotion and Disease Prevention

28. This standard is about prevention of end stage organ disease and increasing the availability of donor organs. The applicant responded with a discussion of its efforts to educate the public about transplantation as an option. Please describe the applicant's efforts or plans to "actively… engage in health promotion and disease prevention activities aimed at reducing the prevalence of end stage organ disease" and

[8] Average life expectancy of end stage renal disease patients undergoing renal dialysis, National Kidney Foundation, https://www.kidney.org/atoz/content/dialysisinfo

toward "…increasing the availability of donor organs," especially those "…designed to address those at greatest risk for end stage organ failure."

MGTI routinely and regularly provides educational outreach efforts in the Baltimore and DC area. We are also engaged with patient organizations such as the National Kidney Foundation who as well provide educational programs aimed at reducing chronic kidney disease and options for End-Stage Kidney Disease (ESRD) to include, especially, transplantation. Our message to the community as transplant providers therefore includes education about the prevention and/or care for the 2 most common causes of kidney disease– hypertension and diabetes, and the potential for avoiding dialysis and opportunity to potentially obviate transplantation by the proper care of these maladies. Our ongoing efforts in education will continue throughout the Baltimore region as we believe it is our obligation to work to prevent end-organ failure that contributes to the organ shortage crisis that is recognized nationally. Moreover, we feel obligated to educate regarding the profound (and data-supported) advantages of transplantation vs. dialysis as a treatment for ESRD. The latter, especially, includes education regarding the value of living donation as an option due to the associated increased graft survival, often shorter waiting time, decreased complications and fewer incidences of rejection.

MGTI holds bi-annual seminars dedicated specifically to educating the public about living donation, how to begin the conversation in speaking to others about kidney disease and the need for a living donor, and how an individual's care giver may become their donor 'champion' in aiding the potential transplant recipient in these efforts. These events, typically involving multiple lecturers from different disciplines (e.g. social worker, surgeon, nutritionists, nurses) are held in community settings and are moved around the area so as to benefit as many interested parties as possible. A light meal is served and there is ample opportunity for participants to interact with different members of the transplant team.

NEED

29. Please:
    a) Define the existing and/or intended service area population of the applicant;

As stated in the response to Question 15, MFSMC expects to primarily serve residents of Central Maryland (Baltimore City/County, Anne Arundel County, Carroll County, Harford County, and Howard County) and Frederick County. This geography includes the service areas of the four Baltimore MedStar Hospitals (MedStar Franklin Square, MedStar Good Samaritan, MedStar Harbor, and MedStar Union Memorial) and the location of MedStar Advanced Kidney and Liver Disease Clinics serving Baltimore, Anne Arundel, Prince George's, Frederick, Calvert, Charles and St. Mary's Counties).

b) Provide an analysis of need for the project that is population-based, applying utilization rates based on historic trends and expected future changes to those trends;

The following describes the population-based trend used by CMS:

Nationally there are ~450,000 patients who are on dialysis and ~20,000 kidney transplant are performed each year. The ratio=20000/450000=0.04 or ~4%, or ~4:100

Dialysis=468,000

Transplants:

Kidney=19000

Kidney pancreas=800
Kidney liver=700
Kidney heart=150

Extrapolated from Medicare data, USRDS, UNOS data reports:

https://data.medicare.gov/Dialysis-Facility-Compare/Dialysis-Facilities-in-the-U-S-/kwkm-uxp2/data
https://www.unos.org/

From a liver disease viewpoint: Advanced liver disease leads to a high incidence of hepato-renal syndrome and acute kidney injury, life-threatening medical conditions that consist of rapid deterioration in kidney function in patients with cirrhosis or severely advanced liver failure. Up to 50% of patients hospitalized with advanced liver disease develop acute kidney injury and annually 12% of hospitalized patients with cirrhosis develop hepato-renal syndrome. As a result of current organ allocation policy, 10-15% of patients requiring a liver transplant also require a kidney transplant, depending on the year in question, Center practices and population demographics. As a result, MedStar Health concurrently requests certificates of need for both liver and kidney transplant programs so as to address this critical need affecting a significant proportion of patients affected with end stage liver disease.

Sources:

Garcia-Tsao G, Parikh CR, Viola A. Acute kidney injury in cirrhosis. Hepatology 2008; 48:2064–77.

Bucsics 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.

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 hepato-renal syndrome in cirrhosis with ascites. Gastroenterology 1993; 105(1):229-36.

From a kidney disease viewpoint: ***It is clear that liver and kidney dysfunction are tied together closely as the MELD score which is currently utilized to allocate deceased donor livers has recipient creatinine (the critical lab value in assessing kidney function), the most powerful driver in the calculation of that score. A liver patient with end-stage renal disease (ESRD) alone- with a normal Bilirubin and International Normalized Ratio (INR)- has a MELD score of 20 which is the average MELD at the time of liver transplant for in several OPOs. Because of the predisposition to hepato-renal syndrome and acute kidney injury in this population, but relative subjectivity in assessing whether a patient with End-stage Liver Disease (ESRD) requires a kidney, (i.e., Simultaneous Liver-Kidney (SLK) transplantation), a new UNOS policy was approved and went into effect in November 2017 that requires that a nephrologist sign-off on the appropriateness of the candidate for SLK. The process was put into place to assure that kidneys are not being "siphoned off" for SLKs and therefore not available for the over 80,000 active patients Awaiting a kidney alone. The data demonstrate clearly that patients with ongoing renal failure postoperatively following liver transplant have unfavorable outcomes.***

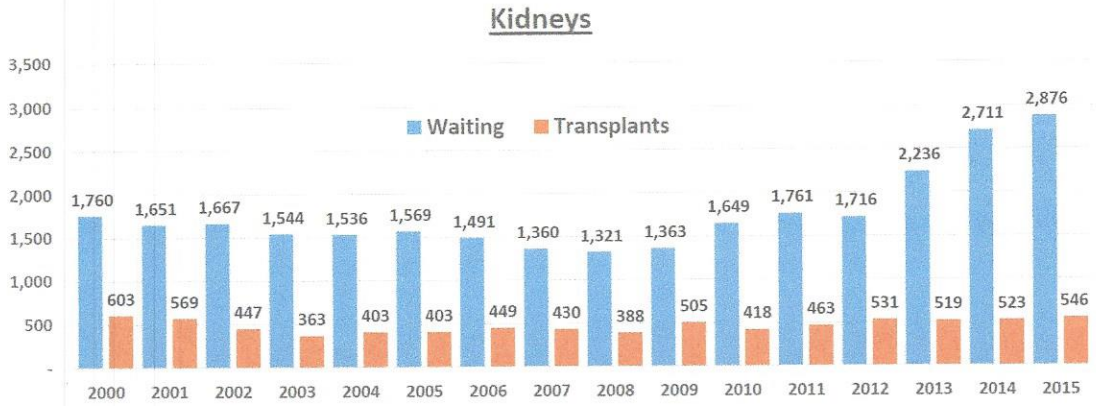
Selected sources:

Al-Riyami, D et al. Decreased Survival in Liver Transplant Patients Requiring Chronic Dialysis: A Canadian Experience. Transplantation, 85:1277-80, May 15, 2008.

Zand, MS et.al. High Mortality in Orthotopic liver transplant recipients who require hemodialysis. Clinical Transplantation, 2011: 25: 213-21.

Figure 21 shows the 15-year growing upward trend in the waiting list for kidneys.

FIGURE 21. NATIONAL 15-YEAR TREND IN PATIENTS WAIT-LISTED FOR KIDNEY TRANSPLANT vs. TRANSPLANTATION PROCEDURES PERFORMED



The table[9] shown above in Figure 21 demonstrates clearly that the supply of organs is inadequate to meet the needs of patients who are candidates for transplantation. The focus of MedStar Health's application relative to need, is to emphasize that a new program at MFSMC can help to augment the supply of available organs through a variety of approaches. Specifically, in its response to application section B. Project Review Standards, (1) Need (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, MFSMC has detailed eight innovative clinical and administrative features of its proposed program that will enable the hospital to increase the supply of donor organs and better serve minority populations in the LLF OPO.

c) Consider the unmet needs of the population to be served in arriving at a determination that the proposed project is needed.

…as required by this criterion.

Again, the State Health Plan has acknowledged the large gap between the supply and demand of donor organs that exists on national as well as state levels. We believe that the proposed MFSMC program can increase the supply of donor organs for patients in the LLF OPO. We also are confident in our ability to meet the needs of the minority population more completely, based on our experience. Finally, we feel strongly that we can make a meaningful impact on logistical issues facing individuals who need the long-term multi-specialty care that characterizes transplantation services by creating a high quality, attentive program that meets insurance considerations while situating in-network services closer to home, family, work and community providers.

[9] *Ibid. p. 18*

NO QUESTION 30 APPEARS IN THE ORIGINAL SET OF QUESTIONS

31. Please support with specificity the statement (p.79) that "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." Explain the prospective innovations in clinical care, medical therapy, surgical approaches and clinical research, and how they will increase the supply of available donor organs.

MGTI will implement the same standards and protocols that have driven its Washington site to success over many years as follows:

- ***Greater utilization of High Kidney Donor Profile Index (KDPI) donors for transplantation, i.e., consideration of donors >age60+, those with certain systemic illnesses or exposure to infectious diseases – in a manner that is compatible with recipient clinical characteristics. In other words, judiciously matching donor and recipient risk factors permits less discard of potentially usable organs and decreases mortality of the waiting list.***
- ***Expansion of more unrelated, non-directed and compatible pair donations; Living Donor Transplant overall has grown 74% over the last four years due to attention to matching "difficult to match patients".***
- ***MGTI serves as the area's "incompatibles repository", coordinating paired exchanges among transplant centers to expand the pool of locally-available organs.***
- ***Implementation of Desensitization Protocols for Human Leukocyte Antigen (HLA) incompatibility.***
- ***The Center for Translational Transplant Medicine (CTTM) is involved with a variety of studies to advance the field, in particular, those which mediate the risk of organ rejection and graft loss:***
  - ***New treatments for antibody-mediated graft rejection***
  - ***Strategies to minimize post-transplant CMV (a herpes-related virus) infections***
  - ***Techniques to reduce post-transplant wound infections***
  - ***Novel immunosuppressive strategies to obviate organ injury and increase graft survival time. Non-invasive methods to detect early delayed graft function (DGF)***

32. Please articulate very plainly what the goals and objectives of this proposal are.

MedStar Health believes that the reputation of its transplantation program at MGTI speaks for itself relative to the benefit that it has brought to the Washington community in terms of innovation – particularly in the area of augmentation of organs available for transplantation, excellence in quality, attention to communication and flexibility in operation – all attributes that it proposes to extend to the Baltimore region. MedStar's desire to create a kidney transplant program adjunctively with the liver transplant program, is driven by the clinical imperative to support the 10-15% of patients with advanced liver disease who need a simultaneous kidney transplant.

We also are confident in our ability to meet the needs of the minority population more completely, based on the experience in the District of Columbia. Finally, we feel strongly that we can make a meaningful impact on logistical issues facing individuals who need the long-term multi-specialty care that characterizes transplantation services by creating a high quality, attentive program that meets insurance considerations while situating in-network services closer to home, family, work and community providers. Individual patients, as well as their community providers, have expressed enthusiasm for having MedStar Health as an available transplant option in the Baltimore region based on the quality and delivery of services, reputation of our physicians and attention to communication and follow up.

33. With kidney transplant programs available in DC and Baltimore, please explain the "clinical and geographic gaps" in terms of community need rather than MedStar system needs, which seem to be the crux of the applicant's response.

MGTI's philosophy of care is to offer all available options for treatment to the patients that it serves. This implies the continuous research of new diagnostic options, medical management alternatives and surgical approaches to care. MGTI leads the country in specific areas of innovation that include un-related paired kidney exchange, liver screening for hepatitis in affected populations, dual kidney transplantation of high KDPI donors, novel surgical approaches to expand the utilization of single organs among multiple recipients and, importantly, judicious consideration of higher risk donors for transplantation in appropriate recipients to improve the distribution of organs in a context of enhanced long-term survival.

As well, successful population health management involves the integration of all facets of an individual's health, that is, biological, social and psychological factors that influence recovery from acute illness, compliance with health care regimens and maintenance of behaviors that favor long-term excellent health. A "home base" for all aspects of individual healthcare provides a number of tangible benefits that include a familiar environment of care; an habitual cadre of providers; available family and other supportive "human" resources and relief from the anxiety of the cost and effort involved in travel superimposed on an already stressful situation.

34. Explain why utilizing the existing programs in Baltimore results in "critical components in the delivery of high quality care (being) compromised or lost altogether."

Restated from the response to Question 24:

MGTI will implement the same standards and protocols that have driven its Washington site to success over many years as follows:

- ***Greater utilization of High Kidney Donor Profile Index (KDPI) donors for transplantation, i.e., consideration of donors >age60+, those with certain systemic illnesses or exposure to infectious diseases– in a manner***

that is compatible with recipient clinical characteristics. In other words, the judicious matching donor and recipient risk factors permits less discard of potentially usable organs, hastens time to transplant for certain individuals, and decreases mortality of the waiting list. MGTI has higher donor acceptance rates (i.e. higher use of KDPI donor organs) than any regional or national program for all subsets of donated kidneys.

- *Expansion of more unrelated, non-directed and compatible pair donations; Living Donor Transplant overall has grown 74% over the last four years due to attention to matching "difficult to match patients". Living Donor transplant procedures grew almost 19% between calendar year 2016-2017.*

- *MGTI serves as the area's "incompatibles repository", coordinating paired exchanges among transplant centers to expand the pool of locally-available organs.*

- *Implementation of Desensitization Protocols for Human Leukocyte Antigen (HLA) incompatibility. Implementation of desensitization protocols for patients who have HLA incompatibilities will have the effect of increasing the supply of donor organs for Marylanders.*

- *The Center for Translational Transplant Medicine (CTTM) is involved with a variety of studies to advance the field, in particular, those which mediate the risk of organ rejection and graft loss:*
    - *New treatments for antibody-mediated graft rejection*
    - *Strategies to minimize post-transplant CMV (a herpes-related virus) infections*
    - *Techniques to reduce post-transplant wound infections*
    - *Novel immunosuppressive strategies to obviate organ injury and increase graft survival time*
    - *Non-invasive methods to detect early delayed graft function (DGF)*

- *Other MGTI Efforts*
  A consensus conference aimed at improving organ utilization, with participants from CMS, UNOS, NKF and others that was chaired by Dr. Cooper in late May 2017,was mentioned in the application. This group has produced a white paper that is in publication currently. CMS has requested regular meetings to review the progress of suggested implementations with this conference and the manuscript.

MGTI's philosophy of care is to offer all available options for treatment. This implies the continuous research of new diagnostic options, medical management alternatives and surgical approaches to care. MGTI leads the country in specific areas of innovation that include un-related paired kidney exchange, liver screening for hepatitis in affected populations, dual kidney transplantation of high KDPI donors, novel surgical approaches to expand the utilization of single organs among multiple recipients and,

importantly, judicious consideration of higher risk donors for transplantation in appropriate recipients to improve long-term survival.

VIABILITY OF THE PROPOSAL

Note: questions in the TABLES section below will ask for separate tables for each of the Liver and Kidney applications.

35. The discussion of volume assumptions states that "Kidney transplant volumes were estimated based on patients under dialysis treatment in MFSMC immediate vicinity, "among other things. Please explain the empirical numerical relationship between patients under dialysis treatment and the number of kidney transplants.

The standard methodology follows:

Nationally there are ~450,000 patients who are on dialysis and ~20,000 kidney transplant are performed each year. The ratio=20000/450000=0.04 or ~4%, or ~4:100

Dialysis=468,000

Transplants:

Kidney=19000

Kidney pancreas=800
Kidney liver=700
Kidney heart=150

Extrapolated from Medicare data, USRDS, UNOS data reports:

https://data.medicare.gov/Dialysis-Facility-Compare/Dialysis-Facilities-in-the-U-S-/kwkm-uxp2/data
https://www.unos.org/

36. Please explain the Centers of Excellence designation raised in this section, i.e.:

a) Who makes this designation, based on what?

The largest managed care organizations (MCOs), e.g., Aetna, Kaiser Permanente, CIGNA, BlueCross Blue Shield, as well as some employer groups, have created the "Center of Excellence" (COE) designation for certain high cost and/or high volume programs in order to ensure that their members have access to those Centers that have the experience and expertise to handle their needs at the lowest cost.

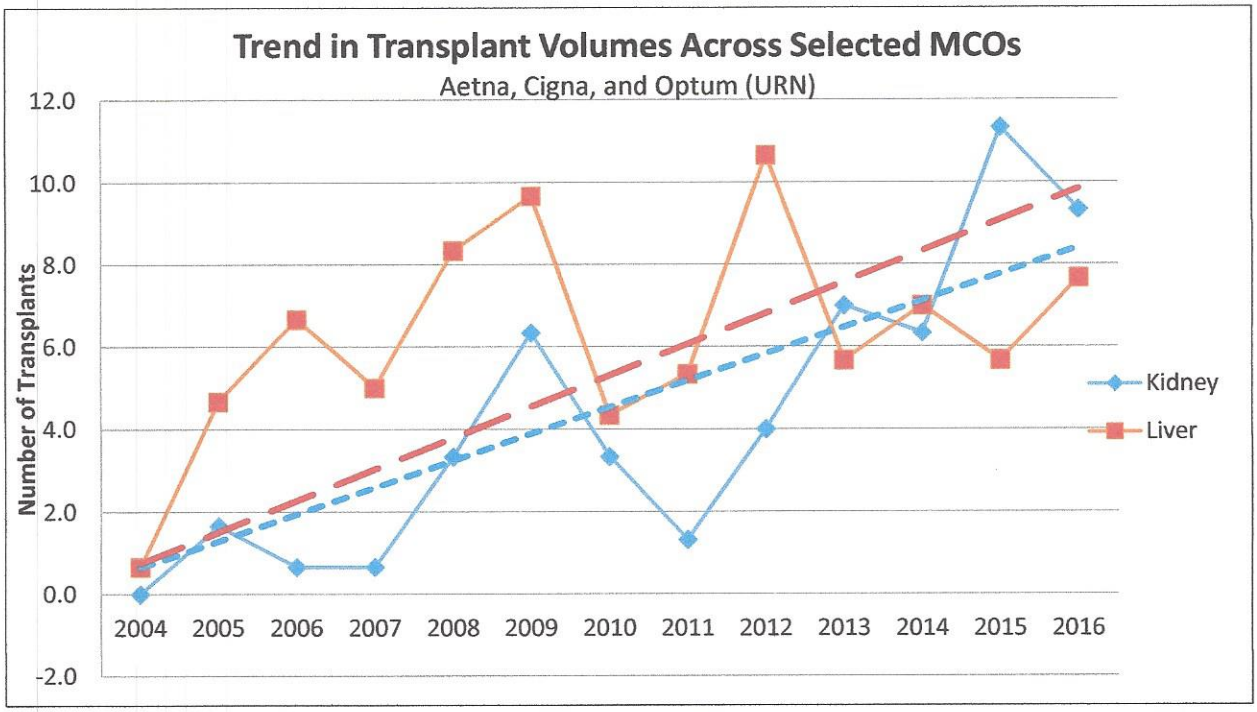
Centers wishing to participate must meet certain criteria established by each MCO regarding minimal volume thresholds, time that the program has been in operation , staffing requirements, physician credentialing, and importantly, clinical outcomes (graft and patient survival per SRTR). Once approved, candidates for transplantation are directed to these sites

preferentially; in some circumstances, complete coverage may not be provided unless the individual subscriber utilizes a designated COE.

b) What is the assumed relationship between such designation and program volumes? Justify any assumption that such a designation boosts volume.

The graphic below, Figure 22, shows the trend in volume since contract inception for several major managed care organizations with which MedStar Health serves as a designated Center of Excellence. As only selected plans are represented, volumes exceed these projections on an actual basis, but the upward trend shown characterizes the overall experience. Keep in mind that CMS assumes responsibility for payment after 30 months on the waiting list have elapsed.

FIGURE 22. TREND IN MCO-DIRECTED TRANSPLANT VOLUMES



Source: MedStar Health, Internal Data

IMPACT

37. Summarize the impact on the existing Baltimore kidney transplant programs in terms of volume and revenue. References back to other parts of the application without being specific as to where such information can be found leaves open too much possibility for misinterpretation.

Pages 60-61 in the application document the underlying assumptions regarding the volume shift from Maryland Hospitals to MFSMC as follows:

- ***FY15-FY17 referrals are based on estimates based on data available from the MedStar Health Renal Disease Program.***
- ***The primary source of patients in program year 1 will be referrals from MedStar's Advanced Kidney Disease Clinics at MFSMC, in Frederick, Maryland and in Annapolis, Maryland, as well as the Renal Programs at MedStar Good Samaritan MedStar Union Memorial hospitals.***
- ***As the program begins to mature in year 2 (FY20), and more MedStar providers become aware of the program, MFSMC projects 40% fewer cases will be transferred to JHH/UMMS. By program year 3 (FY21), as the program begins to develop a quality reputation, another ~40% fewer cases will be transferred to JHH/UMMS. Keep in mind that the baseline volumes are very low so as a percentage, the volume impact is negligible.***
- ***Referrals from non-MedStar providers are estimated at 5 or fewer in year 3.***

The table below, Figure 23, summarizes the projected shift in kidney transplant volume by transplant center.

FIGURE 23. PROJECTED SHIFT IN KIDNEY TRANSPLANT VOLUMES BY CENTER

	Actual			Proj.	Program Years		
Metric	FY15	FY16	FY17	FY18	FY19	FY20	FY21
Referrals UMMS	12	4	7	8	8	5	3
Referrals to Johns Hopkins	10	4	6	8	7	4	2
Total Referrals	**22**	**8**	**13**	**16**	**15**	**9**	**5**
% Variance from Prior Year					**-6%**	**-40%**	**-44%**

To summarize, MedStar Health has referred an average of 14 cases annually to the existing Baltimore transplant centers over the past three years. MFSMC has used this average annual volume as the basis for projecting the volume shift from these programs to the proposed MFSMC program. MFSMC expects that the creation of its kidney transplant program will result in a decline of ten (10) cases per year (2.1%) from the volume of the two Baltimore centers (FY 15-18 Actual and Projected Average Annual Referrals to JHH/UMMS (14.7) minus FY18-21 Projected Average Annual Referrals to JHH/UMMS (9.6)).

38. As the applicant is an existing hospital, please follow the instructions to provide a summary description of the impact of the proposed project on costs and charges of the applicant hospital, consistent with the information provided in the application tables package. ***These tables are provided as an attachment to this document.***

39. Please submit an electronic version of the excel tables package. ***Provided***

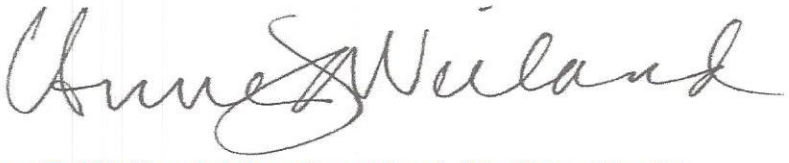
Submit financial and workforce tables that are limited to the addition of a kidney transplant program (contrasted with the tables provided, which include both the proposed liver and kidney transplant programs). ***Financial and workforce tables are provided as an attachment.***

40. Explain the relationship between outpatient visits and transplants (as shown on table I).

The calculation includes evaluation clinic visits, lab/imaging etc, and ongoing OP visits for patients on the waiting lists. The spreadsheet is extensive and can be provided if requested. Staff extrapolated transplant volume from these data.

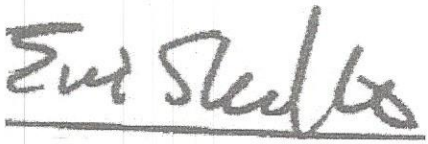
END OF RESPONSES TO COMPLETENESS QUESTIONS

"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."



Anne P. Weiland, Vice President, MedStar Health
on behalf of MedStar Health

"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."



Eric Slechter, Director, Business Planning, MedStar Health
on behalf of MedStar Health

Attachment 11: MFSMC Financial Projection Assumptions *Updated for Completeness Submission*

MedStar Franklin Square Entire Facility Assumptions:

FY17 was updated for actual 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. Transplant Program Revenues: Beginning in FY19, kidney and liver project revenue projections assumed $148,848 Per Liver Transplant and $87,203 per Kidney Transplant which is 75% of comparable academic center charges

B. Inpatient Non-Transplant Discharges: Non-Transplant revenues are based on patient activity expected to occur at MFSMC as a direct result of the transplant programs for pre and post admissions and "halo" volume expectations as a result of having additional clinical expertise to treat complex patients. Rates based on MFSMC revenue per discharge expectations.

C. Ancillary Transplant Program Revenues: Ancillary outpatient revenues are based on patient activity expected to occur in MFSMC as a direct result of the transplant programs and are derived from MGUH experience and procedural pre and post operation testing. Rates based on MFSMC revenue per transplant/non-transplant discharge expectations.

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 and estimates of Hospitalist professional fee revenue for non-transplant discharges.

Expenses

A. FTE Requirements: Please see Workforce Tab L for specific FTE requirements related to the program.

B. Transplant variable expenses relate to organ acquisition, supplies, purchased services, drugs, and variable salary and wages based on current experience at MGUH

C. Non-Transplant variable expenses (inpatient and outpatient activity) relate to supplies, purchased services, drugs, and variable salary and wages based on current experience at MGUH for similar population set.

Expense reductions and savings initiatives

The projections include savings meant to counteract inflationary pressures. The 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 focusing on the following:

A. Improved performance through enhanced clinical productivity

B. Reducing 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 synergies in the oversight of our employed provider network

D. Improving the process of care as it relates to length-of-stay management across the continuum of care and management of observation status patients

Table Number	Table Title	Instructions
Table A	Physical Bed Capacity Before and After Project	All applicants whose project impacts any nursing unit, regardless of project type or scope, must complete Table A.
Table B	Departmental Gross Square Feet	All applicants, regardless of project type or scope, must complete Table B for all departments and functional areas affected by the proposed project.
Table C	Construction Characteristics	All applicants proposing new construction or renovation must complete Table C.
Table D	Site and Offsite Costs Included and Excluded in Marshall Valuation Costs	All applicants proposing new construction or renovation must complete Table D.
Table E	Project Budget	All applicants, regardless of project type or scope, must complete Table E.
Table F	Statistical Projections - Entire Facility	Existing facility applicants must complete Table F. All applicants who complete this table must also complete Tables G and H.
Table G	Revenues & Expenses, Uninflated - Entire Facility	Existing facility applicants must complete Table G. The projected revenues and expenses in Table G should be consistent with the volume projections in Table F.
Table H	Revenues & Expenses, Inflated - Entire Facility	Existing facility applicants must complete Table H. The projected revenues and expenses in H should be consistent with the projections in Tables F and G.
Table I	Statistical Projections - New Facility or Service	Applicants who propose to establish a new facility, existing facility applicants who propose a new service, and applicants who are directed by MHCC staff must complete Table I. All applicants who complete this table must also complete Tables J and K.
Table J	Revenues & Expenses, Uninflated - New Facility or Service	Applicants who propose to establish a new facility and existing facility applicants who propose a new service and any other applicant who completes a Table I must complete Table J. The projected revenues and expenses in Table J should be consistent with the volume projections in Table I.
Table K	Revenues & Expenses, Inflated - New Facility or Service	Applicants who propose to establish a new facility and existing facility applicants who propose a new service and any other applicant that completes a Table I must complete Table K. The projected revenues and expenses in Table K should be consistent with the projections in Tables I and J.
Table L	Work Force Information	All applicants, regardless of project type or scope, must complete Table L.

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			$0
(2) Contingency Allowance			$0
(3) Gross interest during construction period			$0
(4) Other *(Specify/add rows if needed)*			$0
SUBTOTAL	***$0***	***$0***	***$0***
TOTAL CURRENT CAPITAL COSTS	**$0**	**$0**	**$0**
d. *Land Purchase*			
e. Inflation Allowance			$0
TOTAL CAPITAL COSTS	**$0**	**$0**	**$0**
2. Financing Cost and Other Cash Requirements			
a. Loan Placement Fees			$0
b. Bond Discount			$0
c. Legal Fees (CON)			$0
d. Legal Fees (Other)			$0
e. Non-Legal Consultant Fees (CON application related - specify what it is and why it is needed for the CON)			$0
f. Non-Legal Consultant Fees (Other)			$0
g. Liquidation of Existing Debt			$0
H. Debt Service Reserve Fund			$0
i. Other *(Specify/add rows if needed)*			$0
SUBTOTAL	***$0***	***$0***	***$0***
3. Working Capital Startup Costs			$0
TOTAL USES OF FUNDS	***$0***	***$0***	***$0***
B. Sources of Funds			
1. Cash			$0
2. Philanthropy (to date and expected)			$0
3. Authorized Bonds			$0
4. Interest Income from bond proceeds listed in #3			$0
5. Mortgage			$0
6. Working Capital Loans			$0
7. Grants or Appropriations			
a. Federal			$0
b. State			$0
c. Local			$0
8. Other *(Specify/add rows if needed)*			$0
TOTAL SOURCES OF FUNDS			**$0**
	Hospital Building	***Other Structure***	***Total***
Annual Lease Costs (if applicable)			
1. Land			$0
2. Building			$0
3. Major Movable Equipment			$0
4. Minor Movable Equipment			$0
5. Other *(Specify/add rows if needed)*			$0

* Describe the terms of the lease(s) below, including information on the fair market value of the item(s), and the number of years, annual cost, and the interest rate for the lease.

TABLE F. STATISTICAL PROJECTIONS - ENTIRE FACILITY

INSTRUCTION: Complete this table for the entire facility, including the proposed project. Indicate on the table if the reporting period is Calendar Year (CY) or Fiscal Year (FY). For sections 4 & 5, the number of beds and occupancy percentage should be reported on the basis of licensed beds. In an attachment to the application, provide an explanation or basis for the projections and specify all assumptions used. Applicants must explain why the assumptions are reasonable. See additional instruction in the column to the right of the table.

	Two Most Recent Years (Actual)		Current Year Actual***	Projected Years (ending at least two years after project completion and full occupancy) Include additional years, if needed in order to be consistent with Tables G and H.			
Indicate CY or FY	**FY15**	**FY16**	**FY17**	**FY18**	**FY19**	**FY20**	**FY21**
1. DISCHARGES							
a. General Medical/Surgical*	14,076	14,045	14,877	14,058	14,011	14,105	14,158
b. ICU	1,276	1,198	1,175	1,180	1,185	1,185	1,185
Total MSGA	**15,352**	**15,243**	**16,052**	**15,238**	**15,196**	**15,290**	**15,343**
c. Pediatric	481	280	250	270	280	275	275
d. Obstetric	3,203	2,955	2,798	2,964	2,964	2,964	2,964
e. Acute Psychiatric[1]	2,205	2,255	2,183	2,260	2,260	2,265	2,250
Total Acute	***21,241***	***20,733***	***21,283***	***20,732***	***20,700***	***20,794***	***20,832***
f. Rehabilitation	0	0	0	0	0	0	0
g. Comprehensive Care	0	0	0	0	0	0	0
h. Other (Specify/add rows of needed)	0	0	0	0	0	0	0
TOTAL DISCHARGES	***21,241***	***20,733***	***21,283***	***20,732***	***20,700***	***20,794***	***20,832***
2. PATIENT DAYS							
a. General Medical/Surgical*	63,789	64,513	65,460	56,926	54,035	51,341	49,736
b. ICU	7,725	7,066	7,050	6,962	6,992	6,992	6,992
Total MSGA	**71,514**	**71,579**	**72,510**	**63,888**	**61,027**	**58,333**	**56,728**
c. Pediatric	1,195	720	551	720	720	720	720
d. Obstetric	7,984	7,262	6,766	7,196	6,910	6,620	6,437
e. Acute Psychiatric	12,649	12,750	11,292	12,805	12,805	12,805	12,805
Total Acute	***93,342***	***92,311***	***91,119***	***84,609***	***81,462***	***78,478***	***76,690***
f. Rehabilitation	0	0	0	0	0	0	0
g. Comprehensive Care	0	0	0	0	0	0	0
h. Other (Specify/add rows of needed)	0	0	0	0	0	0	0
TOTAL PATIENT DAYS	***93,342***	***92,311***	***91,119***	***84,609***	***81,462***	***78,478***	***76,690***
3. AVERAGE LENGTH OF STAY (patient days divided by discharges)							
a. General Medical/Surgical*	4.5	4.6	4.4	4.0	3.9	3.6	3.5

TABLE F. STATISTICAL PROJECTIONS - ENTIRE FACILITY

INSTRUCTION: Complete this table for the entire facility, including the proposed project. Indicate on the table if the reporting period is Calendar Year (CY) or Fiscal Year (FY). For sections 4 & 5, the number of beds and occupancy percentage should be reported on the basis of licensed beds. In an attachment to the application, provide an explanation or basis for the projections and specify all assumptions used. Applicants must explain why the assumptions are reasonable. See additional instruction in the column to the right of the table.

	Two Most Recent Years (Actual)		Current Year Actual***	Projected Years (ending at least two years after project completion and full occupancy) Include additional years, if needed in order to be consistent with Tables G and H.			
Indicate CY or FY	**FY15**	**FY16**	**FY17**	**FY18**	**FY19**	**FY20**	**FY21**
b. ICU	6.1	5.9	6.0	5.9	5.9	5.9	5.9
Total MSGA	4.7	4.7	4.5	4.2	4.0	3.8	3.7
c. Pediatric	2.5	2.6	2.2	2.3	2.3	2.3	2.3
d. Obstetric	2.5	2.5	2.4	2.4	2.3	2.2	2.2
e. Acute Psychiatric	5.7	5.7	5.2	5.3	5.3	5.3	5.3
Total Acute	4.4	4.5	4.3	4.1	3.9	3.8	3.7
f. Rehabilitation	-	-	-	-	-	-	-

TABLE F. STATISTICAL PROJECTIONS - ENTIRE FACILITY

INSTRUCTION: Complete this table for the entire facility, including the proposed project. Indicate on the table if the reporting period is Calendar Year (CY) or Fiscal Year (FY). For sections 4 & 5, the number of beds and occupancy percentage should be reported on the basis of licensed beds. In an attachment to the application, provide an explanation or basis for the projections and specify all assumptions used. Applicants must explain why the assumptions are reasonable. See additional instruction in the column to the right of the table.

	Two Most Recent Years (Actual)		Current Year Actual***	Projected Years (ending at least two years after project completion and full occupancy) Include additional years, if needed in order to be consistent with Tables G and H.			
Indicate CY or FY	**FY15**	**FY16**	**FY17**	**FY18**	**FY19**	**FY20**	**FY21**
g. Comprehensive Care	-	-	-	-	-	-	-
h. Other (Specify/add rows of needed)	-	-	-	-	-	-	-
TOTAL AVERAGE LENGTH OF STAY	**4.4**	**4.5**	**4.3**	**4.1**	**3.9**	**3.8**	**3.7**
4. NUMBER OF LICENSED BEDS							
a. General Medical/Surgical*	240	251	240	240	240	240	240
b. ICU/CCU	28	27	27	27	27	27	27
Total MSGA	**268**	**278**	**267**	**267**	**267**	**267**	**267**
c. Pediatric	9	9	9	9	9	9	9
d. Obstetric	37	37	37	37	37	37	37
e. Acute Psychiatric	40	40	40	40	40	40	40
Total Acute	***354***	***364***	***353***	***353***	***353***	***353***	***353***
f. Rehabilitation	0	0	0	0	0	0	0
g. Comprehensive Care	0	0	0	0	0	0	0
h. Other (Specify/add rows of needed)	0	0	0	0	0	0	0
TOTAL LICENSED BEDS	***354***	***364***	***353***	***353***	***353***	***353***	***353***
5. OCCUPANCY PERCENTAGE ***IMPORTANT NOTE:** Leap year formulas should be changed by applicant to reflect 366 days per year.*							
a. General Medical/Surgical*	72.8%	70.2%	74.7%	65.0%	61.7%	58.4%	56.8%
b. ICU	75.6%	71.5%	71.5%	70.6%	70.9%	70.8%	70.9%
Total MSGA	**73.1%**	**70.3%**	**74.4%**	**65.6%**	**62.6%**	**59.7%**	**58.2%**
c. Pediatric	36.4%	21.9%	16.8%	21.9%	21.9%	21.9%	21.9%
d. Obstetric	59.1%	53.6%	50.1%	53.3%	51.2%	48.9%	47.7%

TABLE F. STATISTICAL PROJECTIONS - ENTIRE FACILITY

INSTRUCTION: Complete this table for the entire facility, including the proposed project. Indicate on the table if the reporting period is Calendar Year (CY) or Fiscal Year (FY). For sections 4 & 5, the number of beds and occupancy percentage should be reported on the basis of licensed beds. In an attachment to the application, provide an explanation or basis for the projections and specify all assumptions used. Applicants must explain why the assumptions are reasonable. See additional instruction in the column to the right of the table.

	Two Most Recent Years (Actual)		Current Year Actual***	Projected Years (ending at least two years after project completion and full occupancy) Include additional years, if needed in order to be consistent with Tables G and H.			
Indicate CY or FY	**FY15**	**FY16**	**FY17**	**FY18**	**FY19**	**FY20**	**FY21**
e. Acute Psychiatric	86.6%	87.1%	77.3%	87.7%	87.7%	87.5%	87.7%
Total Acute	**72.2%**	**69.3%**	**70.7%**	**65.7%**	**63.2%**	**60.7%**	**59.5%**
f. Rehabilitation	-	-	-	-	-	-	-
g. Comprehensive Care	-	-	-	-	-	-	-
h. Other (Specify/add rows of needed)	-	-	-	-	-	-	-
TOTAL OCCUPANCY %	**72.2%**	**69.5%**	**70.7%**	**65.7%**	**63.2%**	**60.7%**	**59.5%**

TABLE F. STATISTICAL PROJECTIONS - ENTIRE FACILITY

INSTRUCTION: Complete this table for the entire facility, including the proposed project. Indicate on the table if the reporting period is Calendar Year (CY) or Fiscal Year (FY). For sections 4 & 5, the number of beds and occupancy percentage should be reported on the basis of licensed beds. In an attachment to the application, provide an explanation or basis for the projections and specify all assumptions used. Applicants must explain why the assumptions are reasonable. See additional instruction in the column to the right of the table.

	Two Most Recent Years (Actual)		Current Year Actual***	Projected Years (ending at least two years after project completion and full occupancy) Include additional years, if needed in order to be consistent with Tables G and H.			
Indicate CY or FY	**FY15**	**FY16**	**FY17**	**FY18**	**FY19**	**FY20**	**FY21**
6. OUTPATIENT VISITS							
a. Emergency Department[2]	86,609	78,770	71,487	72,200	71,000	70,500	70,000
b. Same-day Surgery[3]	13,352	12,965	12,280	13,857	14,296	14,407	14,488
c. Laboratory[4]							
d. Imaging[4]							
e. Other (Specify/add rows of needed)[5]	340,800	330,748	306,263	273,480	283,962	286,104	292,577
TOTAL OUTPATIENT VISITS	***440,761***	***422,483***	***390,030***	***359,537***	***369,258***	***371,011***	***377,065***
7. OBSERVATIONS**							
a. Number of Patients	10,699	10,419	8,886	9,800	9,750	9,700	9,650
b. Hours	487,874	466,110	340,910	387,100	385,125	383,150	381,175

* Include beds dedicated to gynecology and addictions, if separate for acute psychiatric unit.

** Services included in the reporting of the "Observation Center", direct expenses incurred in providing bedside care to observation patients; furnished by the hospital on the hospital's premises, including use of a bed and periodic monitoring by the hospital's nursing or other staff, in order to determine the need for a possible admission to the hospitals as an inpatient. Such services must be ordered and documented in writing, given by a medical practitioner; may or may not be provided in a distinct area of the hospital.

***Fluctuations in categorizing of patients originating in the ED between Inpatient and Observation status accounts for the large FY16-FY17 variance.

[1]Includes only those patients discharged from MFSMC's Psychiatric Unit. Some patients cared for on medical floors are discharged with Psychiatric MS-DRGs. These patient are not included in this count. They are included in the General Medical/Surgical count.

[2]Excludes ED pateint visits that resulted in an admission.

[3]This data represents all MFSMC patient visits with a Same Day Surgery Code, including endoscopy, interventional pain, etc. Some of these cases do not take place in MFSMC's ORs and so are not included in the OR Need calulation.

[4]MFSMC accounts for Imaging and Laboratory volume in Relative Value Units (RVUs) not patient visits. For consistency in the summing of outpatient visits, MFSMC is not including the RVUs here. MFSMC will forward the Commission staff the appropriate RVU data at the staff's request.

[5]Includes clinic visits, physician office visits, etc.

TABLE G. REVENUES & EXPENSES, UNINFLATED - ENTIRE FACILITY

INSTRUCTION: Complete this table for the entire facility, including the proposed project. Table G should reflect current dollars (no inflation). Projected revenues and expenses should be consistent with the projections in Table F and with the costs of Manpower listed in Table L. Manpower. Indicate on the table if the reporting period is Calendar Year (CY) or Fiscal Year (FY). In an attachment to the application, provide an explanation or basis for the projections and specify all assumptions used. Applicants must explain why the assumptions are reasonable. Specify the sources of non-operating income. See additional instruction in the column to the right of the table.

	Two Most Recent Years (Actual)		Current Year (Actual)	Projected Years (ending at least two years after project completion and full occupancy) Add columns if needed in order to document that the hospital will generate excess revenues over total expenses consistent with the Financial Feasibility standard.						
Indicate CY or FY	**FY 2015**	**FY 2016**	**FY 2017**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**			
1. REVENUE										
a. Inpatient Services	$ 342,280	$ 349,256	$ 352,651	$ 347,948	$ 347,498	$ 354,318	$ 356,997			
b. Outpatient Services	$ 321,486	$ 343,454	$ 343,652	$ 365,075	$ 368,527	$ 372,573	$ 374,127			
Gross Patient Service Revenues	***$ 663,766***	***$ 692,710***	***$ 696,304***	***$ 713,022***	***$ 716,025***	***$ 726,891***	***$ 731,124***	***$ -***	***$ -***	***$ -***
c. Allowance For Bad Debt	$ 18,511	$ 26,600	$ 21,919	$ 27,068	$ 27,124	$ 27,576	$ 27,758			
d. Contractual Allowance	$ 149,425	$ 153,170	$ 151,745	$ 154,794	$ 156,219	$ 157,969	$ 159,533			
e. Charity Care	$ 2,956	$ 6,765	$ 6,354	$ 6,520	$ 6,485	$ 6,595	$ 6,639			
Net Patient Services Revenue	***$ 492,874***	***$ 506,175***	***$ 516,286***	***$ 524,641***	***$ 526,197***	***$ 534,751***	***$ 537,195***	***$ -***	***$ -***	***$ -***
f. Other Operating Revenues (Specify/add rows if needed)	$ 12,281	$ 13,273	$ 13,875	$ 11,800	$ 11,933	$ 11,813	$ 11,818			
NET OPERATING REVENUE	***$ 505,155***	***$ 519,448***	***$ 530,161***	***$ 536,440***	***$ 538,130***	***$ 546,564***	***$ 549,012***	***$ -***	***$ -***	***$ -***
2. EXPENSES										
a. Salaries & Wages (including benefits)	$ 258,764	$ 272,890	$ 277,836	$ 274,989	$ 268,272	$ 265,686	$ 257,549			
b. Contractual Services	$ 4,704									
c. Interest on Current Debt	$ 8,916	$ 7,671	$ 7,824	$ 7,789	$ 7,775	$ 8,938	$ 9,138			
d. Interest on Project Debt	$ -									
e. Current Depreciation	$ 24,281	$ 22,855	$ 22,526	$ 22,814	$ 22,817	$ 22,821	$ 23,621			
f. Project Depreciation	$ -				$ -	$ -	$ -			
g. Current Amortization	$ -									
h. Project Amortization	$ -									
i. Supplies	$ 75,260	$ 75,283	$ 77,519	$ 76,673	$ 74,879	$ 74,038	$ 73,486			
j. Other Expenses (Specify/add rows if needed)	$ 71,457	$ 82,737	$ 87,410	$ 93,789	$ 96,168	$ 98,444	$ 100,992			
k. Purchased Services	$ 44,339	$ 46,921	$ 35,435	$ 35,799	$ 34,513	$ 34,346	$ 34,177			
TOTAL OPERATING EXPENSES	***$ 487,721***	***$ 508,357***	***$ 508,549***	***$ 511,853***	***$ 504,424***	***$ 504,273***	***$ 498,963***	***$ -***	***$ -***	***$ -***
3. INCOME										
a. Income From Operation	**$ 17,434**	**$ 11,091**	**$ 21,611**	**$ 24,588**	**$ 33,705**	**$ 42,291**	**$ 50,049**	**$ -**	**$ -**	**$ -**
b. Non-Operating Income	$ 37	$ (201)								
SUBTOTAL	***$ 17,471***	***$ 10,890***	***$ 21,611***	***$ 24,588***	***$ 33,705***	***$ 42,291***	***$ 50,049***	***$ -***	***$ -***	***$ -***
c. Income Taxes										
NET INCOME (LOSS)	***$ 17,471***	***$ 10,890***	***$ 21,611***	***$ 24,588***	***$ 33,705***	***$ 42,291***	***$ 50,049***	***$ -***	***$ -***	***$ -***

TABLE G. REVENUES & EXPENSES, UNINFLATED - ENTIRE FACILITY

INSTRUCTION: Complete this table for the entire facility, including the proposed project. Table G should reflect current dollars (no inflation). Projected revenues and expenses should be consistent with the projections in Table F and with the costs of Manpower listed in Table L. Manpower. Indicate on the table if the reporting period is Calendar Year (CY) or Fiscal Year (FY). In an attachment to the application, provide an explanation or basis for the projections and specify all assumptions used. Applicants must explain why the assumptions are reasonable. Specify the sources of non-operating income. See additional instruction in the column to the right of the table.

	Two Most Recent Years (Actual)		Current Year (Actual)	Projected Years (ending at least two years after project completion and full occupancy) Add columns if needed in order to document that the hospital will generate excess revenues over total expenses consistent with the Financial Feasibility standard.						
Indicate CY or FY	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021			
4. PATIENT MIX										
a. Percent of Total Revenue										
1) Medicare	43.1%	43.8%	44.5%	44.5%	44.5%	44.5%	44.5%			
2) Medicaid	25.5%	24.9%	25.4%	25.4%	25.4%	25.4%	25.4%			
3) Blue Cross	10.3%	9.4%	9.3%	9.3%	9.3%	9.3%	9.3%			
4) Commercial Insurance	8.6%	8.5%	7.9%	7.9%	7.9%	7.9%	7.9%			
5) Self-pay	3.7%	3.5%	2.7%	2.7%	2.7%	2.7%	2.7%			
6) Other	8.8%	9.9%	10.2%	10.2%	10.2%	10.2%	10.2%			
TOTAL	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*0.0%*	*0.0%*	*0.0%*
b. Percent of Equivalent Inpatient Days										
1) Medicare	43.1%	43.8%	44.5%	44.5%	44.5%	44.5%	44.5%			
2) Medicaid	25.5%	24.9%	25.4%	25.4%	25.4%	25.4%	25.4%			
3) Blue Cross	10.3%	9.4%	9.3%	9.3%	9.3%	9.3%	9.3%			
4) Commercial Insurance	8.6%	8.5%	7.9%	7.9%	7.9%	7.9%	7.9%			
5) Self-pay	3.7%	3.5%	2.7%	2.7%	2.7%	2.7%	2.7%			
6) Other	8.8%	9.9%	10.2%	10.2%	10.2%	10.2%	10.2%			
TOTAL	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*0.0%*	*0.0%*	*0.0%*

TABLE H. REVENUES & EXPENSES, INFLATED - ENTIRE FACILITY

INSTRUCTION: Complete this table for the entire facility, including the proposed project. Table H should reflect inflation. Projected revenues and expenses should be consistent with the projections in Table F. Indicate on the table if the reporting period is Calendar Year (CY) or Fiscal Year (FY). In an attachment to the application, provide an explanation or basis for the projections and specify all assumptions used. Applicants must explain why the assumptions are reasonable. See additional instruction in the column to the right of the table.

	Two Most Recent Years (Actual)		Current Year (Actual)	Projected Years (ending at least two years after project completion and full occupancy) Add columns if needed in order to document that the hospital will generate excess revenues over total expenses consistent with the Financial Feasibility standard.						
Indicate CY or FY	**FY 2015**	**FY 2016**	**FY 2017**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**			
1. REVENUE										
a. Inpatient Services	$ 342,280	$ 349,256	$ 352,651	$ 350,981	$ 354,489	$ 369,368	$ 378,052			
b. Outpatient Services	$ 321,486	$ 343,454	$ 343,652	$ 369,799	$ 374,572	$ 380,810	$ 385,633			
Gross Patient Service Revenues	***$ 663,766***	***$ 692,710***	***$ 696,304***	***$ 720,780***	***$ 729,061***	***$ 750,178***	***$ 763,685***	***$ -***	***$ -***	***$ -***
c. Allowance For Bad Debt	$ 18,511	$ 26,600	$ 21,919	$ 27,331	$ 27,656	$ 28,387	$ 28,856			
d. Contractual Allowance	$ 149,425	$ 153,170	$ 151,745	$ 154,672	$ 155,941	$ 157,493	$ 158,790			
e. Charity Care	$ 2,956	$ 6,765	$ 6,354	$ 6,591	$ 6,630	$ 6,816	$ 6,938			
Net Patient Services Revenue	***$ 492,874***	***$ 506,175***	***$ 516,286***	***$ 532,186***	***$ 538,834***	***$ 557,483***	***$ 569,101***	***$ -***	***$ -***	***$ -***
f. Other Operating Revenues (Specify/add rows if needed)	$ 12,281	$ 13,273	$ 13,875	$ 11,800	$ 11,933	$ 11,813	$ 11,818			
NET OPERATING REVENUE	***$ 505,155***	***$ 519,448***	***$ 530,161***	***$ 543,986***	***$ 550,767***	***$ 569,296***	***$ 580,919***	***$ -***	***$ -***	***$ -***
2. EXPENSES										
a. Salaries & Wages (including benefits)	$ 258,764	$ 272,890	$ 277,836	$ 284,743	$ 287,524	$ 295,869	$ 297,429			
b. Contractual Services	$ 4,704									
c. Interest on Current Debt	$ 8,916	$ 7,671	$ 7,824	$ 7,789	$ 7,775	$ 8,938	$ 9,138			
d. Interest on Project Debt	$ -									
e. Current Depreciation	$ 24,281	$ 22,855	$ 22,526	$ 22,814	$ 22,817	$ 22,821	$ 23,621			
f. Project Depreciation	$ -				$ -	$ -	$ -			
g. Current Amortization	$ -									
h. Project Amortization	$ -									
i. Supplies	$ 75,260	$ 75,283	$ 77,519	$ 80,269	$ 82,225	$ 85,305	$ 88,952			
j. Other Expenses (Specify/add rows if needed)	$ 71,457	$ 82,737	$ 87,410	$ 96,758	$ 102,308	$ 107,869	$ 113,833			
k. Purchased Services	$ 44,339	$ 46,921	$ 35,435	$ 36,401	$ 35,697	$ 36,131	$ 36,583			
TOTAL OPERATING EXPENSES	***$ 487,721***	***$ 508,357***	***$ 508,549***	***$ 528,774***	***$ 538,347***	***$ 556,933***	***$ 569,557***	***$ -***	***$ -***	***$ -***
3. INCOME										
a. Income From Operation	***$ 17,434***	***$ 11,091***	***$ 21,611***	***$ 15,212***	***$ 12,419***	***$ 12,363***	***$ 11,362***	***$ -***	***$ -***	***$ -***
b. Non-Operating Income	$ 39	$ (201)								
SUBTOTAL	***$ 17,473***	***$ 10,890***	***$ 21,611***	***$ 15,212***	***$ 12,419***	***$ 12,363***	***$ 11,362***	***$ -***	***$ -***	***$ -***
c. Income Taxes										
NET INCOME (LOSS)	***$ 17,473***	***$ 10,890***	***$ 21,611***	***$ 15,212***	***$ 12,419***	***$ 12,363***	***$ 11,362***	***$ -***	***$ -***	***$ -***
4. PATIENT MIX										
a. Percent of Total Revenue										
1) Medicare	43.1%	43.8%	44.5%	44.5%	44.5%	44.5%	44.5%			
2) Medicaid	25.5%	24.9%	25.4%	25.4%	25.4%	25.4%	25.4%			
3) Blue Cross	10.3%	9.4%	9.3%	9.3%	9.3%	9.3%	9.3%			
4) Commercial Insurance	8.6%	8.5%	7.9%	7.9%	7.9%	7.9%	7.9%			
5) Self-pay	3.7%	3.5%	2.7%	2.7%	2.7%	2.7%	2.7%			
6) Other	8.8%	9.9%	10.2%	10.2%	10.2%	10.2%	10.2%			
TOTAL	***100.0%***	***100.0%***	***100.0%***	***100.0%***	***100.0%***	***100.0%***	***100.0%***	***0.0%***	***0.0%***	***0.0%***

TABLE H. REVENUES & EXPENSES, INFLATED - ENTIRE FACILITY

INSTRUCTION: Complete this table for the entire facility, including the proposed project. Table H should reflect inflation. Projected revenues and expenses should be consistent with the projections in Table F. Indicate on the table if the reporting period is Calendar Year (CY) or Fiscal Year (FY). In an attachment to the application, provide an explanation or basis for the projections and specify all assumptions used. Applicants must explain why the assumptions are reasonable. See additional instruction in the column to the right of the table.

	Two Most Recent Years (Actual)		Current Year (Actual)	Projected Years (ending at least two years after project completion and full occupancy) Add columns if needed in order to document that the hospital will generate excess revenues over total expenses consistent with the Financial Feasibility standard.						
Indicate CY or FY	**FY 2015**	**FY 2016**	**FY 2017**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**			
b. Percent of Equivalent Inpatient Days										
Total MSGA										
1) Medicare	43.1%	43.8%	44.5%	44.5%	44.5%	44.5%	44.5%			
2) Medicaid	25.5%	24.9%	25.4%	25.4%	25.4%	25.4%	25.4%			
3) Blue Cross	10.3%	9.4%	9.3%	9.3%	9.3%	9.3%	9.3%			
4) Commercial Insurance	8.6%	8.5%	7.9%	7.9%	7.9%	7.9%	7.9%			
5) Self-pay	3.7%	3.5%	2.7%	2.7%	2.7%	2.7%	2.7%			
6) Other	8.8%	9.9%	10.2%	10.2%	10.2%	10.2%	10.2%			
TOTAL	***100.0%***	***100.0%***	***100.0%***	***100.0%***	***100.0%***	***100.0%***	***100.0%***	***0.0%***	***0.0%***	***0.0%***

TABLE I. STATISTICAL PROJECTIONS - NEW FACILITY OR SERVICE

INSTRUCTION: After consulting with Commission Staff, complete this table for the new facility or service (the proposed project). Indicate on the table if the reporting period is Calendar Year (CY) or Fiscal Year (FY). For sections 4 & 5, the number of beds and occupancy percentage should be reported on the basis of licensed beds. In an attachment to the application, provide an explanation or basis for the projections and specify all assumptions used. Applicants must explain why the assumptions are reasonable. See additional instruction in the column to the right of the table.

	Projected Years (ending at least two years after project completion and full occupancy) include additional years, if needed in order to be consistent with Tables J and K.						
Indicate CY or FY	**FY 2019**	**FY 2020**	**FY 2021**				
1. DISCHARGES							
a. Kidney Transplants	12	24	44				
b. Non-Transplant	8	21	38				
c. ICU/CCU							
Total MSGA	**20**	**45**	**82**	**0**	**0**	**0**	**0**
c. Pediatric							
d. Obstetric							
e. Acute Psychiatric							
Total Acute	***20***	***45***	***82***	***0***	***0***	***0***	***0***
f. Rehabilitation							
g. Comprehensive Care							
h. Other (Specify/add rows of needed)							
TOTAL DISCHARGES	***20***	***45***	***82***	***0***	***0***	***0***	***0***
2. PATIENT DAYS							
a. Kidney Transplants	60	120	248				
b. Non-Transplant	39	99	181				
c. ICU/CCU							
Total MSGA	**99**	**219**	**429**	**0**	**0**	**0**	**0**
c. Pediatric							
d. Obstetric							
e. Acute Psychiatric							
Total Acute	***99***	***219***	***429***	***0***	***0***	***0***	***0***
f. Rehabilitation							
g. Comprehensive Care							
h. Other (Specify/add rows of needed)							
TOTAL PATIENT DAYS	***99***	***219***	***429***	***0***	***0***	***0***	***0***
3. AVERAGE LENGTH OF STAY							
a. Kidney Transplants	5.0	5.0	5.6	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
b. Non-Transplant	4.9	4.7	4.8				
Total MSGA	5.0	4.9	5.2	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
c. Pediatric	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
d. Obstetric	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
e. Acute Psychiatric	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
Total Acute	5.0	4.9	5.2	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
f. Rehabilitation	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
g. Comprehensive Care	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
h. Other (Specify/add rows of needed)	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
TOTAL AVERAGE LENGTH OF STAY	5.0	4.9	5.2	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!

TABLE I. STATISTICAL PROJECTIONS - NEW FACILITY OR SERVICE

INSTRUCTION: After consulting with Commission Staff, complete this table for the new facility or service (the proposed project). Indicate on the table if the reporting period is Calendar Year (CY) or Fiscal Year (FY). For sections 4 & 5, the number of beds and occupancy percentage should be reported on the basis of licensed beds. In an attachment to the application, provide an explanation or basis for the projections and specify all assumptions used. Applicants must explain why the assumptions are reasonable. See additional instruction in the column to the right of the table.

	Projected Years (ending at least two years after project completion and full occupancy) include additional years, if needed in order to be consistent with Tables J and K.						
Indicate CY or FY	**FY 2019**	**FY 2020**	**FY 2021**				
4. NUMBER OF LICENSED BEDS							
a. General Medical/Surgical*							
b. ICU/CCU							
Total MSGA	**0**	**0**	**0**	**0**	**0**	**0**	**0**
c. Pediatric							
d. Obstetric							
e. Acute Psychiatric							
Total Acute	***0***	***0***	***0***	***0***	***0***	***0***	***0***
f. Rehabilitation							
g. Comprehensive Care							
h. Other (Specify/add rows of needed)							
TOTAL LICENSED BEDS							
5. OCCUPANCY PERCENTAGE ***IMPORTANT NOTE:** Leap year formulas should be changed by applicant to reflect 366 days per year.*							
a. General Medical/Surgical*	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
b. ICU/CCU	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
Total MSGA	**#DIV/0!**	**#DIV/0!**	**#DIV/0!**	**#DIV/0!**	**#DIV/0!**	**#DIV/0!**	**#DIV/0!**
c. Pediatric	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
d. Obstetric	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
e. Acute Psychiatric	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
Total Acute	**#DIV/0!**	**#DIV/0!**	**#DIV/0!**	**#DIV/0!**	**#DIV/0!**	**#DIV/0!**	**#DIV/0!**
f. Rehabilitation	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
g. Comprehensive Care	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
h. Other (Specify/add rows of needed)	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
TOTAL OCCUPANCY %	**#DIV/0!**	**#DIV/0!**	**#DIV/0!**	**#DIV/0!**	**#DIV/0!**	**#DIV/0!**	**#DIV/0!**
6. OUTPATIENT VISITS							
a. Emergency Department							
b. Same-day Surgery							
c. Laboratory							
d. Imaging							
e. Other (Specify/add rows of needed)	2,669	4,138	8,230				
TOTAL OUTPATIENT VISITS	***2,669***	***4,138***	***8,230***	***0***	***0***	***0***	***0***
7. OBSERVATIONS**							
a. Number of Patients							
b. Hours							

*Include beds dedicated to gynecology and addictions, if separate for acute psychiatric unit.

** Services included in the reporting of the "Observation Center", direct expenses incurred in providing bedside care to observation patients; furnished by the hospital on the hospital's premises, including use of a bed and periodic monitoring by the hospital's nursing or other staff, in order to determine the need for a possible admission to the hospitals as an inpatient. Such services must be ordered and documented in writing, given by a medical practitioner; may or may not be provided in a distinct area of the hospital.

TABLE J. REVENUES & EXPENSES, UNINFLATED - NEW FACILITY OR SERVICE

INSTRUCTION: After consulting with Commission Staff, complete this table for the new facility or service (the proposed project). Table J should reflect current dollars (no inflation). Projected revenues and expenses should be consistent with the projections in Table I and with the costs of Manpower listed in Table L. Manpower. Indicate on the table if the reporting period is Calendar Year (CY) or Fiscal Year (FY). In an attachment to the application, provide an explanation or basis for the projections and specify all assumptions used. Applicants must explain why the assumptions are reasonable. Specify the sources of non-operating income.

	Projected Years (ending at least two years after project completion and full occupancy) Add years, if needed in order to document that the hospital will generate excess revenues over total expenses consistent with the Financial Feasibility standard.						
Indicate CY or FY	**FY 2019**	**FY 2020**	**FY 2021**				
1. REVENUE							
a. Inpatient Services	$ 888	$ 2,517	$ 4,648				
b. Outpatient Services	$ 521	$ 1,149	$ 2,104				
Gross Patient Service Revenues	***$ 1,409***	***$ 3,666***	***$ 6,752***	***$ -***	***$ -***	***$ -***	***$ -***
c. Allowance For Bad Debt	$ 49	$ 125	$ 230				
d. Contractual Allowance	$ 179	$ 451	$ 886				
e. Charity Care	$ 13	$ 31	$ 61				
Net Patient Services Revenue	***$ 1,168***	***$ 3,059***	***$ 5,575***	***$ -***	***$ -***	***$ -***	***$ -***
f. Other Operating Revenues (Specify)							
NET OPERATING REVENUE	***$ 1,168***	***$ 3,059***	***$ 5,575***	***$ -***	***$ -***	***$ -***	***$ -***
2. EXPENSES							
a. Salaries & Wages (including benefits)	$ 1,650	$ 2,472	$ 2,909				
b. Contractual Services							
c. Interest on Current Debt							
d. Interest on Project Debt							
e. Current Depreciation							
f. Project Depreciation							
g. Current Amortization							
h. Project Amortization							
i. Supplies	$ 192	$ 407	$ 739				
j. Other Expenses (Specify)	$ 341	$ 683	$ 1,273				
k. Purchased Services	$ 66	$ 137	$ 221				
TOTAL OPERATING EXPENSES	***$ 2,250***	***$ 3,700***	***$ 5,142***	***$ -***	***$ -***	***$ -***	***$ -***
3. INCOME							
a. Income From Operation	**$ (1,082)**	**$ (641)**	**$ 433**	**$ -**	**$ -**	**$ -**	**$ -**
b. Non-Operating Income							
SUBTOTAL	***$ (1,082)***	***$ (641)***	***$ 433***	***$ -***	***$ -***	***$ -***	***$ -***
c. Income Taxes							
NET INCOME (LOSS)	***$ (1,082)***	***$ (641)***	***$ 433***	***$ -***	***$ -***	***$ -***	***$ -***

TABLE J. REVENUES & EXPENSES, UNINFLATED - NEW FACILITY OR SERVICE

INSTRUCTION: After consulting with Commission Staff, complete this table for the new facility or service (the proposed project). Table J should reflect current dollars (no inflation). Projected revenues and expenses should be consistent with the projections in Table I and with the costs of Manpower listed in Table L. Manpower. Indicate on the table if the reporting period is Calendar Year (CY) or Fiscal Year (FY). In an attachment to the application, provide an explanation or basis for the projections and specify all assumptions used. Applicants must explain why the assumptions are reasonable. Specify the sources of non-operating income.

	Projected Years (ending at least two years after project completion and full occupancy) Add years, if needed in order to document that the hospital will generate excess revenues over total expenses consistent with the Financial Feasibility standard.						
Indicate CY or FY	**FY 2019**	**FY 2020**	**FY 2021**				
4. PATIENT MIX							
a. Percent of Total Revenue							
1) Medicare	28.6%	46.2%	41.9%				
2) Medicaid	42.9%	25.3%	25.3%				
3) Blue Cross	18.6%	17.7%	20.8%				
4) Commercial Insurance	10.0%	10.8%	12.0%				
5) Self-pay							
6) Other							
TOTAL	***100.0%***	***100.0%***	***100.0%***	***0.0%***	***0.0%***	***0.0%***	***0.0%***
b. Percent of Equivalent Inpatient Days							
Total MSGA							
1) Medicare	28.6%	46.2%	41.9%				
2) Medicaid	42.9%	25.3%	25.3%				
3) Blue Cross	18.6%	17.7%	20.8%				
4) Commercial Insurance	10.0%	10.8%	12.0%				
5) Self-pay							
6) Other							
TOTAL	***100.0%***	***100.0%***	***100.0%***	***0.0%***	***0.0%***	***0.0%***	***0.0%***

TABLE K. REVENUES & EXPENSES, INFLATED - NEW FACILITY OR SERVICE

INSTRUCTION: After consulting with Commission Staff, complete this table for the new facility or service (the proposed project). Table K should reflect inflation. Projected revenues and expenses should be consistent with the projections in Table I. Indicate on the table if the reporting period is Calendar Year (CY) or Fiscal Year (FY). In an attachment to the application, provide an explanation or basis for the projections and specify all assumptions used. Applicants must explain why the assumptions are reasonable.

	Projected Years (ending at least two years after project completion and full occupancy) Add years, if needed in order to document that the hospital will generate excess revenues over total expenses consistent with the Financial Feasibility standard.						
Indicate CY or FY	**FY 2019**	**FY 2020**	**FY 2021**				
1. REVENUE							
a. Inpatient Services	$ 888	$ 2,522	$ 4,668				
b. Outpatient Services	$ 521	$ 1,155	$ 2,126				
Gross Patient Service Revenues	***$ 1,409***	***$ 3,677***	***$ 6,794***	$ -	$ -	$ -	$ -
c. Allowance For Bad Debt	$ 49	$ 125	$ 231				
d. Contractual Allowance	$ 179	$ 414	$ 758				
e. Charity Care	$ 13	$ 32	$ 61				
Net Patient Services Revenue	***$ 1,168***	***$ 3,107***	***$ 5,743***	$ -	$ -	$ -	$ -
f. Other Operating Revenues (Specify/add rows of needed)							
NET OPERATING REVENUE	***$ 1,168***	***$ 3,107***	***$ 5,743***	$ -	$ -	$ -	$ -
2. EXPENSES							
a. Salaries & Wages (including benefits)	$ 1,650	$ 2,552	$ 3,101				
b. Contractual Services							
c. Interest on Current Debt							
d. Interest on Project Debt							
e. Current Depreciation							
f. Project Depreciation							
g. Current Amortization							
h. Project Amortization							
i. Supplies	$ 192	$ 429	$ 822				
j. Other Expenses (Specify/add rows of needed)	$ 341	$ 697	$ 1,323				
k. Purchased Services	$ 66	$ 140	$ 230				
TOTAL OPERATING EXPENSES	***$ 2,250***	***$ 3,818***	***$ 5,477***	$ -	$ -	$ -	$ -
3. INCOME							
a. Income From Operation	**$ (1,082)**	**$ (712)**	**$ 267**	$ -	$ -	$ -	$ -
b. Non-Operating Income							
SUBTOTAL	***$ (1,082)***	***$ (712)***	***$ 267***	$ -	$ -	$ -	$ -
c. Income Taxes							
NET INCOME (LOSS)	***$ (1,082)***	***$ (712)***	***$ 267***	$ -	$ -	$ -	$ -

TABLE K. REVENUES & EXPENSES, INFLATED - NEW FACILITY OR SERVICE

INSTRUCTION: After consulting with Commission Staff, complete this table for the new facility or service (the proposed project). Table K should reflect inflation. Projected revenues and expenses should be consistent with the projections in Table I. Indicate on the table if the reporting period is Calendar Year (CY) or Fiscal Year (FY). In an attachment to the application, provide an explanation or basis for the projections and specify all assumptions used. Applicants must explain why the assumptions are reasonable.

	Projected Years (ending at least two years after project completion and full occupancy) Add years, if needed in order to document that the hospital will generate excess revenues over total expenses consistent with the Financial Feasibility standard.						
Indicate CY or FY	**FY 2019**	**FY 2020**	**FY 2021**				
4. PATIENT MIX							
a. Percent of Total Revenue							
1) Medicare	28.6%	46.2%	41.9%				
2) Medicaid	42.9%	25.3%	25.3%				
3) Blue Cross	18.6%	17.7%	20.8%				
4) Commercial Insurance	10.0%	10.8%	12.0%				
5) Self-pay							
6) Other							
TOTAL	***100.0%***	***100.0%***	***100.0%***	***0.0%***	***0.0%***	***0.0%***	***0.0%***
b. Percent of Equivalent Inpatient Days							
1) Medicare	28.6%	46.2%	41.9%				
2) Medicaid	42.9%	25.3%	25.3%				
3) Blue Cross	18.6%	17.7%	20.8%				
4) Commercial Insurance	10.0%	10.8%	12.0%				
5) Self-pay							
6) Other							
TOTAL	***100.0%***	***100.0%***	***100.0%***	***0.0%***	***0.0%***	***0.0%***	***0.0%***

TABLE L. WORKFORCE INFORMATION

INSTRUCTION: List the facility's existing staffing and changes required by this project. Include all major job categories under each heading provided in the table. The number of Full Time Equivalents (FTEs) should be calculated on the basis of 2,080 paid hours per year equals one FTE. In an attachment to the application, explain any factor used in converting paid hours to worked hours. Please ensure that the projections in this table are consistent with expenses provided in uninflated projections in Tables F and G. See additional instruction in the column to the right of the table.

	CURRENT ENTIRE FACILITY			PROJECTED CHANGES AS A RESULT OF THE PROPOSED PROJECT THROUGH THE LAST YEAR OF PROJECTION (CURRENT DOLLARS)			OTHER EXPECTED CHANGES IN OPERATIONS THROUGH THE LAST YEAR OF PROJECTION (CURRENT DOLLARS)			PROJECTED ENTIRE FACILITY THROUGH THE LAST YEAR OF PROJECTION (CURRENT DOLLARS) *	
Job Category	**Current Year FTEs**	**Average Salary per FTE**	**Current Year Total Cost**	**FTEs**	**Average Salary per FTE**	**Total Cost** *(should be consistent with projections in Table G, if submitted).*	**FTEs**	**Average Salary per FTE**	**Total Cost**	**FTEs**	**Total Cost** *(should be consistent with projections in Table G)*
1. Regular Employees											
Administration *(List general categories, add rows if needed)*											
Office/Clerical	233.6	$47,908	$11,193,150	3.5	$86,531	$302,860	-19.3	$47,908	-$922,726	217.9	$10,573,284
Management	103.1	$226,573	$23,350,567				-13.2	$226,573	-$2,983,344	89.9	$20,367,223
Total Administration	336.7	$102,595	$34,543,716	3.5	$86,531	$302,860	-32.4	$120,454	-$3,906,070	307.8	$30,940,506
Direct Care Staff *(List general categories, add rows if needed)*											
RN	776.1	$100,880	$78,294,967	8.0	$89,214	$713,711	-62.3	$100,880	-$6,283,800	721.8	$72,724,878
Care Associates	238.4	$42,278	$10,080,005				-19.7	$42,278	-$833,411	218.7	$9,246,594
Physicians	157.2	$425,455	$66,864,467	3.0	$333,333	$1,000,000	-12.2	$350,000	-$4,254,474	148.0	$63,609,994
Intern/Residents	84.8	$83,283	$7,064,917				0.0	$83,283	$0	84.8	$7,064,917
Other Direct Care	132.6	$111,023	$14,716,099	1.0		$54,579	-12.2	$122,721	-$1,496,533	121.4	$13,274,145
Total Direct Care	1389.1	$127,437	$177,020,456	12.0	$147,357	$1,768,290	-106.4	$120,996	-$12,868,218	1294.7	$165,920,528
Support Staff *(List general categories, add rows if needed)*											
Technologists	198.2	$78,169	$15,494,683				-15.8	$78,169	-$1,238,359	182.4	$14,256,324
Medical Assistants	73.0	$43,637	$3,186,359	1.0	$45,427	$45,427	-5.6	$43,637	-$244,773	68.4	$2,987,013
Clinical Pharmacist	30.9	$156,550	$4,840,530				-2.5	$156,550	-$392,324	28.4	$4,448,205
Other Support Staff	67.1	$171,617	$11,508,667	2.0	$58,583	$117,166	-5.2	$171,617	-$897,920	63.8	$10,727,913
Service/Trade	233.5	$41,169	$9,614,529				-18.9	$41,169	-$777,261	214.7	$8,837,268
Other Non Patient Care	385.8	$56,064	$21,626,692				-35.4	$61,971	-$2,195,821	350.3	$19,430,871
Total Support	988.5	$67,042	$66,271,459	3.0	$54,198	$162,593	-83.5	$68,818	-$5,746,459	908.0	$60,687,593
REGULAR EMPLOYEES TOTAL	***2714.3***	***$102,360***	**$277,835,631**	***18.5***		**$2,233,743**	***-222.3***	***$101,316***	**-$22,520,747**	**2510.5**	**$257,548,628**
2. Contractual Employees											

TABLE L. WORKFORCE INFORMATION

Administration *(List general categories, add rows if needed)*											
			$0			$0			$0	0.0	$0
			$0			$0			$0	0.0	$0
			$0			$0			$0	0.0	$0
			$0			$0			$0	0.0	$0
Total Administration			$0			$0			$0	0.0	$0
Direct Care Staff *(List general categories, add rows if needed)*											
			$0			$0			$0	0.0	$0
			$0			$0			$0	0.0	$0
			$0			$0			$0	0.0	$0
			$0			$0			$0	0.0	$0
Total Direct Care Staff			$0			$0			$0	0.0	$0
Support Staff *(List general categories, add rows if needed)*											
			$0			$0			$0	0.0	$0
			$0			$0			$0	0.0	$0
			$0			$0			$0	0.0	$0
			$0			$0			$0	0.0	$0
Total Support Staff			$0			$0			$0	0.0	$0
CONTRACTUAL EMPLOYEES TOTAL			$0			$0			$0	0.0	$0
Benefits *(State method of calculating benefits below)* **:**											
TOTAL COST	***2714.3***		***$277,835,631***	***18.5***		***$2,233,743***	***-222.3***		***-$22,520,747***		***$257,548,628***

TABLE M. (AD-HOC) REVENUES & EXPENSES, INFLATED - CONSOLIDATED LIVER AND KIDNEY NEW FACILITY OR SERVICE

INSTRUCTION: After consulting with Commission Staff, complete this table for the new facility or service (the proposed project). Table K should reflect inflation. Projected revenues and expenses should be consistent with the projections in Table I. Indicate on the table if the reporting period is Calendar Year (CY) or Fiscal Year (FY). In an attachment to the application, provide an explanation or basis for the projections and specify all assumptions used. Applicants must explain why the assumptions are reasonable.

	Projected Years (ending at least two years after project completion and full occupancy) Add years, if needed in order to document that the hospital will generate excess revenues over total expenses consistent with the Financial Feasibility standard.						
Indicate CY or FY	**FY 2019**	**FY 2020**	**FY 2021**				
1. REVENUE							
a. Inpatient Services	$ 2,909	$ 6,024	$ 12,286				
b. Outpatient Services	$ 1,924	$ 3,164	$ 6,482				
Gross Patient Service Revenues	***$ 4,834***	***$ 9,188***	***$ 18,769***	***$ -***	***$ -***	***$ -***	***$ -***
c. Allowance For Bad Debt	$ 164	$ 312	$ 632				
d. Contractual Allowance	$ 548	$ 972	$ 1,963				
e. Charity Care	$ 43	$ 79	$ 167				
Net Patient Services Revenue	***$ 4,079***	***$ 7,825***	***$ 16,006***	***$ -***	***$ -***	***$ -***	***$ -***
f. Other Operating Revenues (Specify/add rows of needed)							
NET OPERATING REVENUE	***$ 4,079***	***$ 7,825***	***$ 16,006***	***$ -***	***$ -***	***$ -***	***$ -***
2. EXPENSES							
a. Salaries & Wages (including benefits)	$ 2,468	$ 4,171	$ 5,429				
b. Contractual Services							
c. Interest on Current Debt							
d. Interest on Project Debt							
e. Current Depreciation							
f. Project Depreciation	$ 4	$ 8	$ 8				
g. Current Amortization							
h. Project Amortization							
i. Supplies	$ 755	$ 1,246	$ 2,683				
j. Other Expenses (Specify/add rows of needed)	$ 770	$ 1,308	$ 2,691				
k. Purchased Services	$ 145	$ 253	$ 483				
TOTAL OPERATING EXPENSES	***$ 4,142***	***$ 6,986***	***$ 11,294***	***$ -***	***$ -***	***$ -***	***$ -***
3. INCOME							
a. Income From Operation	***$ (62)***	***$ 839***	***$ 4,712***	***$ -***	***$ -***	***$ -***	***$ -***
b. Non-Operating Income							
SUBTOTAL	***$ (62)***	***$ 839***	***$ 4,712***	***$ -***	***$ -***	***$ -***	***$ -***
c. Income Taxes							
NET INCOME (LOSS)	***$ (62)***	***$ 839***	***$ 4,712***	***$ -***	***$ -***	***$ -***	***$ -***

TABLE M. (AD-HOC) REVENUES & EXPENSES, INFLATED - CONSOLIDATED LIVER AND KIDNEY NEW FACILITY OR SERVICE

INSTRUCTION: After consulting with Commission Staff, complete this table for the new facility or service (the proposed project). Table K should reflect inflation. Projected revenues and expenses should be consistent with the projections in Table I. Indicate on the table if the reporting period is Calendar Year (CY) or Fiscal Year (FY). In an attachment to the application, provide an explanation or basis for the projections and specify all assumptions used. Applicants must explain why the assumptions are reasonable.

	Projected Years (ending at least two years after project completion and full occupancy) Add years, if needed in order to document that the hospital will generate excess revenues over total expenses consistent with the Financial Feasibility standard.						
Indicate CY or FY	**FY 2019**	**FY 2020**	**FY 2021**				
4. PATIENT MIX							
a. Percent of Total Revenue							
1) Medicare	28.6%	46.2%	41.9%				
2) Medicaid	42.9%	25.3%	25.3%				
3) Blue Cross	18.6%	17.7%	20.8%				
4) Commercial Insurance	10.0%	10.8%	12.0%				
5) Self-pay							
6) Other							
TOTAL	***100.0%***	***100.0%***	***100.0%***	***0.0%***	***0.0%***	***0.0%***	***0.0%***
b. Percent of Equivalent Inpatient Days							
1) Medicare	28.6%	46.2%	41.9%				
2) Medicaid	42.9%	25.3%	25.3%				
3) Blue Cross	18.6%	17.7%	20.8%				
4) Commercial Insurance	10.0%	10.8%	12.0%				
5) Self-pay							
6) Other							
TOTAL	***100.0%***	***100.0%***	***100.0%***	***0.0%***	***0.0%***	***0.0%***	***0.0%***