

October 4, 2022

By E-Mail

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Re: MedStar Franklin Square Medical Center

Application to Establish Liver Transplantation Services

Docket No.: 17-03-2406

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 introduce liver 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 (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 state 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), and with COMAR 10.24.15.05(2), JHH and UMMC each qualifies as an interested party in this review because

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each is authorized to provide liver transplantation services 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 #31, #36). UMMC filed the first motion on October 15, 2018 (DI #31) and renewed the motion on November 26, 2018 (DI #36) and December 16, 2019 (DI #42). Franklin Square opposed the motion to stay the review. (DI #33).

UMMC's motion to stay the application is denied. I note that the new liver distribution policy was approved by the Organ Procurement and Transplantation Network (OPTN) in December 2018 and went into effect on February 4, 2020. The Motion is therefore moot as the policies are now implemented and there is no basis to stay the application.

Motion for Submission of More Recent Data

UMMC's motions also request that Franklin Square update its analyses consistent with the new organ allocation policies. Similarly, Franklin Square filed a Motion to Submit Additional Data and Set Briefing Schedule on November 12, 2019. (DI #38). Johns Hopkins opposed Franklin Square's motion, disputing the relevance of the data. (DI #41).

The Franklin Square and UMMC motion requesting that Franklin Square have an opportunity to update its application is granted. I note that significant time has passed since the original submission, and I cannot adequately or accurately assess the needs of the health care system without the most up-to-date information.

Franklin Square should submit a new updated application considering the new liver allocation policy and the updates in liver transplantation data from 2017 through 2022. Franklin Square shall also make any changes to other parts of its application necessitated by the update of its application, including changes in its needs assessment or case volume projections. Additionally, Franklin Square shall update information regarding the revenues and expenses related to its introduction of liver transplantation services and shall include a

¹ Organ Procurement and Transplantation Network Policies, pp. 161-216 https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf



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comprehensive statement of the underlying assumptions used in development of financial projections.

I intend to render my decision with the benefit of the latest available data and information. For this reason, I may use in my Recommended Decision information from the OPTN Liver & Intestinal Transplantation Committee.²

I request that Franklin Square submit its updated application within 45 days of receipt of this Order. After receipt of the applicant's updated application, I will determine whether further information is needed to complete the filing. When it is determined that the filing is complete, I will notify the parties initiating a 30-day period for interested parties to respond to the updated application. Franklin Square may file a response within 15 days after receiving the comments. No reply filings are permitted unless I specifically agree that a reply may be filed.

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 Wynee Hawk Chief, Certificate of Need



²Two Year Monitoring Report of Liver and Intestine Acuity Circle Allocation, Removal of DSA and Region as Units of Allocation, DHHS Contract No. 250-2019-00001C, August 5, 2022 https://optn.transplant.hrsa.gov/media/k5yi4jvl/data_report_liver_full_2yrallocation_20220805_final_508_com_pliant.pdf.

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