EXHIBIT 2

BEFORE THE MARYLAND HEALTH CARE COMMISSION

IN THE MATTERS OF	)
APPLICATION OF MEDSTAR FRANKLIN SQUARE MEDICAL CENTER FOR A KIDNEY TRANSPLANT SERVICE	)
Docket No. 17-03-2405	)
and	)
APPLICATION OF MEDSTAR FRANKLIN SQUARE MEDICAL CENTER FOR A LIVER TRANSPLANT SERVICE	)
Docket No. 17-03-2406	)

MEDSTAR FRANKLIN SQUARE MEDICAL CENTER'S OPPOSITION TO THE UNIVERSITY OF MARYLAND MEDICAL CENTER'S MOTION FOR STAY

MedStar Franklin Square Medical Center ("MFSMC"), through undersigned counsel and pursuant to COMAR § 10.24.01.01 *et seq.*, hereby opposes interested party University of Maryland Medical Center's ("UMMS") Motion for Stay of the Certificate of Need ("CON") Review process (the "Motion") only as to MFSMC's application for a kidney and liver transplant facility service.[1]

UMMS's Motion is premised entirely on a pending change in the kidney and liver allocation policies by the Organ Procurement Transplant Network ("OPTN") as implemented by

[1] As will be discussed in more detail in text and MFSMC's accompanying motion, UMMS has inexplicably sought to stay only MFSMC's proposed services, notwithstanding that Suburban Hospital ("Suburban") is currently pursuing a Certificate of Need for liver transplant services at Suburban Hospital in Bethesda, Maryland.

its contract with the United Network for Organ Sharing ("UNOS"). Specifically, UMMS asserts that OPTN will adopt a new liver allocation policy following an OPTN Board of Directors meeting in December 2018, *see* Motion at 9-10, and that a final policy change for kidney allocation will be submitted to the OPTN Board for approval in December 2019. *Id.* at 10. Further, according to the Motion, the pending changes in allocation policy will render "obsolete" the existing Donation Service Area ("DSA") as a basis for organ allocation, *id.* at 11, and render moot any justification for MFSMC's programs. *See generally id. at* 10-13.

MFSMC appreciates that the federal government has recognized access as a critical issue in transplantation and subsequently mandated that OPTN change organ allocation policy with respect to liver and kidney transplant. That said, the initiation of that ongoing process is no reason to indefinitely postpone the consideration and possible implementation of organ transplant services that are designed to serve the critical needs of Maryland residents. Simply put, there is no way that either UMMS or this Commission can know precisely when a new policy will be finalized, whether it will be subject to further revision, and under what terms it will be implemented, nor can it predict with certainty the impact on existing or proposed transplantation services.

Even assuming that a new liver allocation policy is approved in December, implementation will require that a variety of processes be created and tested in the clinical environment, perhaps most importantly, the sophisticated software used today to support organ matching would need to be reprogrammed to be consistent with the new allocation policy. Likewise, the Motion indicates that the impetus for a new allocation policy was partially based on a lawsuit filed on behalf of several liver transplant candidates listed for longer than average waiting times prior to receiving organs. *Id.* at 5-6. It is conceivable that any new policy will be

found objectionable and lead to delaying litigation by those who believe that it has an adverse impact personally. However, the idea that the Commission should simply defer assessing the need for new services until all potential delays to that policy are resolved -- a timeframe that is completely unknowable -- is entirely unreasonable.

There is precedent for assuming that any new policy will not be implemented in short order. By way of recent example, the "Share 35" liver allocation policy was announced in June of 2012. *See* June 27, 2012 OPTN Announcement, available at https://optn.transplant.hrsa.gov/news/board-approves-new-liver-allocation-requirements-transplantation-of-non-resident-candidates/. That policy, however, was not implemented until one year later, in June 2013. *See* September 4, 2014 OPTN/UNOS Liver and Intestinal Transplantation Committee Meeting Summary at 1, available at https://optn.transplant.hrsa.gov/media/1356/liver_meetingsummary_20140904.pdf (noting that Share 35 was implemented on June 13, 2013. The new allocation policy discussed in the Motion is likely to be as complicated to implement as Share 35, if not more so.

The logic of the Motion is even more tenuous as applied to kidney transplantation. According to the Motion, a working committee has been formed to propose changes to the kidney allocation policy, but those proposals have not yet even been forwarded for comment. *Id.* at 10. In fact public comment is not scheduled to take place until early 2019, and hence, a new kidney policy will not be submitted for OPTN's approval until December 2019 at the earliest. *Id.* In the meantime, UMMS would have the Commission refuse to consider the need for new programs.

Furthermore, even once a new policy is submitted and implemented, it is unlikely that reliable and valid data that would allow the Commission to meaningfully evaluate the impact on

existing and proposed transplantation services will be available for months, perhaps years. In other words, the implementation of a new policy is only one part of the equation; how the policy affects organ availability, patient access across disparate geography, patient behavior and choice, and importantly, clinical parameters including transplant rates, waiting list metrics and outcome measures, will not be known in the near term. It would hardly serve the needs of Maryland patients for the Commission to delay its decision pending an unknown date when sufficient data may become available.

Moreover, MedStar does not agree that the continued existence of a DSA-based allocation policy is the sole criterion on which MFSMC's (or any other applicant's) proposed transplantation services should be based. The Motion implies that the major justification for MFSMC's programs relates to its ability to increase the supply of donor organs and that a change in the DSA-based allocation policy renders this justification moot since DSA allocation-related "boundaries" will cease to exist. *Id.* 2. To the contrary, the ability to increase the supply or use of donor organs is just one element of MFSMC's proposal and of the State Health Plan standards governing the review of a proposed transplantation service. *See* COMAR § 10.24.15.04(B)(1)(a). The project review standards for such programs encompass a host of considerations, including Access, Cost Effectiveness, Impact, Health Promotion, Disease Prevention and Minimum Volume Requirements. *See generally* COMAR § 10.24.15.04. MFSMC's program applications address each of these standards; the Commission is charged with their contextual review. The logic of the Motion reduces the project review to the evaluation of but one question– whether the project would increase organ availability. We do not believe that the State Health Plan contemplates such limited review based on the full array of standards governing new transplantation programs.

MFSMC believes the Motion should be denied, and its application should move forward. However, if the Commission concludes that UMMS's arguments are persuasive, MFMSC believes that the UMMS reasoning should be applied equally to the pending application by Suburban for a liver transplant program at Suburban Hospital (Docket No. 17-15.2400). Specifically, if, as the Motion suggests, the impending elimination of a DSA-based organ allocation policy is the beginning and the end of the review standards for evaluating proposed transplantation services in the State of Maryland, then all pending applications for transplant services should be stayed. Accordingly, while MFSMC urges the Commission to simply deny the Motion, if the Commission decides to grant the Motion, MFSMC is concurrently filing, along with this Opposition, a motion to stay consideration of the Suburban project for the same reasons argued by UMMS.

Respectfully submitted,

David C. Tobin, Esq.
Jennifer C. Concino, Esq.
Tobin, O'Connor & Ewing
5335 Wisconsin Ave., N.W.
Suite 700
Washington, D.C. 20015
202-362-5900

Attorneys for MedStar Franklin Square Medical Center

November 5, 2018

CERTIFICATE OF SERVICE

I hereby certify that on November 5, 2018, a copy of the foregoing Opposition was served by e-mail and first class mail on:

Suellen Wideman, Esq.
Assistant Attorney General
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore MD 21215-2299
suellen.wideman@maryland.gov

Gregory W. Branch, M.D.
Health Officer | Director of Health and Human Services
Baltimore County Health Department
6401 York Road, 3d Floor
Baltimore MD 21212-2130
gbranch@baltimorecountymd.gov

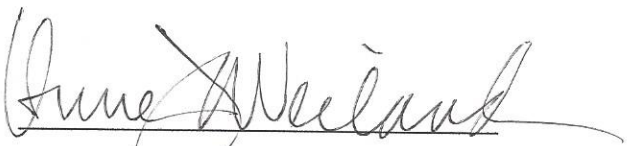
Conor B. O' Croinin, Esq.
Zuckerman Spaeder LLP
100 E. Pratt Street, Suite 2440
Baltimore MD 21202-1031
cocroinin@zuckerman.com

Thomas C. Dame
Ella R. Aiken
Hannah L. Perng
Gallagher Evelius & Jones LLP
218 North Charles Street, Suite 400
Baltimore MD 21201
(410) 727-7702
eaiken@gejlaw.com
tdame@gejlaw.com
hperng@gejlaw.com

David C. Tobin

Affirmation

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



11.05.18

Anne P. Weiland
Vice President - Surgery, Orthopaedics
and Neurosciences

(date)