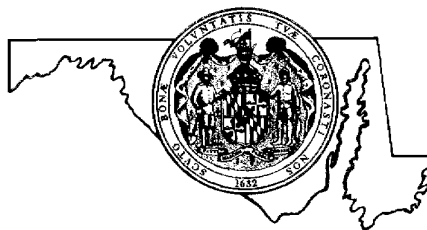


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STATE OF MARYLAND



Ben Steffen
EXECUTIVE DIRECTOR

MARYLAND HEALTH CARE COMMISSION

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May 10, 2021

By E-Mail

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Re: MedStar Franklin Square Medical Center
Application to Establish Kidney Transplantation Services
Docket No.: 17-03-2405

Dear Counsel:

I am writing to notify you that I have been appointed, pursuant to COMAR 10.24.01.09A(1)(b), to serve as Reviewer of the application by MedStar Franklin Square Medical Center (Franklin Square) for a Certificate of Need to establish kidney transplantation services at its hospital in Rosedale (Baltimore County), Maryland.

I have considered the requests for interested party status filed by Johns Hopkins Hospital (JHH) and the University of Maryland Medical Center, Inc. (UMMC), as well as the responses to comments filed by Franklin Square. Both JHH and UMMC currently provide liver transplantation services in the same planning region as the proposed program. Each states that the proposed Franklin Square program will have a potentially detrimental impact on its existing program. I find that, in accordance with COMAR 10.24.01.01B(2) and (20), JHH and UMMC

each qualifies as an interested party in this review because each is authorized to provide the same service as that proposed by the applicant in the same planning region used for purposes of determining need under the State Health Plan.

I will now address pending motions that the parties have filed.

Motions to Stay the Review

UMMC filed both initial and renewed motions to stay this review based on organ allocation policy changes that had not, as of the date of UMMC's filings, gone into effect. (DI #32, #41). UMMC's motion also requests that I require Franklin Square to update its analyses consistent with the new organ allocation policies. Franklin Square opposed the motion. (DI #34).

UMMC's motion is denied in part and approved in part. I note that the new allocation policy for kidneys was approved by the Organ Procurement and Transplantation Network (OPTN) in December 2019 and went into effect on March 15, 2021. (See <https://optn.transplant.hrsa.gov/learn/professional-education/kidney-allocation-system/removal-of-dsa-and-region-from-kidney-allocation-policy/>). I will not stay this review but will require Franklin Square to update its assessment of need for a new kidney transplantation program under the need standard, COMAR 10.24.15.04B, and the need criterion, COMAR 10.24.01.08G(3)(b), taking the new kidney allocation policy into account. Franklin Square shall also make any changes to other parts of its application that will result from changes, if any, in its need and/or case volume projections. Franklin Square must detail changes, if any, in its underlying assumptions.

I anticipate that Franklin Square will be able to update its assessment of need on or before June 8, 2021. I request that Franklin Square inform all by May 17, 2021 whether it can make needed changes by that date. Franklin Square may submit data that supports its updated needs assessment. After receipt of the applicant's updated needs analysis, I will determine whether I need to ask questions on the filing. When I determine that the filing is complete, counsel will let the parties know, initiating the 15-day period for interested parties to make comments on the filing. If an interested party comments on the filing, it may include data that supports its comments. Square may make Franklin Square may file one response to comments within 15 days after receiving the comments. No reply filings are permitted unless I specifically agree that a reply may be filed.

Submission of More Recent Data

Franklin Square filed a Motion to Submit Additional Data and Set Briefing Schedule on November 12, 2019, to which it attached a motion by MedStar Georgetown University Hospital that had been filed in the then-pending review of the application by Suburban Hospital to establish a liver transplantation program. (DI #39). In its memorandum in response to the motion, UMMC stated that MedStar should be required to update the analyses in its application when the new allocation policies were implemented. (DI #41). Johns Hopkins opposed Franklin

Square's motion, disputing the relevance of the data. (DI #42). The motion is denied, with the exceptions noted in my ruling, above, requiring Franklin Square to submit updated analyses that account for the acuity circle allocation policy for kidneys now in effect.

I intend to render my decision with the benefit of the latest reasonably available data and information. For this reason, I am entering into the record of the review and may use in my Recommended Decision information from the following sources:

(1) **Organ Procurement and Transplantation Network (OPTN), various years - CY2020.** This data is available at: <https://optn.transplant.hrsa.gov/data/view-data-reports/>. This data includes: kidney transplant volume and characteristics; donor volume and characteristics; and waitlist volume and characteristics.

(2) **United Network for Organ Sharing (UNOS)/OPTN, CY 2013-2021.** The attached spreadsheet contains data that reflects transplant type by region, residence of recipient, and ethnicity of transplant recipients for Maryland and the District of Columbia Regions.

(3) **Scientific Registry of Transplant Recipients (SRTR), Bi-annual Organ Procurement Organization (OPO) Reports.** Data released June 2015-Janauary 2021 is available at: <https://www.srtr.org/reports-tools/opo-specific-reports/opo?code=MDPC> (for the Living Legacy Foundation OPO); and <https://www.srtr.org/reports-tools/opo-specific-reports/opo?code=DCTC> (for the Washington Regional Transplant Community OPO).

SRTR OPO-Specific Reports, The Living Legacy Foundation of Maryland

Release Date: June 16, 2015
Release Date: December 16, 2015
Release Date: June 16, 2016
Release Date: January 5, 2017
Release Date: July 6, 2017
Release Date: January 5, 2018
Release Date: August 9, 2018
Release Date: January 7, 2019
Release Date: July 8, 2019
Release Date: January 7, 2020
Release Date: August 4, 2020
Release Date: January 7, 2021

SRTR OPO-Specific Reports, Washington Regional Transplant Community

Release Date: June 16, 2015
Release Date: December 16, 2015
Release Date: June 16, 2016
Release Date: January 5, 2017
Release Date: July 6, 2017
Release Date: January 5, 2018

Counsel
Re: MedStar Franklin Square CON Application
Docket No. 17-03-2405
May 10, 2021
Page 4

Release Date: August 9, 2018
Release Date: January 7, 2019
Release Date: July 8, 2019
Release Date: January 7, 2020
Release Date: August 4, 2020
Release Date: January 7, 2021

(4) **SRTR Bi-annual Program-Specific Reports.** Data can be accessed at: <https://www.srtr.org/reports-tools/program-specific-reports>. For current reports, click “Find and Compare Transplant Programs,” choose “Kidney,” and then the program name (such as Georgetown, Johns Hopkins Hospital, University of Maryland Medical Center). You can view and download each Complete Report (PDF). Archived program reports are available at: <https://www.srtr.org/reports-tools/program-specific-reports/>, where you should scroll to bottom of page, and download reports released June 2015-January 2021. For these earlier reports, you must download all reports for all programs and organs across the U.S. The program-specific reports that I am entering into the record are:

SRTR Program-Specific Reports for U.S. Transplant Centers, Transplant Program (Kidney):

Release Date: June 16, 2015
Release Date: December 16, 2015
Release Date: June 16, 2016
Release Date: January 5, 2017
Release Date: July 6, 2017
Release Date: January 5, 2018
Release Date: October 9, 2018
Release Date: January 7, 2019
Release Date: July 8, 2019
Release Date: January 7, 2020
Release Date: August 4, 2020
Release Date: January 7, 2021

Please note that, together, the two types of SRTR reports contain: service area profile information; transplant volume; transplant rates; transplant recipient characteristics; donation volume; donation rates; donor characteristics; waiting list activity; and characteristics of waiting list candidates.

(5) *One-Year Monitoring Report of Liver and Intestine Acuity Circle Allocation: Removal of DSA and Region as Units of Allocation* (prepared for OPTN Liver & Intestinal Transplantation Committee by Samantha M. Noreen-Burns, Ph.D, UNOS Research Dept.), https://optn.transplant.hrsa.gov/media/4542/data_report_liver_full_lyrallocation_20210405.pdf. Although this report addresses liver allocation after one year under the acuity circle allocation policy, it may be helpful regarding expectations for changes in the allocation of kidneys.


Commission staff will download the listed reports for inclusion in the record.

Counsel
Re: MedStar Franklin Square CON Application
Docket No. 17-03-2405
May 10, 2021
Page 5

All filings in this review must continue to be submitted in Portable Document Format by email to the parties in this review, to Ms. Ruby Potter, and others copied on the e-mail by which this letter ruling is sent. In addition, as previously requested, please send a copy of all filings to Ms. Potter in Word format, since having filings in that format will assist me in this review.

I remind the parties that the *ex parte* prohibitions in the Administrative Procedure Act, Maryland Code Ann., State Gov't §10-219, apply to this proceeding until the Commission issues a final decision.

Sincerely,



Michael J. O'Grady, Ph.D.
Commissioner/Reviewer

cc: Paul Parker, Director, Center for Health Care Facilities Planning and Development
Kevin McDonald, Chief, Certificate of Need
Moirra Lawson, PhD, MPH, Program Manager, Certificate of Need
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