TO: Commissioners
David C. Tobin, Esquire, MedStar Franklin Square Medical Center
Conor B. O'Croinin, Esquire, Counsel for The Johns Hopkins Hospital
Thomas Dame, Esquire, Counsel for University of Maryland Medical Center

FROM: Michael J. O'Grady, Commissioner/Reviewer

RE: Recommended Decision
Application to Establish Kidney Transplantation Services
Docket No.: 17-03-2405

DATE: August 18, 2022

Enclosed is my Recommended Decision in the review of the Certificate of Need (CON) application by MedStar Franklin Square Medical Center (Franklin Square) to establish kidney transplantation services.

The relevant State Health Plan (SHP) chapters considered in this review were COMAR 10.24.15.04B, the Organ Transplant Services and COMAR 10.24.10, the Acute Hospital Services. Also considered were the general CON review criteria at COMAR 10.24.01.08G(3)(a) through (f). I considered the comments of Johns Hopkins Hospital (JHH) and University of Maryland Medical Center (UMMC), interested parties, and the entire record in this review and recommend that the Maryland Health Care Commission **DENY** Franklin Square's application for a Certificate of Need to establish kidney transplantation services.

Franklin Square has failed to comply with the Need, and Cost Effectiveness standards in COMAR 10.24.15.04B, the Organ Transplant Services Chapter of the State Health Plan. It also failed to meet the Need and Availability of More Cost-Effective Alternatives CON review criteria in COMAR 10.24.01.08G(3)(b) and (c). My attached Recommended Decision details my analysis and findings regarding applicable standards and criteria.

Background

As outlined in the Organ Transplant Services Chapter, the Commission determined that organ transplantation is a specialized tertiary-level service that requires clinical expertise and a hospital setting with the most advanced diagnostic, surgical, and monitoring equipment. A specialized service like organ transplantation is intended to be available to a substantial regional population base in a limited number of general hospitals to promote both high quality care and an efficient scale of operation. The Chapter maintains the long-standing three-hour, one-way drive time standard for reasonable geographic access to this service. There are currently two kidney

transplant centers in Maryland, both located in Baltimore, at Johns Hopkins Hospital and the University of Maryland Medical Center. There are also two kidney transplant centers in the District of Columbia at MedStar Georgetown University Hospital (MGTI), and at George Washington University Hospital (GWU). I recognized JHH and UMMC, which provide kidney transplantation services in the planning region, as interested parties in this review. The most recent data on kidney transplant volumes in the Maryland Region and Washington Region Donation Service Areas (DSAs) that cover Maryland is shown immediately below.

Number of Kidney Transplants in the LLF DSA and WRTC DSA Regions, CY 2012-2021

Transplant Center	2012	2013	2014	2015	2016	2017	2018	2019	2020*	2021*
JHH	206	233	255	254	208	190	218	251	212	249
UMMC	297	262	245	264	210	242	222	143	148	168
LLF DSA Total	**503**	**495**	**500**	**518**	**418**	**432**	**440**	**394**	**360**	**417**
MGTI	61	73	87	183	205	202	208	267	304	246
GWUH	-	-	-	-	55	48	56	68	57	65
MedStar Washington	70	90	69	18	-	-	-	-		
Fairfax	108	95	99	76	88	88	99	114	95	131
WRTC DSA Total	**239**	**258**	**255**	**277**	**248**	**238**	**263**	**449**	**456**	**440**
Total	**742**	**753**	**755**	**795**	**766**	**770**	**803**	**843**	**816**	**857**

Source: OPTN.transplant.hrsa.gov
Note: Transplant rates during 2020-2021 may have been affected by the COVID pandemic

The Organ Transplant Services Chapter of the State Health Plan is unique. Need for an organ transplant cannot be addressed solely by building or improving infrastructure. A patient in need of an organ transplant is placed on a waiting list and must wait for a compatible organ donation from a living or deceased donor. Thus, the Need standard, at COMAR 10.24.15.04B(1)(a), prescribes that an applicant demonstrate need for a new transplant service by addressing its proposed program's ability "to increase the supply or use of donor organs …." (emphasis added). Additionally, for this tertiary specialized service, the Access standard, at COMAR 10.24.15.04B(3)(c) dictates that "travel to an organ transplant center… is not, in and of itself, considered a barrier to access, if the drive time in less than three hours one-way."

Project Description

Franklin Square, in partnership with MGTI, seek to establish a kidney transplantation program at Franklin Square's campus in Baltimore County. This application was submitted concurrently with an application to establish a liver transplantation program at Franklin Square. The applicant proposes that the site will provide multi-organ transplants for patients requiring both a kidney and liver transplant (i.e., hepato-renal syndrome).

There are no capital costs associated with the proposed kidney transplantation service. The projected annual cost for operating this service at full implementation (the third year of operation in which the applicant projects the performance of 44 kidney transplantations) is $8.7 million. At full implementation, Franklin Square projects a positive margin of $693,000 for the program.

Recommendation

I recommend that the Maryland Health Care Commission DENY Franklin Square's application for a Certificate of Need to establish a kidney transplant service because the applicant did not satisfy all applicable State Health Plan standards and CON review criteria adopted by the Commission. Specifically, the application did not meet the requirements of Need, and Cost Effectiveness standards in COMAR 10.24.15.04B, and the Need and Availability of More Cost-Effective Alternatives criteria in COMAR 10.24.01.08G (3).

Franklin Square failed to demonstrate that its proposed program would be able to increase the supply or use of donor kidneys, or that there is an unmet need for services that its kidney transplantation program would remedy. Franklin Square's proposed kidney transplant service is simply not needed because there are currently four high-performing existing kidney transplantation services within geographic accessibility to the population.

In May 2021, MHCC gave Franklin Square an opportunity to update its original data submission to bolster its argument for program need and to account for major policy changes in the distribution of kidneys for transplant. Franklin Square submitted minimal data in response to this request, and failed to provide an updated assessment of need taking into account the new kidney allocation policy.

Further Proceedings

This matter will be placed on the agenda of a meeting of the Maryland Health Care Commission on September 15, 2022, which begins at 1:00 p.m. at 4160 Patterson Avenue in Baltimore. This meeting is expected to be a "hybrid" meeting at which Commissioners and persons with matters before the Commission may attend in person or attend virtually through a Zoom webinar format. However, I request that representatives who plan to speak on behalf of the applicant and interested parties attend the meeting in person. Please let the Commission know as soon as possible if there are any concerns with my request to appear in person. The link to register to attend the meeting will be placed on the Commission's meeting page: https://mhcc.maryland.gov/mhcc/pages/home/meeting_schedule/meeting_schedule.aspx?id=0. After registering, each person will receive a confirmation email containing information about joining the Commission meeting via the Internet. The Commission will issue a final decision based on the record of the proceeding.

As provided in COMAR 10.24.01.09B, an applicant or interested party may submit written exceptions to the enclosed Recommended Decision. Written exceptions must identify specifically those findings or conclusions to which exception is taken, citing the portions of the record on which each exception is based. Copies of exceptions and responses to exceptions must be communicated to all parties, via regular mail or email, by the due date and time shown below. If the deadline is met via email, please assure that paper copies of the exceptions or response to exceptions are also mailed to the Commission the same day.

Oral arguments during the exceptions hearing before the Commission will be limited to 10 minutes for the applicant, and 10 minutes for the interested party unless extended by the Chairman. The schedule for the submission of exceptions and any response to exceptions is as follows:

Submission of exceptions:	August 25, 2022
Submission of responses:	August 30, 2022
Exceptions hearing:	September 15, 2022, Monthly Commission meeting starts at 1:00 p.m.

cc: Patricia Nay, M.D., Executive Director, Office of Health Care Quality, MDH
Katie Wunderlich, Executive Director, HSCRC
Stan Lustman, Assistant Attorney General, HSCRC
Caitlin Tepe, Assistant Attorney General, MHCC
Paul Parker, Director, Health Care Facilities Planning and Development, MHCC
Wynee Hawk, Chief, CON, MHCC
Moira Lawson, Program Manager, MHCC
Gregory W. Branch, M.D., Health Officer, Baltimore County

IN THE MATTER OF	*	**BEFORE THE**
	*	
FRANKLIN SQUARE	*	**MARYLAND HEALTH**
	*	
HOSPITAL CENTER	*	**CARE COMMISSION**
	*	
DOCKET NO. 17-03-2405	*	

****

Reviewer's Recommended Decision

August 18, 2022

TABLE OF CONTENTS

I. INTRODUCTION....1
A. Background....1
B. The Applicant....6
C. The Project....7
D. Reviewer's Recommendation....7

II. PROCEDURAL HISTORY....8
A. Review of the Record....8
B. Interested Parties in the Review....8
C. Local Government Review and Comment....8
D. Community Support....8

III. REVIEW AND ANALYSIS....9
A. COMAR 10.24.01.08G (3) (a)-THE STATE HEALTH PLAN....10
COMAR 10.24.10 – Acute Hospital Services
10.24.10.04A-General Standards....10
1. Information Regarding Charges....10
2. Charity Care Policy....11
3. Quality of Care....13

COMAR 10.24.15 – Organ Transplant Services....16
.04A- General Standards....16
(2) Compliance with CMS and UNOS Requirement....16
.04B – Project Review Standards....17
(1) Need....17
(2) Minimum Volume Requirements....29
(3) Access....31
(4) Cost Effectiveness....33
(5) Impact....37
(6) Certification and Accreditation....39
(7) Health Promotion and Disease Prevention....40

B. COMAR 10.24.01.08G (3) (b)-NEED....41

C. COMAR 10.24.01.08G (3) (c)-AVAILABILITY OF MORE COST-EFFECTIVE ALTERNATIVES....43

D. COMAR 10.24.01.08G (3) (d)-VIABILITY OF THE PROPOSAL....45

E. COMAR 10.24.01.08G (3) (e)-COMPLIANCE WITH CONDITIONS OF PREVIOUS CERTIFICATES OF NEED....47

F. COMAR 10.24.01.08G (3) (f)-IMPACT ON EXISTING PROVIDERS 48

IV. SUMMARY AND RECOMMENDATION.....……. 49

FINAL ORDER…… 51

APPENDIX 1: RECORD OF THE REVIEW

APPENDIX 2: HSCRC Opinion Letter

I. INTRODUCTION

A. Background

National Trends in Organ Transplantation

In the United States, the demand for transplant organs has grown substantially over time and far exceeds the supply of available organs. In 1991, there were 6,953 organ donors, 15,756 transplants, and 23,198 people on waitlists for organs. By 2020, the number of donors more than doubled to 18,318, while the number of transplants similarly increased to 39,036, and the number of people on the waitlist for an organ transplant increased to 90,303.[1]

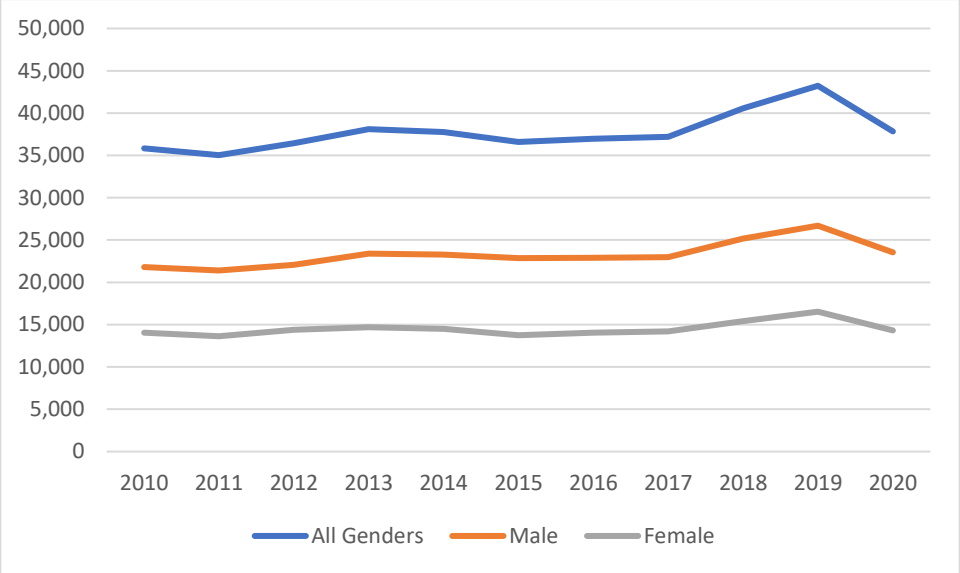
Kidneys are the most transplanted organ in the U.S. with 24,670 kidney transplants performed nationwide in 2021.[2] Increased kidney transplant volumes have been broadly distributed across age groups, racial groups, and gender, and have increased for patients with end stage renal disease. A decrease in transplant volume was seen in 2020, which may be linked to the COVID-19 pandemic.

The available evidence indicates that the number of individuals on the national kidney transplant waitlist have remained stable in recent years.[3] The waitlist has remained stable since 2014 even as new candidates are added because the organ availability has improved.

The largest age/gender cohort on the kidney waitlist is men between the ages of 50 and 64 years old. This age group accounted for about 40% of waitlist candidates in 2008 and 43.5% in 2019. From 2008- 2019, the proportion of Asian and Hispanic transplant candidates has gradually grown, increasing from 8% in 2008 to 10% in 2019 for Asians and 18% in 2008 to 20% in 2019 for Hispanics.[4,5]

[1] Health Resources and Services Administration. Organ Donation Statistics. https://www.organdonor.gov/statistics-stories/statistics/data.html, Accessed October 29, 2021.
[2] Organ Procurement and Transplantation Network. optn.transplant.hrsa.gov, Accessed October 29, 2021
[3] ibid
[4] Organ Procurement and Transplantation Network SRTR Annual Data Report: Kidney.
[5] United States Renal Data System 2020 annual report – available from: adr.usrds.org/2020/end-stage-renal-disease/6-transplantation

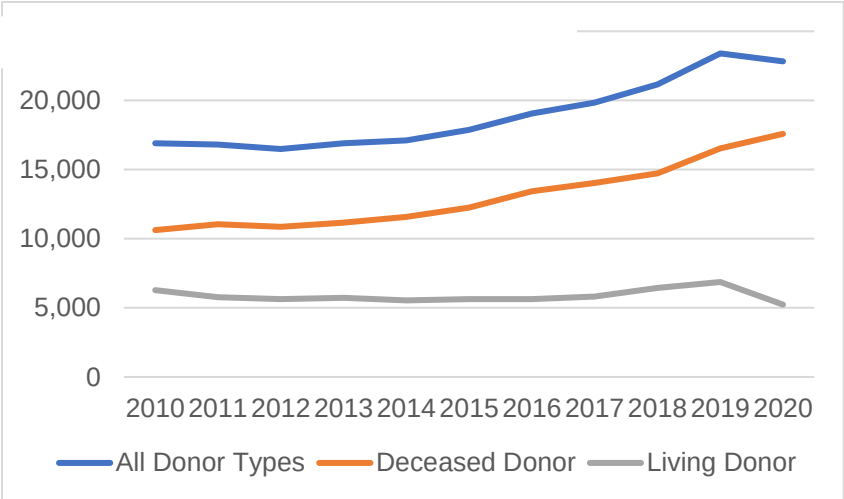
Figure I-1 New Additions to the Kidney Transplant Waitlist, U.S.



Source: optn.transplant.hrsa.gov/data

The increase in organ availability has yielded increases in both living donor and deceased donor transplants. (Figure I-2). In 2019, most of the organs available for transplantation in the U.S. were from deceased donors (70%), while living donors accounted for 30% of all transplants.

Figure I-2 Adult Kidney Transplants by Donor Type, U.S.



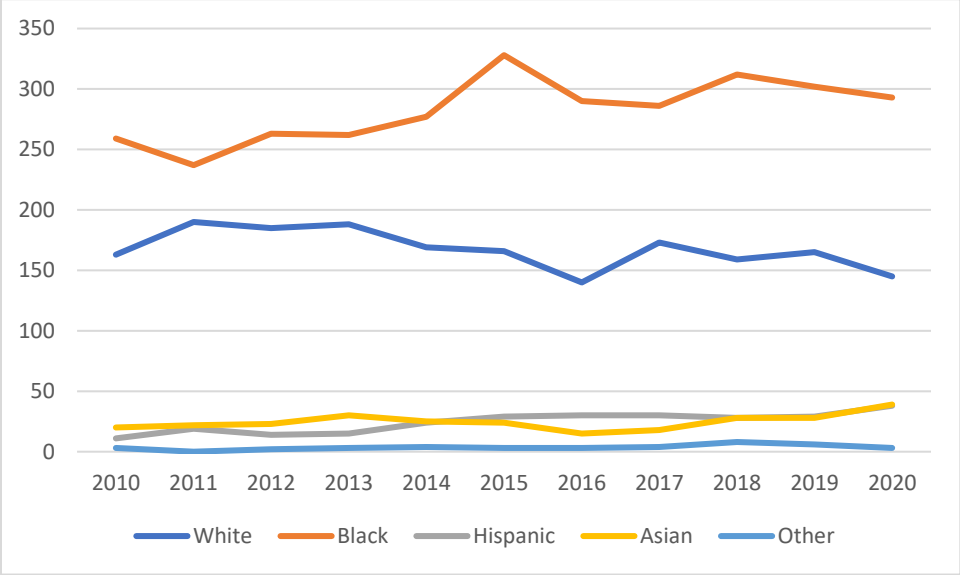
Source: SRTR.transplant.hrsa.gov

Maryland Kidney Transplant Trends

In Maryland, new candidates being added to the waitlist have declined after peaking in 2014.[6] As of October 29, 2021, there were 1,873 Maryland residents on the waitlist for kidney transplants.[7] Deceased donors made up 76% of kidney donations in 2021, with living donors making up 24% of donations.[8]

The number of kidney transplants for Black, Hispanic and Asian Maryland residents have remained stable from 2010 through 2020. The number of transplants for White residents has declined. (Figure I-3).

Figure I-3 Kidney Transplants by Ethnicity, Maryland Residents



Source: SRTR.transplant.hrsa.gov

The Use of High-Risk Kidneys in Transplants

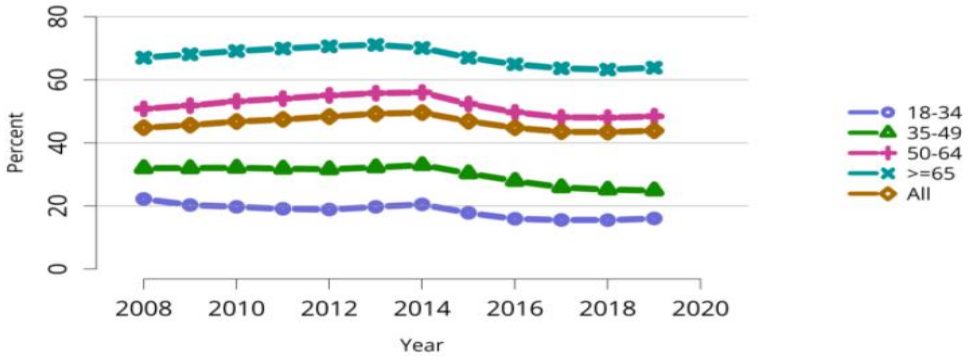
The Kidney Donor Risk Index (KDRI) is an estimate of the relative risk of post-transplant kidney graft rejection. The risk is calculated by assessing several donor characteristics, including age, history of diabetes, height, cause of death, weight, serum creatinine, ethnicity, Hepatitis C Virus (HCV) status, history of hypertension, and donation after circulatory death (DCD) Status.[9] The Kidney Donor Profile Index (KDPI) is calculated from the KDRI to estimate post-transplant

[6] Organ Procurement and Transplantation Network. optn.transplant.hrsa.gov/data/view-data-reports/state-data/#, Accessed October 29, 2021. The number of transplants show an increasing trend from 2010 to 2015 and then a downward trend starting from 2016.
[7] Organ Procurement and Transplantation Network. optn.transplant.hrsa.gov/data/view-data-reports/state-data/#, Accessed October 29, 2021.
[8] Organ Procurement and Transplantation Network. optn.transplant.hrsa.gov/data/view-data-reports/state-data/#, Accessed October 29, 2021.
[9] Organ Procurement and Transplantation Network. Guide to Calculating and Interpreting the Kidney Donor Profile Index (KDPI). optn.transplant.hrsa.gov/media/1512/guide_to_calculating_interpreting_kdpi.pdf

longevity.[10]

Kidneys with the lowest KDRI values are expected to function well for the longest period of time after transplant. Low KDRI organs are first offered to younger and healthier patients who are more likely to survive for a relatively long time following a transplant. Kidneys with high KDRI scores are expected to function for a shorter amount of time and may be best used to help candidates who are older, diabetic, or otherwise less able to stay on dialysis for a long time.[11] Older candidates (age >65) were more willing to accept a high-risk kidney compared to younger candidates, such as a kidney from a hepatitis-C virus positive donor. (Figure I-4).

Figure I-4 Use of High-Risk Kidneys by Patient Age, Maryland Residents



Source: SRTR.transplant.hrsa.gov

The Department of Health and Human Services (HHS) has contracted with the United Network for Organ Sharing (UNOS) to develop, monitor, and enforce the rules governing allocation, procurement, and transplantation of all organs. UNOS divides the U.S. into 11 regions. Maryland is in Region II, which also includes Delaware, the District of Columbia (D.C.), New Jersey, Pennsylvania, West Virginia, and Northern Virginia. Within regions, the Centers for Medicare & Medicaid Services (CMS) designates Organ Procurement Organizations (OPOs) to facilitate organ procurement and transplantation at the local level. One OPO is designated to each Donation Service Area (DSA).[12] There are two DSAs that cover jurisdictions in Maryland: the Living Legacy Foundation (LLF DSA) and the Washington Regional Transplant Community DSA (WRTC DSA).

The proposed program at Franklin Square would be located within the Living Legacy Foundation DSA (LLF DSA), which serves all but three Maryland jurisdictions, excluding Charles, Montgomery, and Prince George's Counties. There are currently two existing kidney transplant programs in the LLF DSA: (1) Johns Hopkins Hospital (JHH) and (2) the University of Maryland Medical Center (UMMC), both located in Baltimore City. The LLF DSA had a

[10]Organ Procurement and Transplantation Network. optn.transplant.hrsa.gov/media/1512/guide_to_calculating_interpreting_kdpi.pdf

[11] United Network for Organ Sharing. Questions and answers for transplant candidates about kidney allocation (unos.org)

[12] United Network for Organ Sharing. https://unos.org/transplant/how-we-match-organs/

population of 3,981,345 in 2020.[13]

The Washington Regional Transplant Community DSA (WRTC DSA) serves the Maryland jurisdictions of Charles, Montgomery and Prince George's Counties as well as Washington, D.C., 17 Virginia jurisdictions in the northern region of the state, and two West Virginia jurisdictions. There are five existing kidney transplant programs in this DSA: (1) MedStar Georgetown Transplant Institute (MGTI), (2) George Washington University Hospital (GWUH), and (3) Children's National Medical Center (pediatric transplants), all in D.C.; (4) Inova Fairfax Medical Campus (Fairfax) in Falls Church, Virginia; and (5) Walter Reed National Military Medical Center, a U.S. Department of Defense hospital located in Bethesda, Maryland (Montgomery County). Only MGTI, GWUH, and Fairfax serve an adult general population. The WRTC DSA had a population of 6,177,224 in 2020.[14]

In an attempt to achieve a more equitable distribution of organs, the Organ Procurement and Transplantation Network (OPTN), a public-private partnership that links all professionals involved in the U.S. donation and transplantation system, adopted changes in its kidney allocation rules in 2021.[15] It replaced the pre-2021 policy which allocated the distribution of kidneys based on donation service area (DSA). In the post- 2021 policy, the kidneys are distributed with a more consistent measure of distance between donor hospital and transplant hospital for each patient. Now, kidney offers are made first to candidates listed at transplant hospitals within 250 nautical miles of the donor hospital. If offers are not accepted for candidates within this area, an available kidney is then offered to candidates beyond the 250 nautical mile distance.[16]

It is unclear whether increasing the number of kidney transplantation programs in a DSA leads to better or worse health outcomes for patients. Evidence exists to show that increasing the number of transplant programs within a DSA can lead to improved access to transplantation, as well as. increased use of higher risk organs and increased numbers of patients wait-listed.[17,18] A 2014 study found that greater market competition might be associated with increased patient mortality and graft failure related to more aggressive use of high-risk kidneys, but these outcomes are still an improvement compared to patients on chronic dialysis.[19]

Contrariwise, there is evidence that DSAs with a single transplant center are more likely to have higher patient mortality and worse graft outcomes, compared to DSAs with a geographically clustered, dispersed, or random distribution of transplant centers.[20] There is little evidence to suggest that an "optimal" number of transplantation centers within a DSA can be determined.

---

[13] U.S. Census Bureau, U.S. Dept. of Commerce, 2020 Census of Population
[14] U.S. Census Bureau, U.S. Dept. of Commerce, 2020 Census of Population
[15] https://optn.transplant.hrsa.gov/news/new-kidney-pancreas-allocation-policies-in-effect
[16] United Network for Organ Sharing. unos.org/news/new-policy-adopted-to-improve-kidney-pancreas-distribution/
[17] Cho, P.S., Saidi, R.F., Cutie, C.J., and Ko, D.S.C. (2015). Competitive Market Analysis of Transplant Centers and Discrepancy of Wait-Listing of Recipients for Kidney Transplantation. International Journal of Organ Transplantation Medicine. 6(4): 141-149.
[18] Adler, J.T., Yeh, H., Markmann, J.F., Axelrod, D.A. (2016) Is Donor Service Area Market Competition Associated With Organ Procurement Organization Performance? Transplantation. 2016 Jun;100(6):1349-55.
[19] Adler, J.T., Sethi, R.K.V., Yeh, H., Markmann, J.F., Nguyen, L.L. (2014). Market competition influences renal transplantation risk and outcomes. Annals of Surgery. 260: 550-557.
[20] Adler, J.T., Yeh, H., Markmann, J.F., and Nguyen, L. (2015). Temporal Analysis of Market Competition and Density in Renal Transplantation Volume and Outcome. Transplantation. 100(3): 670-7.

The need for organ transplants continues to exceed the organ supply. The organ shortage causes most patients to wait for a transplant, according to the OPTN.[21] Based on OPTN data as of June 19, 2022, the patient waitlists for kidneys were as follows:

- 1,222 at JHH
- 664 at UMMC
- 756 at MGTI
- 223 at GWUH
- 466 at Fairfax

Table I-1 below shows the number of kidney transplants that took place in the LLF DSA and WRTC DSA transplant centers over the past ten years.

Table I-1 Number of Kidney Transplants in the LLF DSA and WRTC DSA Regions, CY 2012-2021

Transplant Center	2012	2013	2014	2015	2016	2017	2018	2019	2020*	2021*
JHH	206	233	255	254	208	190	218	251	212	249
UMMC	297	262	245	264	210	242	222	143	148	168
LLF DSA Total	**503**	**495**	**500**	**518**	**418**	**432**	**440**	**394**	**360**	**417**
MGTI	61	73	87	183	205	202	208	267	304	246
GWUH	-	-	-	-	55	48	56	68	57	65
MedStar Washington	70	90	69	18	-	-	-	-		
Fairfax	108	95	99	76	88	88	99	114	95	131
WRTC DSA Total	**239**	**258**	**255**	**277**	**248**	**238**	**263**	**449**	**456**	**440**
Total	**742**	**753**	**755**	**795**	**766**	**770**	**803**	**843**	**816**	**857**

Source: OPTN.transplant.hrsa.gov
Note: Transplant rates during 2020-2021 may have been affected by the COVID pandemic.

B. The Applicant

Franklin Square Hospital Center d/b/a MedStar Franklin Square Medical Center (Franklin Square) is a 364-bed general hospital owned by MedStar Health, Inc. that is located at 9000 Franklin Square Drive in Rosedale (northeast Baltimore County). It provides acute inpatient services for patients needing hospitalization for medical/surgical, oncology, cardiology, obstetric, neonatal, gynecologic, pediatric, and behavioral health services. In FY 2020, it was the seventh largest general hospital in Maryland, based on acute inpatient average daily census.

Franklin Square also provides an array of outpatient diagnostic and treatment services that are typical for a hospital of this size, including ten dialysis centers for chronic dialysis services situated within a two-mile radius of Franklin Square.

MedStar Health, Inc. is a $5.3 billion not-for-profit hospital and health care system based in Columbia, Maryland. It operates seven Maryland general hospitals—located in Baltimore City, Baltimore, Montgomery, Prince George's, and St. Mary's Counties—and two general hospitals

[21] Organ Procurement and Transplantation Network. optn.transplant.hrsa.gov/news/one-year-monitoring-report-shows-increase-in-kidney-transplants-following-policy-changes/

and a specialty rehabilitation hospital in D.C. It also operates a primary and specialty care physician network, outpatient rehabilitation sites, and home health agencies. MedStar Georgetown Transplantation Institute (MGTI) is based at MedStar Georgetown University Hospital, a D.C. academic medical center that also provides liver, kidney, small bowel, colon, stomach, and multi-organ transplants.

C. The Project

Franklin Square, in partnership with MGTI, seek to establish a kidney transplantation program at Franklin Square's campus in Baltimore County. Introducing kidney transplantation services at Franklin Square would add a third program to the Baltimore area and the LLF DSA. This application was submitted concurrently with an application to establish a liver transplantation program at Franklin Square. The applicant proposes that the site will provide multi-organ transplants for patients requiring both a kidney and liver transplant (i.e., hepato-renal syndrome).

In explaining the need for the Franklin Square transplantation program, the applicant emphasized the reputation and experience of the MGTI program and the Center for Translational Transplant Medicine (CTTM), founded in collaboration with Georgetown University in 2013. The applicant believes that by integrating with MGTI's multi-organ transplant program and research enterprise located in Washington, DC, patients will be afforded additional access and specialized expertise. Franklin Square states that the program will be able to increase the available organ supply and the number of transplant recipients. The applicant proposes that kidney transplant volume will reach 44 transplants by the third year of the program. By implementing a transplantation program at Franklin Square, the applicant plans to provide services in the LLF DSA using the experience and resources of the MGTI program operating in the WRTC DSA.

The applicant does not report a need for capital expenditures for facilities construction, renovation, or equipment for this project. (DI #4, p. 4). Franklin Square believes that it already has the surgical facilities, ancillary space, and equipment needed for a kidney transplantation program. The program is projected to require an operating expenditure in the third year of operation of $8.7 million. The following table profiles expenditures projected for the proposed program and the projected number of kidney transplant procedures in these years. (DI #4, Exh. 1, Table J).

Table I-2: Total Estimated Operating Expenses

	Year 1	Year 2	Year 3
Salaries & Wages (including benefits)	$1,842,000	$ 3,764,000	$ 4,657,000
Supplies & Drugs	$357,000	$591,000	$1,208,000
Other Expenses: Contingency, Outpatient Activity, Organ Acquisition	$863,000	$1,450,000	$2,849,000
Total Operating Expenses	**$3,062,000**	**$5,805,000**	**$8,714,000**
Projected Kidney Transplant Procedures	12	24	44

Source: DI #4, Exh. 1 and Table J and p.64

D. Reviewer's Recommendation

I recommend that the Maryland Health Care Commission deny Franklin Square's application for a Certificate of Need to establish a kidney transplant service at Franklin Square Hospital Center. The applicant has the burden to show that it has met all State Health Plan (SHP)

standards and criteria for review by a preponderance of the evidence. COMAR 10.24.01.08G(1). It has failed to comply with the following standards:

(1) The Need Standard, COMAR 10.24.15.04B(1);

(2) The Cost Effectiveness Standard, COMAR 10.24.15.04B(4);

(3) The Need criterion, COMAR 10.24.01.08G(3)(b); and

(4) The Availability of More Cost-Effective Alternatives criterion, COMAR 10.24.01.08G(3)(c).

I find that residents of Maryland currently have convenient access to at least four quality kidney transplant services and the applicant failed to prove the proposed project would meet an unmet need.

II. PROCEDURAL HISTORY

A. Review of the Record

Please see Appendix 1, Record of the Review.

B. Interested Parties

I recognized Johns Hopkins Hospital (JHH) and the University of Maryland Medical Center (UMMC) as interested parties in this review. Both JHH and UMMC are authorized to provide the same service as the applicant, in the same planning region for purposes of determining need under the State Health Plan. The interested parties assert that the applicant was unable to show: (1) the need for a third transplant program in Baltimore; (2) existing barriers to care that a third transplant program could address; and (3) sufficient data-based evidence to support its project. (DI #30, DI# 31). In addition, JHH argues that Franklin Square failed to address the impact of the proposed project on existing programs and UMMC argues that the proposed program is not cost effective in light of alternatives. JHH and UMMC both urge the Commission to deny Franklin Square's CON application.

C. Local Government Review and Comment

No local government officials submitted comments on the proposed project.

D. Community Support

Franklin Square provided letters of support from 60 individuals, including 22 physicians currently practicing within the MedStar system, 24 physicians working in community practice, and 14 patients currently on dialysis and awaiting kidney transplant. (DI #4, attachment 6).

III. REVIEW AND ANALYSIS

The Commission is required to evaluate the application in accordance with the general Certificate of Need review criteria at COMAR 10.24.01.08G (3) (a) through (f). The first of these six general criteria require the Commission to consider and evaluate this application according to all relevant State Health Plan ("SHP") standards and policies. The applicable SHP chapters are COMAR 10.24.10, Acute Inpatient Services and COMAR 10.24.15, Organ Transplant Services.

In its application, Franklin Square stated that the kidney transplant program at MGTI is superior to the two programs currently operating in Maryland. While this information does not directly address any specific SHP standard, it factors into Franklin Square's arguments that its proposed project is needed and cost effective. Therefore, the statements from the applicant and response from interested parties on this information should be considered as part of the application review process. I will review this interchange here before addressing the first criteria, the State Health Plan, and evaluating the relevant State Health Plan standards.

The applicant provided data to show that waitlist mortality rates at MGTI are lower than national, regional and OPO/DSA rates. (DI #4, p. 14). More recent data provided by the applicant show that the waitlist mortality rate at MGTI is equivalent to that at JHH and slightly better than that at UMMC. (DI #48, p.5). The applicant also provided data to show a higher proportion of individuals were on the waitlist at JHH and UMMC for five years or longer than those waitlisted at MGTI. (DI #48, p. 10). Franklin Square also provided evidence that the proportion of those on the MGTI waitlist considered "inactive" was smaller than the same proportion at either JHH or UMMC. (DI #14, p. 8). Being put on temporary inactive status can lead to longer wait times for organs.

The applicant also points to 2021 UNOS data that shows that one-year graft survival rates at MGTI are marginally higher than national rates and higher than the rate achieved by either JHH or UMMC. (DI #48, p. 2). In response to MedStar's comments, JHH provided the most recent SRTR program specific data published July 6, 2021, to show that the three-year graft survival rate was 89.9% for JHH, 84.7% for UMMC, and 85.6% for MGTI. (DI #53, p.15).

Reviewer's Analysis and Findings

MGTI has a high-quality kidney transplant program with certain metrics that marginally outperform JHH and UMMC and other metrics that under-perform the two existing programs. All three programs provide high quality care to their patients. It is not surprising that MGTI has a lower number of individuals waiting more than five years for a transplant than the existing Maryland programs, as the program is younger.[22] It was not until 2017/2018 that MGTI's waitlist numbers were similar to those of the Maryland programs.

Additionally, placement on inactive status on the waitlist is dependent on a number of variables often outside the control of the transplant program. A patient can be put on a temporarily

[22] Scientific Registry of Transplant Recipients. www.srtr.org/reports/program-specific-reports/

inactive waitlist due to health status, financial reasons, or other reasons that would make transplant outcomes riskier.[23] According to research, the majority of those placed on inactive status are placed there for medical reasons outside of their diagnosis of kidney failure, most commonly heart disease or cancer.[24] The research shows that the active/inactive waitlist status is most dependent on the overall health status of the population being served and not necessarily on how well a program is run.[25]

The small differences between MGTI and JHH graft survival rates do not present a compelling reason to influence the decision in this review. One- and three-year graft survival rates are more dependent on post-surgery care that is often provided at hospitals other than that at which the surgery was performed. I find that all three high volume programs in the Baltimore/Washington D.C. region[26] provide good quality care for kidney transplant patients and that the applicant has not provided sufficient evidence that a new program is needed.

A. COMAR 10.24.01.08G(3)(a), State Health Plan.
An application for a Certificate of Need shall be evaluated according to all relevant State Health Plan standards, policies, and criteria.

COMAR 10.24.10. Acute Inpatient Services

COMAR 10.24.10.04A — General Standards.

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

(a) Maintenance of a Representative List of Services and Charges that is readily available to the public in written form at the hospital and on the hospital's internet web site;

(b) Procedures for promptly responding to individual requests for current charges for specific services/procedures; and

(c) Requirements for staff training to ensure that inquiries regarding charges for its services are appropriately handled.

[23] National Kidney Foundation. https://www.kidney.org/transplantation/transaction/TC/winter14/UNOS_Committee
[24] Shafi S, Zimmerman B, Kalil R. Temporary inactive status on renal transplant waiting list: causes, risk factors, and outcomes. Transplant Proc. 2012 Jun;44(5):1236-40.
[25] Grams ME, Massie AB, Schold JD, Chen BP, Segev DL. Trends in the inactive kidney transplant waitlist and implications for candidate survival. Am J Transplant. 2013 Apr;13(4):1012-1018.
[26] According to Sonnenberg et al., (Sonnenberg EM, Cohen JB, Hsu JY, et al. Association of Kidney Transplant Center Volume With 3-Year Clinical Outcomes. Am J Kidney Dis. 2019;74(4):441-451.), GWU, with an average of 57 kidney transplants per year from 2016 – 2019, is categorized as a low volume program.

Applicant's Response

The Franklin Square policy states "[a] list of common inpatient and outpatient procedures are maintained on the hospital's website."[27] This list includes charges for 300 inpatient and outpatient procedures at the hospital. The policy states that the list of charges will be updated quarterly. (DI# 4, Exhibit 2).

Additionally, the applicant's policy states that a written copy of a representative list of services and prices is also available in the hospital's Financial Counseling Department. The information is reviewed and updated regularly based on the average charge for twelve months by procedure code. Contact information is provided for further questions. The applicant states that requests will receive a response within 24 hours. The list is available upon request.

The applicant's policy states that "[a]ssociates handling inquiries will be trained on the policy and procedure, and how to manage patient's questions about average estimated charges." (DI #4, Attachment 2).

Reviewer's Analysis and Findings

I verified that the list of charges is available on the applicant's website at https://www.medstarfranklinsquare.org/for-patients/patients-and-visitors/billing-and-insurance/price-transparency-disclosure/. The list of charges was updated on December 31, 2021. The applicant has met 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; and**

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.**

[27] MedStar Franklin Square Medical Center. Estimated Average Charges for Common Procedures. Price Transparency Disclosure - MedStar Franklin Square Medical Center, Accessed November 8, 2021.

(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.

Applicant's Response

The applicant's charity care policy (DI #4, Attachment 3) states that "MedStar will provide a financial assistance probable and likely eligibility determination to the patient within two business days from receipt of the initial financial assistance application." (DI #17, attachment A). The applicant provided a copy of both the MedStar charity care policy as well as its application form for a probable determination of coverage.

Franklin Square states that it provides "public notices yearly" about its charity care policy "in local newspapers serving the hospital's target population," that it displays its Financial Assistance Policy information "at all hospital registration points" and that it provides its Financial Assistance Policy information as "part of all registration or discharge processes and answering questions on how to apply for assistance." (DI #14 p. 12).

Franklin Square highlighted that charity care increased in both absolute dollars and as a percentage of total operating expenses in each year between FY2011 and FY2013, before declining in both of these measures between FY2014 and FY2017. The primary reason set forth for the decline in Franklin Square charity care between 2014 and 2017 is the expansion of the Maryland Medicaid program implemented in January 2014. Franklin Square states that prior to the implementation of this latest Maryland's Medicaid expansion (FY 2013), the Maryland Department of Health reported that the number of state residents enrolled in Medicaid, the Maryland Children's Health Program, and the Primary Adult Care Program was just over one million. The applicant notes that by FY 2015, there were about 1.25 million enrollees, a 25% increase within 18 months of the expansion of eligibility. (DI #4, pp. 33-34).

Franklin Square cited data showing that, statewide, Maryland hospitals experienced a 22.6% increase in gross inpatient revenue from Medicaid, while seeing a steep (73.5%) decline in the inpatient revenue associated with self-pay patients, and a 30.0% decline in charity care provided by Maryland hospitals. Franklin Square stated that the impact of the Maryland Medicaid program expansion was greater for Franklin Square than was typical among Maryland hospitals. "Franklin Square experienced a 53.6% increase in gross hospital revenue from patients covered by Medicaid, much greater than the 22.6% state average; it also experienced a decline of 59.7% in charity care expense, which was significantly larger than the 30.0% average decline in charity care in the state (the impact on self-pay at Franklin Square was very close to the state average)." (DI #4, p. 36).

Franklin Square attributed this atypical impact to three factors.

1. Franklin Square's Primary Service Area (PSA) is comprised of communities that skew to the low end of median income distribution among Baltimore County Census Designated Places. Three of the four lowest median income communities in the county are in Franklin Square's PSA, while the fourth is in Franklin Square's secondary service area (Dundalk, Essex, Parkville, Middle River);

2. Eastern Baltimore County has a very active coalition of organizations called the Baltimore County Southeast Area Network (BCSAN), which focuses on improving the quality of life and health status of eastern Baltimore County residents. BCSAN took an active role in informing residents of the change in the eligibility requirements of the Maryland Medicaid program and supporting members of the community with the application process for program enrollment; and

3. Franklin Square states that it has been committed to identifying uninsured patients who may qualify for insurance under the expanded Maryland Medicaid program and facilitating the enrollment process.

Reviewer's Analysis and Findings

I find that the applicant's policy meets the requirements of subpart (a) of this standard. The applicant has a policy in place to provide patients with an assessment of likely eligibility for provision of charitable services or other medical assistance within two business days of a request. (DI #4, Attachment 3).

I also reviewed the most recent HSCRC Community Benefit Report for FY 2019, as shown in the preceding Table III-1, and found that Franklin Square was ranked in the third quartile of all hospitals for the ratio of CBR charity care to total operating expenses in 2019 ranking 36th out of 51 Maryland hospitals covered in the report. The reported nominal value of charity care increased from $5.15 million to $10.28 million between FY 2017 and FY 2019.

Table III-1: CBR Charity Care Metrics, MedStar Franklin Square and Maryland

FY 2014 - FY 2019	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019
Ratio of CBR Charity Care to Total Operating Expenses	2.9%	1.2%	1.0%	1.0%	1.4%	1.9%
Maryland Quartile Rank-Franklin Square	4th	4th	4th	4th	3rd	3rd
Statewide Average-All Hospitals	3.4%	2.5%	2.0%	1.8%	1.9%	1.9%

Source: https://hscrc.maryland.gov
CBRs, FY 2014-2019

The applicant has met the requirements of this standard.

(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.

Applicant's Response

Franklin Square is licensed, in good standing, with the Maryland Department of Health and is Medicare and Medicaid certified, in good standing, with respect to the conditions of participation. The applicant is accredited by the Joint Commission with the last survey completed in 2016. (DI #4, Attachment 4). The applicant notes a number of recent honors and awards conferred upon the hospital. (DI #4, Attachment 4).

I note that subpart (b) of this standard no longer reflects a sound approach to indexing hospital performance because of the substantial expansion and modification of MHCC's facility performance reporting. The Hospital Performance Evaluation Guide (HPEG), with a distinct list of "Quality Measures," reflected a state of the art in hospital "report cards" when this general standard was established in 2009 but that is no longer the case. MHCC staff discussed this standard with the applicant prior to filing of the application.

MHCC recently expanded performance measure reporting on an updated Maryland Health Care Quality Reports website. For quality reports, MHCC now focuses on two priority areas: (1) patient experience, as reported by the Centers for Medicare and Medicaid Services (CMS) in its Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey; and (2) healthcare associated infections, as tracked by CDC's National Healthcare Safety Network (NHSN).[28]

Franklin Square stated that it 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. (DI #4, Attachment 4).

Franklin Square stated that it rated below average on 18 performance measures of the Maryland Health Care Quality Report. The applicant provided corrective actions implemented by the hospital to address each of the areas of concern as shown in the table below. (DI #17, pp. 7-8).

[28] COMAR 10.24.10 is currently being updated and a proposed update of these standards by MHCC is planned in FY 2023.

Table III-2: Quality Measures Requiring Corrective Actions Reported by Franklin Square

Performance Measure	Corrective Action
How often did nurses always communicate well with patients?	Bedside shift report and inviting patient and families to attend daily IM(Interdisciplinary Model of Care) rounds
How often did doctors always communicate well with patients?	5-minute physician sit-down at bedside
How often did staff always explain about medicines before giving them to patients?	Information sheets for nursing with common medication indication information and Pharmacy rounding on select patients
Were patients always given information about what to do during their recovery at home?	Pilot discharge folder to address info such as discharge medications, follow-up appointments, etc.
How well do patients understand their care when they leave the hospital?	Pilot discharge folder to address info such as discharge medications, follow-up appointments, etc.
How often were the patients' rooms and bathrooms always kept clean?	Environmental Services leaving high-touch area cards in patient rooms of the areas that have been cleaned, with a contact number if additional housekeeping was needed
How often did patients always receive help quickly from hospital staff?	A "no pass zone" to respond to call bells in a more timely manner and purposeful hourly rounding to proactively address patient needs
How often was patients' pain always well-controlled?	This measure was discontinued in the in January 2018 Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey
How do patients rate the hospital overall?	Key drivers are communication with doctors and communication with nurses. Efforts are focused on daily meetings with patient, physician and nurse to discuss daily treatment plans, etc.
How long patients spent in the emergency department before leaving for their hospital room	Full-capacity protocol in place when criteria met and patients meeting criteria are transferred to the floors in a hallway location to begin their inpatient care
How long patients spent in the emergency department before being sent home	FastER[29] which focuses on evaluating patients in outpatient locations or transferring appropriate post-MSE patients to appropriate care setting
How long patients spent in the emergency department before they were seen by a healthcare professional	FastER which focuses on evaluating patients in outpatient locations or transferring appropriate post-MSE patients to appropriate care setting
How long patients who came to the emergency department with broken bones had to wait before receiving pain medication	FastER which focuses on evaluating patients in outpatient locations
Patients who left the emergency department without being seen	Evaluating reasons why patients leave the Emergency Department (ED) and when during their ED visit they leave. Focus is on shorter wait-times to treatment and patient triage at time of check in.
How long patients who come to the hospital with chest pain or possible heart attack waited to get a test that detects heart damage after a heart attack	FastER which focuses on evaluating patients in outpatient locations with the intention of reserving the main ER for more acute patients with lower ESI scores
Patients who had a low-risk surgery and received a heart-related test, such as an MRI, at least 30 days prior to their surgery though they do not have a heart condition	Cardiac computed tomography angiography service for patients presenting to the ED with chest pain. This exam can rule out coronary artery stenosis as cause of chest pain much faster than traditional stress testing. 3

[29] FASTER is an acronym reiterating the importance of quickly recognizing the signs and symptoms of a stroke

	hours vs. 8 – 12 hours

Reviewer's Analysis and Findings

I find that Franklin Square is currently in compliance with all necessary licenses and accreditations. The applicant outlined its focus on areas which need improvement, defined as measures for which the hospital's performance was below the state average. Most of these involved deficits in communication and longer than average Emergency Department wait times. The applicant has met the requirements of this standard within the constraints of the current measures used by the MHCC Center for Quality Measurement and Reporting to report hospital performance.

COMAR 10.24.15, Organ Transplant Services

10.24.15.04 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.

(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.

Applicant's Response

The three general standards of COMAR 10.24.10.04A were addressed in the immediately preceding section of this Recommended Decision.

The applicant states that it "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 operation." (DI #4, p. 41). Subpart (b) is not applicable to this project, which does not involve introduction of hematopoietic stem cell bone marrow transplant services.

Reviewer's Analysis and Findings

I find that the applicant has met the general standards of COMAR 10.24.10 (see immediately preceding section of this Recommended Decision). Franklin Square has agreed to comply with all the requirements of CMS with respect to kidney transplantation and to obtain

UNOS certification within the first year of operation. The application is consistent with these requirements.

10.24.15.04 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.**

Applicant's Response

The applicant proposes that it will increase the supply of donor organs as follows:

1. Support the Living Legacy Foundation organ donation efforts

MedStar Health states that it will actively participate in and support the LLF DSA and that all of the MedStar hospitals in Maryland and D.C. have systems in place to ensure support of the donor identification and retrieval efforts of the LLF of Maryland. (DI #4, p.43).

2. Expanded use of High-Risk Organs

According to Franklin Square, establishment of the new program at Franklin Square will lead to greater utilization of High Kidney Donor Profile Index donor organs, which will allow the use of organs from individuals over the age of 60 or organs with exposure to infectious disease in a manner that is compatible with recipient clinical characteristics and will decrease the discard of potentially usable organs. The applicant provided data to suggest that MGTI used high and medium risk donor organs at higher rates than other transplant centers in the region. (DI #4, pp.46-47).

Table III-3: Acceptance Rates for Deceased Donor Organs (2016)

	MGTI	OPO/DSA*	Region**	USA
Overall				
Offers	21,055	32,977	258,727	1,533,978
Accept	128	266	1,565	12,467
Expected Accept	61.3	157.7	1,713.5	12,458.5
Accept Ratio	2.05	1.68	0.91	1.00
Low KDRI Donors				
Offers	2,292	3,887	41,219	254,475
Accept	28	101	616	4,911
Expected Accept	17.8	65.4	664.1	4,909.0
Accept Ratio	1.52	1.53	0.93	1.00
Medium KDRI Donors				
Offers	9,509	15,676	132,406	968,063
Accept	72	133	802	6,441
Expected Accept	32.7	73.0	874.9	6,435.2
Accept Ratio	2.13	1.80	0.92	1.00
High KDRI Donors				
Offers	9,254	13,414	85,102	311,440
Accept	28	32	147	1,115
Expected Accept	10.9	19.2	174.4	
Accept Ratio	2.33	1.60	0.84	1.00

Source: DI #4, p. 47

* Washington Regional Transplant Center

** UNOS Region 2 which includes: Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, and West Virginia

The applicant provided Scientific Registry of Transplant Recipients[30] (SRTR) data (shown in the following table) intended to show that even though MGTI utilized high and medium risk kidneys at higher rates than either JHH or UMMC, its outcomes (expressed as observed/expected rates of death or graft failure) for these transplant procedures was better than the outcomes at the existing programs at JHH and UMMC. (DI #14, p. 7).

[30] Scientific Registry of Transplant Recipients. www.srtr.org/

Table III-4: Kidney Transplant Outcome Data

Kidney Outcome Data SRTR Jan 2018 Release			
Center	CY 2016 Volume	O/E Patient Death*	O/E Graft Failure*
MGTI	226	0.86	1.17
CNMC *	21	0.00	0.00
U Maryland	223	0.85	1.39
Hopkins	212	1.47	1.10
Source: SRTR Jan 2018 Release. A ratio > 1 indicates worse than expected outcomes **Note that MGTI performs all kidney transplant procedures at CNMC.*			
Kidney Outcome Data SRTR Jan 2018 Release			
Center	CY 2017 Volume	O/E Patient Death*	O/E Graft Failure*
MGTI	218	0.73	1.11
CNMC *	21	0.00	0.00
U Maryland	273	1.14	1.61
Hopkins	196	1.65	1.19
Source: SRTR July 2017 Release. A ratio > 1 indicates worse than expected outcomes ** Note that MGTI performs all kidney transplant procedures at CNMC.*			

The applicant also states that MGTI is one of the largest importers of kidneys for transplantation, far exceeding other programs in the region and even in the entire country. More than 50% of kidneys transplanted to MGTI wait-listed patients in the last two-year period are from either regional or national sources. (DI #14, p. 19).

3. Increased use of organs from living donors

According to Franklin Square, establishing a Franklin Square kidney transplantation program will lead to increased numbers of transplants from living donors. Franklin Square presented data (see table below) to show that MGTI performed more transplants from living donors than either JHH or UMMC, more than doubling the number seen at either of the Maryland centers during the COVID-19 pandemic. (DI #48, p. 3) Franklin Square states that it plans to replicate MGTI's Living Donor Transplantation Program's success.

Table III-5: Number of Live Donor Transplants, MGTI and the Maryland Transplant Centers

	CY 2016	**CY 2017**	**CY 2018**	**CY 2019**	**CY 2020***
MGTI	66	77	98	110	101
JHH	53	42	61	66	34
UMMC	67	77	68	49	43

*Annualized based on 7 months of data

Source: DI #48, p.3

4. Active participation in the National Kidney Registry

The applicant states that MGTI's active participation in the National Kidney Registry (NKR) will be replicated at Franklin Square and provide a major advantage for donor/recipient pairs who are not able to donate directly to each other. MGTI is described as ranking third in the

nation, in the first half of 2017, with respect to the number of NKR transplants. The applicant also states that MGTI has not had to decline organs because surgical resources were unavailable, which did occur at other programs, including those in Maryland, during the 2017 period reviewed in its application. The applicant states that it will replicate this full-time surgical availability capability at Franklin Square. (DI #4, pp. 50-53).

5. Expanded use of desensitization protocols

The applicant states that MGTI has expertise in the use of desensitization protocols for Human Leukocyte Antigen (HLA) incompatibility, which allows for the safe and effective transplantation of donor organs into patients with otherwise incompatible blood characteristics. The applicant states that it will use this expertise in its new program and implementing desensitization protocols for patients who have HLA incompatibilities at Franklin Square will increase the supply of donor organs for Marylanders. (DI #4, pp. 53-54).

6. Active participation in paired kidney exchange programs

The applicant states that MGTI's active participation in regional and national paired kidney exchange programs has allowed for transplants in highly sensitized patients, including some previously classified as non-transplantable. It describes MGTI's patient and graft survival outcomes as among the best in the country. The applicant states that Franklin Square and MGTI will offer paired kidney exchanges to Maryland residents and that paired kidney exchange implementation at Franklin Square will increase the supply of donor organs for Marylanders. (DI #4, pp.54-56).

7. Participation in the National Consensus Conference

MGTI participated in the National Consensus Conference in 2017 that was aimed specifically at improving organ utilization, including reducing the rate of organs discarded. The applicant claims that the initiative has the potential to increase the number of transplants by up to 2,000 per year nationally. (DI #4, pp.56-57).

8. Participation in advanced clinical research

Franklin Square states that it will participate in clinical research that is advancing the field of kidney transplantation through the Center for Translational Transplant Medicine (CTTM) at Georgetown. CTTM has managed a portfolio of 83 research studies that the applicant states will continue to produce future innovations that will further increase the supply of donor organs for Franklin Square patients. (DI #4, pp.57-58).

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

Applicant's Response

The applicant states that it will primarily serve residents of Baltimore City, Baltimore County, Anne Arundel County, Carroll County, Harford County, Howard County, and Frederick County. This geography includes the service areas of the four Baltimore-area MedStar Hospitals (Franklin Square, Good Samaritan, Harbor, and Union Memorial) and the locations of MedStar

Advanced Kidney and Liver Disease Clinics in Baltimore, Anne Arundel, Frederick, Prince George's, Calvert, Charles and St. Mary's Counties. (DI #14, p.24).

Franklin Square believes that its program "will provide MedStar Health patients in the Baltimore area with fuller access to a continuum of care provided by MedStar Health in their local community." (DI #4, p. 59). The applicant states that the volume shifts from existing programs in the region will be minimal and that referrals from MedStar to the area's existing programs will result in only 10 fewer referrals per year to those two programs. (DI #14, p 23). The applicant notes that the annual kidney transplant case volumes of JHH and UMMC are well above the threshold volume established in the SHP. Thus, the applicant argues that any shift of cases from existing programs to a new Franklin Square program will not have a negative impact on either existing program.

(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.

Applicant's Response

Franklin Square provided the following table to show utilization trends in the LLF DSA. (DI #4, p. 62).

Table III-6: Adult Kidney Transplants – Living Legacy Foundation OPO, CY 2006-2016

Center	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	%Var (2006-2016)
JHH	193	175	161	242	201	209	199	225	245	248	202	5%
UMMC	229	242	218	253	209	244	295	259	244	260	208	-9%
Total	422	417	379	495	410	453	494	484	489	508	420	-3%

Source DI #4, p.62

The chart shows, generally, a growth trend through CY 2015, with a decline in cases at both Baltimore programs in 2016. The applicant believes that these drops were due to "certain regulatory issues and leadership changes" at UMMC and JHH. The applicant states that "these types of programmatic changes can have an impact on volume." (DI #14, p. 24).

Interested Party Comments

Johns Hopkins Hospital

JHH rebuts Franklin Square's assertion that it can increase the number of organs available in the LLF DSA. It states that "MedStar fails to analyze the level of services already being provided in the LLF DSA by the two high-volume, competitive programs" and that the application is "devoid of a quantitative analysis of the services provided by the two existing programs." JHH states that the applicant never defines the population to be served, and includes Charles County

data in its calculations, a county that is served by the WRTC DSA, not the LLF DSA. (DI #30, p. 9).

JHH comments on each of the eight pathways by which the applicant proposes to increase the supply of donor organs.

(1) Participation in the LLF OPO: In response to Franklin Square's claim that it actively supports the LLF OPO (DI#4, pp.43-44), JHH notes that "there is nothing preventing MedStar from either actively participating in the LLF OPO or from focusing greater attention on the LLF OPO" (DI#30, p. 10) without opening a new transplantation program. Additionally, JHH does not believe that opening a new transplantation program in the LLF OPO will bolster the number of organs.

(2) Greater utilization of KDPI organs with higher risk scores, as well as those from non-local sources: Johns Hopkins does not believe that the data referenced by the applicant accurately describes the actual level of higher-risk organ use at the existing transplantation programs in Baltimore. It claims that the method used to profile organ use by risk mischaracterizes the JHH program on this question. JHH comments that the applicant provides regional and national data instead of hospital-level data and, thus, includes hospitals outside of Maryland, many of which are less robust than the hospitals in Baltimore. JHH states that

> *between 2012 and 2017, Johns Hopkins imported between 47% and 62% of the kidneys it has transplanted. These include kidneys that were turned down by other transplant programs. Accordingly, Johns Hopkins is meeting the need of the local population by consistently importing a significant number of kidneys from other parts of the country and making optimal use of marginal organs.* (DI #30, p. 11).

(3) Increasing living donor kidney transplants: Johns Hopkins states that the applicant has not presented data that presents a true picture of the existing living donor programs within the LLF DSA. The applicant shows data over a five-and-a-half-year period and concludes that MGTI's numbers show a favorable growth trend but does not provide the data that shows that during this time period, UMMC and JHH performed 331 more adult, non-military live kidney transplants in the LLF DSA than were done in the WRTC DSA. The data shows that this represents an additional 55.2 live donor transplants per year in the LLF DSA than the WRTC DSA, despite the fact that the WRTC DSA has 1.6 million more residents and three kidney transplant programs that perform adult, non-military kidney transplants. (DI #30, p. 12).

(4) Participation in the National Kidney Registry: Johns Hopkins states that it joined the Registry in 2013 and has performed 76 transplants through NKR exchanges. UMMC also participates in the NKR and has, on occasion, engaged directly with JHH in kidney swaps. JHH notes that since both Baltimore area programs already participate in the NKR, it is unclear how this will enable Franklin Square to increase the number of donor organs available.

JHH disagrees with the applicant's statement that "surgical unavailability declines" of organs from the NKR resulted in "turndowns of otherwise medically suitable kidneys for patients

awaiting transplant," (DI #4, p. 52), and stated that the turndowns resulted from the unavailability of an operating room on a particular day. In response, JHH explained that "paired exchanges involve live kidney donors, and require significant coordination, and they sometimes need to be rescheduled. No 'medically suitable 'kidneys' are ever turned away when a paired exchange is rescheduled. To the contrary, each and every one of the transplants referenced in this report was rescheduled and performed with the same participants." (DI #30, p. 14).

(5) Desensitization Protocols for Human Leukocyte Antigen Incompatibility: JHH contests MedStar's assertion that MGTI is one of the few programs in the nation that offers desensitization protocols and states that

> *both the University of Maryland and Johns Hopkins perform desensitization protocols. In fact, Johns Hopkins pioneered methods of desensitization utilizing plasmapheresis through which the antibodies are removed, allowing for kidney compatibility. These seminal protocols were published in the New England Journal of Medicine and the Journal of the American Medical Association. Montgomery, Robert A., et al., Desensitization in HLA-Incompatible Kidney Recipients and Survival, N. Engl. J. Med 318 (July 28, 2011); Montgomery, Robert A., et al., Clinical Results from Transplanting Incompatible Live Kidney Donor/Recipient Pairs Using Kidney Paired Donation, JAMA 1655 (Oct. 5, 2005).* (DI #30, pp. 14-15).

(6) Paired-Kidney Exchange Programs: JHH notes that both of the existing programs in the LLF DSA operate paired kidney exchange programs and that an additional program will not benefit the residents of the LLF DSA. (DI #30, p. 15).

(7) Co-chairing the National Consensus Conference: JHH states that "Beyond the location of the conference, there is no connection to the LLF DSA, and this conference has nothing to do with whether a third kidney transplant program is needed in the LLF DSA." (DI #30, p 16).

(8) MGTI Clinical Developments Advancing the Field of Kidney Transplantation: JHH points to the applicant's statement that MGTI "expects ongoing research to produce future innovations that will further increase the supply of donor organs for patients at Franklin Square." (DI #4, p. 58) JHH believes that the claim is "unaccompanied by analysis of the ongoing research efforts in the LLF DSA, quantification, or anything resembling analytical rigor." (DI #30, p. 16).

Beyond its assertion that the proposed project should be denied for lack of an ability to increase the pool of available organs to address need, JHH also rebuts the applicant's assertion that there is a need for "5,740 kidney transplants in the LLF DSA". (DI #17, p. 25). JHH believes that the calculation of need is overstated, based on national data and the assumption that every dialysis patient requires a transplant. JHH notes that the applicant has not established need based on credible data, or information specific to the health planning region in which the proposed organ transplant service will be located. Additionally, JHH states that the applicant is unclear whether it will be performing simultaneous liver and kidney transplants (SLK) or if these procedures are considered to be high risk.

University of Maryland Medical Center

The University of Maryland Medical Center states that the 2021 directive from the Health Resources Service Administration to eliminate geographic Donation Service Areas and regional barriers from organ allocation policies[31] negates the applicant's argument that a third kidney transplantation program in the Baltimore area is needed:

> *MedStar will not need a hospital in the Baltimore area DSA in order for its patients to benefit from MedStar's purported ability to increase the availability of donated organs in the Baltimore area. MedStar's efforts, under the new allocation policy, should benefit MedStar patients on MGTI and Franklin Square kidney transplant waiting lists equally, because any organ donated in the Baltimore area will be in close proximity to both MGTI and Franklin Square, and the current DSA barrier between the two facilities will no longer exist.* (DI #31, p. 4).

UMMC states that Franklin Square does not comply with the Need standard. It states that MedStar has not quantified the impact that its proposed efforts will have in the LLF DSA as it does not project the "new" organ volume that any one effort will create. UMMC believes that it is therefore impossible to determine whether the proposed increase in supply is worth the costs and risks of adding a new program. (DI #31 p.5).

UMMC points out that the Franklin Square argument relies heavily on its ability to increase the supply of living donor organs. (DI #4, pp. 48-55). UMMC provided data to show that it performed more living donor transplants than MGTI over a 30-month time frame (1/1/2015 to 6/30/2017) and claims that the applicant did not demonstrate that it will be able to improve on the performance of the existing programs in the Baltimore area. (DI #31, pp. 6-7).

UMMC also refutes the applicant's claim that participation within its DSA's OPO is a means of improving organ donor rates. (DI #4, pp. 43-44). UMMC states that this participation is not tied to the existence of an organ transplant service at Franklin Square and is, rather, a requirement included in CMS Conditions of Participation. (42 C.F.R. § 482.45). Therefore, MedStar hospitals will continue to participate in donor programs with OPOs with or without approval of the proposed project.

UMMC cites MedStar's interested party response to the GWUH CON application in the District of Columbia to show that the applicant's arguments in the current application were previously dismissed by the applicant itself. In opposing creation of the GWUH program, MedStar stated that more programs do not equal more organ availability and that there were no hidden untapped sources of organs that will be made available if a new transplantation program is approved. (DI #31, p. 6). UMMC also cited MedStar's opposition to the Suburban Hospital CON application (Docket #17-15-2400) in which it stated that kidney transplant volume at MGTI has

[31] As previously addressed in the "Background" section of this Recommended Decision, OPTN adopted changes in its kidney allocation rules in 2021 that allowed candidates listed at transplant hospitals within 250 nautical miles of the donor hospital to be the first in line to receive offers for available kidneys. If offers are not accepted for candidates within this area, an available kidney is then offered to candidates beyond the 250 nautical mile distance.

been decreasing since 2016 and in which MGTI projected that its 2018 kidney transplant volume would be 200 cases, 26 fewer than its 2016 kidney transplant volume.

Applicant's Response to Interested Party Comments

Franklin Square reiterated that it will increase the number of living donors at the new Franklin Square site. The applicant provided data to show that the trend in living donors at MGTI is positive, while the living donor trends at JHH and UMMC declined after 2015. (DI #36, pp. 6-7).

Franklin Square responds to UMMC's comments that MGTI's transplant volume has been declining since 2016. The applicant states that there was a volume surge in 2016 and that the "following years reflected a stabilization." (DI #36, p. 8). Franklin Square provided data to show that in 2018, the volume increased to above the 2016 level. (DI #36, p. 9).

The applicant responds to JHH's statement that both existing programs participate in the NKR. Franklin Square points out that UMMC failed to pay its "monetary" and "organ" debts, leading to its being disenrolled by the NKR. The applicant states that UMMC recently repaid the "monetary" part of that debt but has not performed any NKR procedures over the 12 months prior to submission of its response. (DI #36, pp. 9-10).

In response to JHH's comments about the National Consensus Conference, Franklin Square states that because the conference was about "increasing organ supply through scrutinizing innovative approaches to optimizing organ utilization," the conference provided important dialogue on increasing organ supply and pointed out that neither JHH nor UMMC attended. (DI #36, p.11).

Franklin Square also responded to JHH's comments by pointing out that MGTI has a "robust portfolio of ongoing clinical research" into kidney disease, transplantation, use of high-risk organs, immunosuppression, and tissue graft rejection, and provided a list of current research projects at MGTI. (DI #36, p. 12).

Franklin Square detailed the benefits of combined liver and kidney transplant programs to justify concurrent CON applications for both transplant programs. Franklin Square states that MGTI currently performs combined kidney and liver transplants at numbers equivalent to the existing programs in Baltimore and does not consider them particularly high risk. (DI #36, p.13).

Franklin Square responds to the JHH assertion that it is currently meeting the need of the local population and making use of marginal organs. The applicant asserts that both Baltimore programs have had outcome problems "in the context of volume growth." (DI #36, p.14).

Reviewer's Analysis and Findings

The need standard in the State Health Plan requires an applicant to demonstrate need for a new transplant service by addressing the proposed program's ability "to increase the supply or use of donor organs …." (COMAR 10.24.15.04B(1)). Any applicant requesting a CON for a new

organ transplant program is required to demonstrate that it can increase organ supply over and above what is currently available for residents of the state.

Supply of Kidneys

The kidney allocation policy changed in March 2021 and recovered kidneys are now allocated based on nautical miles from the recovery location, not by DSA. With the removal of the geographic barriers, recipients can now receive an organ outside their previously designated DSA. Further, the majority of Marylanders live within a three-hour travel time of both MGTI and the existing Baltimore programs and have access to three high-volume kidney transplant programs.

The applicant identifies eight specific activities to increase the supply or use of donor kidneys for Maryland patients awaiting transplants. I will address each of these points individually.

(1) Participation in the LLF OPO. Franklin Square claims to actively support the LLF OPO. (DI#4, p. 42). However, the applicant does not clearly articulate how opening a new program in the LLF service area will bolster the number of organs available for transplant. While the applicant states that the creation of the new program will lead to an increased focus on organ donation, it provides no evidence to support this statement. I note that, in a letter responding to several questions directed to both OPOs in this review, Charles Alexander, Executive Director of the LLF, wrote, "Increasing the number of transplant programs will not increase the number of organ donors." (DI #58, p.4).

(2) Greater utilization of High Kidney Donor Risk Index (KDRI) organs, as well as those from non-local sources. The applicant provided data through 2016 in an effort to demonstrate a high level of transplantation at MGTI of kidneys with a higher risk KDRI. It states that it will use a similar level of higher risk organs at Franklin Square. (Table III-4). The applicant based its argument on the offer acceptance ratio, a construct of expected acceptances with a high level of uncertainty. According to SRTR, the confidence interval of offer acceptance ratio is 95%. The uncertainty in the ratio can lead to a misunderstanding of the data. For instance, for UMMC, the offer acceptance ratio for High KDRI kidneys was 1.15 in 2019, meaning that it was 15% more likely to accept High KDRI kidneys than national acceptance practices. The 95% confidence interval shows that the actual acceptance rate can lie anywhere between 0.76 and 1.61, meaning that it could have an acceptance ratio of 24% below the national rate or 61% above the national rate. Therefore, to rely on these numbers as a predictor of transplant rates in a new program is statistically unsound.

The applicant's data on kidney transplants did not include a category of kidneys referred to as Very High KDRI (or Hard-to-Place) kidneys. Updated kidney transplant numbers, including this category of organs, are shown below. While use of High KDRI kidneys for transplant is higher at MGTI than either of the two programs in the LLF DSA, the number of Very High KDRI kidneys used for transplantation at MGTI was consistently lower than that reported for either of the existing programs in the LLF DSA. When looking at the proportion of total indexed transplants that were high or very high risk during the three years shown in the following table, the MGTI program had an average of 29% compared to the JHH average of 14%. However, it is notable that JHH had a reported 23% of total transplants in these higher risk indices in 2019, the same level experienced

by MGTI as recently as 2017. It is more notable that UMMC had approximately the same average level of transplants that were high or very high KDRI (30%) as MGTI (29%) over the three-year period.

Table III-7: Kidney Transplants by KDRI Level

	CY 2017	CY 2018	CY 2019
MGTI			
Low	27 (26%)	23 (22%)	25 (17%)
Medium	52 (51%)	55 (52%)	68 (46%)
High	20 (19%)	22 (21%)	46 (31%)
Very High	4 (4%)	5 (5%)	10 (7%)
JHH			
Low	75 (48%)	72 (47%)	61 (31%)
Medium	61 (37%)	56 (37%)	94 (48%)
High	6 (4%)	15 (10%)	16 (8%)
Very High	16 (10%)	9 (6%)	27 (14%)
UMMC			
Low	46 (23%)	44 (28%)	18 (17%)
Medium	99 (49%)	78 (49%)	46 (44%)
High	20 (10%)	16 (10%)	26 (25%)
Very High	36 (18%)	21 (13%)	14 (14%)

Source: SRTR Program Specific Reports, released January 2018 – 2020

(3) Increasing living donor kidney transplants. The applicant states that while it has a growing living donor kidney transplant program, the Maryland centers show a declining rate of use of living donor kidneys. Recent information from SRTR shows that while MGTI does have a higher proportion of transplants using living donor kidneys when compared to the two Maryland hospitals, living donor transplants at both JHH and UMMC have increased since 2017.

Table III–8: Proportion of Total Kidney Transplants that are Living Donor Transplants MGTI and Maryland Programs

Program	CY 2017	CY 2018	CY 2019
MGTI	38%	47%	41%
JHH	22%	28%	26%
UMMC	32%	31%	34%

Source: SRTR Program Specific Reports, released January 2018 – 2020

While the applicant focuses on a robust living donor kidney transplant program, it is unclear that a new program in the Baltimore area would significantly increase living donor transplants beyond those available at the existing programs.

(4) Participation in the National Kidney Registry. The applicant states that active participation in the National Kidney Registry will lead to a higher availability of kidneys for transplant in Maryland. The existing programs in the LLF DSA are also active participants in NKR, and it is not made clear by the applicant how Franklin Square's creation of a new program, participating in NKR, will increase the number of available organs.[32]

[32] National Kidney Registry. www.kidneyregistry.org/referral/centers-map

(5) Desensitization Protocols for Human Leukocyte Antigen Incompatibility. While desensitization protocols for HLA incompatibility are valuable tools in organ transplant programs, these protocols are not unique to MGTI and are already in use at JHH and UMMC. Therefore, the protocol use is not a novel technology or process that will increase organ availability.

(6) Paired-Kidney Exchange Programs. While the applicant has been successful in using paired kidney exchange programs, these programs are also in use at JHH and UMMC. A new program at Franklin Square would not be bringing novel technologies or processes that will increase organ availability.

(7) Co-chairing the National Consensus Conference. While I find that it is commendable that MGTI hosted the National Consensus Conference that focused on organ availability, I do not find that hosting such a conference would lead to an increase in organ availability in Maryland. Neither would non-attendance at the conference signal that viable organs are being ignored.

(8) MGTI Clinical Developments Advancing the Field of Kidney Transplantation. The applicant states that MGTI "expects ongoing research to produce future innovations that will further increase the supply of donor organs for patients at Franklin Square." (DI #4, p. 58). Medical research must go through extensive peer review and publication. During that process, any such breakthroughs are available to the medical community in general. Thus, while MGTI's transplantation research may lead to breakthroughs that can increase the availability of kidneys, I do not believe that this research will be limited to benefiting a program at Franklin Square by increasing available organs for use at that program alone.

Projected Volume Shifts

The applicant does not project drawing a significant number of patients from the area's other programs and emphasizes the benefits of MedStar patients remaining in network for a transplant. While there is some continuity of care benefit associated with staying within a health system, MGTI uses MedStar Georgetown University Hospital for adult transplants, which is accessible to Maryland residents and located within a three-hour commute for the vast majority. By MGTI's admission, JHH and UMMC receive a very limited number of referrals from the MedStar system. The applicant does not state that the patient's health is endangered by seeking a transplant outside of the MedStar system, and in the era of growing interoperability of electronic medical records and the expanded role of CRISP, the State-designated Health Information Exchange, it seems likely that an acceptable level of continuity of care can be achieved by health systems working together for the good of a patient.

Utilization Trends

According to both the LLF and WRTC OPOs, the implementation of the new kidney allocation policy is still too recent to provide a significant amount of data; however, it is expected to increase the availability of kidneys to all three of the existing large volume kidney transplant centers currently serving Marylanders. This projected increase in organ availability has occurred without the implementation of any new transplant programs. (DI #57, pp. 2-3; DI #58, p.3).

Beyond the new allocation policy, both organizations believe that the best way to increase the number of kidneys available for transplant is to increase the number of individuals signing up to be organ donors.

Summary

The applicant has not presented sufficient evidence that an additional transplant program would increase the supply of additional kidneys for Maryland residents. I do not find that Maryland residents need an alternative to the existing transplant centers in Baltimore and the District of Columbia.

I find that the applicant has not met the need standard.

(2) <u>Minimum Volume Requirements</u>

(a) An applicant shall demonstrate that a proposed organ transplantation service can generate the minimum annual case volume (see table below) 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.

Minimum Annual Case Volume Requirements by Organ Type
(Table 2 in the SHP)

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

Applicant's Response

Franklin Square projects that its kidney transplant program will exceed the 30-case minimum annual case volume requirement for adults by year three of the program's operation. The applicant claims that the program will generate case volume through referrals from the MedStar Good Samaritan Hospital, and MedStar Union Memorial Hospital nephrology programs in Baltimore City as well as outreach clinics located at Franklin Square and in Annapolis, Frederick and, more recently, Ellicott City. The program also expects referrals from Mid-Atlantic Nephrology Associates (MANA), the Nephrology Center of Maryland and other practicing nephrologists. (DI #4, pp. 64-65, Attachment 6).

Table III-9: Franklin Square Kidney Transplant Case Volume Projection

Year 1	Year 2	Year 3
12	24	44

Source: DI#4, p.64

The applicant explained the basis for its case projections as follows:

1) Franklin Square projects that the patient population of two chronic dialysis centers operated on MedStar hospital campuses by DaVita will produce about 22 transplant cases for the new transplant program per year;

2) MGTI transplant candidates will be double listed at both MGTI and Franklin Square. Franklin Square projects that five patients per year who would otherwise obtain transplants at MedStar Georgetown University Hospital will receive transplants at Franklin Square when the program is implemented; and

3) Franklin Square projects that it will receive referrals from its own nephrology program, from Mid-Atlantic Nephrology Associates physicians, Maryland Kidney Group physicians, and Fresenius Kidney Care Porter Dialysis, a large renal dialysis service with seven centers in eastern Baltimore County. The hospital projected 17 cases from these sources by year three of operation. (DI #17, pp. 33-34).

The applicant acknowledged that if its application for a CON is approved, it will close the program if: (i) the service is unable to sustain the minimum annual case volume for any two consecutive year period and cannot provide an acceptable explanation as to why it failed to maintain the minimum case volume; and develop a credible plan for achieving the minimum annual threshold case volume that is approved; or (ii) the program fails to achieve the minimum annual case volume by a deadline established by the Commission as a result of the program's failure to achieve the minimum annual case volume requirements. (DI#14, p. 35).

Reviewer's Analysis and Findings

I find that the applicant's case volume projection for Year 3 of operation is credible and is based on referral sources that are likely to be receptive to referring patients to a new MedStar transplant program. Recent utilization figures suggest that the program will likely maintain at least the minimum case volume in subsequent years. The applicant agrees to close the program if the minimum case numbers are not met for two consecutive years or by a deadline imposed by the Commission. I find that the applicant has demonstrated an ability to meet this standard.

(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.

Applicant's Response

The proposed program located in the Rosedale area of northeast Baltimore County will be accessible within a three-hour drive for at least 95 percent of Maryland residents. Franklin Square does not seek to justify the need for additional kidney transplantation services on the basis of barriers to access. (DI #4, p. 67).

Interested Party Comments

Johns Hopkins Hospital

JHH notes that Franklin Square fails to establish that barriers to access exist. JHH points to the applicant's statement that there are existing gaps in access for "underserved populations such as children and those requiring multi-organ transplant." (DI #4, p. 65). JHH states that the applicant does not substantiate the statement that children face barriers to access in the LLF DSA, and adds that the applicant is not providing transplantation to children at the Franklin Square site. JHH also states that the existing programs serving patients in the LFF DSA provide multi-organ transplants. Additionally, JHH challenges the applicant's assertion that minority patients are faced with barriers to access because they "receive transplants at lower rates than non-minorities," and provides data to show that Black patients receive higher numbers of transplants per population in the existing Baltimore programs as compared to the programs in the WRTC DSA. (DI #30, p. 20).

University of Maryland Medical Center

UMMC asserts that no access barriers exist and that patients in the LLF DSA, including minority patients, have access to two high-quality kidney transplant programs. Adding a third program would contradict the Commission's express policy that "the public is best served if a limited number of general hospitals provide specialized services to a substantial population base." COMAR 10.24.15.03.

UMMC rejects the applicant's claim that MGTI provides greater access to minority populations. UMMC provides data to show that UMMC performs kidney transplants on a significantly larger population of minority patients than MGTI. (DI #31, p. 9).

Additionally, UMMC asserts that driving distance to MGTI is not a barrier to access as MGTI is within 50 miles of the existing programs in Baltimore and the proposed program at Franklin Square is within 10 miles of the existing JHH and UMMC programs. UMMC cites the State Health Plan Chapter which provides that "travel to an organ transplant center located in a health planning region other than where the organ transplant recipient resides is not, in and of itself, considered a barrier to access, if the drive time in less than three hours one-way." COMAR 10.24.15.04B(3).

UMMC also cited MedStar's opposition to the Suburban Hospital CON application

(Docket #17-15-2400) in which it asserted that there is no expectation that residents of a DSA be transplanted within that same DSA. (DI #31, p.11). Therefore, UMMC maintains that MedStar patients can easily be served at MGTI (WRTC DSA), even if they live in the Baltimore area (LLF DSA).

Applicant's Response to Interested Party Comments

Franklin Square believes that since it does not claim barriers to access as a justification for this application, the access standards do not need to be satisfied. The applicant again states that MedStar serves the minority population in greater proportion than either existing center in Baltimore. (DI #36, pp. 15-16).

Reviewer's Analysis and Findings

The standard requires that an applicant show that the medical center is accessible within a three-hour one-way drive time for 95 percent of Maryland residents and that those applicants that seek to justify the need for additional organ transplantation services on the basis of barriers to access show that these barriers exist. An applicant is not required to justify its CON request on the basis of barriers to access.

I find that the applicant has shown that the proposed program is accessible within the drive time requirements of the standard. Because the applicant is not basing the justification of its program on addressing barriers to care, it is not required to present evidence that barriers exist or whether it can address these barriers.

(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.

Applicant's Response

Franklin Square believes that MGTI's innovative surgical techniques will better meet the needs of the proposed population by increasing the number of transplants performed. (DI #14, pp. 37-38). In support of this assertion, Franklin Square notes that while the waitlist for kidney transplants grows each year, 20% of available organs are not transplanted.

The applicant also states that it is confident in its ability to "meet the needs of the minority population more completely, based on experience, as MGTI enrolls a higher percentage of minority patients on its waitlist leading to a higher percentage of kidney transplants compared to either UMMS or Johns Hopkins." (DI #14, p. 39).

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; and

Applicant's Response

Franklin Square asserts it will increase the availability of donor kidneys to benefit Maryland patients. Additionally, the applicant believes that patients benefit from care that is provided within one integrated system. (DI #24, p. 5).

MedStar has added outpatient evaluation sites for kidney and liver transplant at Maryland sites in Frederick, Annapolis, Ellicott City and at MedStar Southern Maryland Hospital Center and MedStar Franklin Square Medical Center. The applicant states that these locations were created expressly to offer access for patients that would find travel for preoperative evaluation and postoperative follow up challenging.

In addressing section (b), the applicant refers to Table H, Revenues and Expenses. Table H, which gives Revenue and Expense data for the entire facility, shows that the hospital will continue to be profitable throughout the first five years of project implementation. Table K and J showed information that the project would be profitable by the third year.

b) **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**.

Applicant's Response

Franklin Square states that as a "community teaching hospital," it has a lower cost structure and charge per case than the two academic medical centers that currently provide transplant services in the LLF DSA. Franklin Square also asserts that by collaborating with the existing MGTI infrastructure, and by locating many of its administrative and data collection and reporting functions at MGTI, it can deliver the service in a highly cost-effective manner, providing the following comparison. (DI #4, pp. 18, 68-69). As shown, in FY 2016, Franklin Square projects an average charge that is 25% less than UMMC's average charge and 41% less than JHH's average charge.

Table III-10: Average Charge per Kidney Transplant Procedure (FY2016)

Provider	Average Charge per Kidney Transplant
JHH	$148,500
UMMS	$116,270
Franklin Square (projected)	$87,203

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

Interested Party Comments

University of Maryland Medical Center

UMMC believes that a program at Franklin Square would not be cost effective and would result in increased costs, asserting that the applicant underestimated the staffing levels needed to run a transplant program. UMMC states that MedStar's projected physician staffing of just three physicians is insufficient for a 24/7/365 program, as is required by OPTN bylaws. (DI #3, p. 13).

UMMC also notes that the shared resources outlined in the application (administrative, data collection, and reporting) between Franklin Square and MGTI is problematic and will not comply with OPTN bylaws. UMMC stated that "A transplant surgeon must be readily available in a timely manner to facilitate organ acceptance, procurement, and transplantation, and a transplant surgeon or transplant physician may not be on call simultaneously for two transplant programs more than 30 miles apart unless the circumstances have been reviewed and approved." (DI #31, p. 14).

UMMC does not believe that the applicant has described the proposed lean staffing model in sufficient detail to determine whether it could meet all staffing requirements. UMMC states the there is no mention of anesthesiologists, pharmacists, or experts in histocompatibility and immunogenetics, immunology, infectious disease, pathology, physical therapy and rehabilitation medicine, pulmonary medicine, including respiratory therapy support, and radiology in the applicant's staffing plan. (DI #31, p. 14-15).

Additionally, UMMC believes that Franklin Square misleadingly frames its program as a more cost-efficient alternative by comparing its projected charges to those of UMMC and JHH, based on each program's average charge per kidney transplant case. Since MGTI does not charge all payers the same rates, UMMC notes that a more appropriate cost comparison must consider the program's projected payer mix which includes 41.9% Medicare patients and 25.3% Medicaid patients. UMMC states that

> *because of Maryland's Total Cost of Care Model State Agreement with CMS, Medicare and Medicaid charges are actually significantly higher in Maryland than nationally. MedStar's proposed charges exceed MGTI's CMS reimbursement rates for Medicare transplant recipients and likely Medicaid transplant recipients as well and therefore, as a result, 67.2% of the patients MedStar shifts from MGTI will likely pay more, not less, for kidney transplant services.* (DI #31, p. 15-16).

UMMC cites MedStar's opposition to the Suburban Hospital CON application (Docket #17-15-2400) in which it argued that increased competition does not lead to increased numbers of transplants and improved patient survival. UMMC points to comments made in that opposition that consolidation of programs at MGTI and MedStar Washington Hospital Center in 2015 decreased the competition between these programs and resulted in greater efficiency in operations, volume growth, and lower costs. UMMC stated that MedStar further summarized its argument

with studies finding that increased competition led to various risks, including increased graft failure and increased costs. (DI #31, p. 12).

UMMC also cited MGTI's comments in opposition to the George Washington University Hospital CON application (a CON filed in D.C. in 2014) for a kidney and pancreas transplantation program in which the Medical Director of MGTI's Kidney and Pancreas Transplant Program, Basit Javaid, M.D., "cautioned that the addition of a new transplant center in [D.C.] would, in light of the limited organ donor pool, destabilize existing area transplant centers by diluting its clinical expertise, thereby risking degrading its surgical outcomes and weakening its financial viability." (DI #31, p. 60). UMMC pointed out that MedStar further argued that the "existence of a low-utilization transplant program in [MedStar's] service area raises concerns regarding cost, quality, and duplication of services." (DI #31, p. 73).

Applicant's Response to Interested Party Comments

Franklin Square states that it stands by its staffing and cost analysis and that it will comply with all OPTN bylaws. The applicant states that it will hire staff based on volume growth, adding staff as the program grows and providing training as needed to support the program. Franklin Square states that it will meet all CMS standards and that all physicians and ancillary staff will be on site. The only off-site resources will be administrative oversight and data management services.

The applicant also stands by its comparison with the other programs in Baltimore, insisting that its charges would be lower than both existing programs; further, it asserts that MGTI charges are irrelevant in the context of a Maryland-based program. (DI #36, p. 17).

The applicant believes that its comments in opposition to previous CON applications are not in conflict with the current application, noting that consolidation and competition are different concepts. Consolidation of programs demonstrates the ability to manage available resources, reduce redundancies and streamline operations.

Reviewer's Analysis and Findings

I find that the applicant has not satisfied paragraph (a) of the Cost Effectiveness standard, which requires demonstration of why existing programs cannot meet the need for organ transplantation for the proposed population to be served. As discussed, in my analysis of the Need standard, Maryland residents are served by four existing kidney transplant programs that perform at or above national averages on performance benchmarks reported in the SRTR and that also meet CMS' expected outcome requirements. DSA boundaries do not define where patients should be expected to receive a transplant. Rather, the boundaries were established to determine which OPO is responsible for the recovery and assessment of organs at donor hospitals in the designated DSA, which are then offered to transplant centers and their patients in accordance with national policies.[33]

[33] See the description of OPOs on the UNOS website at unos.org/transplant/opos-increasing-organ-donation/.

The applicant has not satisfied paragraph (b) of the Cost Effectiveness Standard, which requires demonstration of how the new program would benefit the population to be served. As stated in the Need Standard analysis, there is insufficient evidence to show that Franklin Square could increase the supply or use of organs and that it would provide an additional benefit not already being provided by the existing programs. Also, the applicant failed to document the projected annual costs of the proposed service over a period of a least five years. Table K in Attachment 1 shows three-year projections of revenues and expenses of the new service but falls short of providing the five-year requirement.

I considered the applicant's argument with respect to paragraph (c) which requires estimates of the costs to the healthcare system as a whole and the benefits of the proposed program, quantifying the benefits to the extent feasible over a period of five years. The applicant states that the costs of services would be lower in a community hospital setting. According to HSCRC, organ acquisition costs and direct costs for the new program would likely be the same as the costs at the four existing centers, but indirect costs and overhead would likely be less expensive at Franklin Square. (DI #63, p. 3). The applicant did not specifically account for any increases in global budget revenue that Franklin Square would receive after implementation of the new project, beyond its revenue projections. It did not provide information on charges for transplantation at MGTI.

Although the project presents the possibility of lowering charges for payors of kidney transplant services, on balance, I cannot find that Franklin Square has demonstrated that its proposed establishment of an organ transplant service is cost-effective standard because it failed to demonstrate that: (a) the existing programs cannot meet the need for the proposed population and (b) how the new program would benefit the population being served justifying the projected costs. Further, the State Health Plan requires the applicant to quantify, to the extent feasible, the benefits of the establishment of its proposed organ transplant service to service area population, document at least five years of projected costs, at a program-level and at the health care system-level and showing that the value of the benefits justify these projected costs. The applicant has not provided this information and therefore has not met its burden.

(5) <u>Impact</u>

(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;

(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.

Applicant's Comments

Franklin Square does not believe that a third kidney transplantation program will have an impact on the ability of the existing LLF DSA programs to meet threshold volume requirements and is projecting a modest impact on case volume at the two transplant centers located in the LLF DSA. Franklin Square projects that referrals from hospitals in the MedStar system to the two existing programs will drop by about 10 patients per year by the third year of the program. Thus, the applicant states that its project will not have a major financial or operational effect on either program, as both perform an average of 200+ kidney transplants per year. It notes that this is well above the annual threshold volumes required for a kidney transplant program. The applicant predicts that the majority of patients obtaining surgery in the new program will be referred from dialysis and nephrology programs in the MedStar system. (DI #4, pp. 61-64).

The applicant also notes that MGTI is currently performing kidney transplants on Baltimore area residents and that those residents would benefit from having a closer transplant center in Baltimore County. (DI #14, p. 41).

Interested Party Comments

Johns Hopkins Hospital

Johns Hopkins states that the applicant has not provided sufficient data to "meaningfully analyze" the impact that a new program would have on the two existing programs in Baltimore because the applicant states that "MedStar does not maintain data on those referrals, so it was only able to guess the number." (DI#30, pp 21-22). Further, JHH points out that MedStar does not translate the relationship between the number of referrals and the number of transplants performed in its CON application at page 60 of the application. (DI #30, pp. 21-22).

JHH points out that Franklin Square did not respond to MHCC staff's direct question as to whether it projects to serve patients who are not currently receiving transplants. The applicant "does not say one way or the other," and characterizes its non-response as a "tacit admission that it cannot project that its proposed new program will meet any need in the LLF DSA that is not already being served." Further, JHH maintains that the applicant's proposal to add a low-volume third program in the LLF DSA would be inconsistent with the State Health Plan, which favors a small number of high-volume organ transplant programs. (DI #30, pp. 21-22).

Applicant's Response to Interested Party Comments

Franklin Square states that it has provided sufficient evidence to show that establishing a third kidney transplant program in Baltimore will not interfere with JHH maintaining case volumes above the SHP threshold level of 30 patients per year. It states that its project will not have an adverse impact on the financial viability of the JHH program and will not have an adverse impact on patient access to kidney transplant services. (DI #36, p. 14).

Reviewer's Analysis and Findings

Information in the record suggests that sources associated with MedStar Health refer approximately 15 patients per year to JHH and UMMC for kidney transplantation. In this proposal, the applicant estimates a reduction in this patient flow to approximately five patients per year. This reduction would have a small impact on the size of the existing programs in Baltimore, given recent case volumes the programs have experienced. It is not likely that the Franklin Square project, as projected to operate by the applicant, would have a significant impact on the viability of either existing program.

The location of the proposed program in Baltimore County will not have a detrimental impact for Maryland residents on access to kidney transplantation within a three-hour one-way commute. Subpart (e) of this standard is not applicable in this review.

Therefore, I find that the applicant has met the standard.

(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.

Applicant's Response

The applicant states that the new program at Franklin Square will be UNOS and CMS- certified within the first year of operation. (DI #4, p. 73). Subpart (b) of this standard is not applicable in this review. Franklin Square is fully accredited by The Joint Commission (TJC). (DI #4, Attachment 2).

Reviewer's Analysis and Findings

I find that the applicant meets this standard.

(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.

Applicant's Response

The applicant states that all hospitals in the MedStar system have active disease prevention and self-management programs including the Living Well Chronic Disease Self-Management Program, which is based on the Stanford University Chronic Disease Self-Management Program model and includes components targeting prevention and lifestyle modification.

Patients with one or more chronic conditions are identified through the electronic health record and referred to the program by their physician or through fliers available in various clinic and community locations. MedStar also implements a Diabetes Self-Management Education Program aimed at managing diabetes effectively, which includes prevention education. When physicians identify severe cases of diabetes, they refer patients to the Diabetes Boot Camp, a 12 week program concerning glucose control. Physicians also refer diabetes patients to classes aimed to slow the progression of kidney disease run by Davita's Kidney Smart program. Additionally, MedStar has created *MedStar Health InFocus*, a patient education website that provides patients with information on managing Type II diabetes, reducing the risk of heart failure, and performing cardiac rehab exercises. MedStar hospitals also conduct Speakers Bureaus featuring physicians who provide seminars and education on diabetes prevention, management and care to the community.

MedStar educates physicians and other professionals on disease prevention through meetings, symposia and in-house continuing education programs. In addition to patient education, Kidney Smart educators offer programs for staff members. (DI #17, pp. 17-20).

To educate community members about kidney transplantation and kidney donation, MGTI engages with patient organizations such as the National Kidney Foundation which provides educational programs aimed at reducing chronic kidney disease and options for End-Stage Renal Disease (ESRD) including transplantation. MedStar promotes the advantages of transplantation

vs. dialysis as a treatment for ESRD. MedStar provides education regarding the value of living donation as an option due to the associated increased graft survival, shorter waiting time, decreased complications and fewer incidences of rejection. MGTI holds seminars in the community to educate the public about "living donation, how to begin the conversation in speaking to others about kidney disease and the need for a living donor, and how an individual's care giver may become their donor 'champion' in aiding the potential transplant recipient in these efforts." (DI #14, p. 42).

Reviewer's Analysis and Findings

I find that the applicant has health promotion and disease prevention programs in place that are aimed at reducing the prevalence of end stage organ disease and increasing the availability of donor organs and has preventive services in place for those at greatest risk of kidney disease.

I find that the applicant complies with this standard.

B. COMAR 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.

Applicant's Response

The applicant states that it has demonstrated the need for a transplant center at Franklin Square, on the following bases:

1. The program at Franklin Square will offer additional innovation in clinical care, medical therapy, surgical approaches and clinical research that will increase the supply of available donor organs for residents of the State of Maryland needing a transplant. (*supra*, pp. 17-21);

2. The program at Franklin Square will reduce wait times for patients in need of kidney transplants. The applicant provided data showing that between 1988 and 2020, MGTI had a low number of individuals waiting for a kidney for five years or more as compared to the other area programs. (DI #48, pp. 9-10). The applicant asserts that the new program at Franklin Square will be able to replicate the shorter waiting times seen at MGTI; and

3. The project will improve on the current levels of kidney transplantation for minority populations in Baltimore.

To support this assertion, the applicant provided data (see the following table) to show that MGTI had a higher percentage of minority individuals on both its waitlist and transplant list than the region or country as a whole. The applicant states that it will replicate this proportion at the proposed Franklin Square program, increasing transplantation for minorities in Maryland.

Table III-11: Race/Ethnicity of Waiting List and Transplant Patients MGTI, OPTN Region, and the U.S.

	MGTI	OPTN Region	U.S.
Waitlist			
White	20.6%	40.1%	36.4%
African American	64.6%	44.2%	33.3%
Hispanic/Latino	8.4%	7.3%	19.6%
Asian	6.0%	7.0%	9.1%
Other	0.3%	0.5%	1.6%
Transplants			
White	25.3%	49.1%	45.8%
African American	61.1%	35.6%	27.5%
Hispanic/Latino	10.1%	9.0%	18.3%
Asian	3.0%	5.4%	6.3%
Other	0.5%	0.9%	2.1%

Source: DI #4, p.15

The applicant states that MedStar Health has a "population health" focus that involves caring for its patients through the continuum of care, from prevention through diagnosis, treatment and aftercare and notes that MedStar manages approximately 250,000 covered lives, the majority of which are Maryland residents. It asserts that 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.

Franklin Square states that while the existing programs are able to provide kidney transplantation services to patients in the LLF DSA that are matched with a donor organ, too few patients receive a kidney transplant. The applicant states that its proposed program in collaboration with MGTI's expertise, innovation, and outreach, "will increase the supply of donor organs available in the LLF DSA and so increase the number of Marylanders who receive kidney transplants." (DI #14, p. 37).

Reviewer's Analysis and Findings

There is an applicable Need standard in the State Health Plan chapter addressing organ transplantation, COMAR 10.24.15. The arguments for and against the applicant's ability to increase the supply of available organs, a primary theme of that standard, have been addressed in this Recommended Decision, in my review of the Need standard (COMAR 10.24.15.04 B(1) (*supra*, pp. 17-29).

The applicant asserts that MGTI patients have shorter wait times for kidney transplantation than the patients at JHH and UMMC and that this shorter wait time will be replicated at Franklin Square. The data presented includes wait times from 1988 to 2021. Both JHH and UMMC have been relatively high-volume programs for decades, enrolling hundreds of new patients onto their waitlists each year. MGTI is a much younger program in its current form, with fewer individuals on the waitlist prior to 2015, when waitlisted patients at MedStar Washington Hospital Center were transferred to the MGTI waitlist. According to the SRTR report released in June 2011, waitlist additions at MGTI were less than a third of those at Johns Hopkins and less than a fifth of

those at UMMC.[34] Because the applicant had so few individuals being added to the waitlist prior to 2015, the number of those waiting for an organ for more than five years would be expected to be low. (DI #48, p.9).

Franklin Square also argues that the new program will make kidney transplants more available for minority populations in Maryland. It bases this assertion on the proportion of minority persons on its waiting and transplantation lists. Using updated 2019 data, it is clear that MGTI serves a higher proportion of minority individuals than JHH, but that the mix of patients on the waitlist and transplant lists at UMMC is similar to that of MGTI.

Table III-12: Race/Ethnicity of Waitlist and Transplant Patients MGTI, JHH, and UMMC

	MGTI	Johns Hopkins	UMMC
Waitlist			
White	25.2%	39.5%	36.5%
African American	57.3%	46.6%	55.6%
Hispanic/Latino	6.1%	4.2%	2.4%
Asian	10.7%	9.7%	4.8%
Other	0.7%	0.0%	0.8%
Transplants			
White	15.9%	42.7%	24.4%
African American	70.1%	44.3%	67.0%
Hispanic/Latino	7.6%	5.9%	4.3%
Asian	6.4%	5.9%	4.3%
Other	0.0%	1.1%	0.0%

Source: SRTR Program Specific Reports, released August 4, 2020

I find that the applicant has not provided sufficient evidence that kidney transplant candidates who reside in Maryland have unmet needs that could be addressed by the new program. I find that the new program will not significantly improve care for the patients who already have access to four quality transplant centers in the Washington Region DSA and Maryland Region DSA.

I recommend that the Commission find that there is not a need for the proposed project at this time.

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

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

Before proceeding to summarize the applicant's response to this criterion, I note that CON applicants receive additional guidance to respond to this criterion. Instructions within the CON application materials ask the applicant to first do two things: describe the planning process that was used to develop the proposed project, including a full explanation of the primary goals or

[34] Scientific Registry of Transplant Recipients. www.srtr.org/reports/program-specific-reports/

objectives of the project or the problem(s) being addressed by the proposed project, and; identify the alternative approaches to achieving those goals or objectives or solving those problem(s) that were considered during the project planning process. The applicant is asked to include, among the alternatives considered, the possibility of the services being provided through existing facilities or through population-health initiatives that would reduce the need for hospital services. Finally, the applicant is asked to describe the hospital's population health initiatives and explain how the projections and proposed capacities take these initiatives into account.

For each alternative approach, an applicant is expected to describe the effectiveness and costs, with the cost analysis going beyond development costs to consider life cycle costs. The applicant's narrative should clearly convey the analytical findings and reasoning that supported the project choices made. It should demonstrate why the proposed project provides the most effective method to reach stated goal(s) and objective(s) or the most effective solution to the identified problem(s) for the level of costs required to implement the project, when compared to the effectiveness and costs of alternatives.

Applicant's Response

Franklin Square states that it seeks to establish a kidney transplantation program to increase the availability of kidney transplants in the Baltimore region. This will be accomplished by increasing the number of available organs. The program aims to provide better local access to kidney transplant services for MedStar patients at significantly lower charges than either existing transplant program in Maryland can offer.

The applicant provided three alternative options for meeting these objectives (DI #4, pp.81-83), which are summarized as follows:

Utilize the existing transplant centers in Baltimore. The applicant states that some MedStar patients have historically elected to undergo kidney transplantation at one of the two Baltimore transplant centers but that this option does not allow for the continuity of care for patients receiving care in the MedStar system. Franklin Square cites the importance of providing a full continuum of services and believes that 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." Franklin Square states that it has shown that charges for care are higher at the currently available centers than those projected for its proposed program (a function of its cost basis as a community hospital rather than an academic medical center). Thus, the applicant states that the proposed program offers a more efficient care model at lower cost;

Refer patients to MGTI in Washington DC. The applicant states that MedStar system physicians have a preference for referring patients living in Central Maryland to MGTI in order to maintain the continuum of care. The applicant states that MGTI's location in Washington, D.C. creates a geographic challenge for many MedStar Health transplant patients who live in the Baltimore area and that "this alternative does not achieve MedStar's goal of providing care to its patients in their own communities whenever possible"; or

Establish a program at Franklin Square. The applicant believes that establishing organ

transplant services at MedStar Franklin Square is the most efficient and cost-effective solution.

The applicant states that the proposed program will be fully integrated with MGTI, and will achieve MedStar Health's strategic goals and objectives in the following ways:

1. It will maintain continuity of care for MedStar Health patients within the MedStar Health System;

2. The proposed location is convenient to MedStar's Central Maryland patients. MGTI has laid the groundwork for the establishment of this program and the provision of transplantation-related services in outreach sites throughout Central Maryland; and

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

Reviewer's Analysis and Findings

Cost effectiveness is also a standard in the State Health Plan. COMAR 10.24.15.04B(4). UMMC's argument that the proposed project is not cost effective, and the applicant's response, were previously detailed during my review of this standard. (*supra*, pp. 32-35).

In response to these criteria, the applicant discusses and compares the merits of three "approaches" to serving a kidney transplant patient population largely defined as persons residing nearer Baltimore than D.C. who are or are likely to become patients of MedStar Health. The approaches are, in essence, binary; maintain the status quo, in which Maryland patients continue to use the two existing programs and MedStar affiliates refer kidney transplant patients to MGTI; or implement the proposed establishment of a third Baltimore-area transplant program.

While the applicant articulates the benefits of continuity of care within the MedStar system, only a relatively small number of MedStar patients are referred outside the MedStar system to JHH and UMMC. The distance to MedStar's program at MGTI is within a reasonable commute from Central Maryland for a highly specialized service used by only a few hundred patients in an average year. Accessibility to effective continuity of care should be achievable across health systems without creating MedStar transplant centers in both Maryland and D.C., in a time of increasing interoperability of electronic medical records and information sharing through CRISP. I find that the applicant has not made the case that a comparison of the cost effectiveness of the proposed project and the cost effectiveness of providing the service through alternative existing facilities clearly indicates the superiority of the proposed project, in terms of cost savings and/or improved program effectiveness in providing kidney transplant services.

D. COMAR 10.24.01.08G(3)(d), Viability of the Proposal.

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

necessary to sustain the project.

Applicant's Response

With respect to the availability of resources to implement the proposed project, the applicant projects no requirement for capital investment. The project will use existing hospital space. The estimated annual operating cost includes salaries, supplies, including drugs, and other expenses for outpatient services and organ acquisition. Franklin Square provided audited financial statements which document the availability of resources to implement this project. (DI #4, Exh. 7).

With respect to the availability of resources to sustain the proposed project, the applicant's utilization and financial forecast is summarized in Table III-13 below. Franklin Square projects that, by Year 3, the service will require 29 full-time equivalent (FTE) employees to provide care for 44 new kidney transplant cases. (DI #4, Exh. 1I; DI #4, Exh. 1L). The applicant projects hiring 17 direct patient care, four management, and eight support staff FTEs for a total cost of $4.7 million in salaries and benefits. (DI #4 Exh. 1L). As shown in the table, the applicant projects that the project will generate net income by the third year of operation, as patient volume increases. (DI #4, Exh. 1L).

Table III-13: Utilization and Financial Projection Profile

Proposed MedStar Franklin Square Kidney Transplant Program	Year 1	Year 2	Year 3
Utilization			
Kidney Transplants	12	24	44
Discharges	12	24	44
Patient Days	30	42	90
Revenue			
Gross Patient Revenue	$2,656,000	$5,658,000	$11,190,000
Allowance for Bad Debt	93,000	195,000	385,000
Contractual Allowance	361,000	663,000	1,297,000
Charity Care	24,000	51,000	101,000
Net Operating Revenue	$2,179,000	$4,749,000	$9,407,000
Expenses			
Salaries and Wages	$1,842,000	$3,764,000	$4,657,000
Project Depreciation	4,000	8,000	8,000
Supplies	357,000	591,000	1,208,000
Other Expenses	770,000	1,282,000	2,559,000
Purchased Services	90,000	160,000	282,000
Total Operating Expenses	$3,062,000	$5,805,000	$8,714,000
Net Income	($883,000)	($1,056,000)	$693,000

Source: DI # 4, Table F, Table I

With respect to community support, the applicant provided numerous letters of support from MedStar-associated physicians, physicians in community-based practices, and community members currently awaiting a transplant. (DI #4, Attachment 6).

Reviewer's Analysis and Findings

Based on its financial performance as a large community hospital and its reported liquid assets, I find that Franklin Square has the available resources to implement this project. I also considered the review and comments of HSCRC staff (see Exhibit 2), which questioned how the new kidney allocation policy would affect the viability of the project.

The statistical volume projections and the financial projections have not been amended since first submitted in March 2018, and therefore do not account for the effects, if any, of the new allocation policy. Staff is not currently able to judge the potentially material impact of this 2021 organ allocation policy change. However, I do not believe this uncertainty raises serious concerns with respect to the likely ongoing viability of the proposed program. (DI #63, p. 3).

I find that, the proposed kidney transplantation service would be likely to achieve case volumes that generate sufficient revenue and, potentially, levels of net income necessary to sustain the service.

Finally, the applicant has demonstrated that the project is supported by members of the MedStar Health, physicians unaffiliated with the MedStar system, and patients currently awaiting kidney transplants.

On this basis, I find that the proposed project is viable.

E. COMAR 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.

MHCC has issued three CONs to Franklin Square in the past 15 years. The applicant completed all projects in compliance with all terms and conditions of approval.

On July 20, 2006 (D.N. 05-03-2173), the hospital was authorized to undertake a substantial modernization project involving construction of a five-story building addition. The approved cost of the project was $224,878,180. The project was subsequently redesigned, and the last Quarterly Report submitted to MHCC on October 25, 2010 identified an estimated total cost of $193,368,591. On December 10, 2010, MHCC determined that the project was complete and had been implemented consistent with the terms of the CONO. On September 18, 2008 (D.N. 08-03-2250) Franklin Square was authorized to convert its child psychiatric unit to an adolescent psychiatric unit. The Commission approved the project with a condition requiring Franklin Square to file post-implementation reports with MHCC focused on the disposition of children and adolescents who presented with psychiatric symptoms. On June 15, 2017, the hospital was authorized (D.N. 16-03-2380) to replace its 16 operating room (OR) surgical suite and surgical support areas with a replacement surgical suite with 14 ORs in a new two-story building connected to its 2010 inpatient tower. The approved cost of the project was

$70,000,000.

The applicant's track record in implementing CON application approvals is acceptable.

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

An applicant shall provide information and analysis with respect to the impact of the proposed project on existing health care providers in the service area, 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.

Applicant's Response

Franklin Square states that an average of 15 patients per year are referred from MedStar physicians to JHH and UMMC for kidney transplantation and estimates a reduction in this flow of referrals from MedStar providers to these two established kidney transplant programs following implementation of its proposed project. By year three of the program, MedStar referrals to JHH and UMMC are estimated to total five patients. (See the MedStar numbers in the following table.) MedStar stated that it expects that referrals to a newly established program at Franklin Square would come from MedStar's Advanced Kidney Disease Clinics at Franklin Square, in Frederick and Annapolis, as well as from the renal programs at MedStar Good Samaritan and MedStar Union Memorial Hospital. As the program becomes more established, Franklin Square expects that more MedStar affiliated physicians will refer their patients to the Franklin Square program. (DI #14, pp. 51-52).

Table III-14 Trend in Referrals to UMMS and Johns Hopkins from MedStar Health Affiliates

	Actual			Projected			
Metric	**FY 2015**	**FY 2016**	**FY 2017**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2121**
Referrals to UMMS	12	4	7	8	8	5	3
Referrals to Johns Hopkins	10	4	6	8	7	4	2
Total referrals	22	8	13	16	15	9	5
Change from prior year					-6%	-40%	-44%

Source: DI#4, p.23

The applicant maintains that establishing a kidney transplantation program at Franklin Square will improve geographic access for MedStar patients in Central Maryland, when compared to accessing services at MGTI, and that it will better serve minority populations in the area.

The applicant asserts that a program that shares resources with a transplant center and carries the lower cost structure of a community hospital will be more cost-effective than the programs in Baltimore City, thereby providing savings to the health care delivery system.

Reviewer's Analysis and Findings

Impact is also a standard in the State Health Plan. COMAR 10.24.15.04B(5) (*supra*, pp 37-40).

The kidney transplant programs at JHH and UMMC each provide more than 200 transplants per year, with only a small fraction of patients from MedStar affiliate referrals. As I have also discussed at *supra* p. 39, the impact of adding a third kidney transplant program is likely to have a minimal impact on the viability of the existing programs or on costs and charges. A new program should provide marginally better access to some central Maryland patients who would otherwise look to obtain a transplant at MGTI in D.C. and it is also likely to be able to provide kidney transplant services at a lower price than the academic medical centers in the LLF DSA. For these reasons, I find the impact of the proposed project on existing health care providers in the service area, 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, to be acceptable and not a basis for denying the application.

V. SUMMARY AND RECOMMENDATION

I recommend that the Maryland Health Care Commission DENY the application of Franklin Square Hospital Center to introduce kidney transplantation services. The applicant has not met its burden to prove that the project is needed as required by the State Health Plan, COMAR 10.24.15.04B(1), and review criteria, COMAR 10.24.01.08G(3)(b). Further, the applicant has not demonstrated that its project is cost effective as required by COMAR 10.24.15.04B(4) and 10.24.01.08G(3)(c).

The Need Standard, COMAR 10.24.15.04B(1)

An applicant must demonstrate that it has the ability to increase the supply or use of donor organs. Projected utilization for the proposed project is primarily derived from an assumed shift of cases from existing transplant centers that would otherwise perform the procedures to the new program at Franklin Square. As stated in response to completeness questions, Franklin Square "is not asserting the existing programs are not able to provide the transplant services to those LLP patients who are matched with a donor organ." (DI# 14, p. 37)(emphasis in original). Instead, Franklin Square's application depends on its ability to increase the supply or use of donor organs. Franklin Square ultimately failed to present a credible plan to increase kidney donations or to better utilize the existing supply of kidneys.

The Cost Effectiveness Standard, COMAR 10.24.15.04B(4)

Franklin Square failed to demonstrate that the projected need for kidney transplant services can most cost-effectively be met through its proposed project. While the addition of kidney transplant services at Franklin Square would reduce travel time to a MedStar transplantation center for some patients in north and central Maryland, kidney transplantation facilities and services are adequately accessible currently at MGTI or at non-MedStar Maryland providers.

The Need Criterion, COMAR 10.24.01.08G(3)(b)

Franklin Square has not met the requirements of the Need criterion to demonstrate that there is an unmet need for its proposed kidney transplant service. It expressly chose not to justify its program based on barriers to access and therefore did not produce evidence to support this

standard. It failed to present a credible plan to increase kidney donations or to better utilize the existing supply of kidneys.

The Organ Transplant Services Chapter of the SHP dictates that kidney transplant services are a specialized, tertiary service that should be regionalized. The Chapter includes the following policy statement: "For specialized services, the public is best served if a limited number of general hospitals provide specialized services to a substantial population base. This pattern promotes high quality care and an efficient scale of operation." COMAR 10.24.15.03, p. 8. The four existing programs in Maryland and D.C. are already accessible to Maryland residents.

The Availability of More Cost-Effective Alternatives Criterion, COMAR 10.24.01.08G(3)(c)

Franklin Square did not demonstrate that its proposed project is the most cost-effective alternative in comparing the cost effectiveness of the proposed project with the cost effectiveness of providing the service through alternative existing facilities. Increase in the supply of kidneys for donation and more effective use of organ supply can be accomplished through existing outreach, education, research, and clinical practice efforts rather than through development of a third kidney transplant program in Maryland.

Because the project is not needed and not cost effective, I recommend that Franklin Square Hospital Center's application for a CON be denied.

IN THE MATTER OF	*	**BEFORE THE**
	*	
FRANKLIN SQUARE	*	**MARYLAND HEALTH**
	*	
HOSPITAL CENTER	*	**CARE COMMISSION**
	*	
DOCKET NO. 17-03-2405	*	

****

FINAL ORDER

Upon consideration of the Reviewer's Recommended Decision and the full record in this review, it is this 18th day of August, 2022:

ORDERED, that the attached Recommended Decision of the Reviewer is adopted as the final decision of the Maryland Health Care Commission; and it is further

ORDERED, that the Recommended Decision's findings of fact and conclusions of law are adopted by the Maryland Health Care Commission and incorporated into this order; and it is further

ORDERED, that the application for a Certificate of Need by Franklin Square Hospital Center to introduce kidney transplantation services is **DENIED.**

MARYLAND HEALTH CARE COMMISSION

APPENDIX 1

RECORD OF THE REVIEW

RECORD OF THE REVIEW

Docket Item #	Description	Date
1	Letter of Intent for Kidney Transplant Program submitted by MedStar Franklin Square Medical Center	5/22/17
2	Notice of receipt of LOI and soliciting additional LOI's for kidney transplant programs in the region in the Maryland Register	5/25/17
3	Letters of Support	Various Dates
4	Certificate of Need Application	8/14/17
5	Email correspondence - Potter to Cameron – Acknowledge receipt of application for completeness review	8/15/17
6	Commission requested publication of notification of receipt of the MedStar Franklin Square Medical Center's proposal in the Baltimore Sun	8/15/17
7	Commission requested publication of notification of receipt of the MedStar Franklin Square Medical Center's proposal in the Maryland Register	8/15/17
8	The Baltimore Sun provided the notice of receipt of application that published	8/23/17
9	E-mail – McDonald/Webster – Licensure status of the hospital with OHCQ	10/6/17
10	Following completeness review, Commission staff found the application incomplete and requested additional information	10/12/17
11	Applicant requested and Commission approved an extension to file completeness questions until 1/12/18	10/26/17
12	Applicant requested and Commission approved an extension to file completeness questions until 2/15/18	1/10/18
13	Applicant requested and Commission approved an extension to file completeness questions until 3/1/18	2/13/18
14	Commission received responses to the request for additional information	3/1/18
15	Following second completeness review, Commission staff found the application incomplete and requested additional information	5/4/18
16	Applicant requested and Commission approved an extension to file completeness questions until 6/1/18	5/9/18
17	Commission received responses to the request for additional information	6/1/18
18	Email correspondence- McDonald to Cameron – Formal start of Review of Application will be 8/31/18 and request for additional information	8/6/18
19	Email correspondence- Potter to Baltimore Sun paper – Request to publish notice of formal start of review	8/6/18
20	Maryland Register – Request to publish notice of formal start of review	8/6/18
21	Baltimore Sun – Notice of formal start of review	8/14/18
22	FORM – Request Local Health Planning Comments	8/24/18
23	Email correspondence- Cameron to McDonald –Update to application at end of fiscal year	8/7/18
24	Email correspondence- Cameron to McDonald – Additional information at requested in 8/6/18 letter	8/23/18
25	Baltimore County chooses not to comment on application	9/6/18
26	E-mail correspondence Wideman/Cameron – discussion of filing date for IP comments	9/25/18
27	E-mail correspondence – Aiken/Wideman/ Cameron – Agreed filing date for comments on application will be 10/15/18	9/25/18
28	E-Mail correspondence Cameron to Local Health Dept. in Service Area – Copy of applications for comments	10/15/18
29	E-Mail correspondence Wideman/Aiken – Guidance on submitting IP comments and local health depts.	10/15/18
30	Commission received Interested Party Comments from Johns Hopkins Hospital	10/15/18
31	Commission received Interested Party Comments from University of Maryland	10/15/18

	Medical Center	
32	University of Maryland Medical Center's Motion for Stay of CON Review of MedStar Franklin Square Transplant Programs	10/15/18
33	E-mail correspondence Widman/Tobin – Deadline for FS to respond to comments is 11/20/18	10/29/18
34	Commission received MedStar Franklin Square Medical Center Opposition to the Motion for Stay of Certificate of Need Review	11/5/18
35	E-mail correspondence Cameron/Wideman – Inquiry concerning Hopkins into Motion to Stay Filing	11/8/18
36	Commission received MedStar Franklin Square Medical Center response to interested party comments	11/20/18
37	Commission received University of Maryland Medical Center Reply in Further Support of its Motion for Stay of the CON Review	11/26/18
38	Commission requests information from HSCRC	10/29/19
39	MedStar Franklin Square Medical Center's Motion to Submit Additional Data and Set Briefing Schedule	11/12/19
40	Email correspondence	11/22/19
41	UMMC Response to Motion to Submit Additional Data and In Support of Renewed Motion for Stay of Certificate of Need Review	12/16/19
42	Johns Hopkins Hospital Response to the Motion to Submit Additional Data by MedStar Franklin Square	12/16/19
43	UMMC's Renewed Motion for Stay of Certificate of Need Review of MedStar Health's Applications Proposing the Establishment of Living and Kidney Transplant Services	12/16/19
44	MedStar Franklin Square Medical Center's Unified Reply in Support of its Motion to Submit Additional Data and Set Briefing Schedule and Response to UMMC Renewed Motion to Stay	12/30/19
45	O'Grady to Tobin, O'Croinin and Dame, appointment of reviewer and request for data and application updates	5/10/21
46	MedStar Franklin Square Medical Center's request for deadline extension to submit data and application updates	5/17/21
47	Commission approves extension of deadline	5/27/21
48	MedStar Franklin Square Medical Center submits data and application updates	7/9/21
49	Commission acknowledges receipt of data updates	7/29/21
50	Johns Hopkins Hospital requests extension of deadline to submit interested party comments	8/3/21
51	UMMC requests extension of deadline to submit interested party comments	8/3/21
52	Commission approves extension of deadline	8/4/21
53	Johns Hopkins Hospital submits interested party comments	9/16/21
54	UMMC submits interested party comments	9/16/21
55	O'Grady to Alexander, request for information from the Living Legacy Foundation	9/17/21
56	O'Grady to Brigham, request for information from the Washington Regional Transplant Community	9/17/21
57	Information submission from the Washington Regional Transplant Community	9/27/21
58	Information submission from the Living Legacy Foundation	10/1/21
59	MedStar Franklin Square Medical Center submits reply to interested party comments	10/1/21
60	O'Grady to UNOS, request for information	10/4/21
61	O'Grady to HSCRC, request for information	10/13/21
62	Information submission from UNOS	10/28/21
63	Information submission from HSCRC	11/23/21

APPENDIX 2

HSCRC Opinion Letter

maryland
health services
cost review commission

MEMORANDUM

TO: Michael J. O'Grady, Ph.D., Commissioner/Reviewer, MHCC
Wynee Hawk, Chief, Certificate of Need Division, MHCC
Moira Lawson, Program Manager, Certificate of Need Division, MHCC

FROM: Katie Wunderlich, Executive Director, HSCRC
Jerry Schmith, Director, Revenue & Regulation Compliance, HSCRC
Bob Gallion, Associate Director III, Revenue & Regulation Compliance, HSCRC

DATE: November 16, 2021

RE: MedStar Franklin Square Medical Center ("Franklin Square")
CON Application to Establish Kidney Transplant Services
Docket No. 17-03-2405

****

This memo is in response to your request dated October 13, 2021. Franklin Square filed a Certificate of Need ("CON") application August 14, 2017, proposing the introduction of a kidney transplantation program. You have requested that the staff of HSCRC provide its opinion on the general financial feasibility and viability of the proposed kidney transplant services and provide insight regarding certain assumptions made.

BACKGROUND

There are currently two kidney transplantation programs in Baltimore, one at Johns Hopkins Hospital ("JHH") and one at University of Maryland Medical Center ("UMMC"). Both programs are now averaging over 200 kidney transplants per year. In addition, there are two kidney transplantation programs in Washington, D.C., one at MedStar Georgetown University Hospital ("Georgetown"), which is also averaging over 200 kidney transplants per year, and one at George Washington University Hospital ("George Washington"), which is averaging over 50 kidney transplants per year. JHH and UMMC are recognized as interested parties in this review.

THE PROJECT

There are no capital costs for the project. Franklin Square anticipates that it will do 12 transplants in the 1st year of operation (FY 2019), 24 in the 2nd year (FY 2020), and 44 in the 3rd year (FY 2021), resulting in net losses of $1,082,000 and $641,000, respectively, in the first two years of operation, with a net income of $433,000 in year three.

Franklin Square estimates that referrals of MedStar patients to the existing Baltimore programs will decline from about fifteen (15) per year (collectively) to about five (5).

ANALYSIS

The State Health Plan requires the applicant to address whether its proposed program is cost effective as compared to the existing programs in its service area. Franklin Square contends that its cost structure is significantly lower than that of either JHH or UMMC. To make that case, Franklin Square used the following methodology. Franklin Square compared its general cost structure as measured by charge per ECMAD of $13,099 to that of JHH ($16,640) and UMMC ($19,544) using data from the 9 months ending March 2017. Then, extrapolating from those general cost structures, Franklin Square calculated and compared the per case kidney transplant costs of its proposed program of $87,203 with those of JHH ($148,500) and UMMC ($116,270) for kidney transplants, using data from the 6 months ending March 2016.

QUESTIONS from MHCC to HSCRC

1) HSCRC staff is asked to review the financial projections provided by the applicant, as well as the assumptions (revenue, expenses, staffing, and utilization) upon which these projections are based, as provided in the CON application and subsequent filings, and comment on the financial feasibility of the project and the reasonableness of the assumptions. In addition, HSCRC staff is asked to comment on the viability of the project (a criterion that encompasses the availability of resources to implement the proposed project and the sustainability of the proposed new kidney transplant service over time).

2) Franklin Square states that because it is a community hospital, its charges for kidney transplants would be significantly less than those at the existing programs in large academic medical centers such as JHH or UMMC. Does HSCRC staff believe that a new kidney transplantation program at Franklin Square would be expected to have lower charges and therefore be more cost effective than the programs at JHH and UMMC as projected by Franklin Square?

3) How will a shift in kidney transplant cases from Georgetown to Franklin Square impact the spending and savings targets HSCRC must meet under the Medicare Total Cost of Care model?

HSCRC REVIEW, DISCUSSION, and OPINION:

HSCRC staff ("staff") has reviewed the following: 1) the CON application dated August 14, 2017; 2) the subsequent Franklin Square Completeness Responses dated March 1, 2018 and June 1, 2018; 3) Franklin Square Additional Information dated August 23, 2018; 4)Franklin Square Motion Responses dated November 5, 2018, November 12, 2019, and December 30, 2019; 5) Franklin Square Interested Party Responses dated November 20, 2018; and 6) Franklin Square Reviewer's Responses dated July 9, 2021 and October 1, 2021.

Upon review of the statistical and financial information provided in the CON and subsequent completeness responses, it was noted that such information was most recently updated as submitted March 1, 2018, reflecting actual data through fiscal 2017 and projected data beginning with fiscal 2018. The three (3) years of operations for the transplant services were projected to be fiscal 2019 through fiscal 2021. Given that at this time fiscal 2021 has come to pass, and it is very likely that the operation if approved, would not begin in earnest before fiscal 2023 or perhaps fiscal 2024, staff is acknowledging that the projections are likely at least four (4) years old, and perhaps five (5). MHCC has notified HSCRC staff that we are not to expect responses to our inquiries previously submitted, and that we are not to expect to receive updated projections. Therefore, we have based our opinion upon what we have reviewed. Accordingly, our opinion does not incorporate any material changes that may have been made to the information previously reviewed. What follows are HSCRC staff responses to the questions raised by MHCC:

1) Consistent with the assumptions presented in the CON, all of Maryland's facilities (inclusive of Franklin Square) would continue to achieve kidney transplant volumes more than the minimums required, even after Franklin Square's kidney transplant service matured and volumes grew. The minimum annual case volume for adult kidney transplant programs is thirty (30) cases per year.

After netting out the revenue projected for the kidney transplant services, the projected gross patient service revenues for the entire facility, with inflation, as presented on Table H, appear reasonable through fiscal year 2021 compared to the approved Global Budgeted Revenue (GBR) for Franklin Square. The average annual growth rate projected on such revenue beyond fiscal 2017 is 2.1%, which is reasonable compared to Franklin Square's average annual GBR growth rate of approximately 3.9%.

The average annual operating profit margin for the entire facility, as per the audited financial statements for the five (5) years ended fiscal 2019 (pre-COVID), was 4.0%. The average annual operating profit margin for the entire facility with inflation as presented on Table H for the three (3) years ending fiscal 2021 is projected to be 2.1%. If the three (3) years ending fiscal 2021 were presented without the profits assumed on the kidney transplant services, such average

operating margin would measure approximately 2.2%. Holding all else equal, this would imply a conservative projection of operating expenses and resulting margins, save for any impact of the current COVID pandemic.

Based upon staff's review of the information presented and subject to any material changes to that information, which may have been brought to light, the HSCRC believes that the kidney transplant services project appears to be financially feasible. However, staff has not received a response to the questions that were forwarded to MHCC, nor has the staff been afforded an opportunity to discuss how Franklin Square calculated the projected revenue assumed in Table H and the additional revenue assumed in Table K. While staff realizes that Franklin Square would receive some increase to its GBR revenue if the program is approved, staff is not certain whether the revenue assumed in the projections is reasonable.

Further, staff understands that the primary resource challenge and limiting factor of any organ transplant program, is not so much in the number of organs to be used, but rather in the number of organs to be supplied. Effective March 15, 2021, the allocation of available kidneys follows a new national policy model, whereby a donated kidney is first made available to compatible candidates within a 250 nautical mile radius around the donor hospital. This policy is significantly different from the former allocation policy, which was based upon donation service areas, in which the Living Legacy Foundation (LLF) and the Washington Regional Transplant Community (WRTC) operated as Organ Procurement Organizations, with WRTC serving the DC metro area, and LLF serving the balance of Maryland, including the Baltimore metro area. The statistical volume projections and the financial projections have not been amended since first submitted in March 2018, and therefore do not account for the effects, if any, of the new allocation policy. Staff is not currently able to judge the potentially material impact of this organ allocation change; however, such uncertainty does put into question the ongoing viability of the proposed program.

2) Generally, the organ acquisition and direct transplant costs should be relatively uniform across the hospitals. If all the programs are operating with approximately the same number of physicians, cost of supplies, length of stay, and other direct costs, etc., then the main difference would be overhead cost, indirect cost, and capital costs at Franklin Square versus JHH or UMMC. The indirect costs will be lower at a community hospital when compared to an Academic Medical Center.

In general, Academic Medical Centers have higher overhead and indirect costs than community hospitals. They are included in a separate peer group to help account for these differences. Holding all else equal, the overhead, indirect, and capital costs at Franklin Square will be less than that of JHH and UMMC, and likely result in a lower overall rate structure that reflects the lower cost of a non-Academic Medical Center. Additionally, Franklin Square is not a relatively inefficient provider as measured in the Inter-hospital Cost Comparison (ICC) compared to other community hospitals. Again, if the direct costs are comparable, then the overhead and indirect costs would be more in line with a community hospital and most likely result in a lower set of unit rates than at an Academic Medical Center.

3) In general, this proposal to add kidney transplants to Franklin Square, to the extent that volume shifts from Georgetown and pertains to out-of-state residents, aligns with staff's belief that border, or regional/national hospitals have a built-in advantage in our Model in that they can lower their cost per case, while at the same time not negatively affect total cost of care performance. This is because these hospitals can export a service to a non-Maryland resident, thereby spreading fixed costs over more patients, which has no bearing on Maryland resident Total Cost of Care (TCOC.)

In terms of the impact on the Maryland Medicare TCOC model, kidney transplants are currently carved out of the market shift policy. So Franklin Square would only be subject to a market shift adjustment for Maryland residents currently being provided these services at another Maryland hospital if transplants become part of a service line that is assessed in the market shift algorithm. If the charges at Franklin Square are less than at the Academic Medical Centers, as Franklin Square has estimated, then the impact would be positive.

For volumes currently being provided outside of Maryland, there exists a methodology that was previously used for JHH that staff believes could be employed for Franklin Square as well. Staff suggests that Franklin Square may be allowed a charge per case that would consider the full cost of the organ plus a 50% variable cost factor applied to all

other costs. If this is the final methodology used, then the impact would depend on how much the patient is currently being charged at Georgetown compared to the new GBR allowed revenue for Franklin Square.