BEFORE THE MARYLAND HEALTH CARE COMMISSION

IN THE MATTER OF THE APPLICATION OF MEDSTAR FRANKLIN SQUARE MEDICAL CENTER FOR A CON TO ESTABLISH A LIVER TRANSPLANT PROGRAM AT FRANKLIN SQUARE CAMPUS IN ROSEDALE	Docket No. 17–03–2406 December 16, 2019
IN THE MATTER OF THE APPLICATION OF MEDSTAR FRANKLIN SQUARE MEDICAL CENTER FOR A CON TO ESTABLISH A KIDNEY TRANSPLANT PROGRAM AT FRANKLIN SQUARE CAMPUS IN ROSEDALE	Docket No. 17–03–2405 December 16, 2019

RESPONSE BY JOHNS HOPKINS HOSPITAL TO THE MOTION TO SUBMIT ADDITIONAL DATA BY MEDSTAR FRANKLIN SQUARE

In accordance with COMAR 10.24.01.10(B), The Johns Hopkins Hospital responds to the motion to submit additional data by MedStar Franklin Square Medical Center ("MedStar").

Introduction

MedStar's motion should be denied for three reasons.

First, the additional data that MedStar has proffered is misleading and irrelevant. MedStar offers data about the volume of liver transplants in the two Donation Service Areas ("DSAs") that serve Maryland residents and data about outcomes of liver transplants in those DSAs. But neither metric formed the basis for its applications for certificates of needs. And the data has nothing to do with kidney transplants. So

updating that information does not advance the Commission's review of either application.

Second, the Commission has not yet assigned a Commissioner to review MedStar's applications. And no one from the Commission has requested additional data, let alone the kind of data that MedStar suddenly asserts is now relevant to its applications.

Third, rather than prolong these proceedings, the Commission should assign reviewers and proceed promptly to deny both of MedStar's applications. MedStar failed to show need in its applications. And nothing about the proffered data furthers any argument or analysis it made in those applications or provides any new basis for the Commission to find a need for the proposed programs.

Background

I. MedStar's Applications.

On August 14, 2017, MedStar Franklin Square filed two separate applications to open liver and kidney transplant services in the Living Legacy Foundation Donation Service Area ("LLF DSA") at Franklin Square. MedStar based its applications on claims that it can improve on the high-volume programs in the LLF DSA by reducing demand for liver and kidney transplants and by increasing the supply of both organs. MedStar proposed to reduce demand for these organs by better managing liver disease and kidney disease in the region. And it proposed to increase the supply of livers through rare procedures such as split liver transplants and living donor

transplants and the supply of kidneys through various methods already being employed in the LLF DSA.

MedStar did not base its application to open a liver transplant program on either the volume of adult liver transplants being performed in the LLF DSA or a comparison of the volumes of adult liver transplants in the WRTC DSA and LLF DSA.

II. Comments by Hopkins and the University of Maryland.

Both Hopkins and the University of Maryland filed interested party comments in response to MedStar's applications. In those comments, the University of Maryland and Hopkins made clear that MedStar had failed to show that MedStar can increase organ supply. They also pointed out that MedStar does not require a certificate of need to better manage liver or kidney disease.

III. The Motion to Stay by the University of Maryland.

The University of Maryland filed a motion to stay both applications. The University of Maryland contended that proposed policy changes to liver and kidney allocation were set to take place in the immediate future, claiming that "there is no uncertainty about when the forthcoming changes to liver and kidney allocation policy will occur." Maryland Reply in Support of Motion to Stay 4. That was more than a year ago. Yet liver allocation policy remains the same, as does kidney allocation policy. And after more than a year, we are no closer to "certainty" about when, if ever, the proposed policies will take hold.

The proposed liver allocation policy—the acuity circles policy—remains the subject of intense litigation at the federal district court and appellate court levels. It

is currently the subject of a stay ordered by the United States District Court for the Northern District of Georgia. That Court is considering whether to enjoin the policy permanently.

Argument

I. MedStar Does Not Address Kidney Transplants in its Motion.

MedStar has proffered data related to liver transplants only. It has offered nothing regarding kidney transplants. On that basis alone, the Commission should deny MedStar's motion to submit updated data and briefing in connection with its kidney application.

II. MedStar's Liver Transplant Data is Misleading and Irrelevant.

As for its liver application, the data that MedStar cites is irrelevant to its application. MedStar has proposed to open a center at Franklin Square to perform adult liver transplants. But MedStar cites data that include pediatric transplants. MedStar includes this data without saying so to create the appearance that the gap between adult liver transplants performed in the LLF DSA and WRTC DSA—while still significant—is not as large as it actually is. But because MedStar never attempted to show need based on volumes of adult liver transplants, let alone a difference in volumes between the two DSAs, the information is irrelevant. If anything, the data show that the programs in the LLF DSA are performing at a high level and meeting the needs of the residents of the LLF DSA, while the sole program in the WRTC DSA is falling far short of meeting the existing need.

Adult volumes by DSA from 2014 through 2018 are illustrated in the table below:

ADULT LIVER TRANSPLANTS IN LLF DSA AND WRTC DSA					
	2014	**2015**	**2016**	**2017**	**2018**
LLF	199	241	291	260	227
WRTC	79	49	84	97	92
Gap	120	192	207	163	135

More than twice as many transplants were performed in the LLF DSA than in the WRTC DSA every year from 2014 through 2018. The gap between the two DSAs has been consistent, and while it was not as great in 2018 as it was in the two preceding years, it remains greater in 2018 than in 2014.

Worse yet, MedStar omits 2015 data to avoid drawing attention to a problem that Suburban's proposed program would address. In 2015, MedStar performed just 49 adult transplants. Because there is only one center in the WRTC DSA, there was no other center in the DSA to offset MedStar's reduced volume.

In the LLF DSA, however, when volume drops at one center, the other center is able to limit the impact of the reduction. For example, MedStar highlights reduced volume at the University of Maryland in 2018, MedStar Motion at 2, but that reduction was offset in part by an increase of 16 adult liver transplants at Hopkins.

MedStar creates the impression that the volume gap that Suburban identified in its comments has narrowed substantially only by presenting data beginning in 2016, the year in which transplants peaked in the LLF DSA, and ending in 2018, when University of Maryland transplant volumes fell. The long-term trend reflects a consistent gap between the single-center WRTC DSA and the two-center LLF DSA.

Even with diminished performance by the University of Maryland, the programs in the LLF DSA still performed more than twice the number of transplants than the program in the WRTC DSA.

MedStar's proffered outcome data fares no better. That data, misleadingly presented with a graph that begins at 82.00% (rather than zero), does not advance the Commission's review of MedStar's application. MedStar never based its application on outcomes in the first place. So "updating" that data does not advance the Commission's inquiry.

Because MedStar's proffered data is misleading and irrelevant, the Commission should deny MedStar's motion.

III. There is No Reviewer and the Commission Has Not Requested Additional Data.

There is no mechanism for an applicant to supplement its applications with additional information, and MedStar cites none. Rather, the regulations governing applications for certificates of need make clear that requests for additional information should come, if at all, from the reviewer, the Commission, or the staff. *See* COMAR 10.24.01.09(F)(3)(b). And for good reason. After MedStar filed its application, the Commission requested additional information through completeness questions. MedStar responded. The application was docketed. Interested parties filed comments, and MedStar responded. In non-comparative reviews where interested party comments are filed, a single Commissioner is appointed as the reviewer. COMAR 10.24.01.09(A). A reviewer has not yet been appointed. MedStar should not be permitted to lob in additional information out of the blue, particularly when that

information does not relate to the assertions of supposed need in the original applications and is not responsive to a specific request from the reviewer for information needed to make a decision.

IV. Rather Than Invite Further Delay, The Commission Should Rule on MedStar's Applications.

"The Commission's specific mandate by the Legislature is to review and, where appropriate, issue certificates of need. . . ." *Medstar Health* v. *Maryland Health Care Comm'n*, 376 Md. 1, 6, 827 A.2d 83, 86 (Md. 2003). By statute and regulation, the Commission must rule on a certificate of need "no later than 90 days after the application was docketed." Maryland Code, § 19–126(g)(2) of the Health General Article; COMAR 10.24.01.09.[1]

Although the Commission has issued no ruling on Maryland's motion to stay, it appears that the Commission has granted it *de facto*. Yet that motion, which the University of Maryland filed over a year ago in October 2018, was based on a supposed policy change in the offing. Now, more than 13 months later: the policies remain the same and the lack of need for either a liver transplant program or kidney transplant program in the Baltimore region is as apparent as it was when MedStar filed its applications.

Even if more than one year later, the policies actually were set to change, there is no way to predict the effects of the current proposals to alter the model of liver and kidney allocation. There is no dispute that widening the distribution area will

[1] The statutory period is expanded to 150 days if an evidentiary hearing is requested. No hearing was requested here.

increase travel times and add significantly to the costs of transplants. The enhanced focus on the sickest patients may have a negative effect on outcomes. Yet the severity of these effects will not be measurable until long down the road. And there is no way to predict how the public or the OPTN might react to those effects, which may be the prompt for the next—inevitable—policy changes.

Further delay is contrary to law and wasteful. MedStar's applications should be reviewed and denied.

Conclusion

For these reasons, MedStar's motion to submit additional data should be denied.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on December 16, 2019, I caused a copy of Interested Party Johns Hopkins Hospital's Response to the Motion to Submit Additional Data by MedStar Franklin Square to be emailed and mailed to:

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