MARYLAND HEALTH CARE COMMISSION

MATTER/DOCKET NO.
17-03-2406

UPDATED HOSPITAL APPLICATION FOR CERTIFICATE OF NEED

PART I - PROJECT IDENTIFICATION AND GENERAL INFORMATION

1. FACILITY

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

Address:

9000 Franklin Square Drive	Rosedale	21237	Baltimore
Street	**City**	**Zip**	**County**

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

2. OWNER

Name of owner: MedStar Health, Inc.

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

Legal Name of Project Applicant
Franklin Square Hospital Center d/b/a MedStar Franklin Square Medical Center

Address:

9000 Franklin Square Drive	Rosedale	21237	MD	Baltimore
Street	**City**	**Zip**	**State**	**County**

Telephone: 443-777-7000

Name of Owner/Chief Executive: Stuart M. Levine MD

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

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

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

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

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

A. Lead or primary contact:

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

Mailing Address:

10980 Grantchester Way	Columbia	21044	MD
Street	**City**	**Zip**	**State**

Telephone: 410-772-6689

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

Fax: _____

B. Additional or alternate contact:

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

Mailing Address:

100 Irving Street NW	Washington	20010	D.C.
Street	**City**	**Zip**	**State**

Telephone: 202-877-3524

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

Fax: _____

7. TYPE OF PROJECT

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

If approved, this CON would result in:

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

8. PROJECT DESCRIPTION

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

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

Response:

MedStar Franklin Square Medical Center (MFSMC), in partnership with the MedStar Georgetown Transplant Institute (MGTI), seeks to establish a liver transplantation program at MFSMC in Rosedale, Maryland. An application was docketed originally in 2018 but review was deferred until this time. Hence, this renewed application is submitted at the request of Maryland Health Care Commission (MHCC)-appointed reviewer, Michael J. O'Grady, PhD. While many aspects of the MGTI program remain unchanged, new developments at MFSMC, including in the marketplace, are addressed in the application.

Organ Allocation Policy

Organ allocation policies are continuously evolving. Changes to liver allocation policy in calendar year 2020 removed the geographic boundaries of both the donor service area (DSA) and region, with intent to reduce differences in medical urgency scores among different areas, thus improving access to patients in greater need. Currently, allocation of deceased donor livers follows radius-based acuity circles which attempt to balance both patient need (based on severity of illness) and distance from the donor hospital. These changes in allocation have resulted in broader sharing of organs, which now travel to patients of highest acuity.

Current allocation policy will have little effect, positive or negative, on the proposed liver transplant program at MFSMC or the other two programs currently operating in Baltimore. Older considerations regarding access to organs based on DSA boundaries are now irrelevant.

MedStar Health patients in the Baltimore region will greatly benefit from the continuity of care afforded by receiving liver transplant services in their local area rather than repeated commuting to MGTI in the District of Columbia. At this time, many such candidates for transplant, who reside in the Baltimore area and access services at MFSMC are required to travel back and forth between Baltimore and MGTI for various aspects of their integrated transplant care. However, dual listing patients at MFSMC and MGTI will be offered and may result in a modest increase in organ availability for individual patients.

As before, MedStar Health maintains that a new transplant program at MFSMC will afford the Baltimore metropolitan area the same outstanding level of clinical expertise, superior clinical outcomes and exceptional patient experience that characterize MGTI in Washington, D.C., unequivocally one of the largest, most successful programs in the nation. As described in detail in this document, MFSMC and MGTI expect to effect improvement in both demand and supply sides of the organ acquisition equation in the Baltimore region.

MGTI brings to MFSMC the full range of treatment options for liver diseases, including hepatitis, as well as malignant tumors. Thus, the transplant program will treat a much broader population of patients than just those receiving transplant, bringing more choices in treatment for regional residents. MGTI's level of achievement in evaluating and transplanting minority populations continues to exceed both local and national benchmarks. *See infra,* Minority Patients Figures. 4 and 5. Importantly, a highly advanced clinical research platform underlies all clinical activities as described in the comprehensive list of current studies provided as Attachment A.

Finally, the cost structure at MFSMC is significantly lower than either existing transplant center in Baltimore. *See infra,* Cost Effectiveness at Figures 8 and 9. Hence, MFSMC provides a more cost-effective option for transplantation in Maryland, serving to lower costs across the health care system in the

state.

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

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

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

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

Response:

MedStar Franklin Square Medical Center Transplant Center Comprehensive Project Description

Introduction

MedStar Health

MedStar Health is a $6 billion not-for-profit healthcare system based in Columbia, Maryland serving residents across the Baltimore-Washington, D.C. region. MedStar Health is comprised of tertiary and quaternary care medical centers including MedStar Georgetown University Hospital (MGUH) (an academic medical center), MedStar Washington Hospital Center (a quaternary medical center), seven community hospitals, and an acute care rehabilitation hospital. An extensive delivery system includes a primary and specialty care physician network, a comprehensive configuration of outpatient rehabilitation sites, home health services and ambulatory care venues that offer physician consultation, urgent care, and surgery. MGTI is based at MGUH, where all inpatient transplantation procedures are performed.

Organ Transplantation

The evolution of solid organ transplantation over the last five decades has markedly altered the outcome of end-stage organ failure. The incidence of liver diseases and liver cancer continues to grow exponentially in our country. As many as 100,000 people per year die from liver disease or liver malignancies and the number of patients awaiting transplant increases every year. MedStar Health's advanced liver disease and transplant program, based at MGTI, ranks as one of the nation's premier transplant programs ranking in the top 25 of programs nationally by volume, while maintaining superior patient and graft outcomes. MedStar Health proposes to integrate its established program at MGTI with MFSMC in its Baltimore region to afford Maryland residents access to another superior transplant center but at much lower cost to the system, given its community hospital profile.

MGTI Liver Transplant Program

MGTI is under the clinical and administrative direction of Thomas M. Fishbein MD, an international leader in the field of liver and small bowel transplantation. Trained at Mt. Sinai Medical Center in New York City, Dr. Fishbein has overseen an approximate 200% increase in liver transplant volume at MGTI since his arrival in late 2003. MGTI's pediatric liver transplant program is consistently one of the two largest in the United States. Both adult and pediatric liver transplant programs have been very successful in terms of volume and outcomes. Figure 1 below shows cumulative liver transplant volume for the three local programs 2019-2022.

Figure 1

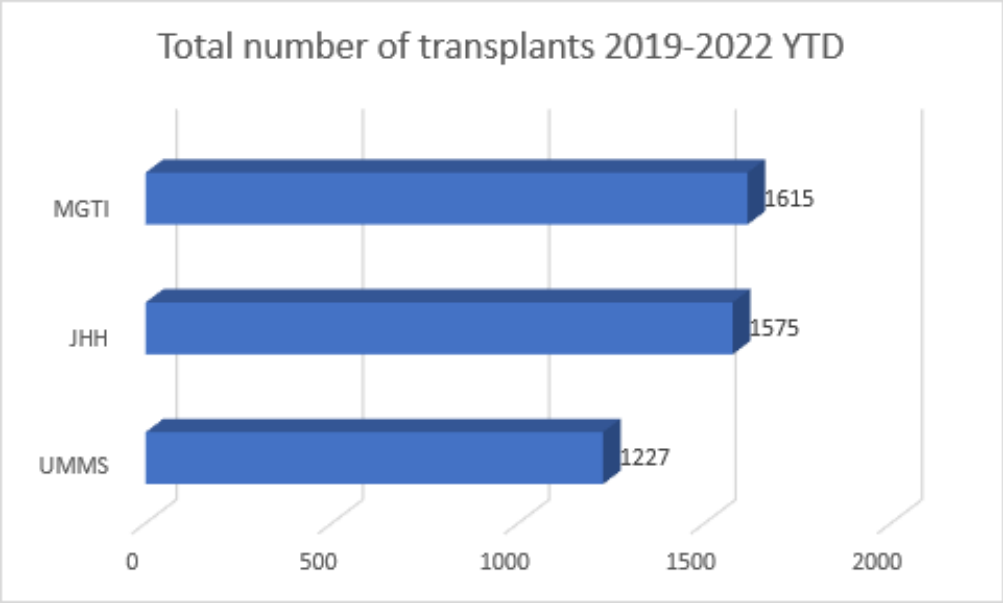

Figure 2 below shows Liver Transplant Graft Survival for the major area programs.

Figure 2 Liver Graft Survival by Center

SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

University of Maryland Medical System
Center Code: MDUM
Transplant Program (Organ): Liver
Release Date: July 6, 2022
Based on Data Available: April 30, 2022

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

C. Transplant Information

Table C7. Adult (18+) 1-year survival with a functioning graft
Single organ transplants performed between 01/01/2019 and 03/12/2020, and 06/13/2020 and 06/30/2021
Deaths and retransplants are considered graft failures
Follow-up ends on 3/12/2020 for recipients transplanted prior to 3/13/2020

	MDUM	U.S.
Number of transplants evaluated	196	17,361
Estimated probability of surviving with a functioning graft at 1 year (unadjusted for patient and donor characteristics)	84.06%	92.28%
Expected probability of surviving with a functioning graft at 1 year (adjusted for patient and donor characteristics)	92.30%	--
Number of observed graft failures (including deaths) during the first year after transplant	24	1,106
Number of expected graft failures (including deaths) during the first year after transplant	12.24	--
Estimated hazard ratio*	1.83	--
95% credible interval for the hazard ratio**	[1.19, 2.59]	--

SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

Johns Hopkins Hospital
Center Code: MDJH
Transplant Program (Organ): Liver
Release Date: July 6, 2022
Based on Data Available: April 30, 2022

SRTR Program-Specific Report
Feedback?: SRTR@SRTR.org
1.877.970.SRTR (7787)
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C. Transplant Information

Table C7. Adult (18+) 1-year survival with a functioning graft
Single organ transplants performed between 01/01/2019 and 03/12/2020, and 06/13/2020 and 06/30/2021
Deaths and retransplants are considered graft failures
Follow-up ends on 3/12/2020 for recipients transplanted prior to 3/13/2020

	MDJH	U.S.
Number of transplants evaluated	236	17,361
Estimated probability of surviving with a functioning graft at 1 year (unadjusted for patient and donor characteristics)	94.40%	92.28%
Expected probability of surviving with a functioning graft at 1 year (adjusted for patient and donor characteristics)	93.01%	--
Number of observed graft failures (including deaths) during the first year after transplant	10	1,106
Number of expected graft failures (including deaths) during the first year after transplant	13.75	--
Estimated hazard ratio*	0.76	--
95% credible interval for the hazard ratio**	[0.39, 1.25]	--

SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

Medstar Georgetown Transplant Institute
Center Code: DCGU
Transplant Program (Organ): Liver
Release Date: July 6, 2022
Based on Data Available: April 30, 2022

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

C. Transplant Information

Table C7. Adult (18+) 1-year survival with a functioning graft
Single organ transplants performed between 01/01/2019 and 03/12/2020, and 06/13/2020 and 06/30/2021
Deaths and retransplants are considered graft failures
Follow-up ends on 3/12/2020 for recipients transplanted prior to 3/13/2020

	DCGU	U.S.
Number of transplants evaluated	205	17,361
Estimated probability of surviving with a functioning graft at 1 year (unadjusted for patient and donor characteristics)	90.97%	92.28%
Expected probability of surviving with a functioning graft at 1 year (adjusted for patient and donor characteristics)	91.24%	--
Number of observed graft failures (including deaths) during the first year after transplant	16	1,106
Number of expected graft failures (including deaths) during the first year after transplant	14.29	--
Estimated hazard ratio*	1.10	--
95% credible interval for the hazard ratio**	[0.65, 1.67]	--

Figure 3 below shows Liver Patient Survival for the three major area programs.

Figure 3

SRTR SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

University of Maryland Medical System
Center Code: MDUM
Transplant Program (Organ): Liver
Release Date: July 6, 2022
Based on Data Available: April 30, 2022

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

C. Transplant Information

Table C16. Adult (18+) 1-year patient survival
Single organ transplants performed between 01/01/2019 and 03/12/2020, and 06/13/2020 and 06/30/2021
Retransplants excluded
Follow-up ends on 3/12/2020 for recipients transplanted prior to 3/13/2020

	MDUM	U.S.
Number of transplants evaluated	190	16,729
Estimated probability of surviving at 1 year (unadjusted for patient and donor characteristics)	86.22%	94.25%
Expected probability of surviving at 1 year (adjusted for patient and donor characteristics)	93.89%	--
Number of observed deaths during the first year after transplant	19	768
Number of expected deaths during the first year after transplant	9.17	--
Estimated hazard ratio*	1.88	--
95% credible interval for the hazard ratio**	[1.16, 2.76]	--

SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

Johns Hopkins Hospital
Center Code: MDJH
Transplant Program (Organ): Liver
Release Date: July 6, 2022
Based on Data Available: April 30, 2022

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

C. Transplant Information

Table C16. Adult (18+) 1-year patient survival
Single organ transplants performed between 01/01/2019 and 03/12/2020, and 06/13/2020 and 06/30/2021
Retransplants excluded
Follow-up ends on 3/12/2020 for recipients transplanted prior to 3/13/2020

	MDJH	U.S.
Number of transplants evaluated	231	16,729
Estimated probability of surviving at 1 year (unadjusted for patient and donor characteristics)	94.69%	94.25%
Expected probability of surviving at 1 year (adjusted for patient and donor characteristics)	94.64%	--
Number of observed deaths during the first year after transplant	9	768
Number of expected deaths during the first year after transplant	9.89	--
Estimated hazard ratio*	0.93	--
95% credible interval for the hazard ratio**	[0.46, 1.55]	--

SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

Medstar Georgetown Transplant Institute
Center Code: DCGU
Transplant Program (Organ): Liver
Release Date: July 6, 2022
Based on Data Available: April 30, 2022

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

C. Transplant Information

Table C16. Adult (18+) 1-year patient survival
Single organ transplants performed between 01/01/2019 and 03/12/2020, and 06/13/2020 and 06/30/2021
Retransplants excluded
Follow-up ends on 3/12/2020 for recipients transplanted prior to 3/13/2020

	DCGU	U.S.
Number of transplants evaluated	197	16,729
Estimated probability of surviving at 1 year (unadjusted for patient and donor characteristics)	92.09%	94.25%
Expected probability of surviving at 1 year (adjusted for patient and donor characteristics)	93.55%	--
Number of observed deaths during the first year after transplant	13	768
Number of expected deaths during the first year after transplant	9.98	--
Estimated hazard ratio*	1.25	--
95% credible interval for the hazard ratio**	[0.70, 1.96]	--

Dr. Fishbein has recruited an extraordinary team of seven surgeons who are fully trained in all aspects of organ transplantation including liver, as well as hepatobiliary surgery (surgery involving the liver, pancreas and biliary tract). A large team of Advanced Practice Providers (APPs) supplement the surgical team.

In addition, through a team of eight fellowship-trained, highly experienced transplant hepatologists led by Rohit S. Satoskar MD, a nationally regarded transplant hepatology expert who trained at the University of Chicago Hospitals, patients can be evaluated for transplant within two weeks of referral, at one of a variety of MedStar sites located across the Baltimore-Washington region. One of the fully trained transplant hepatologists has been engaged full-time at MFSMC for several years, to provide prompt on-site expertise in evaluating patients with advanced liver disease and failure, both outpatient and inpatient.

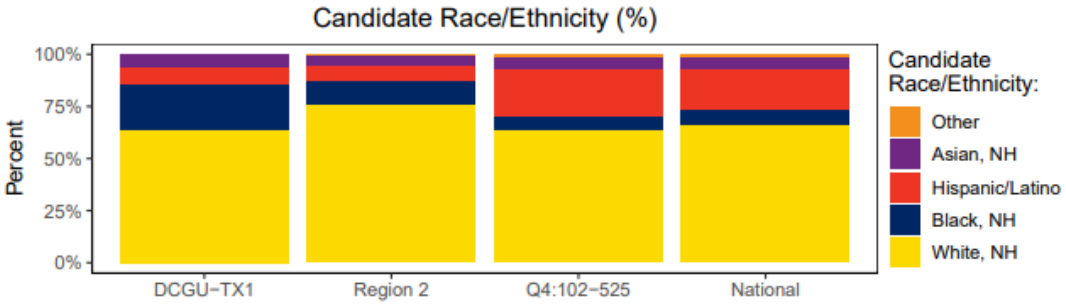
Clinical Research

MGTI is committed to advancing the field of transplantation, which it accomplishes through its strict attention to excellence in clinical care while maintaining an active research enterprise through the Center for Translational Transplant Medicine (CTTM), a multi-disciplinary approach to transplantation research which was founded in collaboration with Georgetown University in 2013. A list of ongoing research is provided as Attachment A.

Minority Patients

MGTI is a leader in the transplantation of minority candidates. Although it has been noted that these candidates may not receive transplants as quickly as do non-minority candidates, transplant registry data (SRTR) show that MGTI has both wait-listed and transplanted more minority (African American, Hispanic/Latino, Asian, Other) liver candidates than regional and national averages (see Figures 4 and 5 below). By contrast, both current programs in Baltimore transplant minorities at significantly lower rates than the MGTI program despite the large minority population in Baltimore. More than 36% of candidates are minorities compared with a regional average of 23% and a national average of 32%. The percentage transplanted is even higher, with almost 44% falling into a minority category, versus 23% regionally and 32% nationally. MGTI is committed to providing access to these populations in both Washington and Baltimore metropolitan areas. Patients being seen at the MFSMC advanced liver disease clinic fall into a similar profile.

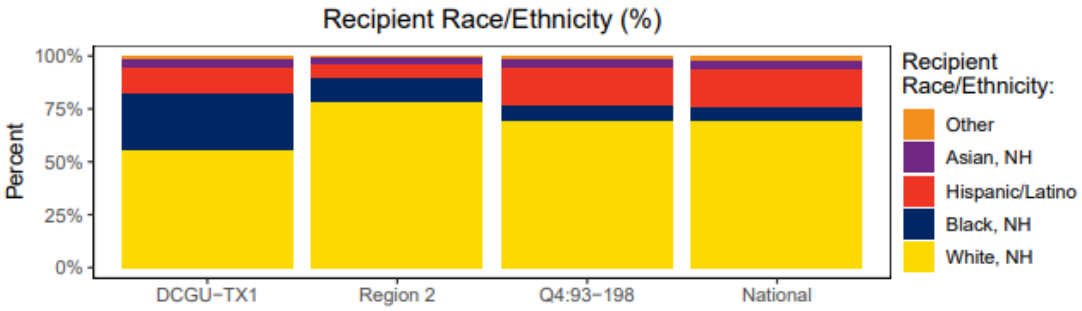
Figure 4



	DCGU-TX1	Region 2	Q4:102-525	National
White, NH	63.68%	76.15%	64.02%	66.47%
Black, NH	22.11%	10.84%	6.32%	6.82%
Hispanic/Latino	8.42%	7.98%	22.92%	20.17%
Asian, NH	5.79%	4.44%	5.51%	4.96%
Other	0.00%	0.60%	1.22%	1.59%
Total	100.00%	100.00%	100.00%	100.00%

Figure 2 displays the distribution of age and race/ethnicity for all liver candidates waiting on September 30, 2022. While 46.92% of candidates waiting nationally were 50-64, 27.75% were 65+ years old. Overall, White, NH candidates were the majority, followed by Hispanic/Latino, Black, NH, and Asian, NH candidates. Nationally, Other racial and ethnic groups accounted for 1.59% of the waiting list.

Figure 5



	DCGU-TX1	Region 2	Q4:93-198	National
White, NH	55.34%	78.80%	69.90%	69.26%
Black, NH	27.18%	10.79%	6.79%	7.00%
Hispanic/Latino	11.65%	6.24%	17.73%	17.64%
Asian, NH	4.85%	3.90%	4.46%	4.26%
Other	0.97%	0.26%	1.12%	1.84%
Total	100.00%	100.00%	100.00%	100.00%

Figure 2 displays the distribution of age and race/ethnicity for all recipients of liver transplants performed between July 1, 2021 and June 30, 2022. While 44.51% liver transplants nationally were performed on recipients ages 50-64, 21.81% were performed on recipients 35-49 years old. Overall, the majority of liver transplants were performed on White, NH recipients, followed by Hispanic/Latino, Black, NH, and Asian, NH recipients. Nationally, Other racial and ethnic recipients accounted for 1.84% of liver transplants.

Other Key Transplant Statistics

Median Time to Transplant**.** *Median Time to Transplant* is a measure of time awaiting transplant. The graphic below shows a comparison of the interval from listing to transplantation in months among the 3 major centers:

Figure 6

Months to Transplant at 50th percentile of patients.

SRTR July 2022	**MGTI**	**JHH**	**UMMS**
50th percentile	9.3	12.1	10.4

Source: SRTR July 2022

Transplant Rate. *Transplant Rate* is a measure of how frequently patients undergo transplant per every 100 patients per year waiting. Both living and deceased donor transplants are counted. MGTI's Rate of Transplantation is higher than other Maryland transplant Centers. For example, the transplant rate for MGTI is 54 while the JHH rate is 37 and the UMMS rate is 30. MGTI patients are evaluated and listed for transplant in a timely manner that enables a short interval between listing and organ availability, with attention to ensuring an optimal outcome.

MedStar Franklin Square Medical Center

MFSMC is a 354-bed hospital, and one of the largest in both Baltimore county and the state of Maryland based on annual admission volume. MFSMC is a community hospital with over 50 years of service in the area. In recent years it has added an increasingly complex set of services that, given its profile, can be offered at lower cost than the same services provided at an academic medical center.

MFSMC offers an impressive array of tertiary services, including:

- C-PORT service for acute cardiac intervention;
- Recent MHCC approval to expand to CPORT-E service provision, with a robust elective cardiac catheterization program now underway;
- A Level III Neonatal Intensive Care Unit;
- A Thrombectomy capable Stroke Center, approved by The Joint Commission and MIEMSS, as a pathway to Comprehensive Stroke Certification (CSC).
- A new rooftop helipad that in its first two years of operation has enabled a nearly ten-fold increase in the numbers of critical care transfers to the facility. The helipad is located directly above the Emergency Department, ICUs, and OR pavilion providing patients with immediate direct access to these areas.

MFSMC was chosen by MedStar Health as the preferred hospital location for an integrated, Baltimore-based, liver transplant program. This is based on the capabilities listed above, as well as the availability of sophisticated critical care resources, advanced Oncology and Gastroenterology programs, strong GME training programs in Internal Medicine, Family Practice, and General Surgery and one of the busiest emergency departments in the state. MFSMC is an ideal site for the location of a new transplant center for liver diseases given its busy center for the diagnosis and treatment of digestive diseases. Its relative distance from the two centers operating currently in Baltimore offers an additional convenient resource for area residents. Over the last year, MedStar Health has initiated a hepato-biliary transplant program at the site, led by a fully trained liver transplant surgeon.

In 2020, the hospital opened 14 new operating rooms (ORs), augmenting the footprint in a new state-of-the-art pavilion built specifically for that purpose. The new ORs are vastly improved in terms of space and technological capabilities. With respect to transplantation, a specially designed 835 square foot suite affords adequate space to accommodate the large pieces of equipment that are needed, with an adjacent fully prepped ~210 square foot positive pressure laminar flow “back table room” where organ preparation can be completed. It has been designed to accommodate additional lighting and a boom for equipment when the need presents.

Advanced Liver Disease Treatment at MFSMC. MedStar Health has deployed a full-time, board certified hepatologist on-site to identify patients with advanced liver disease toward advancing their treatment as early as possible. As well, MedStar Health has in-house radiologic support for interventional radiologic procedures (IR) required by these types of patients for diagnosis and treatment.

As shown in the figure below, patients needing transplantation currently are being transferred to MGTI for listing and transplantation. Far better for the patients and the state would be the inception of a new fully equipped liver transplant program at MFSMC. Patients and physicians in the local vicinity and beyond are enthusiastic about the potential of improved access - and convenience - to a top tier transplant center in the community.

Figure 7

Transfers to MGTI for Liver Transplant

Listed	2017	2018	2019	2020	2021
Total	26	35	22	26	31

Transplanted	2017	2018	2019	2020	2021
Total	16	8	6	18	19

Commitment to Population Health

MedStar Health's strategy to manage population health is based on its continued development of a distributed care delivery network (DCDN) through providing broad access for the patients served by MedStar Health. The essential concept is that services are provided to patients closer to home, rather than have them travel. This objective is accomplished by situating new and existing services across the service area. MedStar Health has accomplished this goal very effectively in Maryland, the District of Columbia, and Northern Virginia through a variety of clinical outpatient sites, physician practices, rehabilitation locations and more. Specific to transplant, MedStar Health has several outpatient evaluation sites already and should the Certificate of Need be granted, will be planning to expand to more local Baltimore locations.

In addition to the build out of the DCDN, MedStar has continued to increase the number of covered lives for which it is responsible overall, and specifically in the Baltimore area, through the inception of insurance products, which include *MedStar Select* and *MedStar Family Choice*. MedStar Health has participated in the state's Health Choice program since 1997 and has consistently provided high quality and cost-effective care to its enrollees. Today, *MedStar Family Choice* is at risk for providing care for almost 110,000 Medicaid recipients, a 25% increase in enrolled lives since 2017. *MedStar Select*, an insurance product available to all MedStar Health associates, has broad participation. These programs require and pay significant attention to utilization management, effective transitions in care, risk, and illness stratification, and care coordination for the populations served, all elements essential to improving population health.

MedStar Health's plan to locate liver transplant services at MFSMC furthers its commitment to managing population health, as it ensures better access to needed services for the nearly 175,000 covered lives that MedStar manages in addition to the broader cohort of patients living with advanced liver disease in the Baltimore area. MedStar Health believes that continuity of care is essential to all patients, but especially for those with complicated medical conditions, such as liver diseases that require the input of multi-disciplinary specialists for both acute and long-term management. MedStar Health's broad network of providers in and around the Baltimore area has been built strategically to serve the broader Baltimore region, as described in the previous narrative.

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

MedStar Health's goal is to manage the Liver Transplant Program at MFSMC with all necessary resources, while keeping the financial overhead of the operation as lean as possible through sharing resources with the MGTI program in Washington, D.C. The expanded program - with two service sites - will prioritize quality of care and patient experience as well as superior clinical outcomes. As one example,

all data coordination and reporting, and Quality Assessment Performance Improvement (QAPI) indicator tracking (a UNOS requirement) will remain centralized under MGTI's seasoned leadership in Washington. Administrative leadership will be centralized at MGTI as well. All clinical staff at MFSMC will be tied closely to the central program at MGTI to share resources and provide experienced clinical expertise and support.

Since 2015, MedStar has been laying the groundwork to provide the full range of transplant-related services to those patients in need in the Baltimore region. To date, in anticipation of expanded services, MGTI has extended all services required for referral, triage, evaluation, and listing of transplant candidates to MFSMC. MGTI has also expanded follow up services required for the long-term maintenance of patient and organ health after transplantation. Building on MGTI's existing platform of highly effective clinical care, excellent graft and patient outcomes and efficient operations, MGTI expects to provide patients seeking transplantation at MFSMC with greater availability and access to the same level of quality available in Washington but at a lower cost relative to the two transplant programs in Baltimore.

MFSMC's lower cost position can be measured by both the HSCRC's equivalent case mix adjusted discharge (ECMAD) data showing the average charge per ECMAD as well as actual discharge data for transplants conducted at Johns Hopkins and the University of Maryland. The ECMAD data for fiscal year 2021 using HSCRC Abstract Tapes are as follows:

Figure 8
Average Charge per ECMAD Comparison

Provider	Charge Per ECMAD	%Higher Than MFSMC
UMMS	$20,526	21.4%
Johns Hopkins	$18,598	10.0%
State Average	$18,499	9.4%
MFSMC	$16,909	--

Source: HSCRC Abstract Tapes for FY 2021, excluding Oncology Drugs

With MFSMC proposed pricing at 25% below the lowest charge at Baltimore's academic medical centers, MFSMC can provide the following cost differential to Medicare, Medicaid, and commercial insurers, as shown below:

Figure 9

Average Charge per Case Comparison

Provider	Average Charge per Liver Transplant	% Higher Than MFSMC
Johns Hopkins	$ 260,867	33.3%
UMMS	$ 304,089	55.4%
MFSMC Projected	$ 195,650	--

Source: HSCRC case mix data FY 21

Integrated resources, well-developed facilities and applied technology enable MFSMC to extend the expertise of MGTI to the Baltimore region. At present, MFSMC maintains a 20-bed critical care unit directed by George Pyrgos MD, an experienced, Hopkins-trained, board-certified specialist in pulmonary and critical care medicine. MFSMC has dedicated a portion of the critical care unit as an intermediate care unit for liver transplant patients. MFSMC staff are fully trained by MGTI staff, who continue as an available resource. MGTI's Quality Assurance and Performance Improvement (QAPI) function has brought aboard personnel and systems for optimal training and maintenance of competencies for all MFSMC staff. MGTI and MFSMC will recognize cost savings because the MFSMC programs can leverage MGTI's existing staffing infrastructure. Also, the administrative and data collection and reporting functions will be based at MGTI toward effecting greater efficiency in operations.

Current operating room capabilities have been assessed and are more than adequate to sustain the case complexity anticipated. The new fourteen room operating suite that opened in July 2020, provides an enhanced environment of care and larger space to
accommodate needed equipment and technology for liver transplantation.

Summary

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

[Regarding questions related to Table B, and Questions 9, 10, 11,12 and 13, note that as these issues are irrelevant to the current project and not applicable, they have been deleted]

PART II - PROJECT BUDGET

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

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

Response:

MFSMC already owns several pieces of the equipment needed for the program. The liver transplant program will need to augment these only minimally as noted below, so that both OR and ICU are served, and back-up is available. Capital expenditures required for the liver transplant project are shown in Figure 10, and the Project Budget is shown in Figure 11, below.

Figure 10

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

Source: Internal MedStar Health/vendor data

[1]The TEG - Thromoblast Hemostasis Analysis System is a diagnostic instrument used in the OR and ICU to assess bleeding/blood clotting risk.

[2]GEMStat is another system used to assist with treating bleeding/coagulation issues.

Figure 11 Project Budget

PROJECT BUDGET			
INSTRUCTION : Estimates for Capital Costs (1.a-e), Financing Costs and Other Cash Requirements (2.a-g), and Working Capital Startup Costs (3) must reflect current costs as of the date of application and include all costs for construction and renovation. Explain the basis for construction cost estimates, renovation cost estimates, contingencies, interest during construction period, and inflation in an attachment to the application. See additional instruction in the column to the right of the table.			
NOTE : Inflation should only be included in the Inflation allowance line A.1.e. The value of donated land for the project should be included on Line A.1.a as a use of funds and on line B.8 as a source of funds			
	Hospital Building	***Other Structure***	***Total***
A. USE OF FUNDS			
1. CAPITAL COSTS			
a. New Construction			
(1) Building			$0
(2) Fixed Equipment			$0
(3) Site and Infrastructure			$0
(4) Architect/Engineering Fees			$0
(5) Permits (Building, Utilities, Etc.)			$0
SUBTOTAL	**$0**	**$0**	**$0**
b. Renovations			
(1) Building			$0
(2) Fixed Equipment (not included in construction)			$0
(3) Architect/Engineering Fees			$0
(4) Permits (Building, Utilities, Etc.)			$0
SUBTOTAL	**$0**	**$0**	**$0**
c. Other Capital Costs			
(1) Movable Equipment	$75,800		$75,800
(2) Contingency Allowance			$0
(3) Gross interest during construction period			$0
(4) Other *(Specify/add rows if needed)*			$0
SUBTOTAL	***$75,800***	***$0***	**$75,800**
TOTAL CURRENT CAPITAL COSTS	**$75,800**	**$0**	**$75,800**
d. *Land Purchase*			
e. Inflation Allowance			$0
TOTAL CAPITAL COSTS	**$75,800**	**$0**	**$75,800**
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	***$75,800***	***$0***	***$75,800***
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

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

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

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

   Stuart M. Levine MD
   President
   MedStar Franklin Square Medical Center
   9000 Franklin Square Drive
   Rosedale, Maryland 21237

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

   Stuart M. Levine MD
   President
   MedStar Harbor Hospital
   Baltimore, Maryland 21202
   February 1993 – May 2012

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

   No

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

findings of non-compliance and related documentation including reports of non-compliance, responses of the facility, and any final disposition or conclusions reached by the applicable authority.

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

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

No

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

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

President,
MedStar Franklin Square Medical Center

Stuart M. Levine MD
Printed Name

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

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

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

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

10.24.01.08G (3) (a). <u>The State Health Plan</u>.

COMAR 10.24.10: Acute Care Hospital Services

.04 Standards.

A. General Standards.

(1) <u>Information Regarding Charges.</u>

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

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

<u>Response</u>:

Regarding part (a) of the standard, MFSMC maintains a representative list of services and charges that is readily available to the public in written form on the hospital's web site at: https://*www.medstarhealth.org/price-transparency-disclosures*.

Please see previous application and all completeness information for full response to this standard.

(2) Charity Care Policy.

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

(a) The policy shall provide:

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

(ii) Minimum Required Notice of Charity Care Policy.

1. *Public notice of information regarding the hospital's charity care policy shall be distributed through methods designed to best reach the target population and in a format understandable by the target population on an annual basis;*
2. *Notices regarding the hospital's charity care policy shall be posted in the admissions office, business office, and emergency department areas within the hospital*
3. *Individual notice regarding the hospital's charity care policy shall be provided at the time of preadmission or admission to each person who seeks services in the hospital.*

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

Response:

Regarding part (a), MFSMC provides medical services to all patients regardless of their ability to pay. MFSMC posts formal notices in both English and Spanish at primary access points, including the main patient entrance, the Woman's Pavilion entrance, the ambulatory services entrance, the emergency department entrance, and all admitting/ registration areas, that it complies with the Omnibus Budget Reconciliation Act of 1989 (OBRA) and affirms MFSMC's obligation and commitment to treat emergent and acute patients regardless of the patient's ability to pay (see Attachment 3 for examples). The hospital also provides a one-page summary of its financial assistance policy to all patients who receive medical care. See *https://www.medstarhealth.org/financial-assistance-policy* for complete detail.

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

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

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

In the most recent HSCRC Charity Care Report (FY21), MFSMC was ranked in the bottom quartile of the

ratio of charity care dollars to total expenses among Maryland Acute Care Hospitals. The table below, compiled from Maryland Hospitals' Community Benefits Reports posted on the Health Services Cost Review Commission website, details the amount of charity care MFSMC provided in the FY19-22 period as well as its quartile ranking of charity care as a percentage of total operating expenses compared to other Maryland acute hospitals.

Figure 12

MFSMC Charity Care
Dollars of Care Provided & Ranking Among Maryland Hospitals FY 17-22

Source: http://hscrc.maryland.gov/init_cb.cfm
*TE = Total Operating Expenses

	FY2017	FY2018	FY2019	FY2020	FY2021	FY2022
Charity Care $	$ 5,147,814	$ 7,344,175	$ 10,276,998	$ 12,318,684	$ 9,875,732	$ 13,546,067
% Charity Care of TE	1.0%	1.4%	1.9%	2.2%	1.6%	2.4%
Maryland Quartile Rank	3rd	3rd	3rd	3rd	3rd	TBD

As the Figure indicates, the amount of charity care MFSMC provided to its community in the FY 17-22 period grew each year, both in absolute dollars of charity care and as a percentage of total MFSMC operating expenses, except for fiscal year 2021. The decline in fiscal year 2021 was temporary and occurred statewide as evidenced by MFSMC's consistent ranking in the 3rd quartile compared to other Maryland hospitals. This decline statewide is likely a result of the Covid-19 pandemic. In fiscal year 2022, charity care exceeded pre-pandemic levels, both in absolute dollars and as a percentage of total MFSMC operating expenses. It is also important to note that charity care expenditures have more than doubled since fiscal year 2017.

Figure 13
Maryland Hospital Gross Acute Inpatient Revenue by Selected Payer & Charity Care Expense
FY13-21

	Total Charges by Select Payer Categories for Statewide								
Payor Category	**FY 2013**	**FY 2014**	**FY 2015**	**FY 2016**	**FY 2017**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**
Medicaid FFS	634,069,220	643,800,595	592,591,352	602,243,787	522,550,524	552,021,724	540,332,309	546,801,954	545,882,461
Medicaid HMO	973,281,939	1,172,314,911	1,398,691,762	1,402,716,437	1,521,929,648	1,642,130,291	1,665,044,211	1,735,644,999	1,926,218,613
Total	**1,607,351,159**	**1,816,115,506**	**1,991,283,114**	**2,004,960,224**	**2,044,480,172**	**2,194,152,015**	**2,205,376,520**	**2,282,446,952**	**2,472,101,074**
Self Pay	373,921,430	230,355,022	112,069,758	106,848,140	89,846,841	94,254,661	95,821,477	133,131,748	172,689,122
Charity/ No Charge*	https://hscrc.maryland.gov/Pages/init_cb.aspx								

Source: Medicaid (FFS & HMO) and Self Pay - HSCRC Inpatient Discharge Data, FY 2013 - FY 2021; run on Oct 12 2022. Please note, the source data may have been updated for a variety of reasons and will differ from the results that were provided by the requestor.

	Total Charges by Select Payer Categories for MedStar Franklin Square Hospital								
Payor Category	**FY 2013**	**FY 2014**	**FY 2015**	**FY 2016**	**FY 2017**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**
Medicaid FFS	14,845,989	15,975,679	15,441,847	13,414,531	12,746,241	13,067,286	12,087,547	14,704,636	12,532,159
Medicaid HMO	36,240,435	47,609,724	63,638,218	61,781,660	62,664,621	69,642,143	69,230,406	77,245,550	76,183,570
Total	**51,086,424**	**63,585,404**	**79,080,065**	**75,196,191**	**75,410,862**	**82,709,429**	**81,317,953**	**91,950,186**	**88,715,729**
Self Pay	10,430,927	6,750,788	2,730,794	3,130,785	2,893,338	2,288,945	2,609,859	3,471,447	4,018,525
Charity/ No Charge*	https://hscrc.maryland.gov/Pages/init_cb.aspx								

Source: Medicaid (FFS & HMO) and Self Pay - HSCRC Inpatient Discharge Data, FY 2013 - FY 2021; run on Oct 12 2022. Please note, the source data may have been updated for a variety of reasons and will differ from the results that were provided by the requestor.

(3) Quality of Care.

An acute care hospital shall provide high quality care.

(a) Each hospital shall document that it is:

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

(ii) Accredited by the Joint Commission; and

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

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

Response:

MFSMC collects and reviews its quality performance data monthly to monitor and improve its performance. These measures include Serious Safety Events, Acute Care Core Measures, and Patient and Employee Safety Measures. See Attachment x for a fuller description of MFSMC's approach to Quality and Safety. MFSMC was most recently granted accreditation by The Joint Commission (TJC) in July 2022 and is licensed through the Department of Health and Mental Hygiene.

COMAR 10.24.15: Organ Transplant Services

A. General Standards

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

Response:

MFSMC complies with this standard.

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

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

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

Response:

Regarding part (a), MFSHC agrees to comply and maintain compliance with all requirements of CMS and

UNOS certification for its proposed transplant program and to be certified by UNOS within the first year of operations.

Part (b) does not apply to this project.

B. Project Review Standards

(1) Need

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

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

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

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

Response

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

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

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

(1) Reducing the demand for donor organs through:
   a. Medical management with intervention as appropriate.
   b. Advancements in clinical research related to cellular therapy/bio-artificial liver see clinical research, Attachment A.

(2) Increasing the supply of donor organs:
   a. Active participation in, and support of the local organ procurement organization.

b. Application of expanded donor criteria.
c. Broader application of advanced surgical techniques.
d. Expansion of living donor transplant options
e. Clinical research initiatives aimed at improving the viability of marginal donor organs.

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

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

Medical treatment of patients with Hepatitis C viral infection (HCV) and other advanced liver diseases can reduce the need for liver transplantation, thus increasing the supply of donor organs for other transplant candidates. The development of all-oral, interferon-free regimens for the treatment of HCV was a breakthrough in the treatment of this type of liver disease, affecting both aspects of the program's equation. HCV has historically been the single leading indication for liver transplant and the cause of more deaths in the United States today than HIV. Viral infection with HCV can lead to cirrhosis and hepato-cellular carcinoma but is curable with all-oral, well-tolerated medications. The FDA approved medications now include pangenotypic regimens which will cure themajority of those who are treated.

The treatment and cure of HCV leads to a diminished need for liver transplant in those patients. Though it is difficult to quantify the decrease in the need for donor livers because of these interventions, this medical treatment frees up donor organs for patients whose liver disease cannot be treated medically and whose only recourse is transplantation. MGTI's widespread use of these treatment regimens, combined with its medical expertise and community outreach, serves to reduce the demand for liver transplants.

As part of its efforts to reduce the need for liver transplantation, MGTI has worked to greatly expand community outreach through a *Liver Screening Program* to detect Hepatitis B virus (HBV) infection and HCV infection, as well as non-alcoholic fatty liver disease (NAFLD). It was the first of its type in the mid-Atlantic region, and MGTI and MFSMC plan to resume offering this community outreach in the MFSMC area now that the Covid pandemic has receded. The program aims to identify "at risk" individuals and get them into treatment early. The program provides free screening for individuals who live in areas with an expected high prevalence of liver disease (*e.g.*, those of Asian descent) and others that also have a higher prevalence of viral hepatitis but are generally under-diagnosed. Moreover, the program also offers social and financial screening services aimed at enrolling underserved patients into health insurance programs forwhich they may qualify, but about which they may lack awareness. Because Fairfax and Loudoun Counties in Virginia and Montgomery County in Maryland have high percentages of Asians (at last count, almost 400,000 collectively), MedStar focused on these areas for outreach to primary audiences, community gatherings, faith-based organizations - as well as primary care physicians and clinics in the D.C. Metropolitan Area. The Baltimore region will be targeted similarly. The strategy also includes one-on-one outreach by a dedicated Liver Screening Program Coordinator. Finally, the program also targets individuals who exhibit behaviors that may place them at a higher risk. HCV is a major public health issue, and screening programs such as that sponsored by MGTI have been recommended by the US Preventive Services Task Force.

Again, MGTI intends to resume (temporarily interrupted by COVID-19) providing free testing both in its clinic settings and at community fairs. Testing includes evaluation of HBV, HCV and abnormal ALT which may be a marker of non-alcoholic fatty liver disease (NAFLD). NAFLD affects greater than 30% of the US population and is largely undiagnosed. Cirrhosis related to NAFLD remains one of the most common indications for liver transplantation and the most common reason for liver transplant in those older than 65. If testing is reactive, patients are offered a free consultation followed by linkage to care either within MedStar or in the community. By identifying these at-risk patients, they will have access to integrated

therapies including management of underlying comorbidities, nutritional management, and bariatric surgery, all aimed at reducing progression of liver disease. More than 650 individuals were screened in the first year of the program with a goal of more than 1,000 per year.

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

(2) Increasing the supply of donor organs

a. Active participation in the Organ Procurement Organization

MedStar Health is cognizant of the critical role that community hospitals play in the supply of life-saving deceased donor organs; its four Baltimore region hospitals all have systems in place to ensure support of the donor identification and retrieval efforts of the *Infinite Legacy*, the newly merged Baltimore-Washington regional Organ Procurement Organization.

The same can be said for MedStar Health's six hospitals including MedStar Washington Hospital Center, a trauma center, and the largest contributor of donor organs in the Washington region. MedStar Health supports Organ Procurement Organizations (OPOs) by ensuring that candidates for transplantation have access to as many organs from deceased donors as possible from its own hospitals.

As a system, MedStar Health is very invested in, and supportive of, its organ donation committees and seeks regular input from the leadership of those groups which are comprised of critical care medicine specialists, nursing managers, social workers, and other interested parties. MGTI leadership participates in advancing and supporting the objectives of the OPO. MedStar Health believes that the creation of a liver transplant program at MFSMC serves to focus greater attention on organ donation at its Baltimore-area hospitals and in the identification and retrieval of more organs.

b. Expanded donor criteria (EDC) for transplantation

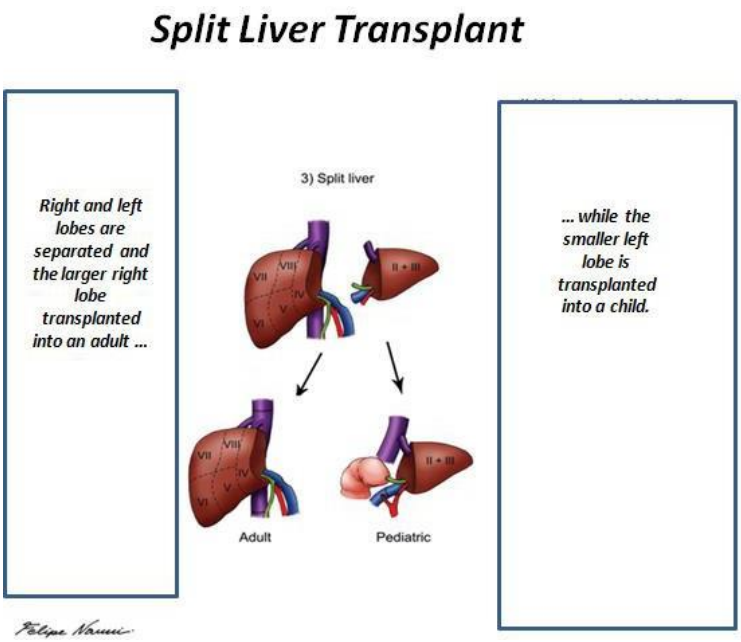
Due to the ongoing problem of donor organ supply, national attention over the last decade has been given to ascertaining whether the established criteria for determining deceased donor suitability are appropriate. After much debate, experts from around the country have reached agreement that certain criteria previously considered exclusionary, including older donors, those with certain systemic illnesses, exposure to infectious diseases, etc., should be reconsidered in a manner that is compatible with recipient clinical characteristics. Matching donor risk to recipient risk factors is critical to the success of this approach, and MGTI clinical expertise enables it to make full use of EDC. protocols for patients. To further expand the donor pool, MGTI continues to evaluate and transplant organs from HCV positive donors into appropriate HCV negative recipients. If transmission of HCV occurs, the recipient is treated with an oral regimen which to date has resulted in universal cure of HCV and no consequence for graft or patient survival. These same protocols will be applied as part of the MFSMC program, with the same anticipated results.

c. Clinical Innovation at MGTI.

Dr. Fishbein's experience with *partial and split liver transplantation* has substantially augmented the number of organs available for recipients in need. In addition, the liver transplant service continues to expand its active living donor liver program to address the shortage of available cadaveric organs.

Split Liver Transplantation. A particularly innovative method of expanding the use of deceased donor organs, is to divide the available organ into segments that can be transplanted into more than one recipient. In this procedure, the largest segments of the liver are separated, and the segmented lobes are then transplanted into two individual recipients (see diagram below).

Figure 14



The operation has the effect of creating two transplantable donor organs out of one donor organ.

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

d. Living Donor Transplantation

MGTI offers living donor transplantation to selected candidates at MGTI and, through its considerable research and experience, MGTI is at the forefront of living donor liver transplantation, a clinical practice available to selected patients at most sophisticated transplant Centers. Living donor transplant involves taking a segment of a living donor's liver and transplanting into a matching recipient. Because the liver has the unique ability to regenerate to full size over time after removal of a segment and to grow to full size after transplantation of a segment, living donor transplantation has become a viable option for individuals who have a relative or friend who is a suitable match and is willing to donate part of his or her organ.

MGTI's Living Donor Program will work to enhance community awareness of the need for liver transplantation and the life-giving solution that is offered through living donation in the Baltimore region. Importantly, the program offers donor and recipient "navigation" services by a registered nurse who helps guide patients through all phases of the donation process from initial interest in donation to the decision point of making a living donation. Figure 15 shows MGTI outcomes versus Baltimore area Centers.

Figure 15
Living Donor Transplantation Survival Among Area Centers

SCIENTIFIC REGISTRY of TRANSPLANT RECIPIENTS

University of Maryland Medical System
Center Code: MDUM
Transplant Program (Organ): Liver
Release Date: July 6, 2022
Based on Data Available: April 30, 2022

SRTR Program-Specific Repc
Feedback?: SRTR@SRTR.or
1.877.970.SRTR (7787)
http://www.srtr.org

C. Transplant Information

Table C7L. Adult (18+) 1-year survival with a functioning living donor graft
Single organ transplants performed between 01/01/2019 and 03/12/2020, and 06/13/2020 and 06/30/2021
Deaths and retransplants are considered graft failures
Follow-up ends on 3/12/2020 for recipients transplanted prior to 3/13/2020

	MDUM	U.S.
Number of transplants evaluated	16	1,036
Estimated probability of surviving with a functioning graft at 1 year (unadjusted for patient and donor characteristics)	93.75%	92.32%
Expected probability of surviving with a functioning graft at 1 year (adjusted for patient and donor characteristics)	92.33%	–
Number of observed graft failures (including deaths) during the first year after transplant	1	61
Number of expected graft failures (including deaths) during the first year after transplant	0.91	–
Estimated hazard ratio*	1.03	–

SCIENTIFIC REGISTRY of TRANSPLANT RECIPIENTS

Johns Hopkins Hospital
Center Code: MDJH
Transplant Program (Organ): Liver
Release Date: July 6, 2022
Based on Data Available: April 30, 2022

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

C. Transplant Information

Table C7L. Adult (18+) 1-year survival with a functioning living donor graft
Single organ transplants performed between 01/01/2019 and 03/12/2020, and 06/13/2020 and 06/30/2021
Deaths and retransplants are considered graft failures
Follow-up ends on 3/12/2020 for recipients transplanted prior to 3/13/2020

	MDJH	U.S.
Number of transplants evaluated	35	1,036
Estimated probability of surviving with a functioning graft at 1 year (unadjusted for patient and donor characteristics)	96.77%	92.32%
Expected probability of surviving with a functioning graft at 1 year (adjusted for patient and donor characteristics)	92.33%	–
Number of observed graft failures (including deaths) during the first year after transplant	1	61
Number of expected graft failures (including deaths) during the first year after transplant	1.97	–
Estimated hazard ratio*	0.75	–

SCIENTIFIC REGISTRY of TRANSPLANT RECIPIENTS

Medstar Georgetown Transplant Institute
Center Code: DCGU
Transplant Program (Organ): Liver
Release Date: July 6, 2022
Based on Data Available: April 30, 2022

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

C. Transplant Information

Table C7L. Adult (18+) 1-year survival with a functioning living donor graft
Single organ transplants performed between 01/01/2019 and 03/12/2020, and 06/13/2020 and 06/30/2021
Deaths and retransplants are considered graft failures
Follow-up ends on 3/12/2020 for recipients transplanted prior to 3/13/2020

	DCGU	U.S.
Number of transplants evaluated	6	1,036
Estimated probability of surviving with a functioning graft at 1 year (unadjusted for patient and donor characteristics)	100.00%	92.32%
Expected probability of surviving with a functioning graft at 1 year (adjusted for patient and donor characteristics)	92.33%	–
Number of observed graft failures (including deaths) during the first year after transplant	0	61
Number of expected graft failures (including deaths) during the first year after transplant	0.36	–
Estimated hazard ratio*	0.85	–

MGTI has deployed a fully trained transplant surgeon, who currently has oversight of hepato-biliary surgery at MFSMC. He has been active at MGTI for 5 years and his expertise will be extended to MFSMC. Living donor transplantation will be offered on-site at MFSMC when clinically appropriate and safe.

e. MGTI Clinical Developments Advancing the Field of Liver Transplantation

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

Since its inception, CTTM has managed a large portfolio of clinical research studies, which are listed in Attachment A. Clinical research involves the following areas of investigation:

- Reducing delayed graft function, rejection, and organ failure. Current clinical and basic research activities aimed at prolonging graft function and survival by finding:
- Strategies to minimize post-transplant CMV infections
- Novel immunosuppressive strategies to avoid organ injury and increase graft survival times including novel immunotherapy approaches that prevent allograft rejection and inflammation as well as enable graft acceptance and tolerance
- Increased opportunities for transplant for patients with Hepatitis C and HIV
- Optimizing patient outcome and the use of marginal donor livers by minimizing ischemic reperfusion injury (IRI) and allowing performance monitoring of donor livers through normothermic machine perfusion with the *OrganOx Metra System*. Historically, organs for transplant have been preserved using cold storage. Increasing data now show that the use of these systems instead of standard cold storage can reduce early allograft dysfunction thus improving patients' outcomes especially when using marginal donor organs.
- Increasing the use of marginal organs through understanding pathways of inflammation that lead to failure of marginal donor livers by studying protective and proinflammatory immunological mechanisms behind liver Ischemic/Reperfusion Injury (IRI) in fatty donor livers.
- Limiting IRI through immunotherapy – the goal of this project – would enlarge the pool of organs that result in successful transplantation, for example, organs that are currently being *discarded* – for fear of triggering IRI – could be used.

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

Response:

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

MedStar Health has existing patients who can benefit from the MFSMC program. MGTI currently provides an unparalleled quality of care for liver transplant services, but its distance from Baltimore is a geographical challenge for many. MGTI currently has 69 patients wait-listed for liver transplant from Maryland counties that orient to Baltimore (i.e., excluding Montgomery County). Those transplant operations could take place at MFSMC, within their home state, Maryland, and closer to their local community.

The table below details liver transplant volume for the area's two current transplant centers in the CY17-CY21 period. As the data indicate, the volume of liver transplants at both centers far exceeds the minimum transplant volume requirement per COMAR 10.24.15.

Figure 16
Liver Transplants
University of Maryland/Johns Hopkins
Actual Adult Volume to Minimum Annual Case Volume Standard

Metric	Volume	UMMS CY17	UMMS CY18	UMMS CY19	UMMS CY20	UMMS CY21	JHH CY17	JHH CY18	JHH CY19	JHH CY20	JHH CY21
Liver	12	161	112	94	87	97	99	115	113	104	134
Variance from Min.	-	149	100	82	75	85	87	103	101	92	122
% Variance from Min.	-	1241%	833%	683%	625%	708%	725%	858%	842%	766%	1016%

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

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

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

In summary, bringing the clinical expertise of MedStar Health's MGTI, a nationally recognized organ transplant provider, to MFSMC will provide an additional option for liver transplantation to Central Maryland residents , helping to reduce demand and increase the supply of livers for those in need. As described above, MGTI will bring expert medical management, and expanded community outreach opportunities such as free screenings and at-risk patient identification programs to help reduce demand.

It will also focus greater attention on organ donation at MedStar's Baltimore-area hospitals and in the identification and retrieval of more organs. MFSMC will be participating in more clinical research as well as the surgical innovations such as expanded donor criteria, partial and split liver and living donor transplants. These approaches will directly impact the patients seeking liver transplant who are located in the Central Maryland region. Providing this choice to Maryland residents also importantly also provides a lower cost alternative to payers, as described elsewhere.

(2) Minimum Volume Requirements

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

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

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

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

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

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

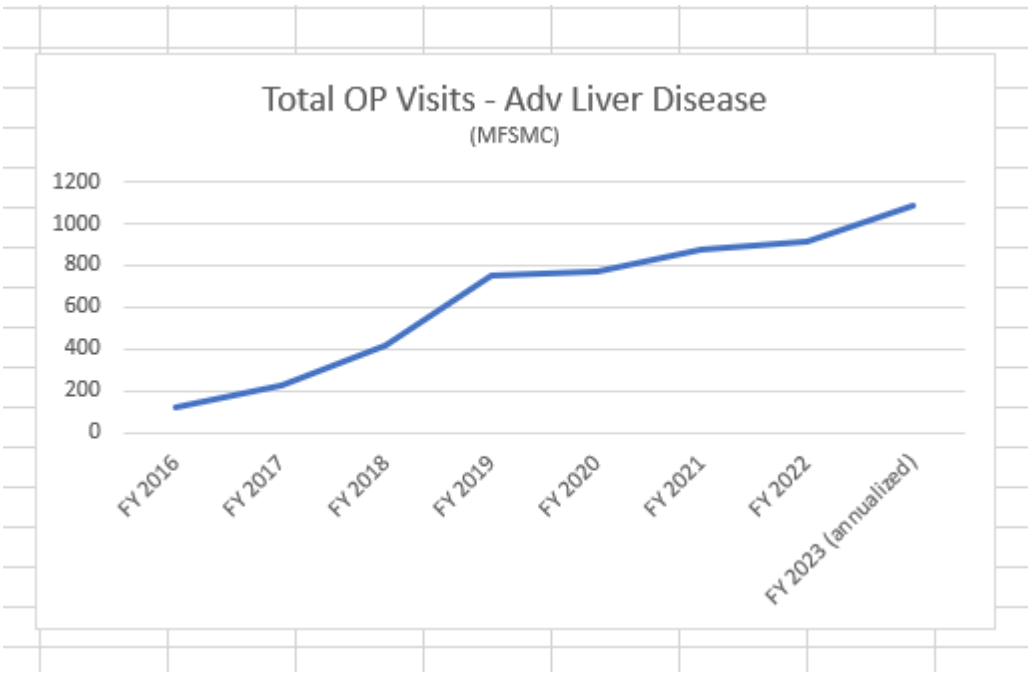
Response:

The minimum volume requirement for liver transplantation is twelve per year. The gastroenterologists associated with the MedStar Health Baltimore hospitals (MFSMC, MedStar Good Samaritan Hospital, MedStar Harbor Hospital and MedStar Union Memorial Hospital) as well as community gastroenterologists, maintain large and diverse medical practices and this fact, together with the amount of liver disease in the MedStar network – and broader patient population - prompted MGTI to establish an Advanced Liver Disease Center at MFSMC in July 2015. In FY2022, the Advanced Liver Disease center saw 912 confirmed patient visits, a 4.5% increase over the previous year. Growing demand for this service at MFSMC resulted in MedStar expanding clinic hours to a current frequency of four days weekly. Overall, clinical volume by July 2023 is anticipated at an 89% growth since clinic inception. An inpatient consultation service for liver diseases is active, increasing the level of care for high acuity liver patients in the hospital. This service is staffed by a full-time hepatologist with advanced practice clinician support.

Volume at MedStar's other centers for advanced liver disease has been growing steadily as shown below in Figure 17. MGTI's Frederick site has shown year-over year growth of 92% in patients seen with advanced liver disease. MGTI also has sites in Annapolis and Ellicott City.

Figure 17 Advanced Liver Disease Clinic Volume Trend at MFSMC

FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023 (annualized)
118	**228**	**422**	**748**	**767**	**873**	**912**	1086



Since Frederick, Annapolis and the Ellicott City locations lie roughly equidistant from Baltimore and Washington, D.C., MedStar patients identified as candidates for liver transplant will have the option to have the procedure at MGTI in Washington, D.C. or MFSMC in Baltimore, through dual listing in both Donation Service Areas (DSA).

Innovation in medical management of liver disease and surgical approaches as described earlier, combined with the ongoing collaboration between MedStar hospitals' donation committees and the OPO, position MFSMC for an increase the supply of transplantable organs available for patients in Baltimore region. Together with the opening of four MedStar Advanced Liver Disease clinics, , MFSMC is confident in the assumption that it will easily exceed the 12-case minimum annual case volume requirements of COMAR 10.24.15B(2) in both year 2 (FY20) and year 3 (FY21) of the program and will grow beyond that volume thereafter.

Summary

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

- Individual candidates for transplantation that have been listed with MGTI will be offered the

advantage of dual listing with two DSAs.

- Patients are being served currently through the variety of Advanced Liver Disease Centers and other sites of care, medical and ancillary providers and services, tele-health communication and community resources.
- The provision of additional services and resources closer to patients' homes and families advantages them greatly.
- MFSMC will offer the same level of innovative medical management, pharmacotherapy and advanced surgical techniques that have extended organ access to patients transplanted at MGTI.
- MFSMC is a lower cost environment than an academic medical center, advantageous financially to state and federal budgets.
- The advantages of managing MedStar Health's own population's health through quality, continuity and efficiency cannot be understated. MedStar should be able to offer its patients full access, closer to home, for all their health care needs, including transplantation.

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

(3) Access

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

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

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

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

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

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

Response:

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

Regarding part (b), this item is not applicable because MFSMC is not seeking to justify the need for an additional transplant program based on barriers to access.

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

(4) Cost Effectiveness

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

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

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

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

Response:

(a) As discussed in the Comprehensive Project Description, above, MedStar Health's innovative surgical approaches offer additional options to patients. In addition, MedStar has demonstrated the ability to serve a much greater percentage of minority patients than either of the existing programs in Baltimore.

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

(c) See the Attachment 1 to original application, *Table H, Revenues & Expenses, Inflated*.[1] As already noted, MFSMC is a community teaching hospital. MFSMC has a lower cost structure and charge per case than the area's two academic medical centers which currently provide transplant services. By integrating with the existing MGTI infrastructure, MFSMC can deliver the service in a highly cost-effective manner.

[1] MedStar Health incorporates by reference the attachments to its August 2017 application.

Figure 8
Average Charge per ECMAD Comparison

Provider	Charge Per ECMAD	%Higher Than MFSMC
UMMS	$20,526	21.4%
Johns Hopkins	$18,598	10.0%
State Average	$18,499	9.4%
MFSMC	$16,909	--

Source: HSCRC Abstract Tapes for FY 2021, excluding Oncology Drugs

MFSMC can provide the following pricing differential as shown below:

Figure 9
Average Charge per Case Comparison

Provider	Average Charge per Liver Transplant	%Higher Than MFSMC
Johns Hopkins	$ 260,867	33.3%
UMMS	$ 304,089	55.4%
MFSMC Projected	$ 195,650	--
Source: HSCRC case mix data FY 21		

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

Although transplant surgery is a clinically resource-intensive, high-cost process, patients with advanced liver disease who do not receive transplants will require intense medical management including periodic intervention. Processes of care may involve ED visits, multiple hospital admissions inclusive of ICU days, and repeated diagnostic and therapeutic procedures. These alternative costs must be considered in the assessment of the cost effectiveness of the MFSMC transplant program initiation.

Considering all these factors, MedStar Health has shown that its proposed program will result in a net reduction in health care expenditures for patients with advanced liver disease.

(5) Impact

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

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

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

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

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

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

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

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

Response:

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

(6) Certification and Accreditation

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

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

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

Response:

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

(7) Health Promotion and Disease Prevention

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

Response:

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

(8) Comparative Reviews

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

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

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

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

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

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

Response: Not applicable.

10.24.01.08G (3) (b). Need.

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

RESPONSE:

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

- The introduction of a new program that offers additional innovation in clinical care, medical therapy, surgical approaches, and clinical research for residents of the state of Maryland needing a transplant.
- MedStar Health's successful record in transplanting minority populations at MGTI and its payor mix at the liver disease clinic at MFSMC provides evidence that this population will have open access to the program.
- By integrating the services at MFSMC with MGTI, and providing transplant services at MFSMC, a lower cost community teaching hospital, MedStar can minimize program overhead and streamline care based on evidence-based best *practices. This approach will result in a high-quality, lower-cost program that benefits the system and ultimately the State of Maryland.
- MedStar Health has a "population health" focus that involves caring for its patients through the continuum – from prevention through diagnosis, treatment, and aftercare. MedStar manages

approximately 175,000 covered lives, the majority of which are Maryland residents. Ensuring that needed transplant services and programs are a part of the system of care, convenient to patients' homes and families is integral to the successful management of the population's health.

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

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

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

Response:

Planning Process, Goals and Objectives

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

Figure 16
Map of MedStar Health/MGTI Liver Transplant Evaluation and Follow Up Clinics

A. MedStar Georgetown University Hospital
3800 Reservoir Rd., NW
Washington, DC 20007

B. MedStar Washington Hospital Center
110 Irving St., NW
Washington, DC 20010

C. MedStar Georgetown Transplant Institute in Fairfax
3020 Hamaker Ct.
Annandale, VA 22031

D. MedStar Southern Maryland Hospital Center
7503 Surratts Rd.
Clinton, MD 20735

E. MedStar Georgetown Transplant Institute in Frederick
163 Thomas Johnson Dr.
Suite E
Frederick, MD 21702

F. MedStar Georgetown Transplant Institute in Annapolis
Annapolis Tech Park
2629 Riva Rd., Suite 110
Annapolis, MD 21401

G. MedStar Franklin Square Medical Center
9000 Franklin Square Dr.
Baltimore, MD 21237

FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023 (annualized)
118	228	422	748	767	873	912	1086

Source: Internal MGTI Data

Note that since the advanced liver disease clinic opened in 2016, it will have experienced an almost 90% growth in (billed) volume by July 2023. MedStar Health leadership meets regularly to evaluate the effectiveness of its existing DCDN and to identify clinical and geographic gaps in the network. Through this process, gaps in access to innovative, timely liver transplant services (in particular, better organ utilization, advanced techniques in surgery and community outreach) have been identified.

Alternative Approaches

MedStar Health evaluated three alternative approaches to meeting the needs for high quality liver transplant services for MedStar Health patients in Central Maryland.

These approaches are detailed below.

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

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

Again, it should be observed that the costs of care are higher at the currently available academic medical Centers, which are known to operate within a higher cost structure. MedStar wishes to introduce a more efficient care model at MFSMC in the region, through a community hospital that offers an equivalently sophisticated level of services at lower cost.

(2) Refer patients to MGTI in Washington D.C.

MGTI currently provides an unparalleled quality of care for liver and liver transplant services; patients are referred there preferentially to maintain the continuum of care for MedStar's Central Maryland transplant patients. MGTI's location in Washington, D.C. creates a geographic challenge that can have an impact on the continuity of care for many MedStar Health transplant patients who live in the Baltimore area. Moreover, this alternative is not an optimal strategy for achieving MedStar Health's goal of providing care to its patients in their own communities and in the lowest cost environment whenever possible. For these reasons, this alternative was also rejected.

(3) Establish a program at MFSMC

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

a) It maintains the continuity of care that supports the highest quality outcomes by providing patients with this important service within the MedStar Health System.

b) It locates this much needed service in a convenient and accessible location for MedStar Health's Central Maryland patients (MFSMC is in the center of this region and is conveniently accessed via Interstate 95 and Interstate 695).

Over the past two years, MGTI has laid the groundwork to provide the full range of transplantation-related services to MedStar's Central Maryland population. To date, in anticipation of expanded services, MGTI has extended all services required for referral, triage, evaluation, and listing of transplant candidates to MFSMC (and three other outreach sites in Central Maryland). MGTI has also extended follow up services required for the long-term maintenance of patient and organ health after transplantation. The establishment of these services creates easy access to the full continuum of transplant care for all MedStar Health Central Maryland transplant patients and locates the program at a community teaching hospital, which has a lower cost structure and a lower average charge per case. The cost savings achieved through this alternative benefit the state health care system overall.

Integrating the established MGTI program with MFSMC offers a clear cost advantage in that the fixed costs already associated with core services in Washington can be spread across a larger case volume,

while variable start-up costs accrue in line with service growth and expansion. Surgical services will be provided initially by existing experienced MGTI surgeons, eliminating the need for a long, costly recruitment process or extended program ramp-up. No construction or renovation costs are anticipated.

Moreover, MFSMC is the favored site within MedStar Health to provide transplant services since it has a well-developed, busy digestive disease center and associated network of supportive gastroenterologists. Its 20-bed state-of-the-art critical care service is managed by a Hopkins-trained physician who is board-certified in pulmonary critical care medicine. MFSMC opened new operating rooms in the summer of 2020, aproject that further enhances the environment of care and patient experience as had been noted earlier.

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

Population Health Initiatives

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

MedStar Family Choice, and the MedStar Select product for MedStar Health Associates continue to grow its population health management capabilities and to invest in quality and safety initiatives.

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

MedStar's outpatient rehabilitation network has 60 sites located within communities across the Baltimore-Washington corridor; 27 of these are in the Baltimore area. MedStar Health owns 33 urgent care sites with two more under development. Many of these are co-located with MedStar Medical Group primary care physicians. Tele- medicine is available at sites that are not co-located. MedStar also has seven multi- specialty outpatient ambulatory centers located in Maryland and the District of Columbia.

10.24.01.08 G (3) (d). <u>Viability of the Proposal</u>.

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

<u>Response</u>

Please note that financial and work force schedules reflect a liver transplant program at MFSMC that is fully integrated with clinical and administrative systems at the well-established and experienced MGTI. The integration described permits program variable costs to align with program growth while limiting

allocation of fixed overhead costs as appropriate to the size of the operation. This rational approach means that the new MFSMC program will provide liver transplant services to Marylanders at a lower cost than the other transplant programs in Maryland in a context of maintaining excellence in clinical care and patient outcomes.

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

See Attachment B for MedStar Health FY21-FY22 Audited Financial Statements.

Volume Assumptions

A. Liver transplant volumes were based on the current experience of the MGTI clinic at MFSMC and in discussions with community gastroenterologists

B. Volumes are lower in the initial years recognizing that MFSMC will not receive CMS certification until year two and the Centers of Excellence designation until year three.

C. Volumes also assume that a large proportion of patients in MedStar Health's Managed Care Programs (e.g., MedStar Family Choice) would undergo transplantation at MFSMC.

Financial Projection Assumptions

MedStar Franklin Square Facility Assumptions

FY17-21 are based on the expected performance for the Fiscal Years Ended June 30, 2017-2021.

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.
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

A. Volume Assumptions:

   Liver transplant volumes were based on the current experience of the MedStar Georgetown Transplant Clinic at MFSMC

B. Transplant Program Revenues:
   Beginning in FY19, liver revenue projections assume $148,848 Per Liver Transplant.

C. Ancillary Transplant Program Revenues:
   Ancillary outpatient volumes are based on patient activity expected to occur in MFSMC as a

direct result of the transplant programs and are derived from MGTI experience and procedural pre- and post operation testing.

D. Professional Fee Transplant Program Revenues:
Professional fee revenue driven off the expectation of employed physician and actual MGTI experience for the entire transplant program to arrive at a per transplant estimate of professional revenues.

Expenses

A. FTE Requirements are based primarily on variable FTE requirements related to volume. Fixed FTE expenses are attributed to MGTI.
B. Transplant project variable expenses relate to organ acquisition, supplies, purchased services, drugs, and variable salary and wages based on current experience at MGTI.

Staffing Assumptions

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

Recruitment

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

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

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

Response:

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

The second CON, Docket No. 16-03-2380, was approved on June 15, 2017. This project was completed,

with opening in 2020.

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

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

Response:

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

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

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

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

Regarding part (c), as a community teaching hospital, MFSMC has a lower cost structure and charge per case than the area's two existing academic medical centers. MFSMC's average charge per case will be significantly lower than the charge per case of either Hopkins or Maryland (see Figure 8, *supra*)**.** From this perspective, performing transplant procedures at MFSMC will bring greater cost efficiency to local and state health care systems.

List of Attachments

Attachment A: List of funded Liver Research Studies Underway

Attachment B: Audited Financial Statements

ATTACHMENT A

No.	Category	GUPass ID	IRB #	AWD	GR	PI	Trial Title	OnCore Name	Funding source (Funded, Unfunded, Close-out)	Date Opened (IRB Approval Date)	IRB Expiration	Service	Status
1	Active		Pro0000434	AWD-4360637	GR409741	Fishbein	A Phase II Randomized Multicenter Placebo-Controlled Blinded Study of Sorafebin Adjuvant Therapy in High Risk Orthotopic Liver Transplant (OLT) Recipients with Hepatocellular Carcinoma (HCC)	SORAFENIB-NCT01624285	UCLA (Bayer Pharma)	UNK	Expired - acknowledged RNI 3/25/22.	Liver	Closing
2	Active		STUDY00000987 (2018-0222)	AWD-7773034	GR412774	He	A phase I single-arm, multi-center pilot study aimed at validating γ-OHPdG as a biomarker and testing the effects of Polyphenon E on its levels in patients with cirrhosis	POLYPHENON-NCT03278925	NCI through NU	6/27/2019	12/1/2022	Liver	Open to enrollment
3	Active		STUDY00004013	AWD-7775076	GR414706	Hsu	Impact of Recent Immigration on Delays of Care Delivery Among Foreign-Born with Chronic Hepatitis B Infection	HBVFB	(USC) Gilead Sciences, Inc.	6/29/2021	N/A	Liver	Open to enrollment
4	Active		STUDY00003636	AWD-7774723	GR424715	Hsu	A Randomized, Double-blind, Placebo-controlled, Phase 2b study to Evaluate Safety and Efficacy and DUR-938 in Subjects with Alcoholic Hepatitis	DURECTAH	Durect Corporation	6/10/2021	6/9/2022	Liver	Open to enrollment
5	Active		STUDY00004157		GR425040	Satoskar	Molecular Assessment and Profiling of Liver Transplant Recipients	MAPLE-NCT04793360	CareDx.	9/9/2021	9/8/2022	Liver	Open to enrollment
6	Active		Not submitted			Satoskar	Effect of Twin Precision Treatment (TPT) in patients with NAFLD- proof of concept study	Not in Oncore	Twin Health	N/A		Liver	Start-up
7	Active		STUDY00004079	AWD-7774990	GR414928	Rangnekar	Noninvasive Assessment of Esophageal Varices in Patients with Unresectable Hepatocellular Carcinoma	Not in OnCore	University of Michigan	7/23/2021	NA	Liver	Active (data only)
8	Active		STUDY0000064	AWD-7773833	GR411645	Smith	C. Smith - HOPE in Action: A clinical trial of HIV-to-HIV liver transplant	HIALIVER-NCT03734393	JHU (National Institute of Allergy and Infectious Diseases)	3/14/2019	12/13/2022	Liver	Open to enrollment
9	Active		STUDY00000882 (2018-0773)	AWD-7773503	GR411587	Smith	C. Smith - Statin Therapy to Reduce Disease Progression from Liver Cirrhosis to Cancer	STATINLIVER-NCT02968810	Northwestern (National Cancer Institute)	12/1/2020	9/22/2022	Liver	Closed to enrollment
10	Active		2017-0198	AWD-7772713	GR412481	Smith, Coleman 61543	A 5-year longitudinal observational study of patients with nonalcoholic fatty liver (NAFL) or nonalcoholic steatohepatitis (NASH)	TARGET-NASH-NCT02815891	TARGET PharmaSolutions, Inc	3/7/2017	1/8/2023	Liver	Open to enrollment
11	Active		2018-1168	AWD-7773487	GR413518	Smith, Coleman 61543	An Observational Study of Patients Undergoing Therapy for Chronic Hepatitis B (HBV) Infection	TARGETHBV-NCT03692897	TARGET PharmaSolutions, Inc	6/27/2022	6/26/2023	Liver	Open to enrollment
12	Active		2017-0147	AWD-7772715	GR412483	Smith, Coleman 61543	A 5-year Longitudinal Observational Study of the Natural History and Management of Patients with Hepatocellular Carcinoma	TARGET-HCC-NCT02954094	TARGET PharmaSolutions, Inc	1/26/2018	1/8/2023	Liver	Open to enrollment

13	Active		STUDY00003613	AWD-7774960	GR424961	Smith, Coleman 61543	A Phase 1, Double Blind, Randomised, Placebo-controlled, Multi-centre, Multiple Ascending Dose Study to Assess the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of AZD2693 in Patients with Non-alcoholic Steatohepatitis (NASH) with Fibrosis Stage 0-3 and Homozygous for the PNPLA3 148M Risk Allele	ASTRAZENECA-NCT04483947	Astra Zeneca Pharmaceuticals, Inc	9/9/2021	Closed effective 2/22/22	Liver	Closed
14	Active		STUDY00000264	AWD-7773969	GR413951	Smith, Coleman 61543	A Phase 3, Randomized, Double-Blind, Placebo- Controlled Study Evaluating the Safety, Tolerability, and Efficacy of GS-9674 in Non-Cirrhotic Subjects with Primary Sclerosing Cholangitis	GILEAD-PSC-NCT03890120	Gilead Sciences, Inc.	12/12/2019	10/10/2022	Liver	Closed to enrollment
15	Start-Up					Smith	VLX-601 Vantage		Mirum			Liver	Start-up
16	Start-Up				TRANSFORM	Smith	TRANSFORM: A 52-week, Randomized, Placebo-controlled, Double-blind, Adaptive Phase 2b/3 Trial of Setanaxib with a 52-week Extension Phase in Patients with Primary Biliary Cholangitis (PBC) and Elevated Liver Stiffness		Genkyotex Suisse SA			Liver	Start-up
17	Start-Up				Gilead 6075	Smith	A Phase 2, Randomized, Double-Blind, Double-Dummy, Placebo-Controlled Study Evaluating the Safety and Efficacy of Semaglutide, and the Fixed-Dose Combination of Cilofexor and Firsocostat, Alone and in Combination, in Subjects with Compensated Cirrhosis (F4) due to Nonalcoholic Steatohepatitis (NASH)		Gilead Sciences, Inc.			Liver	Start-up
18	Start-Up				RED-C RNLC3131 Salix	Smith	A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER STUDY TO ASSESS THE EFFICACY AND SAFETY OF RIFAXIMIN SOLUBLE SOLID DISPERSION (SSD) TABLETS FOR THE DELAY OF ENCEPHALOPATHY DECOMPENSATION IN CIRRHOSIS (RED-C		Salix Pharma			Liver	Start-up
19	Start-Up				NATiv3	Smith	A randomised, double-blind, placebo-controlled, multicentre, Phase 3 study evaluating long-term efficacy and safety of lanifibranor in adult patients with non-cirrhotic non-alcoholic steatohepatitis (NASH) and fibrosis 2 (F2)/fibrosis 3 (F3) stage of liver fibrosis		Inventiva SA			Liver	Start-up

20	Start-Up				ASCEND-NASH	Smith	A Phase 2B, Randomized, Multicenter, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of CRV431 in Adult Subjects with NonAlcoholic Steatohepatitis and Advanced Liver Fibrosis		Hepion Pharma			Liver	Start-up
21	Start-Up				VISTAS	Smith	A Randomized Double-Blind Placebo-Controlled Study to Evaluate the Efficacy and Safety of Volixibat in the Treatment of Cholestatic Pruritus in Patients with Primary Sclerosing Cholangitis (VISTAS) - Phase 2		Mirum			Liver	Start-up
22	Start-Up					Hawksworth	International, Multicenter, Prospective, Non-competitive, Observational study to Validate and Optimize prediction models of 90-day and 1-year allograft failure after liver transplantation: The Improvement study	Improvement	UCLA			Liver	Start-up

ATTACHMENT B

MEDSTAR HEALTH, INC.

Consolidated Financial Statements

June 30, 2022 and 2021

(With Independent Auditors' Report Thereon)

MEDSTAR HEALTH, INC.

Table of Contents

KPMG LLP
750 East Pratt Street, 18th Floor
Baltimore, MD 21202

Independent Auditors' Report

The Board of Directors
MedStar Health, Inc.:

Opinion

We have audited the consolidated financial statements of MedStar Health, Inc. (the Corporation), which comprise the consolidated balance sheets as of June 30, 2022 and 2021, and the related consolidated statements of operations and changes in net assets, and cash flows for the years then ended, and the related notes to the consolidated financial statements.

In our opinion, the accompanying consolidated financial statements present fairly, in all material respects, the financial position of the Corporation as of June 30, 2022 and 2021, and the results of its operations, the changes in its net assets, and its cash flows for the years then ended in accordance with U.S. generally accepted accounting principles.

Basis for Opinion

We conducted our audits in accordance with auditing standards generally accepted in the United States of America (GAAS). Our responsibilities under those standards are further described in the Auditors' Responsibilities for the Audit of the Consolidated Financial Statements section of our report. We are required to be independent of the Corporation and to meet our other ethical responsibilities, in accordance with the relevant ethical requirements relating to our audits. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Responsibilities of Management for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of the consolidated financial statements in accordance with U.S. generally accepted accounting principles, and for the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, management is required to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Corporation's ability to continue as a going concern for one year after the date that the consolidated financial statements are issued.

Auditors' Responsibilities for the Audit of the Consolidated Financial Statements

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditors' report that includes our opinion. Reasonable assurance is a high level of assurance but is not absolute assurance and therefore is not a guarantee that an audit conducted in accordance with GAAS will always detect a material misstatement when it exists. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control. Misstatements are considered material if there is a substantial likelihood that, individually or in the aggregate, they would influence the judgment made by a reasonable user based on the consolidated financial statements.

In performing an audit in accordance with GAAS, we:

- Exercise professional judgment and maintain professional skepticism throughout the audit.
- Identify and assess the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, and design and perform audit procedures responsive to those risks. Such procedures include examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Corporation's internal control. Accordingly, no such opinion is expressed.
- Evaluate the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluate the overall presentation of the consolidated financial statements.
- Conclude whether, in our judgment, there are conditions or events, considered in the aggregate, that raise substantial doubt about the Corporation's ability to continue as a going concern for a reasonable period of time.

We are required to communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit, significant audit findings, and certain internal control related matters that we identified during the audit.

KPMG LLP

Baltimore, Maryland
October 4, 2022

MEDSTAR HEALTH, INC.

Consolidated Balance Sheets

June 30, 2022 and 2021

(Dollars in millions)

Assets		2022	2021
Current assets:			
Cash and cash equivalents	$	846.0	1,523.6
Investments		281.0	473.9
Assets whose use is limited or restricted		72.1	64.7
Receivables:			
Patient accounts receivable, net		963.7	897.4
Other receivables		144.7	130.6
		1,108.4	1,028.0
Inventories		98.8	95.3
Prepaids and other current assets		58.2	55.6
Total current assets		2,464.5	3,241.1
Investments, net of current portion		1,422.4	1,467.0
Assets whose use is limited or restricted, net of current portion		581.5	811.0
Property and equipment, net		2,036.9	1,820.7
Operating lease right-of-use assets, net		269.3	252.3
Interest in net assets of foundation		68.2	83.0
Goodwill and other intangible assets, net		484.4	487.5
Other assets		229.7	230.9
Total assets	$	7,556.9	8,393.5

(Continued)

MEDSTAR HEALTH, INC.

Consolidated Balance Sheets

June 30, 2022 and 2021

(Dollars in millions)

Liabilities and Net Assets		2022	2021
Current liabilities:			
Accounts payable and accrued expenses	$	573.9	543.4
Accrued salaries, benefits, and payroll taxes		469.3	478.4
Current portion of amounts due to third-party payors, net		199.1	562.2
Current portion of long-term debt		67.1	194.3
Current portion of self-insurance liabilities		115.6	100.3
Current portion of operating lease liabilities		60.2	63.0
Other current liabilities		221.2	357.1
Total current liabilities		1,706.4	2,298.7
Long-term debt, net of current portion		1,781.8	1,686.9
Amounts due to third-party payors, net of current portion		—	146.5
Self-insurance liabilities, net of current portion		359.3	328.0
Operating lease liabilities, net of current portion		227.1	212.1
Pension liabilities		187.9	305.3
Other long-term liabilities		272.5	341.5
Total liabilities		4,535.0	5,319.0
Net assets:			
Without donor restrictions – attributable to MedStar Health, Inc.		2,691.7	2,747.5
Without donor restrictions – noncontrolling interest		53.1	51.1
Total net assets without donor restrictions		2,744.8	2,798.6
With donor restrictions		277.1	275.9
Total net assets		3,021.9	3,074.5
Total liabilities and net assets	$	7,556.9	8,393.5

See accompanying notes to consolidated financial statements.

MEDSTAR HEALTH, INC.

Consolidated Statements of Operations and Changes in Net Assets

Years ended June 30, 2022 and 2021

(Dollars in millions)

	2022	2021
Operating revenues:		
Net patient service revenue	$ 5,882.1	5,424.4
Premium revenue	1,006.7	837.5
Other operating revenue	390.4	463.6
Net operating revenues	7,279.2	6,725.5
Operating expenses:		
Personnel	4,094.7	3,689.1
Supplies	1,104.3	983.5
Purchased services	1,131.9	996.7
Other operating	596.3	524.5
Interest expense	51.9	55.8
Depreciation and amortization	219.2	216.4
Total operating expenses	7,198.3	6,466.0
Earnings from operations	80.9	259.5
Nonoperating (losses) gains:		
Investment (losses) gains, net	(270.8)	510.9
Income tax (provision) benefit	(2.9)	13.8
Other nonoperating activities, net	(6.5)	(9.3)
Total nonoperating (losses) gains	(280.2)	515.4
(Deficit) excess of revenues over expenses	$ (199.3)	774.9

(Continued)

MEDSTAR HEALTH, INC.

Consolidated Statements of Operations and Changes in Net Assets

Years ended June 30, 2022 and 2021

(Dollars in millions)

	Without donor restrictions			
	MedStar Health, Inc.	Noncontrolling interest	With donor restrictions	Total
Balance at June 30, 2020	$ 1,699.9	20.2	239.2	1,959.3
Excess of revenues over expenses	769.5	5.4	—	774.9
Change in funded status of defined benefit plans	256.9	—	—	256.9
Distributions to noncontrolling interests	—	(2.9)	—	(2.9)
Net assets released from restrictions used for purchase of property and equipment and other	21.2	—	(21.2)	—
Noncontrolling interests acquired in acquisitions	—	28.4	—	28.4
Net assets released from restrictions for operations	—	—	(10.0)	(10.0)
Contributions	—	—	37.9	37.9
Investment gains on restricted investments, net	—	—	12.4	12.4
Increase in net assets of foundation	—	—	17.6	17.6
Increase in net assets	1,047.6	30.9	36.7	1,115.2
Balance at June 30, 2021	2,747.5	51.1	275.9	3,074.5
(Deficit) excess of revenues over expenses	(207.2)	7.9	—	(199.3)
Change in funded status of defined benefit plans	98.9	—	—	98.9
Distributions to noncontrolling interests	—	(7.3)	—	(7.3)
Net assets released from restrictions used for purchase of property and equipment and other	52.5	—	(52.5)	—
Noncontrolling interests acquired in acquisitions	—	1.4	—	1.4
Net assets released from restrictions for operations	—	—	(11.2)	(11.2)
Contributions	—	—	84.7	84.7
Investment losses on restricted investments, net	—	—	(5.0)	(5.0)
Decrease in net assets of foundation	—	—	(14.8)	(14.8)
(Decrease) increase in net assets	(55.8)	2.0	1.2	(52.6)
Balance at June 30, 2022	$ 2,691.7	53.1	277.1	3,021.9

See accompanying notes to consolidated financial statements.

MEDSTAR HEALTH, INC.

Consolidated Statements of Cash Flows

Years ended June 30, 2022 and 2021

(Dollars in millions)

	2022	2021
Cash flows from operating activities:		
Change in net assets	$ (52.6)	1,115.2
Adjustments to reconcile change in net assets to net cash (used in) provided by operations:		
Depreciation and amortization	219.2	216.4
Loss (gain) on sale of property and equipment and other	0.3	(14.2)
Change in funded status of defined benefit plans	(98.9)	(256.9)
Investment losses (gains), net and change in derivative instrument	293.7	(506.0)
Decrease (increase) in net assets of foundation	14.8	(17.6)
Deferred income tax provision (benefit)	2.8	(14.0)
Donor restricted contributions	(84.7)	(37.9)
Changes in operating assets and liabilities:		
Receivables	(70.0)	(199.8)
Accounts payable and accrued expenses	21.8	197.1
Amounts due to third-party payors	(573.7)	(91.0)
Other	(108.7)	(6.6)
Net cash (used in) provided by operations	(436.0)	384.7
Cash flows from investing activities:		
Purchases of property and equipment, and other	(419.0)	(457.2)
Proceeds from sales of investments and assets whose use is limited or restricted	145.0	232.9
Purchases of investments and assets whose use is limited or restricted	—	(10.7)
Proceeds from sales of alternative investments	83.9	22.8
Purchases of alternative investments	(69.4)	(29.4)
Net settlement payment on derivative instrument	(1.7)	(2.0)
Net cash used in investing activities	(261.2)	(243.6)
Cash flows from financing activities:		
Repayments of revolving credit agreements	—	(680.0)
Repayments of long-term borrowings	(34.3)	(33.3)
Donor restricted contributions	59.8	34.1
Distributions to noncontrolling interests	(5.9)	(2.9)
Net cash provided by (used in) financing activities	19.6	(682.1)
Decrease in cash and cash equivalents	(677.6)	(541.0)
Cash and cash equivalents at beginning of year	1,523.6	2,064.6
Cash and cash equivalents at end of year	$ 846.0	1,523.6
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 74.4	79.7
Supplemental disclosure of noncash investing and financing activities:		
Noncash purchases of property, plant and equipment	$ 51.2	41.2

See accompanying notes to consolidated financial statements.

(1) Description of Organization and Summary of Significant Accounting Policies

(a) Organization

MedStar Health, Inc. (MedStar Health or the Corporation) is a tax-exempt, nonstock Maryland corporation which, through its controlled entities and other affiliates, provides and manages healthcare services in the region encompassing Maryland, Washington D.C. (the District) and Northern Virginia. The Corporation became operational on June 30, 1998 by the transfer of the membership interests of Helix Health, Inc. (Helix – a not-for-profit Maryland Corporation) and Medlantic Healthcare Group, Inc. (Medlantic – a not-for-profit Delaware Corporation) in exchange for the guarantee of the debt of both Helix and Medlantic by the Corporation. The trade names of the principal tax-exempt and taxable entities of the Corporation are:

Tax-Exempt

- MedStar Ambulatory Services
- MedStar Franklin Square Medical Center (MFSMC)
- MedStar Georgetown University Hospital (MGUH)
- MedStar Good Samaritan Hospital
- MedStar Harbor Hospital
- MedStar Health Research Institute
- MedStar Health Visiting Nurse Association
- MedStar Medical Group, LLC
- MedStar Montgomery Medical Center (MMMC)
- MedStar National Rehabilitation Network
- MedStar Southern Maryland Hospital Center
- MedStar St. Mary's Hospital (MSMH)
- MedStar Union Memorial Hospital
- MedStar Washington Hospital Center (MWHC)
- HH MedStar Health, Inc.

Taxable

- Greenspring Financial Insurance, LTD.
- MedStar Accountable Care, LLC
- MedStar Family Choice, Inc. (MFC)
- MedStar Health Urgent Care
- MedStar Pharmacies, Inc.
- MedStar Specialty Pharmacy, LLC

- Parkway Ventures, Inc. and Subsidiaries
- RadAmerica II, LLC

(b) Basis of Presentation

The consolidated financial statements are prepared on the accrual basis of accounting in accordance with U.S. generally accepted accounting principles (U.S. GAAP). All majority owned subsidiaries, direct member entities and controlled affiliates are consolidated. All significant intercompany accounts and transactions have been eliminated.

(c) Use of Estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Future results could differ from current estimates.

(d) Cash Equivalents

All highly liquid investments with an original maturity date of three months or less are considered to be cash equivalents. Cash equivalents for purposes of the consolidated statements of cash flows excludes investments and assets whose use is limited or restricted.

(e) Investments and Assets Whose Use is Limited or Restricted

The Corporation's investment portfolio is considered trading and is classified as current or noncurrent based on management's intention as to use. All securities are reported at fair value principally based on quoted market prices in the consolidated balance sheets. The fair value of alternative investments is measured based on the Net Asset Value (NAV) of the shares in each investment company or partnership as a practical expedient, except for those institutional funds which have readily determinable fair values (RDFV) and are disclosed separately. Purchases and sales of securities are recorded on a trade-date basis.

Investments in unconsolidated affiliates are accounted for under the cost or equity method of accounting, as appropriate, and are included in other assets in the consolidated balance sheets. The Corporation utilizes the equity method of accounting for its investments in entities over which it exercises significant influence. Under the equity method, original investments are recorded at cost and adjusted by the Corporation's share of earnings or losses in these organizations. The Corporation's equity income or loss is recognized in other operating revenue within the consolidated statements of operations and changes in net assets.

Assets whose use is limited or restricted include assets held by trustees under bond indentures, self-insurance trust arrangements, assets restricted by donor, and assets designated by the Board of Directors for future capital improvements and other purposes over which it retains control and may, at its discretion, use for other purposes. Amounts from these funds required to meet current liabilities have been classified in the consolidated balance sheets as current assets.

Investment income (interest and dividends), realized gains and losses on investment sales, and unrealized gains and losses are reported as investment gains, net within the excess of revenues over expenses in the accompanying consolidated statements of operations and changes in net assets (unless the income or loss is restricted). Investment income and realized gains and losses on funds held in trust for self-insurance purposes are included in other operating revenue. Investment returns that are restricted by the donor are recorded as a component of changes in donor restricted net assets, in accordance with donor-imposed restrictions. Realized gains and losses are determined based on the specific security's original purchase price or adjusted cost if the investment was previously determined to be other-than-temporarily impaired.

(f) Inventories

Inventories, which primarily consist of medical supplies and pharmaceuticals at many of the operating entities, are stated at the lower of cost or market, with cost being determined primarily under the weighted average cost or first-in, first-out methods.

(g) Property and Equipment, Net

Property and equipment acquisitions are recorded at cost and are depreciated or amortized over the estimated useful lives of the assets. Interest cost incurred on borrowed funds during the period of construction of capital assets is capitalized as a component of the cost of acquiring those assets, net of any interest earned on unexpended bond proceeds. Depreciation is computed on a straight-line basis. Major classes and estimated useful lives of property and equipment are as follows:

Leasehold improvements	Lease term
Buildings and improvements	10–40 years
Equipment	3–20 years

Gifts of long-lived assets such as land, buildings, or equipment are reported as unrestricted support, and are excluded from the excess of revenues over expenses, unless explicit donor stipulations specify how the donated assets must be used. Gifts of long-lived assets with explicit donor restrictions that specify how the assets are to be used, and gifts of cash or other assets that must be used to acquire long-lived assets, are reported as restricted support. Absent explicit donor stipulations about how long those long-lived assets must be maintained, expirations of donor restrictions are reported when the donated or acquired long-lived assets are placed in service.

Management routinely evaluates the carrying value of its long-lived assets for impairment. No significant impairment charges were recorded against the carrying value of the Corporation's long-lived assets during the years ended June 30, 2022 and 2021.

(h) Interest in Net Assets of Foundation

The Corporation recognizes its rights to assets held by a recipient organization, which accepts cash or other financial assets from a donor and agrees to use those assets on behalf of or transfer those assets, the return on investment of those assets, or both, to the Corporation. Changes in the Corporation's economic interests in the financially interrelated organization are recognized in the consolidated statements of operations and changes in net assets as a component of changes in net assets with donor restrictions.

(i) Goodwill and Other Intangible Assets, Net

Goodwill is an asset representing the future economic benefits arising from assets acquired in a business combination that are not individually identified and separately recognized. As of June 30, 2022 and 2021, the Corporation had one reporting unit, which included all subsidiaries of the Corporation, and held goodwill, net on its consolidated balance sheets of $344.5 and $343.0, respectively. Goodwill is evaluated for impairment annually (or sooner if indicators of impairment arise) using a qualitative assessment to determine whether there are events or circumstances that indicate it is more likely than not that the reporting unit's fair value is less than its carrying amount. Based on this qualitative assessment, the Corporation determined that there was no significant goodwill impairment for the years ended June 30, 2022 and 2021.

Other intangible assets are recorded at fair value and amortized over their estimated useful lives. Other intangible assets were $139.9 and $144.5, net of accumulated amortization of $43.3 and $38.7, as of June 30, 2022 and 2021, respectively. The Corporation recognized amortization expense of $4.6 and $4.5 for the years ended June 30, 2022 and 2021, respectively, related to identifiable intangible assets. Other intangible assets are evaluated for impairment whenever events or circumstances indicate that the carrying value of these assets may not be recoverable. No impairment charges related to other intangibles were recorded for the years ended June 30, 2022 and 2021.

(j) Estimated Professional Liability Costs

The provision for estimated self-insured professional liability claims includes estimates of the ultimate costs for both reported claims and claims incurred but not reported. These estimates are based on actuarial analysis of historical trends, claims asserted and reported incidents. The receivables related to such claims are recorded at their net realizable value and are included in other assets in the accompanying consolidated balance sheets.

(k) Leases

The Corporation determines if an arrangement contains a lease at inception of the contract. Right-of-use assets represent the right to use the underlying assets for the lease term and the associated lease liabilities represent lease payments arising from the lease. Leases are classified as either operating or financing, with the classification determining whether the expense is recognized on a straight-line basis (for operating leases) or based on an effective interest method (for financing leases). These assets and liabilities are recognized at commencement date, when all the risks and benefits incidental to ownership have been conveyed, based on the present value of lease payments over the lease term. Lease term is equal to the noncancelable term plus any options to renew that the Corporation is reasonably certain to renew. The depreciable life of right-of-use assets are limited by the

expected lease term, unless there is a transfer of title or purchase option that is reasonably certain to be exercised at the inception of the lease. A right-of-use asset and lease liability is not recognized for leases with an initial term of 12 months or less and the Corporation does not separate lease and non-lease components by class of underlying asset for certain asset classes. The Corporation recognizes lease payments associated with short-term leases as an expense on a straight-line basis over the lease term. Variable lease payments associated with these leases are recognized and presented in the same manner as all other leases.

Finance leases are included in property and equipment, net and long-term debt in the consolidated balance sheets.

(l) Derivative

The Corporation utilizes a derivative financial instrument to manage its interest rate risks associated with tax-exempt debt. The Corporation does not hold or issue derivative financial instruments for trading purposes. The derivative instrument is recorded within the consolidated balance sheets at its fair value within other long-term liabilities. The Corporation's current derivative investment does not qualify for hedge accounting; therefore, the changes in fair value have been recognized in the accompanying consolidated statements of operations and changes in net assets as mark-to-market adjustments in other nonoperating activities, net.

(m) Net Patient Service Revenue and Net Patient Accounts Receivable

Net patient service revenue, which includes hospital inpatient services, hospital outpatient services, physician services, and other patient services revenues, is recorded at the transaction price estimated by the Corporation to reflect the total consideration due from patients and third-party payors in exchange for providing goods and services in patient care. The Corporation recognizes net patient service revenue in the period in which performance obligations are satisfied under contracts by transferring our services to customers.

The Corporation determines performance obligations based on the nature of the services provided. Generally, performance obligations satisfied over time relate to patients in hospitals receiving inpatient services. The Corporation measures the performance obligation from admission into the hospital to the point when it is no longer required to provide services to that patient, which is generally at the time of discharge. Revenue for performance obligations satisfied at a point in time, such as outpatient services, is recognized when goods or services are provided, and the Corporation does not believe it is required to provide additional goods or services to the patient. Inpatient goods and/or services may include room, meals, ancillary services, etc. These services represent a bundle of goods and services that are distinct and accounted for as a single performance obligation within a patient stay or encounter.

The Corporation's estimate of the transaction price includes estimates of price concessions for such items as contractual allowances, charity care, potential adjustments that may arise from payment and other reviews, and uncollectible amounts, which are determined using a portfolio approach as a practical expedient to account for patient contracts as collective groups rather than individually. Estimates for uncollectible amounts are based on the aging of the accounts receivable, historical collection experience for similar payors and patients, current market conditions, and other relevant factors. Settlements with third-party payors for retroactive revenue adjustments due to audits, reviews or investigations are considered variable consideration and are considered in the determination of the estimated transaction price for providing patient care. These settlements are estimated based on the terms of the payment agreement with the payor, correspondence from the payor and our historical settlement activity, including an assessment to ensure that it is probable that a significant reversal of revenue recognized will not occur. Estimated settlements are adjusted in future periods as adjustments become known or as years are settled or are no longer subject to such audits, reviews or investigations. In addition, the Corporation is committed to ensuring that patients within the communities it serves who lack financial resources have access to necessary hospital services. The Corporation works with uninsured and underinsured patients to gain an understanding of each patient's financial resources prior to admission (for scheduled services) or prior to billing (for emergency services). Based on this information and patient eligibility for charity care, the Corporation records estimated price concessions accordingly.

Subsequent changes to the estimate of the transaction price are generally recorded as adjustments to net patient service revenue in the period of the change. Subsequent changes that are determined to be the result of an adverse change in the payors or patient's ability to pay are recorded as bad debt expense. Bad debt expense for the years ended June 30, 2022 and 2021 was not significant.

(n) Premium Revenue and Medical Claims Expense

Premium revenue consists of amounts received by the Corporation's managed care organization for providing medical services to subscribing participants, regardless of services actually performed, on a per member per month basis. As of June 30, 2022, the managed care organization provides services primarily to enrolled Medicaid beneficiaries in the State of Maryland and the District of Columbia (the District). Premiums under the contracts are recognized as revenue at the estimated net realizable amount during the period in which the Corporation is obligated to provide services to its enrollees. Medical expenses of the managed care organization include actuarially determined estimates of the ultimate costs for both reported claims and claims incurred but unreported and are included in purchased services within the consolidated statements of operations and changes in net assets.

(o) Grants

Grants are accounted for as either an exchange transaction or as a contribution based on terms and conditions of the grant. If the grant is accounted for as an exchange transaction, revenue is recognized as other operating revenue when earned. If the grant is accounted for as a contribution, the revenue is recognized as either other operating revenue, or as donor restricted contributions, depending on the restrictions within the grant.

(p) Contributions Received and Made

Unconditional promises to give cash and other assets to the Corporation are reported at fair value on the date the promise is received. Conditional promises to give are reported at fair value on the date the condition is met. The gifts are reported as donor restricted support if they are received with donor stipulations that limit the use of the donated assets. When a donor restriction is satisfied, that is, when a stipulated time restriction ends or purpose restriction is accomplished, these donor restricted net assets are reclassified as net assets without donor restrictions and reported in the consolidated statements of operations and changes in net assets as net assets released from restrictions. Such amounts are classified as other operating revenue or transfers for additions to property and equipment. Donor restricted contributions whose restrictions are satisfied within the same year as received are reported as contributions without donor restrictions in the accompanying consolidated financial statements.

Contributions made by the Corporation to other not-for-profit organizations are recorded at fair value in other nonoperating activities, net within the consolidated statements of operations and changes in net assets as conditions, if applicable, are met.

(q) Excess of Revenues over Expenses

The consolidated statements of operations and changes in net assets include a performance indicator for the Corporation, which is the excess of revenues over expenses. Consistent with industry practice, changes in net assets that are excluded from excess of revenues over expenses may include contributions of long-lived assets (including assets acquired using contributions that by donor restriction were to be used for the purpose of acquiring such assets), contributions from and acquisitions of and distributions to noncontrolling interests, certain pension adjustments, and other miscellaneous items as defined under U.S. GAAP.

(r) Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that includes the enactment date. Any changes to the valuation allowance on the deferred tax asset are reflected in the year of the change. The Corporation accounts for uncertain tax positions in accordance with the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 740, *Income Taxes*.

(s) Net Assets

The Corporation classifies net assets based on the existence or absence of donor-imposed restrictions. Net assets without donor restrictions represent amounts that arise as the result of operations or contributions, gifts, and grants that have no donor-imposed restrictions. Net assets with donor restrictions are subject to donor-imposed restrictions that must or will be met either by satisfying a specific purpose, passage of time and/or to be maintained by the Corporation in perpetuity. Net assets with donor restrictions primarily consist of pledges and funds received for the purposes of purchasing property and equipment, providing health education, research, and other healthcare services, as donor or other restrictions are satisfied.

The Corporation accounts for and presents noncontrolling interests in a consolidated subsidiary as a separate component of the appropriate class of consolidated net assets. The income attributable to noncontrolling interests is included within operating income within the consolidated statements of operations and changes in net assets.

(t) Fair Value of Financial Instruments

The following methods and assumptions were used to estimate the fair values of financial instruments:

Cash and cash equivalents, receivables, other current assets, other assets, current liabilities and long-term liabilities: The carrying amount reported in the consolidated balance sheets for each of these assets and liabilities approximates their fair value.

The fair values of investments, assets whose use is limited or restricted, and the interest rate swap are discussed in note 3.

(u) New Accounting Pronouncements

From time to time, new accounting guidance is issued by the FASB or other standard setting bodies that is adopted by the Corporation as of the effective date or, in some cases where early adoption is permitted, in advance of the effective date. The Corporation has assessed the recently issued guidance that is not yet effective and, unless otherwise indicated, believes the new guidance will not have a material impact on its consolidated financial position, results of operations, or cash flows.

(v) Reclassifications

Certain prior year amounts have been reclassified to conform with current period presentation, the effects of which are not material.

(Dollars in millions)

(2) Investments and Assets Whose Use is Limited or Restricted

Investments and assets whose use is limited or restricted as of June 30 at fair value consist of the following:

	2022	2021
Cash equivalents	$ 100.2	120.5
Fixed income securities and funds	565.8	761.2
Equity securities	757.9	893.8
Institutional funds with RDFV	206.5	233.4
Alternative investments:		
Commingled equity funds	205.5	283.4
Hedge fund of funds and private equity	521.1	524.3
Total investments and assets whose use is limited or restricted	2,357.0	2,816.6
Less short-term investments and assets whose use is limited or restricted	(353.1)	(538.6)
Long-term investments and assets whose use is limited or restricted	$ 2,003.9	2,278.0

Assets whose use is limited or restricted as of June 30, included in the table above, consist of the following:

	2022	2021
Funds held by trustees	$ —	109.3
Self-insurance funds	325.5	401.8
Funds restricted by donors for specific purposes and endowment	133.1	142.0
Funds designated by board	195.0	222.6
Total assets whose use is limited or restricted	653.6	875.7
Less assets required for current obligations	(72.1)	(64.7)
Long-term assets whose use is limited or restricted	$ 581.5	811.0

(Dollars in millions)

Investment income and realized and unrealized gains for assets whose use is limited or restricted, cash equivalents and investments are comprised of the following for the years ended June 30:

		2022	2021
Other operating revenue:			
Investment income and realized gains	$	21.8	11.8
Investment gains, net:			
Investment income, net		21.2	19.8
Net realized gains on investments		38.3	37.3
Change in unrealized (losses) gains on investments, net		(330.3)	453.8
		(270.8)	510.9
Other changes in net assets:			
Realized net gains on restricted net assets		1.4	1.4
Change in unrealized (losses) gains on restricted net assets, net		(6.4)	11.0
Total investment (losses) gains, net	$	(254.0)	535.1

(3) Fair Value of Financial Instruments

The Corporation follows the guidance within FASB ASC Topic 820, *Fair Value Measurement* (ASC 820), which defines fair value and establishes methods used to measure fair value. The fair value hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy under ASC 820 are described below:

- Level 1 – Quoted prices in active markets for identical assets or liabilities at the measurement date.
- Level 2 – Observable inputs other than quoted prices for the asset, either directly or indirectly observable, that reflect assumptions market participants would use to price the asset based on market data obtained from sources independent of the Corporation.
- Level 3 – Unobservable inputs that reflect the Corporation's own assumptions about the assumptions market participants would use to price an asset based on the best information available in the circumstances.

The Corporation has incorporated an Investment Policy Statement (IPS) into the investment program. The IPS, which has been formally adopted by the Corporation's Board of Directors, contains numerous standards designed to ensure adequate diversification by asset class and geography. The IPS also limits all investments by manager and position size, and limits fixed income position size based on credit ratings, which serves to further mitigate the risks associated with the investment program. As of June 30, 2022, management believes that all investments were being managed in a manner consistent with the IPS.

(Dollars in millions)

The following table illustrates the actual allocations of the Corporation's primary long-term investment portfolio as of June 30:

	2022	2021
Cash and cash equivalents	1 %	2 %
Publicly traded equities – domestic	30	30
Publicly traded equities – international	8	8
Fixed income securities	15	15
Institutional funds with RDFV	10	10
Alternative investments:		
Commingled equity funds	10	13
Hedge funds	21	20
Private equities	5	2
Total	100 %	100 %

The table below presents the Corporation's investable assets and liabilities as of June 30, 2022, aggregated by the three-level valuation hierarchy and separately identifies investments reported at NAV:

	Level 1	Level 2	NAV	Total
Assets:				
Cash and cash equivalents	$ 946.2	—	—	946.2
U.S. Treasury bonds	285.3	—	—	285.3
U.S. agency mortgage backed securities	—	76.0	—	76.0
Corporate bonds	—	162.5	—	162.5
Fixed income mutual funds	0.1	—	—	0.1
All other fixed income securities	—	41.9	—	41.9
Equity mutual funds and ETF's	242.2	—	—	242.2
Institutional funds with RDFV	—	206.5	—	206.5
Common stocks	515.7	—	—	515.7
Alternative investments:				
Commingled funds	—	—	205.5	205.5
Private equity	—	—	89.1	89.1
Hedge funds:				
Custom hedge fund	—	—	89.0	89.0
Other hedge funds	—	—	343.0	343.0
Total assets	$ 1,989.5	486.9	726.6	3,203.0

(Dollars in millions)

	Level 1	Level 2	NAV	Total
Liabilities:				
Interest rate swap	$ —	1.9	—	1.9
Total liabilities	$ —	1.9	—	1.9

The table below presents the Corporation's investable assets and liabilities as of June 30, 2021, aggregated by the three-level valuation hierarchy and separately identifies investments reported at NAV:

	Level 1	Level 2	NAV	Total
Assets:				
Cash and cash equivalents	$ 1,644.1	—	—	1,644.1
U.S. Treasury bonds	447.1	—	—	447.1
U.S. agency mortgage backed securities	—	88.8	—	88.8
Corporate bonds	—	186.3	—	186.3
Fixed income mutual funds	1.0	—	—	1.0
All other fixed income securities	—	38.0	—	38.0
Equity mutual funds and ETF's	281.1	—	—	281.1
Institutional funds with RDFV	—	233.4	—	233.4
Common stocks	612.7	—	—	612.7
Alternative investments:				
Commingled funds	—	—	283.4	283.4
Private equity	—	—	49.0	49.0
Hedge funds:				
Custom hedge fund	—	—	79.9	79.9
Other hedge funds	—	—	395.4	395.4
Total assets	$ 2,986.0	546.5	807.7	4,340.2
Liabilities:				
Interest rate swap	$ —	5.0	—	5.0
Total liabilities	$ —	5.0	—	5.0

There were no changes in valuation methodologies used to measure the fair value of the Corporation's investments as of and for the years ended June 30, 2022 and 2021.

(Dollars in millions)

The following summarizes redemption terms for the hedge fund-of-funds vehicles held as of June 30, 2022:

	Custom Hedge Fund			
	Fund 1	Fund 2	Fund 3	Fund 4
Redemption timing:				
Redemption frequency	Quarterly	40% quarterly 60% greater than quarterly	64% quarterly 36% greater than quarterly	Quarterly
Required notice	70 days	within 120 days	within 95 days	65 days
Audit reserve:				
Percentage held back for audit reserve	10%	up to 10%	up to 10%	5%

The hedge funds include three hedge fund-of-funds and one custom hedge fund. The custom fund is structured as a multi-strategy hedge fund with the Corporation as the sole investor. The investment objective and strategies used by the hedge funds-of-funds and custom hedge fund are similar. The investment objective is to achieve positive absolute returns with low volatility, achieved through investments with multiple underlying managers who are investing across various strategies. Strategies utilized within these hedge funds include, but are not limited to:

- *Credit/Distressed* includes investment companies that focus mainly on opportunities in corporate fixed income securities of companies that are in financial distress, or perceived financial distress, or going through a restructuring or re-organization.
- *Event Driven* includes investment companies that focus on identifying securities that would benefit from the occurrence of a major corporate event.
- *Global Macro* includes investment companies that employ broad mandates to invest globally across all asset classes, including interest rates, currencies, commodities, and equities, in order to benefit from market movements within various countries.
- *Equity Long/Short* includes investment companies that maintain long and short positions in publicly traded equities in order to capture opportunities driven by their perception of securities or industries being overvalued or undervalued.
- *Relative Value* includes investment companies that seek to identify valuation discrepancies between related securities, utilizing fundamental and quantitative techniques to establish equities, fixed income, and derivative positions.

Investments in hedge funds are carried at estimated fair value. Fair value is based on the NAV as a practical expedient of the shares in each investment company or partnership. Such investment companies or partnerships mark-to-market or mark-to-fair value the underlying assets and liabilities in accordance with U.S. GAAP. Realized and unrealized gains and losses of the investment companies and partnerships are included in their respective operations in the current year. Changes in unrealized gains or losses on investments, including those for which partial liquidations were effected in the course of the year, are calculated as the difference between the NAV of the investment at year-end less the NAV of the investment at the beginning of the year, as adjusted for contributions and redemptions made during the year and certain lock-up provisions. Generally, no dividends or other distributions are paid.

Investments in private equity funds, typically structured as limited partnership interests, are carried at estimated fair value using NAV, as a practical expedient, or equivalent as determined by the General Partner in the absence of readily determinable fair values. Distributions under this investment structure are made to investors through the liquidation of the underlying assets. It is expected to take up to ten years to fully distribute the proceeds of those assets. The fair value of limited partnership interests is generally based on fair value capital balances reported by the underlying partnerships, subject to management review and adjustment. Security values of companies traded on exchanges, or quoted on NASDAQ, are based upon the last reported sales price on the valuation date. Security values of companies traded over the counter, but not quoted on NASDAQ, and securities for which no sale occurred on the valuation date are based upon the last quoted bid price. The value of any security for which a market quotation is not readily available may be its cost, provided however, that the General Partner adjusts such cost value to reflect any bona fide third-party transactions in such a security between knowledgeable investors, of which the General Partner has knowledge. In the absence of any such third-party transactions, the General Partner may use other information to develop a good faith determination of value. Examples include, but are not limited to, discounted cash flow models, absolute value models, and price multiple models. Inputs for these models may include, but are not limited to, financial statement information, discount rates, and salvage value assumptions.

The following summarizes the status of commitments to the private equity vehicles held as of June 30, 2022:

		Total commitment	Percentage of commitment contributed	Percentage of commitment remaining
Fund-of-funds	$	30.2	95.7 %	4.3 %
Direct funds		139.0	31.3	68.7
Total	$	169.2		

The valuation of both marketable and nonmarketable securities may include discounts to reflect a lack of liquidity or extraordinary risks, which may be associated with the investment. Determination of fair value is performed on a quarterly basis by the General Partner. Because of the inherent uncertainty of valuation, the determined values may differ significantly from the values that would have been used had a ready market for those investments existed.

(Dollars in millions)

Institutional funds with RDFV are commingled equity and fixed income funds, structured similarly to mutual funds, whose fair value is considered to be readily determinable. These funds' shares can be redeemed on any trading day at the relevant NAV per share on that day, as reported by the funds. There are no significant restrictions on redemption or redemption penalties.

(4) Liquidity and Availability of Resources

Financial assets available within one year of the balance sheet date for general expenditures such as operating expenses and construction costs not financed with tax-exempt debt as of June 30 are as follows:

	2022	2021
Cash and cash equivalents	$ 846.0	1,523.6
Investments (excluding certain alternative investments)	1,620.2	1,895.3
Patient accounts receivable	963.7	897.4
	$ 3,429.9	4,316.3

The Corporation has certain board-designated assets whose use is limited which are available for general expenditures within one year in the normal course of operations, pending board approval. These board-designated assets were $195.0 and $222.6 as of June 30, 2022 and 2021, respectively, and are not included in the table above. The Corporation has other assets whose use is limited for donor restricted purposes, debt service, and for the self-insurance programs for professional and general liability risks, employee health and workers' compensation. These assets whose use is limited are not available for general expenditures within the next year and are not included in the table above (see note 2).

Cash and cash equivalents as of June 30, 2022 and 2021 include $138.7 and $617.4, respectively, of Medicare advanced payments received (see note 10). Investments (excluding certain alternative investments) as of June 30, 2022 and 2021 include $209.7 and $224.4, respectively, of unspent proceeds associated with Series 2020A bonds (see note 7). As part of the Corporation's liquidity management plan, cash in excess of daily requirements is invested in short-term investments and money market funds or held in bank deposits.

(Dollars in millions)

(5) Property and Equipment, net

The components of property and equipment recorded at historical cost and the related accumulated depreciation as of June 30 are summarized as follows:

	2022	2021
Land	$ 109.0	107.2
Buildings and improvements	1,934.6	1,875.1
Equipment	2,517.9	2,379.4
	4,561.5	4,361.7
Less accumulated depreciation and amortization	(3,229.7)	(3,024.9)
	1,331.8	1,336.8
Construction-in-progress	705.1	483.9
	$ 2,036.9	1,820.7

Construction-in-progress includes a variety of ongoing capital projects of the Corporation as of June 30, 2022 and 2021, including the construction of a new surgical pavilion at MGUH, an operating room expansion at MFSMC, which was capitalized during fiscal year 2022, and other capital projects at MWHC that were funded through the Series 2017A bond offering. In connection with these projects, the Corporation has total unspent commitments of $177.5 and $259.0 as of June 30, 2022 and 2021, respectively. Interest expense, net of investment earnings, capitalized for these projects totaled $17.2 and $16.2 as of June 30, 2022 and 2021, respectively.

Depreciation expense related to property and equipment amounted to $213.3 and $210.8 for the years ended June 30, 2022 and 2021, respectively.

(6) Other Assets

Other assets as of June 30 consist of the following:

	2022	2021
Investments in unconsolidated entities	$ 15.8	15.2
Reinsurance receivables	45.3	44.2
Other	168.6	171.5
	$ 229.7	230.9

(Dollars in millions)

The Corporation has investments in other healthcare related organizations that are accounted for under the equity method which total $15.8 and $15.2 as of June 30, 2022 and 2021, respectively. The related ownership interests in these organizations range from 15% to 50%. The Corporation's share of earnings in these organizations was $3.1 and $3.3 for the years ended June 30, 2022 and 2021, respectively, and are recognized in other operating revenue in the consolidated statements of operations and changes in net assets.

As of June 30, 2022 and 2021, other assets also include $126.6 and $139.9, respectively, of investments associated with a nonqualified, tax-deferred compensation plan for which there is an offsetting payable included in other long-term liabilities within the consolidated balance sheets. Generally, these funds are invested in mutual funds that would be considered Level 1 investments.

(7) Debt

As of June 30, the Corporation's outstanding borrowings include the following:

	2022	2021
Maryland Health and Higher Educational Facilities:		
Authority fixed rate revenue bonds:		
Series 1998A 5.25% Term bonds due 2038	$ 82.0	82.0
Series 1998B 5.25% Term bonds due 2038	57.0	57.0
Series 2011 2.00%–5.00% Serial bonds due 2012–2023	6.0	9.6
Series 2011 5.00% Term bonds due 2024–2041	1.0	1.0
Series 2012 2.19% Direct Purchase due 2017–2022	7.1	14.0
Series 2013A 3.00%–5.00% Serial bonds due 2016–2028	55.7	55.7
Series 2013A 4.00%–5.00% Term bonds due 2038–2041	56.9	56.9
Series 2013B 3.00%–5.00% Serial bonds due 2025–2033	60.8	60.8
Series 2013B 4.00%–5.00% Term bonds due 2038	89.0	89.0
Series 2015 2.00%–5.00% Serial bonds due 2016–2033	142.8	151.5
Series 2015 4.00%–5.00% Term bonds due 2038–2045	176.8	176.8
Series 2017A 3.75%–5.00% Term bonds due 2042–2047	395.0	395.0
Unamortized net premium	67.9	73.6
	1,198.0	1,222.9

(Dollars in millions)

	2022	2021
District of Columbia Hospital Revenue Bonds:		
Multimodal revenue bonds at variable rates:		
Series 1998A 0.34%–1.07% at June 30, 2022 Serial bonds due 2008–2038 0.01%–0.05% at June 30, 2021	$ 97.0	101.2
MedStar Health, Inc. Taxable Fixed Rate Revenue Bonds:		
Series 2015 0.80%–3.70% Serial bonds due 2016–2031	65.5	72.2
Series 2020A 3.63% Term bonds due 2047–2049	302.6	302.6
Series 2020B 2.91%-3.63% Term bonds due 2025–2041	43.4	43.4
Notes payable to financial institutions or state agencies under mortgages (floating rates ranging between 1.0%–6.2%) and other	24.3	21.3
Revolving credit agreements	129.8	129.8
Deferred financing costs, net	(11.7)	(12.2)
Total debt, including revolving credit agreements	1,848.9	1,881.2
Less current portion	(67.1)	(194.3)
Long-term debt, net, including revolving credit agreements	$ 1,781.8	1,686.9

Scheduled maturities on borrowings for the next five fiscal years and thereafter are as follows:

2023	$ 67.1
2024	34.0
2025	164.9
2026	36.8
2027	38.4
Thereafter	1,451.5
	$ 1,792.7

The Corporation, which is currently the sole member of an "obligated group" as defined in the Master Trust Indenture, is bound by the provisions of the Master Trust Indenture for payment of any outstanding obligations under existing loan agreements. All the hospitals and certain other affiliates of the Corporation are parties to a guaranty agreement pursuant to which they jointly and severally guarantee the payment and performance of the obligations under the Master Trust Indenture. The Master Trust Indenture requires that certain Material System Affiliates, which is defined therein as any system affiliate that generates in excess of 5.0% of the system's revenues, execute the guaranty agreement unless otherwise exempt pursuant to the provisions of the Master Trust Indenture. The Master Trust Indenture has been amended such that the Corporation's regulated insurance entities, which may constitute Material System Affiliates, are not required to become parties to the guaranty agreement due to regulatory restrictions placed on their assets which make them unable to fulfill the obligations of a guarantor. Parties to the guaranty agreement

currently include: HH MedStar Health, Inc., MedStar Enterprises, Inc., MedStar Georgetown University Hospital, MedStar National Rehabilitation Hospital, MedStar Washington Hospital Center, MedStar Franklin Square Medical Center, MedStar Good Samaritan Hospital, MedStar Harbor Hospital, MedStar Montgomery Medical Center, MedStar Southern Maryland Hospital Center, MedStar St. Mary's Hospital, MedStar Union Memorial Hospital, Parkway Ventures, Inc., MedStar Visiting Nurse Association, Inc., and MedStar Medical Group, LLC. The obligations of the guarantors under the guaranty agreement are currently secured by deeds of trust granted by the hospitals. Under the Master Trust Indenture and the deeds of trust, to support the payments due thereunder, the Corporation and its hospital affiliates, respectively, have pledged their revenues subject to permitted encumbrances. As of June 30, 2022, all the Corporation's Maryland Health and Higher Educational Facilities Authority Revenue Bonds, District Hospital Revenue Bonds, and MedStar Health Taxable Revenue Bonds are secured by obligations issued under the Master Trust Indenture.

Under the Master Trust Indenture, the Corporation is required to maintain, among other covenants, a maximum annual debt service coverage ratio of not less than 1.10 or the Corporation may be required to retain a consultant. In addition, it is an event of default, if the Corporation has a maximum annual debt service coverage ratio below 1.00 for two consecutive fiscal years and as of the end of the second such fiscal year, the Corporation has less than 55 days cash on hand. Under the loan agreements relating to the Series 1998 Bonds (defined below), the Corporation is required to maintain a historical debt service coverage ratio of not less than 2.00 and to maintain at least 65 days cash on hand. In the event the Corporation does not meet either of these requirements, it is required to fund a trustee-held debt service reserve fund securing the Series 1998 Bonds. The amount to be deposited shall equal the lesser of 10% of the principal amount of such outstanding bonds, or the largest annual debt service with respect to such bonds in any future year, or 125% of the average annual debt service of future years. As of June 30, 2022 and 2021, there were no funds required to be held in the debt service reserve fund for the Series 1998 Bonds.

In December 1998, the Maryland Health and Higher Education Facilities Authority (MHHEFA) and the District of Columbia (District) issued bonds (Series 1998 Bonds) on behalf of the Corporation. Bond proceeds of approximately $588.6 were loaned to the Corporation under separate loan agreements with MHHEFA and the District upon execution of obligations pursuant to the Master Trust Indenture. MHHEFA issued $283.5 of Revenue Bonds. Principal and interest under the Series 1998 MHHEFA bonds are insured under municipal insurance policies with Assured and Ambac. The District issued $300.0 of Multimodal Revenue Bonds, including $150.0 Series 1998A, $75.0 Series 1998B, and $75.0 Series 1998C. The District Series 1998A bonds, which consist of three tranches totaling $92.7 in August 2022, are uninsured variable rate demand bonds backed by bank letters of credit. The Series 1998A Tranche I bonds, which remained outstanding in August 2022, consist of approximately $30.9 bonds trading in a daily mode backed by a letter of credit issued by TD Bank, N.A. and remarketed by J.P. Morgan Securities Inc. The letter of credit expires in October 2026. In the event of a failed remarketing, the Tranche I bonds would be tendered to the bank and repaid over a five-year period, beginning 367 days following the date of the failed remarketing. The Series 1998A Tranche II bonds totaled $30.9 in August 2022. These bonds trade in a weekly mode and are remarketed by TD Securities. The letter of credit backing these bonds was issued by TD Bank, National Association and expires in October 2025. In the event of a failed remarketing, the Tranche II bonds would be tendered to the bank and repaid over a five-year period, beginning 367 days following the failed remarketing. The Series 1998A Tranche III bonds totaled $30.9 in August 2022. These

bonds trade in a weekly mode and are remarketed by Citigroup Global Markets Inc. The letter of credit backing these bonds was issued by PNC Bank, National Association and expires in December 2022. In the event of a failed remarketing, the Tranche III bonds would be tendered to the bank and repaid over a five-year period, beginning 367 days following the failed remarketing. None of the Series 1998A bonds were put as of June 30, 2022 and 2021, respectively. The reimbursement obligation with respect to the letters of credit are evidenced and secured by obligations issued by the Corporation under the Master Trust Indenture. The documents related to each of these letters of credit includes financial covenants similar to the bank line of credit described below.

Related to the District Series 1998A bonds, the Corporation entered into an interest rate swap with Wells Fargo Bank, National Association in a notional amount totaling $150.0 (reduced to $39.2 at August 2022). The swap agreement expires in fiscal year 2027. Under the terms of the swap, the Corporation pays a fixed rate and receives a variable rate. Collateral is only required to be posted under the swap in the event that the Corporation's credit ratings are downgraded by two rating agencies below the BBB – or Baa2 – level. To date, no collateral postings have been required. As of June 30, 2022 and 2021, the variable interest rate under these agreements was 0.69% and 0.06%, respectively. The fixed rate was 3.69% as of June 30, 2022 and 2021. The variable rates are capped at 14.0%. The interest rate swap was secured by an obligation issued under the Master Trust Indenture.

Certain of the Corporation's bonds are subject to optional redemption or purchase, as follows: (i) the remaining Series 2011 MHHEFA Bonds maturing on or after August 2022 are subject to redemption or purchase at the option of the Corporation prior to maturity beginning in 2021; (ii) the Series 2013A MHHEFA Bonds maturing on or after August 2024 are subject to redemption or purchase at the option of the Corporation prior to maturity beginning in 2023; (iii) the Series 2015 MHHEFA Bonds maturing on or after August 2025 are subject to redemption or purchase at the option of the Corporation prior to maturity beginning in 2025; (iv) the Series 2015 taxable bonds are subject to redemption at any time, so long as the Corporation makes certain make-whole redemption payments; (v) the Series 2017 MHHEFA Bonds maturing on or after May 15, 2027 are subject to redemption or purchase at the option of the Corporation prior to maturity beginning in 2027; and (vi) the Series 2020A and Series 2020B taxable bonds are subject to redemption at any time, so long as the Corporation makes certain make-whole redemption payments.

The Corporation maintains a $580.0 revolving credit agreement provided by a group of banks. The facility was renewed for a three-year term in June 2022 and expires in June 2025. The outstanding balance on the facility was $129.8 as of June 30, 2022 and 2021. The revolving credit agreement is evidenced by an obligation issued under the Master Trust Indenture and includes certain covenants, including a requirement to maintain Days Cash on Hand of 70 days, measured semi-annually as of each June 30 and December 31, and a Debt Service Coverage ratio of 1.25, measured quarterly on a rolling four quarters basis. The Corporation is required to maintain a minimum credit rating of Baa2 or its equivalent from Standard and Poor's and Moody's Investors Service.

In addition, the Corporation maintains a $30.0 letter of credit facility, provided by a single lender, which is also evidenced by an obligation issued under the Master Trust Indenture. This facility is principally used to securitize certain regulatory obligations under various insurance programs and has terms and conditions similar to the revolving credit agreement. The facility was renewed for a three-year term in June 2022 and expires in June 2025; however, the standby letters of credit issued under the facility can be canceled at the

bank's option each year. As of June 30, 2022 and 2021, standby letters of credit issued pursuant to the facility were $16.5 and $16.8, respectively. No amounts have been drawn by the beneficiaries under the standby letters of credit.

Financing costs are amortized over the estimated duration of the related debt using the effective interest method.

(8) Retirement Liabilities

The Corporation has two qualified defined benefit pension plans, MedStar Health, Inc. Pension Equity Plan (PEP) and MedStar Health, Inc. Cash Balance Retirement Plan (CBRP), covering substantially all full-time employees hired before 2005. MedStar St. Mary's Hospital also has a defined benefit plan that substantially covers all employees of MedStar St. Mary's Hospital who were eligible prior to the plan being frozen. Participation in all plans has been closed to new entrants and all plans are frozen to future benefit accruals.

Benefits under the plans are substantially based on years of service and the employees' career earnings. The Corporation contributes to the plans based on actuarially determined amounts necessary to provide assets sufficient to meet benefits to be paid to plan participants and to meet the minimum funding requirements of the Employee Retirement Income Security Act of 1974, as amended by the Pension Protection Act of 2006, and Internal Revenue Service regulations. Effective July 1, 2000, employees of the Transferred Businesses (see note 16) became participants in one of the Corporation's pension plans and are reflected in the pension information provided below.

The Corporation's investment policies are established by MedStar Health, Inc.'s Investment Committee, which is comprised of members of the Board of Directors, other community leaders, and management. Among its responsibilities, the Investment Committee is charged with establishing and reviewing asset allocation strategies, monitoring investment manager performance, and making decisions to retain and terminate investment managers. Assets of each of the Corporation's pension plans are managed in a similar fashion, as the Corporation's investments and assets whose use is limited, by the same group of investment managers. The Corporation has incorporated an IPS into the investment program. The IPS, which has been formally adopted by the Corporation's Board of Directors, contains numerous standards designed to ensure adequate diversification by asset class and geography. The IPS also limits all investments by manager and position size, and limits fixed income position size based on credit ratings, which serves to further mitigate the risks associated with the investment program. As of June 30, 2022, management believes that all investments were being managed in a manner consistent with the IPS.

(Dollars in millions)

The following table illustrates the actual allocations of the Corporation's primary pension plans' investment portfolio as of June 30:

	2022	2021
Cash	2 %	2 %
Publicly traded equities – domestic	10	11
Publicly traded equities – international	6	5
Fixed income securities	16	15
Institutional funds with RDFV	31	31
Alternative investments:		
Commingled equity funds	11	13
Hedge funds	21	21
Private equities	3	2
Total	100 %	100 %

The tables below present the Corporation's pension plans' investable assets as of June 30 aggregated by the three-level valuation hierarchy and separately identify investments reported at NAV:

2022	Level 1	Level 2	NAV	Total
Assets:				
Cash and cash equivalents	$ 30.1	—	—	30.1
U.S. Treasury bonds	76.6	—	—	76.6
U.S. agency mortgage backed securities	—	33.7	—	33.7
Corporate bonds	—	79.2	—	79.2
All other fixed income securities	—	19.3	—	19.3
Equity mutual funds and ETF's	111.8		—	111.8
Institutional funds with RDFV	—	363.2	—	363.2
Common stocks	104.1	—	—	104.1
Alternative investments:				
Commingled funds	—	—	129.7	129.7
Private equity	—	—	37.0	37.0
Hedge funds:				
Custom hedge fund	—	—	54.8	54.8
Other hedge funds	—	—	187.7	187.7
Total assets	$ 322.6	495.4	409.2	1,227.2

(Dollars in millions)

2021	Level 1	Level 2	NAV	Total
Assets:				
Cash and cash equivalents	$ 42.9	—	—	42.9
U.S. Treasury bonds	71.8	—	—	71.8
U.S. agency mortgage backed securities	—	41.7	—	41.7
Corporate bonds	—	93.7	—	93.7
All other fixed income securities	—	17.5	—	17.5
Equity mutual funds and ETF's	104.7	—	—	104.7
Institutional funds with RDFV	—	436.0	—	436.0
Common stocks	138.5	—	—	138.5
Alternative investments:				
Commingled funds	—	—	181.5	181.5
Private equity	—	—	31.1	31.1
Hedge funds:				
Custom hedge fund	—	—	55.6	55.6
Other hedge funds	—	—	235.1	235.1
Total assets	$ 357.9	588.9	503.3	1,450.1

The general investment strategies, fund structures, valuation methods, and redemption terms for hedge fund-of-funds related to the pension plans' investments are largely the same as those included in the Corporation's primary investment portfolio (see note 3). The Corporation has $2.6 of remaining unfunded commitments to private equity vehicles as of June 30, 2022.

The Corporation established a long-term investment return target of 7.25% and 7.50% for both the PEP and CBRP in 2022 and 2021, respectively. These assumptions are based on historical returns achieved in the investment portfolios and represent the return that can reasonably be expected to be generated on a similarly structured portfolio in the future.

The Corporation recognizes the funded status of defined benefit pension plans in the consolidated balance sheet and the recognition in unrestricted net assets of unrecognized gains or losses, prior service costs or credits and transition assets or obligations. The funded status is measured as the difference between the fair value of the plan's assets and the projected benefit obligation of the plan. The measurement date for the plans is June 30.

The following are deferred pension costs which have not yet been recognized in periodic pension expense, but instead are accrued in unrestricted net assets, as of June 30, 2022 and 2021. Unrecognized actuarial losses represent unexpected changes in the projected benefit obligation and plan assets over time, primarily due to changes in assumed discount rates and investment experience. Unrecognized prior service cost is the impact of changes in plan benefits applied retrospectively to employee service previously

(Dollars in millions)

rendered. Deferred pension costs are amortized into annual pension expense over the expected future lifetime for active employees with frozen benefits.

	Amounts in unrestricted net assets to be recognized during the next fiscal year	Amounts recognized in unrestricted net assets as of: June 30, 2022	June 30, 2021
Net actuarial loss	$ 27.2	896.8	995.7

The following table sets forth the plans' funded status and amounts recognized in the accompanying consolidated financial statements as of June 30:

	2022	2021
Change in benefit obligation:		
Benefit obligation at beginning of year	$ 1,746.7	1,757.4
Interest cost	51.3	51.6
Actuarial (gain) loss	(315.9)	7.2
Benefits paid	(77.9)	(69.5)
Benefit obligation at end of year	1,404.2	1,746.7
Change in plan assets:		
Plan assets at fair value at beginning of year	1,450.1	1,128.1
Actual (loss) return on plan assets	(160.0)	316.5
Company contributions	15.0	75.0
Benefits paid	(77.9)	(69.5)
Plan assets at fair value at end of year	1,227.2	1,450.1
Funded status/net amount recognized	$ (177.0)	(296.6)

The amounts recognized in the consolidated financial statements consist of the following as of June 30:

	2022	2021
Pension assets (included in other assets)	$ 10.9	8.7
Pension liabilities	(187.9)	(305.3)

(Dollars in millions)

The Corporation has estimated $15.0 for its defined benefit contributions for the fiscal year ending June 30, 2023. Expected fiscal year benefit payments for all defined benefit plans is as follows:

2023	$	98.6
2024		100.0
2025		99.9
2026		101.2
2027		104.0
2028–2032		473.5
	$	977.2

Net periodic pension income for the years ended June 30 is as follows:

		2022	2021
Interest cost on projected benefit obligation	$	51.3	51.6
Return on plan assets		(94.7)	(91.5)
Amortization of prior year plan amendments		(0.5)	(0.5)
Recognized actuarial loss		38.2	39.5
Net periodic pension income	$	(5.7)	(0.9)

The assumptions used in determining net periodic pension expense and accrued pension costs shown above are as follows:

	2022	2021
Discount rates for obligations at year end:		
PEP	4.90 %	3.05 %
CBRP	4.95	3.00
MedStar St. Mary's Hospital Pension Plan	4.40	2.65
Discount rates for pension cost:		
PEP	3.05 %	3.05 %
CBRP	3.00	3.00
MedStar St. Mary's Hospital Pension Plan	2.65	2.50
Expected long-term rate of return on plan assets:		
PEP and CBRP	7.25 %	7.50 %
MedStar St. Mary's Hospital Pension Plan	7.00	7.25

(Dollars in millions)

Mortality assumptions for the plans are periodically updated to reflect the most recently published general industry mortality tables.

The Corporation also has various contributory, tax deferred annuity and savings plans with participation available to certain employees. The Corporation matches employee contributions up to 3.0% of compensation in certain plans. The Corporation contributed approximately $52.0 and $46.0 during the years ended June 30, 2022 and 2021, respectively.

(9) Business and Credit Concentrations

The Corporation provides healthcare services through its inpatient and outpatient care facilities located in the State of Maryland, the District and Northern Virginia. The Corporation generally does not require collateral or other security in extending credit; however, it routinely obtains assignment of (or is otherwise entitled to receive) patients' benefits receivable under their health insurance programs, plans or policies (e.g., Medicare, Medicaid, Blue Cross, workers' compensation, health maintenance organizations and commercial insurance policies).

A summary of net patient service revenue by major category of payor for the years ended June 30 is as follows:

	2022	2021
Medicare and Medicare HMO	34 %	34 %
Medicaid and Medicaid HMO	18	17
Carefirst Blue Cross Blue Shield	18	18
Other commercial and managed care payors	24	24
Self-pay	6	7
	100 %	100 %

A summary of net patient receivables by major category of payor as of June 30 is as follows:

	2022	2021
Medicare and Medicare HMO	23 %	21 %
Medicaid and Medicaid HMO	21	20
Carefirst Blue Cross Blue Shield	16	15
Other commercial and managed care payors	34	37
Self-pay	6	7
	100 %	100 %

Certain Maryland-based hospital charges are subject to review and approval by the Health Services Cost Review Commission (HSCRC). The HSCRC has jurisdiction over hospital reimbursement in Maryland by

agreement with the Centers for Medicare and Medicaid Services (CMS). This agreement is based on a waiver from the Medicare Prospective Payment System reimbursement principles granted under Section 1814(b) of the Social Security Act. In January 2014, CMS approved Maryland's waiver for a five-year period beginning January 1, 2014 for inpatient and outpatient hospital services. The waiver tied hospital per capita revenue growth to the state's economic growth of 3.58% and required growth in Medicare spending per beneficiary in Maryland to be 0.5% below the national average. The waiver also imposed quality measures and encouraged population health management.

Under the Maryland HSCRC rate methodology, amounts payable for services to Maryland hospital patients under the Medicare and Medicaid insurance programs are computed at 92.3% of regulated charges. This discount amount does not include managed care organization granted discounts for medical education or adjustments made to Medicare performance under total cost of care. Hospital patients under Blue Cross and approved HMO insurance programs are computed at 98% of regulated charges. Maryland accounts receivable from these third-party payors have been adjusted to reflect the difference between charges and the payable amounts.

In connection with the waiver, the HSCRC introduced the Global Budget Revenue (GBR) model, which covers the Corporation's seven Maryland hospitals. This model moves payment to hospitals from each individual service to a total revenue for each hospital (or a combination of hospitals) to provide hospitals flexibility in the objectives of better care for individuals, higher levels of overall population health, and improved health care affordability. The model removes the financial incentive to increase volume and provides incentives to work with partners to provide care in appropriate settings. In 2018, Maryland entered into a new ten-year model with CMS to include total cost of care benchmarks and savings, which took effect January 1, 2019, and will be re-evaluated at the end of five years. The new waiver is intended to shift care into lower cost settings, improve care coordination, and align incentives among various healthcare providers.

The GBR model has the potential of including both prospective and retrospective rate adjustments. In June 2021, the HSCRC completed and approved a reconciliation of GBR-related COVID-19 support granted to all Maryland hospitals during fiscal year 2020 and Public Health and Social Services Emergency Fund (PHSS Emergency Fund) distributions subsequently received by Maryland hospitals under the Coronavirus Aid, Relief, and Economic Security Act of 2020 (CARES Act), and the Paycheck Protection Program and Health Care Enhancement Act (PPPHCE Act). The impact of this reconciliation on MedStar Health's Maryland hospitals was a retroactive revenue reduction of $77.0, which is recorded within other current liabilities on the consolidated balance sheet as of June 30, 2021. As of June 30, 2022, this liability was satisfied and the Corporation's rates were reduced accordingly. Future actions by the HSCRC cannot be determined at this time.

The Budget Control Act of 2011 mandated significant reductions and spending caps on the federal budget for fiscal years 2012 through 2021. As part of this legislation, a 2% reduction in Medicare spending, known as Sequestration, was implemented beginning April 1, 2013 and the Corporation's Medicare payments subsequent to that date were reduced by the mandatory 2%. The Bipartisan Budget Act of 2015, enacted on November 2, 2015, continued the 2% reductions to Medicare reimbursement imposed under the 2011 Act. The CARES Act revised Medicare policies in order to temporarily boost Medicare reimbursement for added regulatory flexibility, including suspending the annual 2% Medicare sequestration revenue reduction

(Dollars in millions)

through March 31, 2022, and reducing revenue by 1% from April 1, 2022 through June 30, 2022 (see note 10). It is not possible to determine how future congressional actions to reduce the federal deficit in order to end Sequestration will impact the Corporation's revenues.

Through its MFC subsidiary, the Corporation enters into agreements with state Medicaid programs to provide managed care services to eligible Medicaid enrollees in exchange for a premium per member from the state program. This subsidiary participates in an annual rate setting process with the State of Maryland and the District. During the process, the revenues and expenses for all members are evaluated to ensure adequate funding is provided to deliver contracted services. Premium revenue primarily consists of the following at June 30:

		2022	2021
Maryland Medicaid	$	590.3	541.3
District of Columbia Medicaid		402.0	283.9
Total Medicaid	$	992.3	825.2

Medical and clinical expenses from these agreements include claim payments, capitation payments, and estimates of outstanding claims liabilities for services provided prior to the balance sheet date. The estimates of outstanding claims liabilities of $119.0 and $106.4 as of June 30, 2022 and 2021, respectively, are based on management's analysis of historical claims paid reports and review of health services utilization during the period and are included in accounts payable and accrued expenses on the consolidated balance sheets. Changes in these estimates are recorded in the period of change. Claims payments and capitation payments are expensed in the period services are provided to eligible enrollees. Annually, as of December 31, MFC is required to be in compliance with risk-based capital (RBC) statutory funding requirements, and as of the most recent measurement period, MFC is in compliance.

In October 2021, the District issued a new contract to MFC to provide Medicaid managed care services from October 1, 2021 to June 30, 2022 and the D.C. City Council approved the new contract through emergency legislation. The District has subsequently extended this contract through December 29, 2022. The District has issued a new request for proposal for Medicaid managed care services, and MFC has submitted its proposal for this new contract.

(10) Certain Significant Risks and Uncertainties

As a healthcare provider, the Corporation is subject to certain significant inherent risks, including the following:

- Dependence on revenues derived from reimbursement by the federal Medicare and state Medicaid programs;
- Regulation of hospital rates by the State of Maryland HSCRC;
- Government regulation, government budgetary constraints and proposed legislative and regulatory changes, and;

- Lawsuits alleging malpractice or other claims.

Such inherent risks require the use of certain management estimates in the preparation of the Corporation's consolidated financial statements, and it is reasonably possible that a change in such estimates may occur.

The Medicare and state Medicaid reimbursement programs represent a substantial portion of the Corporation's revenues and the Corporation's operations are subject to a variety of other federal, state and local regulatory requirements. In addition, changes in federal and state reimbursement funding mechanisms and related government budgetary constraints could have a significant adverse effect on the Corporation. Similarly, failure by the Corporation to maintain required regulatory approvals and licenses and/or changes in related regulatory requirements could have a significant adverse effect.

Laws and regulations governing the Medicare and Medicaid programs are complex and subject to interpretation. As a result, there is at least a reasonable possibility that recorded estimates will change by a material amount. Estimated settlements are adjusted in future periods as adjustments become known, or as years are settled or are no longer subject to such audits, reviews and investigations. During 2022 and 2021, certain of the Corporation's prior year third-party estimates were adjusted, which resulted in gains of approximately $41.6 and $8.1, respectively.

The healthcare industry is subject to numerous laws and regulations from federal, state and local governments, and the government has increased enforcement of Medicare and Medicaid anti-fraud and abuse laws, as well as the physician self-referral law (Stark Law). The Corporation's compliance with these laws and regulations can be subject to periodic governmental review and interpretation, which can result in regulatory action unknown or unasserted at this time. Management is aware of certain asserted and unasserted legal claims and regulatory matters arising in the ordinary course of business but cannot reasonably predict any particular outcome or operational or financial effects from these matters at this time. The Corporation will continue to monitor all government inquiries and respond appropriately.

Recent government initiatives have focused on curtailing fraud, waste, and abuse in government-funded healthcare programs. To this end, the federal government, and many states, have implemented programs to audit and recover potential overpayments to providers from the Medicare and Medicaid programs. The Corporation's hospitals and providers have periodically received audit requests from Medicare and Medicaid audit contractors, as well as the Office of Inspector General of the U.S. Department of Health & Human Services (HHS). These audit requests have targeted, among other things, medical necessity of inpatient admissions and provider documentation and coding practices. The Corporation's hospitals and providers have cooperated with each of these audit requests and implemented a program to track and manage their effect.

As a result of federal healthcare reform legislation, rules and regulations, substantial changes are occurring in the United States healthcare system. These include numerous provisions affecting the delivery of

healthcare services, the financing of healthcare costs, reimbursement to healthcare providers, the privacy and security of health information, and the legal obligations of health insurers, providers and employers.

(a) COVID-19 Pandemic

In January 2020, the Secretary of HHS declared a national public health emergency due to a novel strain of coronavirus COVID-19 and in March 2020, it was declared a pandemic by the World Health Organization. To contain the spread and impact of COVID-19, and to mitigate the burden on the healthcare system, federal, state and local authorities implemented various restrictive measures, including significant limitations on business activity, travel bans, promotion of physical distancing, mandated quarantines, and shelter-in-place orders. During this time, MedStar hospitals and providers experienced severe volatility with respect to patient volumes, particularly with respect to elective procedures and non-urgent ambulatory visits, resulting in lost revenues.

Throughout fiscal year 2022, MedStar Health's operations and patient volumes continued to experience volatility because of the pandemic. Although elective procedures and non-urgent ambulatory visits resumed in June 2020, MedStar Health has continued to care for a significant number of COVID-19 positive patients in its communities, including another surge which began in December 2021 and peaked in January 2022. Despite the volatility in patient volumes, and a significant increase in patient acuity, non-COVID-19 services were not restricted during the latest surge due to the creation of additional bed capacity and the effective coordination of resources across the system. However, MedStar Health's ongoing response to the COVID-19 pandemic continued to increase operating costs, including personnel and supplies expenses, during the year ended June 30, 2022.

As the COVID-19 pandemic continues to evolve, MedStar Health is unable to determine the full financial impact at this time. The ultimate impact of the pandemic on MedStar Health's financial condition will depend on, among other factors, the duration and severity of the pandemic, including any future surges of COVID-19 positive patients and any resulting impact on patient volumes, negative economic conditions arising from the pandemic, and the impact of government actions and administrative regulations on the hospital industry and broader economy, including through existing and any future relief efforts.

(b) Public Health and Social Services Emergency Fund (PHSS Emergency Fund)

As a result of the COVID-19 pandemic, federal, state, and the District of Columbia governments passed legislation, promulgated regulations, and took other administrative actions intended to assist healthcare providers in providing care to COVID-19 and other patients during the public health emergency. Sources of relief included the CARES Act, which was enacted on March 27, 2020, and the PPPHCE Act, which was enacted on April 24, 2020. Together, the CARES Act and the PPPHCE Act included $175 billion in funding to be distributed to eligible providers through the PHSS Emergency Fund (also known as the Provider Relief Fund or PRF), which is intended to compensate providers for lost revenue and healthcare related expenses attributable to the COVID-19 pandemic and to ensure uninsured Americans have access to testing and treatment for COVID-19. In December 2020, Congress passed the Consolidated Appropriations Act, a new coronavirus relief and government

funding package, which added $3 billion to the PHSS Emergency Fund and made significant changes to how PHSS Emergency Fund distributions could be utilized, including:

- Allowing providers to use any reasonable method to calculate lost revenue, including a variance from budget if such budget had been established and approved prior to March 27, 2020; and
- Allowing a parent entity to re-allocate any PHSS Emergency Fund distributions received, including both general and targeted distributions, within a parent-subsidiary organizational structure.

Additionally, in June 2021, HHS established new deadlines for when recipients of PHSS Emergency Fund distributions must use the funding received (generally 12 to 18 months after receipt of the funds) and issued new post-payment reporting requirements. HHS has made, and continues to make, distributions to providers in areas particularly impacted by COVID-19, including safety net hospitals, rural providers, certain Medicaid providers, and providers requesting reimbursement for testing and treatment of uninsured Americans, among others. Payments from the PHSS Emergency Fund are not subject to repayment so long as providers attest to and satisfy certain terms and conditions required by HHS, including, among other things, that the funds are being used for lost operating revenue and COVID-19 related expenses, limitations on balance billing, and agreeing that PHSS Emergency Funds will not be used to reimburse expenses or losses that other sources are obligated to reimburse. HHS has reserved the right to audit PHSS Emergency Fund recipients and may pursue collection activity for any funds not used in accordance with program requirements or applicable law.

Through June 30, 2022, MedStar Health received PHSS Emergency Fund distributions of $372.2. Of the total distributions received, $47.1 and $206.0 is recognized as other operating revenue on the consolidated statements of operations and changes in net assets for the years ended June 30, 2022 and 2021, respectively. The balance of $119.1 was recognized as other operating revenue on the consolidated statements of operations and changes in net assets for the year ended June 30, 2020. Subsequent to June 30, 2022, MedStar received additional PHSS Emergency Fund distributions totaling $33.6. Payments are recognized as revenue when there is reasonable assurance that the terms and conditions associated with the distributions have been met. CARES Act revenue recognition during fiscal year 2021 included a cumulative re-measurement of lost operating revenue and COVID-19 related expenses in accordance with the terms and conditions and the incurrence of additional COVID-19 related expenses. Amounts recognized as revenue could change in the future based on continuing analysis of lost operating revenue and COVID-19 related expenses, as well as evolving compliance guidance provided by HHS, which could impact MedStar Health's ability to retain some or all of the distributions received.

(c) Medicare Accelerated and Advance Payment Program

To increase cash flow to Medicare providers impacted by the COVID-19 pandemic, the CARES Act expanded the Medicare Accelerated and Advance Payment Program (Program), which allowed for eligible health care facilities to request up to six months of advance Medicare payments. MedStar Health received $703.4 of payments under this program, which represent contract liabilities under ASC 606. Recoupment of these amounts began in April 2021 in accordance with the Program's repayment terms, which specify that for the first 11 months after repayment begins, repayment will occur through an automatic recoupment of 25% of Medicare payments otherwise owed to the provider. In March 2022, recoupment increased to 50% which will continue for six months and at the end of the

six months, Medicare will issue a letter for full repayment of any remaining balance, as applicable. As of June 30, 2022, and 2021, Program advances of $138.7 and $617.4, respectively, are recorded within amounts due to third-party payors, net on the consolidated balance sheets. The amount outstanding as of June 30, 2022 is classified as a current liability (see note 4).

(d) Payroll Taxes

The CARES Act provided for deferred payment of the employer portion of social security taxes through December 31, 2020, with 50% of the deferred amount due December 31, 2021, and the remaining 50% due December 31, 2022. As of June 30, 2022, MedStar Health deferred $46.9, which is recorded within accrued salaries, benefits, and payroll taxes. As of June 30, 2021, MedStar Health deferred $94.1, of which $47.2 is recorded within accrued salaries, benefits, and payroll taxes and $46.9 is recorded within other long-term liabilities on the consolidated balance sheets.

Additionally, the CARES Act created a payroll tax credit designed to encourage employers to retain employees during the pandemic. During the fiscal year ended June 30, 2021, after evaluating eligibility criteria, MedStar Health filed for $15.4 of employee retention payroll tax credits pursuant to the CARES Act. These tax credits were recorded as a reduction of personnel expense on the consolidated statement of operations and changes in net assets.

(e) Other Provisions

The CARES Act revised Medicare policies in order to temporarily boost Medicare reimbursement and allow for added regulatory flexibility, which included the following:

- Effective March 25, 2021, the annual 2% sequestration revenue reduction in Medicare fee for service and Medicare Advantage payments to hospitals, physicians and other providers was suspended through March 31, 2022, and reduced revenue by 1% from April 1, 2022 through June 30, 2022. In order to offset the added expense of the suspension, the fiscal year 2030 sequester cuts will be increased.
- Increased the payment that would otherwise be made to a hospital for treating a Medicare patient admitted with COVID-19 by 20% under the inpatient prospective payment system. The add on payment will be available for the duration of the public health emergency as declared by the Secretary of HHS.
- Through PHSS Emergency Fund distributions, provides claims reimbursement to healthcare providers generally at Medicare rates for testing uninsured individuals for COVID-19 and treating uninsured individuals with a COVID-19 diagnosis.
- Effective March 22, 2022, HHS announced that the COVID-19 Uninsured Program and Coverage Assistance Fund was no longer accepting claims due to insufficient funding.

The impact of these changes is recorded in net patient service revenue on the consolidated statements of operations and changes in net assets for the fiscal years ended June 30, 2022 and 2021.

(Dollars in millions)

(f) Federal Emergency Management Agency (FEMA) Funding

As a result of increased operating and capital costs incurred as a part of the response to the COVID-19 pandemic, MedStar Health requested funding from FEMA for reimbursement of certain eligible costs. In fiscal year 2022, FEMA obligated to MedStar Health total funding of $55.5, of which $50.0 is recorded as other operating revenue on the consolidated statement of operations and changes in net assets for the fiscal year ended June 30, 2022. Cash proceeds of $33.0 and $20.8 were received in fiscal years 2022 and 2021, respectively. The unpaid portion of the recognized funding is recorded within other current liabilities on the consolidated balance sheet as of June 30, 2022. Currently, the timing of FEMA's close-out process for a final award determination, as well as any additional procedures that FEMA may need to complete prior to close-out, including the finalization of potential deductions to the obligated amount, is unknown.

(11) Self-Insurance Programs

The Corporation maintains self-insurance programs for professional and general liability risks, employee health and workers' compensation. Estimated liabilities have been recorded based on actuarial estimation of reported and incurred but not reported claims. The combined accrued liabilities for these programs as of June 30 were as follows:

		2022	2021
Professional and general liability	$	404.6	364.2
Employee health		35.2	27.6
Workers' compensation		35.1	36.5
Total self-insurance liabilities		474.9	428.3
Less current portion		(115.6)	(100.3)
Total self-insurance liabilities, net of current portion	$	359.3	328.0

Assets available to fund these liabilities are held in separate accounts (see note 2). Contributions required to fund professional and general liability, employee health benefits and workers' compensation programs are determined by the plans' administrators based on appropriate actuarial assumptions. The professional and general liability programs are administered through an offshore wholly owned captive insurance company, Greenspring Financial Insurance, LTD.

For professional liability during the fiscal years ended June 30, 2022 and 2021, MedStar Health is responsible for the below described retentions:

(a) Effective January 1, 2022, the Corporation is responsible for the first $15.0 exposure for each and every claim plus an additional inner aggregate. For this period, the inner aggregate exposes the Corporation up to $5.0 per claim with an aggregate of $5.0 above the $7.5 per claim self-insured retention for all claims incurred.

(b) For the period July 1, 2021 to December 31, 2021, the Corporation is responsible for the first $7.5 exposure for each and every claim plus an additional inner aggregate. The inner aggregate exposes the Corporation up to $2.5 per claim with an aggregate of $5.0 above the $7.5 per claim self-insured retention for all claims incurred.

(c) For fiscal years ended June 30, 2022 and 2021, for general liability, except for MMMC and MSMH, the Corporation is responsible for the first $3.0 exposure for each claim. For MMMC and MSMH, the Corporation is responsible for the first $2.0 exposure for each claim. General liability claims are not subject to the inner aggregate excess retention as described above.

Commercial excess re-insurance has been purchased above the self-insured retentions described above in multiple layers and in twin towers; one tower for professional liability and one tower for general liability. Effective January 1, 2016, each tower provides excess re-insurance coverage of up to $175.0 per claim and $175.0 annual aggregate.

The professional and general liabilities as of June 30, 2022 and 2021 have been discounted at a rate of 1.75%. The workers' compensation liabilities as of June 30, 2022 and 2021 have been discounted at a rate of 1.5%.

(12) Endowment Net Assets

The Corporation's endowments consist of individual donor restricted funds established for a variety of purposes. As required by U.S. GAAP, net assets associated with endowment funds are classified and reported based on the existence or absence of donor-imposed restrictions.

(a) Interpretation of Relevant Law

The Corporation has interpreted the State Prudent Management of Institutional Funds Act (SPMIFA) as requiring the preservation of the fair value of the original gift as of the gift date of the donor restricted endowment funds absent explicit donor stipulations to the contrary. As a result of this interpretation, the Corporation classifies as net assets with donor restrictions: (a) the original value of gifts donated to the permanent endowment, (b) the original value of subsequent gifts to the permanent endowment, and (c) accumulations to the permanent endowment made in accordance with the direction of the applicable donor gift instrument at the time the accumulation is added to the fund. In accordance with SPMIFA, the Corporation considers the following factors in making a determination to appropriate or accumulate donor restricted endowment funds:

(1) The duration and preservation of the fund

(2) The purposes of the Corporation and the donor restricted endowment fund

(3) General economic conditions

(4) The possible effect of inflation and deflation

(5) The expected total return from income and the appreciation of investments

(6) Other resources of the Corporation

(7) The investment policies of the Corporation

(b) Endowment Net Assets

Donor restricted endowment funds within net assets with donor restrictions whose use is restricted into perpetuity were $46.4 and $46.9 as of June 30, 2022 and 2021, respectively. Investment returns and other income from these endowment funds whose use is restricted as to time or purpose were $7.6 and $12.5 as of June 30, 2022 and 2021, respectively.

(c) Underwater Endowments

From time to time, the fair value of assets associated with individual donor restricted endowment funds may fall below the level that the donor or SPMIFA requires the Corporation to retain as a fund of perpetual duration. No material deficiencies existed as of June 30, 2022 and 2021.

(d) Investment Strategies

The Corporation has adopted policies for corporate investments, including endowment assets, that seek to maximize risk-adjusted returns with preservation of principal. The endowment assets are invested in a manner that is intended to hold a mix of investment assets designed to meet the objectives of the account. The Corporation expects its endowment funds, over time, to provide an average rate of return that generates earnings to achieve the endowment purpose.

To satisfy its long-term rate-of-return objectives, the Corporation relies on a total return strategy in which investment returns are achieved through both capital appreciation (realized and unrealized) and current yield (interest and dividends). The Corporation employs a diversified asset allocation structure to achieve its long-term return objectives within prudent risk constraints.

The Corporation monitors the endowment funds returns and appropriates average returns for use. In establishing this practice, the Corporation considered the long-term expected return on its endowment. This is consistent with the Corporation's objective to maintain the purchasing power of the endowment assets held in perpetuity or for a specified term as well as to provide additional real growth through new gifts and investment return.

(13) Income Taxes

The Corporation and the majority of its subsidiaries are not-for-profit corporations as defined in Section 501(c)(3) of the Internal Revenue Code (the Code) and are exempt from federal income taxes under Section 501(a) of the Code. The Corporation's tax-exempt businesses generate nominal amounts of unrelated business income subject to income tax. For corporate income tax purposes, the Corporation has two consolidated groups of for-profit, taxable entities. The parent companies of these groups are Parkway Ventures, Inc. and MedStar Enterprises, Inc.

As of June 30, 2022, the Corporation's taxable subsidiaries had $26.8 of gross deferred tax assets with an associated valuation allowance of $15.6 resulting in net deferred tax assets of $11.2, which are included in other assets on the accompanying consolidated balance sheets. The deferred tax assets are comprised of net operating loss carryforwards, many of which expire in 2036 and estimated reversing temporary differences. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets depends on the generation of future taxable income during the periods in which those temporary differences are deductible. The relevant deferred tax balances reflect the federal statutory rate of 21% plus the effective state tax rate. As of June 30, 2021, the Corporation's gross deferred tax assets of $28.3 were offset by an associated valuation allowance of $14.3. The current tax provisions for the years ended June 30, 2022 and 2021 were not significant.

(14) Charity Care and Other Community Benefits

MedStar Health is committed to ensuring that patients within the communities it serves who lack financial resources have access to necessary hospital services. MedStar Health and its healthcare facilities serve the emergency health care needs of everyone who visits the facilities regardless of a patient's ability to pay for care; and assist those patients who are admitted through the admissions process for nonurgent and urgent, medically necessary care who cannot pay for the care they receive.

In meeting this commitment, MedStar Health's facilities work with uninsured patients to gain an understanding of each patient's financial resources prior to admission (for scheduled services) or prior to billing (for emergency services). Based on this information and patient eligibility, the Corporation's facilities assist uninsured and certain underinsured patients that meet medical hardship criteria who reside within the communities served. This assistance is provided in one or more of the following ways:

- Assist with enrollment in publicly funded entitlement programs (e.g., Medicaid and Medicare programs).
- Assist with consideration of funding that may be available from other charitable organizations.
- Provide charity care and financial assistance according to applicable guidelines, including considerations for patients that may be underinsured and for those that may be suffering from a medical hardship.
- Provide financial assistance for payment of facility charges using a sliding scale based on patient family income and financial resources.
- Offer periodic payment plans to assist patients with financing their healthcare services.

Eligibility criteria for financial assistance consider patient's household income in relation to the federal poverty guidelines and the equity value of real property and/or other assets. By definition, free care is available to uninsured patients in households between 0% and 200% of the federal poverty line. Reduced cost-care is based on a sliding-scale and is available to uninsured patients in households between 200% and 400% of the federal poverty line. The Corporation's hospitals utilize a cost to charge ratio methodology to convert charity care to cost. The estimated cost of services provided is determined based on the relationship of total operating costs to gross charges. Total operating costs for purposes of this ratio exclude costs associated with community benefit activities. Total gross patient charges are then offset with

any related reimbursements. The Corporation provided $60.4 and $39.7 of charity care at cost during the years ended June 30, 2022 and 2021, respectively, based on the cost to charge ratio.

In addition to charity care, the Corporation also funds costs of services provided to persons covered by publicly funded programs and numerous programs designed to benefit the healthcare interests of the communities it serves. Examples of these programs are health professional education, community health services, and research to advance care. The costs associated with these programs are recorded in the appropriate operating expense categories. In 2021, the most current period for which the Corporation's community benefits report is available, the total cost of these programs, including charity care services provided and certain other implicit price concessions, was approximately $399.1.

(15) Leases

The Corporation's leases are primarily for real estate, including medical office buildings, and corporate and other administrative offices, as well as medical, IT and office equipment. Real estate lease agreements typically have initial terms of three to ten years, and equipment lease agreements typically have initial terms between two and five years. The Corporation also has a long-term land lease whose original term was ninety-eight years (see note 16).

Real estate leases may include one or more options to renew, with renewals that can extend the lease term from one to ten years. The exercise of lease renewal options is typically at the Corporation's sole discretion. Renewal options are assessed at the commencement date, modification date and when a reassessment event has occurred. The renewal option is included in the lease term when it is reasonably certain to be exercised. The Corporation's lease agreements do not contain any transfer of title or purchase options.

Certain lease agreements for real estate include variable payments based on actual common area maintenance and other operating expenses. These variable lease payments are recognized in other operating expenses but are not included in the right of use asset or liability balances. Real estate leases generally include rental escalation clauses that are factored into our determination of lease payments when appropriate.

In determining the present value of lease payments, the Corporation uses the implicit rate noted within the contract, unless unknown in which case the Corporation's estimated incremental borrowing rate is used. The incremental borrowing rates for the portfolio of leases are based upon indicative borrowing rates for taxable, corporate, investment grade debt with terms that correspond to the various lease terms.

(Dollars in millions)

The following table presents the components of the right-of-use assets and liabilities related to leases and their classification in the consolidated balance sheet:

			2022	2021
Assets:				
Total operating lease assets	Operating lease right-of-use assets, net	$	269.3	252.3
Finance lease assets	Property and equipment, net		2.4	2.7
Total leased assets			271.7	255.0
Liabilities:				
Operating lease liabilities:				
Current	Current portion of operating lease liabilities		60.2	63.0
Long-term	Operating lease liabilities, net of current portion		227.1	212.1
Total operating lease liabilities			287.3	275.1
Finance lease liabilities:				
Current	Current portion of long-term debt		0.3	0.3
Long-term	Long-term debt, net of current portion		3.3	3.5
Total finance lease liabilities			3.6	3.8
Total lease liabilities		$	290.9	278.9

The following table presents the components of lease expense, which is recorded within purchased services and other operating expenses in the consolidated statements of operations and changes in net assets for the years ended June 30, 2022 and 2021:

		2022	2021
Operating lease expense	$	73.4	69.5
Variable and short-term lease expense		24.8	34.2
Total lease expenses	$	98.2	103.7

The weighted average lease term and discount rate for operating leases as of June 30, 2022 are as follows:

	2022	2021
Weighted average remaining lease term for operating leases (years)	8.0	8.2
Weighted average discount rate for operating leases	2.41 %	2.51 %

(Dollars in millions)

The following table reconciles the undiscounted cash flows to the operating lease liabilities recorded on the consolidated balance sheet as of June 30, 2022:

2023	$	64.8
2024		57.2
2025		48.0
2026		41.5
2027		26.6
2028 and thereafter		74.1
Total future minimum lease payments		312.2
Less amount of lease payments representing interest		(24.9)
Present value of future minimum lease payments		287.3
Less current obligations under leases		(60.2)
Long-term lease obligations	$	227.1

Certain leases include provisions allowing the minimum rental payments to be adjusted annually for increases in operating costs and, in some cases, real estate taxes attributable to leased property.

(16) Agreements with Georgetown University

In 2000, the Corporation and Georgetown University (the University) signed certain definitive agreements whereby the Corporation received substantially all of the assets owned by the University that constitutes the MGUH, the Community Practice Network, the Faculty Practice Group and certain office buildings and a parking lot on the campus (collectively referred to as the Transferred Businesses). These agreements became effective July 1, 2000 and transferred control of the identified physical plant and other real property assets of the Transferred Businesses to the Corporation for use as an academic medical center for a minimum of ninety-eight years. At the end of the one hundred and fifty year lease term (including a fifty-two year renewal), the University shall convey all leased assets, excluding the underlying land, to the Corporation for a nominal amount and enter into a rent-free ground lease for the Corporation's use.

The Corporation also entered into an Academic Affiliation and Operations Agreement (Affiliation Agreement) with the University in 2000. Under this agreement, the University makes payments to the Corporation determined by multiplying the University School of Medicine's (SOM) total undergraduate tuition revenue by 36% for providing teaching services. The Corporation recognized $14.9 and $14.5 of tuition revenue during the years ended June 30, 2022 and 2021, respectively, which is recorded within other operating revenue on the consolidated statements of operations and changes in net assets.

In June 2017, the Corporation and the University entered into a refreshed and extended partnership agreement to expand the partnership across MedStar Health, provide enhanced clinical and academic alignment for the next 50 years, and support the construction of a new surgical pavilion at MGUH. As part of the new agreement, an Asset Purchase Agreement (2017 APA) between the Corporation and the University, which amended and extended several existing agreements, went into effect for the fiscal year ended June 30, 2017. Additionally, the Corporation signed a Conditional Pledge Agreement and amended the existing lease agreement to include an additional parcel of land for construction of the new surgical pavilion.

The following are components of the 2017 transaction:

- Under the terms of the 2017 APA, the Corporation acquired the right to use the University's trade name and trademarks system-wide for a period of 50 years in connection with the following service lines: oncology, neurology, cardiac, rehabilitation, behavioral health/psychiatry, orthopedics, radiology and neurosurgery. In exchange for these rights, the Corporation will pay the University a total of $200.0, payable in equal installments over 20 years. As a result of this transaction, in fiscal year 2017, the Corporation recorded an intangible asset of approximately $135.0 in goodwill and other intangible assets, net and a corresponding liability for the same amount in other long-term liabilities. Amortization of the intangible asset is recorded on a straight-line basis over the 50-year term.
- Under an amendment to the existing agreement, the Affiliation Agreement was extended through June 30, 2066 and the original gain-sharing provision was eliminated. Commencing after the close of the 6th year of the amended agreement, the Corporation shall pay the University an annual gain-sharing payment based on the Corporation's audited consolidated earnings from operations margin for the prior fiscal year. No payment shall be required for a fiscal year if in the prior fiscal year the Corporation's consolidated earnings from operations margin is less than 1.5%.
- To support the purpose and operations of the University's School of Medicine (SOM), including research, academics, and the training of medical students, the Corporation also entered into a 50-year Conditional Pledge Agreement with the University. For the fiscal years ended June 30, 2022 and 2021, the SOM met all of the annual conditions, and as a result, the Corporation made payments of $14.0 and $13.1, respectively, to the University, which were recorded in other nonoperating activities, net within the consolidated statements of operations and changes in net assets.

Additionally, MGUH and the University are parties to a fixed fee shared services agreement, under which the University provides the following services to MGUH: utilities, telephone/IT services, transportation services and library services. Expenses charged for all shared services were $13.3 and $13.8 for the years ended June 30, 2022 and 2021, respectively, which is recorded within other operating expenses on the consolidated statements of operations and changes in net assets.

(17) Commitments and Contingencies

The MWHC campus is subject to the lien of a Permitted Encumbrance in the amount of $21.5 to the United States government. This encumbrance was created in the deed of the hospital property from the United States government to MWHC in February 1960. There is no repayment date for this lien stated in the deed. Under enabling legislation, repayment could be required after a determination that the property is no longer

(Dollars in millions)

required for hospital services, or the property is disposed of, in which event all or a portion of the lien may be payable to the government. This lien is subordinated to the Deed of Trust on the MWHC campus.

(18) Functional Expenses

The Corporation considers integrated health services, research and management and general to be its primary functional categories for purposes of expense classification. Management and general include information systems, general corporate management, advertising and marketing. The functional breakdown of expenses incurred by the Corporation are as follows:

	Program activities				
2022	Integrated health services	Research	Fundraising	Management and general	Total
Personnel	$ 3,368.3	41.5	6.4	678.5	4,094.7
Supplies	1,094.0	1.0	0.1	9.2	1,104.3
Purchased services and other	1,335.2	14.7	4.1	374.2	1,728.2
Interest	11.9	—	—	40.0	51.9
Depreciation and amortization	130.8	1.4	—	87.0	219.2
	$ 5,940.2	58.6	10.6	1,188.9	7,198.3

	Program activities				
2021	Integrated health services	Research	Fundraising	Management and general	Total
Personnel	$ 3,026.4	36.0	6.3	620.4	3,689.1
Supplies	982.0	1.0	0.2	0.3	983.5
Purchased services and other	1,184.1	14.1	3.0	320.0	1,521.2
Interest	9.8	—	—	46.0	55.8
Depreciation and amortization	126.7	1.9	—	87.8	216.4
	$ 5,329.0	53.0	9.5	1,074.5	6,466.0

(19) Subsequent Events

Management evaluated all events and transactions that occurred after June 30, 2022 and through October 4, 2022. Except as noted below, the Corporation did not have any events that were required to be recognized or disclosed.

In July and August 2022, the Corporation received $33.6 of additional PHSS Emergency Fund payments under the CARES Act (see note 10).