

**BEFORE THE MARYLAND HEALTH CARE COMMISSION**

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

**INTERESTED PARTY COMMENTS OF THE JOHNS HOPKINS HOSPITAL  
IN RESPONSE TO THE UPDATED NEED ASSESSMENT BY MEDSTAR  
FRANKLIN SQUARE MEDICAL CENTER FOR AN ADDITIONAL KIDNEY  
TRANSPLANT PROGRAM IN THE BALTIMORE-WASHINGTON AREA**

In accordance with COMAR 10.24.01.08F(1)(a)&(b), Interested Party The Johns Hopkins Hospital submits these comments in response to the updated need assessment requested by the Commission on May 10, 2021 and submitted by MedStar Franklin Square Medical Center and MedStar Health, Inc. (collectively “MedStar”) on July 9, 2021 concerning MedStar’s application for a certificate of need to open an additional kidney transplant program in the Baltimore/Washington area.

**Introduction**

The Johns Hopkins Hospital and the University of Maryland both operate adult kidney transplant programs in Baltimore. Georgetown University and The George Washington University operate adult kidney transplant programs in Washington D.C. And Inova Fairfax operates a kidney transplant program in northern Virginia, about 15 minutes from the Maryland border. These high volume programs operate efficiently and perform kidney transplants within the same 250-mile radius of all donor hospitals in the mid-Atlantic. MedStar, which operates the kidney program at

Georgetown University Hospital, has applied to open a sixth adult-civilian kidney transplant program within the Baltimore/Washington area at Franklin Square in Rosedale, Maryland.<sup>1</sup>

MedStar based its application on its claims that it can improve on the two high volume programs in Baltimore by reducing demand for kidney transplants and by increasing the supply of kidneys in the Living Legacy Foundation Donor Service Area (“LLF DSA”). But as addressed in previously-filed interested party comments, even if MedStar were capable of improving the functioning of the LLF DSA (which it is not), MedStar has not even attempted to show a need for a third program in Maryland. And now that kidney allocation policy is no longer based on DSAs, MedStar has not shown a need for another program in Maryland, let alone the need for a sixth program within the Baltimore/Washington area. COMAR 10.24.15(B)(1) & COMAR 10.24.01.08G(3)(b). Nor, for that matter, has MedStar identified barriers to access, COMAR 10.24.15(B)(3)(b), or analyzed the impact that a new program would have on the existing two Baltimore programs, COMAR 10.24.15(B)(5)(d) & COMAR 10.24.01.08G(3)(f).

Although MedStar purports to respond to the Reviewer’s request for an updated need assessment, MedStar’s July 9, 2021 letter adds nothing to its application and avoids confronting the effect of the new kidney allocation policy on its proposed program. Indeed, MedStar purports to support its assertions that the new allocation policy has had no effect on the assumptions underlying its application by citing data

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<sup>1</sup> Children’s National Hospital operates a pediatric kidney transplant program. Walter Reed operates a military adult kidney transplant program.

that predates the implementation of the policy. The reality, however, is that the change in allocation policy further weakens an application that should have been denied at the outset. Because there plainly is no need for an additional kidney transplant program in Maryland, MedStar’s application should be denied.

## **Background**

### **I. The Two Kidney Transplant Programs in Baltimore.**

The University of Maryland and Johns Hopkins maintain kidney transplant programs in the LLF DSA that in 2019 performed a combined 385 adult kidney transplants, and in 2020 (during the COVID pandemic) performed a combined 351 adult kidney transplants. MedStar Letter, Exhibit 4 (excluding pediatric cases).<sup>2</sup> Johns Hopkins operates four solid-organ transplant programs: liver, kidney–pancreas, lung, and heart. It has, for many years, performed multi-organ transplantation, including heart–lung, heart–kidney, heart–liver, lung–kidney, kidney–pancreas, and liver–kidney. The simultaneous liver–kidney transplant (“SLK” transplants) is Johns Hopkins’ most common form of multi-organ transplant. The two programs together perform an average of 24 SLK transplants annually.

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<sup>2</sup> “MedStar Letter” refers to MedStar’s July 9, 2021 letter. “Application” refers to MedStar’s August 14, 2017 application, followed by the page number. “CQ.I” refers to MedStar’s responses to the Commission’s first round of completeness questions and “CQ.II” refers to MedStar’s responses to the Commission’s second round of completeness questions.

		Adult SLK Transplants by Year				
		2016	2017	2018	2019	2020
JHH	18-34 Years	0	1	0	2	0
	35-49 Years	3	2	3	3	1
	50-64 Years	11	8	6	5	0
	65 +	4	4	2	1	1
	<b>Adult Total</b>	<b>18</b>	<b>15</b>	<b>11</b>	<b>11</b>	<b>2</b>
UMMS	18-34 Years	0	1	1	0	1
	35-49 Years	4	2	2	1	1
	50-64 Years	9	13	8	4	6
	65 +	3	3	2	1	1
	<b>Adult Total</b>	<b>16</b>	<b>19</b>	<b>13</b>	<b>6</b>	<b>9</b>
<b>JHH/UMMS Adult Total</b>		<b>34</b>	<b>34</b>	<b>24</b>	<b>17</b>	<b>11</b>
<b>Annual Average</b>		<b>24</b>				

(<https://optn.transplant.hrsa.gov/data/view-data-reports/center-data/> (controlled for liver-kidney, per center)).

## II. The Non-Military, Adult Transplant Programs in Washington, D.C. and Northern Virginia.

There are five kidney transplant centers in the Washington, D.C. Metropolitan area. Two of those centers perform transplants on specialized patients, not implicated by MedStar’s application: Walter Reed National Military Medical Center transplants only Department of Defense healthcare beneficiaries. Children’s National Medical Center operates a pediatric kidney transplant program.

The remaining centers, Georgetown University Hospital, Inova Fairfax Hospital, and The George Washington University Hospital Center predominantly perform adult, non-military kidney transplants—the type of transplants that MedStar requests to perform at Franklin Square. The table below shows the volume of these transplants between 2016 and 2020 at all five centers. (Children’s occasionally performs transplants on teenagers who are categorized as adults.)

	Adult Kidney Transplants by Year				
	2016	2017	2018	2019	2020
MDJH-TX1 Johns Hopkins Hospital	202	185	209	243	203
MDUM-TX1 University of Maryland Medical System	208	241	220	142	148
DCGU-TX1 Medstar Georgetown Transplant Institute	203	201	207	267	302
VAFH-TX1 Inova Fairfax Hospital	88	86	99	114	95
DCGW-TX1 George Washington University Hospital	55	48	56	68	57
DCCH-TX1 Children's National Medical Center	4	3	1	3	2
<b>TOTAL</b>	<b>760</b>	<b>764</b>	<b>792</b>	<b>837</b>	<b>807</b>

(<https://optn.transplant.hrsa.gov/data/view-data-reports/build-advanced/> (controlled for age to show adult recipients)).

### III. MedStar’s Application for a Sixth Adult Civilian Kidney Program in the Baltimore/Washington Area.

MedStar proposes to perform kidney transplants on adult patients only—not pediatric patients (or military patients). MedStar CQ.I 2. It projected that it will perform 12 adult kidney transplants in 2019; 24 in 2020; and 44 in 2021. Application 61. It has not updated these projections. MedStar later clarified that of the 44 cases it projected for year three of its program, only 24 represented new cases. MedStar CQ.II 17. The other 20 of 44 were made up of cases that MedStar intended to syphon from Georgetown, the University of Maryland, and Johns Hopkins. *Id.*

MedStar grounded its application on improvements that it alleges it can make to the LLF DSA. It contended that it could lower demand for kidney transplants and increase the supply of kidneys in this region. Application 4. MedStar asserted that it can lower demand by better managing kidney disease and increase supply through various methods. *Id.* MedStar has been unable to quantify the number of kidneys that it can free up through these methods.

In the end, MedStar rested its application on purported improvements rather than need. *See* Application 4, 8, 57, 60, 79; CQ.I 47, 50, 60, 69. And when asked by the Commission in the first round of completeness questions to explain why the existing programs in Baltimore cannot meet the needs of the local population, MedStar pointed only to the nationwide gap between available kidneys and those in need of a transplant. CQ.I 35-37. In its second round of responses to completeness questions, MedStar claimed that need can be determined by using national rates of dialysis utilization. CQ.II 25. MedStar then assumed that all dialysis patients will “need” a kidney transplant. CQ.II 25. But—as previously noted—not all patients on dialysis qualify for a kidney transplant, and some of those patients who do qualify elect not to have one. In short, calculating need in this manner, without regard to the realities of the limited supply of available organs, and how that supply is allocated, suggested incorrectly that the entire country is in need of infinitely more transplant centers.

#### **IV. The New Kidney Allocation Policy Effective March 15, 2021.**

As early as 2010, the Advisory Committee on Organ Transplantation recommended that organ transplantation policy discontinue reliance on DSAs. In 2017, a lawsuit concerning lung allocation led the Organ Procurement and Transplantation Network (“OPTN”) to remove DSAs from lung allocation policy. This prompted the Secretary of the Department of Health and Human Services to direct the OPTN to eliminate reliance on DSAs and their accompanying regions from all organ allocation policies. The OPTN’s Kidney Committee recommended use of a Fixed Circle Policy. Under this policy, transplant candidates receive a score based on

various criteria. A donated kidney is offered to compatible candidates within a single fixed-distance circle of 250 nautical miles around the donor hospital. The donated organ is first offered to candidates within this circle with the highest score. If no candidate matches, the organ is offered to candidates outside of the circle. The Fixed Circle Policy went into effect on March 15, 2021.

Particularly on the East Coast, a fixed circle of 250 nautical miles covers an expansive territory. To put it in perspective: a fixed circle drawn around Howard County General Hospital in Columbia, includes all of Pennsylvania, New Jersey, Delaware, Washington, D.C., most of Virginia and West Virginia, all five boroughs of New York City, a large swath of New York State, and parts of Connecticut. The new policy, therefore, means that, as a practical matter, all of the adult kidney transplant programs in the Baltimore/Washington area will be vying for kidneys drawn from all of the donor hospitals in the mid-Atlantic.<sup>3</sup>

As a result of this transformation of kidney allocation policy, the Commission directed MedStar on May 10, 2021 to update its assessment of need for a new kidney transplantation program. MedStar responded on July 9, 2021. As though the boundaries of LLF DSA remain relevant to allocation policy, however, MedStar continues to focus on comparing its kidney transplant program at Georgetown with the two Baltimore area programs at The Johns Hopkins Hospital and the University

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<sup>3</sup> See <https://public.tableau.com/app/profile/optn.kidney.committee/viz/KIDNEYALLOCATIONPROPOSALMAPS/FinalMap>.

of Maryland. Johns Hopkins responds with these comments to highlight this critical deficiency in MedStar’s July 9 letter and to respond to misstatements and inflammatory comments MedStar has made in that letter.

### **Argument**

#### **I. MedStar Has Never Shown a Need for a New Kidney Transplant Program.**

It is fundamental, that an applicant for a certificate of need must demonstrate by a preponderance of the evidence that a new organ transplant center is needed. Transplant Chapter 25, COMAR 10.24.15.04B(1).<sup>4</sup> To do so, an applicant must analyze historic utilization rates to show expected future trends. *Id.* at B(1)(c). The applicant must also clearly define the population to be served. MedStar has never squarely addressed these requirements. Instead, MedStar has focused on other arguments that do not establish need, even apart from their deficiencies.

MedStar’s principal contention was that it could improve overall performance in the LLF DSA and increase the supply of organs. Application 4. It first asserted that it could reduce the need for kidney transplants in the LLF DSA. *Id.* But MedStar was never able to quantify that projected reduction. And even putting aside the lack of quantification, proposing to reduce a need does not demonstrate a need. Indeed, MedStar has never required a certificate of need to improve its medical management of patients who suffer from kidney disease. Furthermore, because MedStar’s various proposals to increase the supply of available organs, Application 42-43, have been

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<sup>4</sup> All citations to the “Transplant Chapter” refer to Chapter 15 of the State Health Plan for Facilities and Services: Specialized Health Care Services—Organ Transplant Services, which is incorporated in the Code of Maryland Regulations. COMAR 10.24.15.00.

shown to be unlikely to have any effect, MedStar’s position that it aims to reduce the need for kidney transplants conflicted with its stated goal of “increas[ing] the total number of Marylanders who receive liver or kidney transplants,” Application 92.

To the extent that MedStar has ever addressed need at all throughout this long process, it has failed to carry its burden. MedStar has never defined the population it proposes to serve. And while MedStar insists that it can increase the supply of organs, Application 43, MedStar failed to analyze the level of services already being provided by the two large, high-volume programs in Baltimore. Its application is devoid of a quantitative analysis of the services provided by the two existing programs. It also has consistently ignored the fact that the methods it proposes already are performed throughout the region. In short, the improvements MedStar proposed have always been illusory. Because MedStar has never shown a need, its updated need assessment should be disregarded, and its application denied.

## **II. MedStar Fails to Properly Analyze the New Kidney Allocation Policy.**

Even if the Commission deems it necessary to consider MedStar’s July 9 letter, MedStar has missed the mark. The Commission asked MedStar to address the 2021 change in kidney allocation policy. In its July 9 letter, MedStar asserts that “the new UNOS organ allocation policy has not changed the need for the proposed program as detailed in [MedStar’s] previous filings.” MedStar Letter 1. To support that statement, MedStar contends that its exhibits 4 through 7 show that there have been no “substantive volume shifts resulting from the new policy that would eliminate the need for the program.” *Id.*

As noted, MedStar never established a need that could be eliminated by the new allocation policy. Yet even if MedStar had demonstrated a need, MedStar misplaces reliance on volume data from 2016 to 2020 (Exhibit 4) and 2013 to 2020 (Exhibits 5, 6, and 7). As made clear in Commissioner O’Grady’s May 10 letter, the policy change that the Commission has directed MedStar to address did not go into effect until **March 15, 2021**. So even if MedStar had shown a need to begin with (it has not), its reliance on data from 2013 to 2020 to draw conclusions about a policy implemented in 2021 makes no sense. MedStar does not explain the anomaly.

The reality is that data that predates the policy implementation tells us nothing about the effects of that policy on MedStar’s application. Indeed, the new policy has been in effect for too brief a period for anyone to draw meaningful conclusions about volume shifts. The fact that the policy came into operation during the COVID pandemic heightens the uncertainty of the effects of the policy on any possible need for an additional kidney transplant program in the Baltimore/Washington region.

Worse yet, MedStar avoids discussing the most obvious and tangible effect of the new policy on its application—the relevance of the kidney programs in the Washington D.C. Metropolitan area. MedStar continues to focus on individual, center-level statistics concerning the two Baltimore area programs: Johns Hopkins and the University of Maryland. But the OPTN no longer relies on the donation service area and OPTN regions. Rather, now that kidney allocation is based on the distance between donor and recipient, MedStar’s application must be viewed in light

the existing kidney transplant programs at George Washington University and Inova, not to mention MedStar's own program at Georgetown.

Each of those programs is situated within a three-hour drive time of much of Maryland. COMAR 10.24.15.04(B)(3)(d). And each of those programs (or any combination of them) easily could absorb the 24 new annual cases that MedStar predicted in its original application its new program would handle by its third year of operation. MedStar CQ.II 17. Yet MedStar ignores that fact and continues to frame its arguments as though the DSA/Region model were still in existence. MedStar's failure to confront this change in allocation policy and the State Health Plan's preference for high volume organ transplant programs, State Health Plan at 13, along with the ability of existing programs to handle all of the new cases it forecasts Franklin Square will handle are reasons enough to deny its application.

### **III. MedStar's Assertions Concerning Supply and Access are Unfounded.**

#### **A. MedStar Has Not Shown That It Will Increase Organ Supply.**

In its July 9 letter, MedStar reiterates that "the program's goal is to increase the supply of available organs." MedStar Letter 1. MedStar previously identified methods by which it proclaimed it would increase the supply of kidneys. Johns Hopkins already has responded to each of those methods and explained why none of them will serve to increase the available organ supply. JHH 10/15/2020 Int. Party Comments at 10-16. MedStar has not addressed any of the deficiencies that Johns Hopkins has identified. Nor does MedStar quantify in its July 9 submission the number of additional organs it believes it will make available.

**B. “Fuller Access” to MedStar’s Services Does Not Substitute for Need or Show a Lack of Access.**

As noted previously, MedStar already has conceded that it cannot identify barriers to access. Application 67. Instead, MedStar has offered to provide “fuller access to the continuum of care available [from] MedStar providers.” MedStar Letter 1. As an initial matter, MedStar’s desire to keep patients within its system does not justify a establishing a new program. MedStar’s certificate of need cannot be justified by its desire to avoid future referrals to the existing kidney transplant programs in the Baltimore/Washington area.

And it is not enough for an applicant to suggest ways to *improve* access. Rather, an applicant must show “*barriers* to access,” along with “a credible plan to address those barriers.” Transplant Chapter 27, COMAR 10.24.15.04B(3)(b). MedStar failed to deliver either.

**C. Simultaneous Liver/Kidney Transplants Are Irrelevant.**

Nor does MedStar’s stated intention to serve patients who require liver and kidney transplants help MedStar to carry its burden. MedStar Letter 1. The Commission considers applications for transplant programs for different organs separately and independently. The Commission already determined that another liver program in this area is not needed when it denied Suburban Hospital’s application to open a new liver transplant program. And since the Commission’s denial of Suburban’s application, The George Washington University has established a new liver transplant program in the Washington D.C. area.

In addition, simultaneous kidney/liver transplants are uncommon. Indeed, nowhere in MedStar’s application, responses to completeness questions, or its July 9 submission, does MedStar even attempt to quantify the number of liver/kidney transplants it projects. That is because the number would be so low as to be immaterial to its kidney application and irrelevant in light of the ability of the existing programs at the University of Maryland, Johns Hopkins, Georgetown, and now George Washington University, to easily absorb any additional cases. In any event, MedStar stated in its liver application that it will avoid “patients deemed at high risk,” MedStar Liver CQ.I 35, which would include those patients in need of a simultaneous liver/kidney transplant.

**D. Treatment of Maryland Residents by Georgetown is Irrelevant.**

MedStar makes the puzzling assertion that because the largest proportion of kidney transplant recipients at Georgetown reside in Maryland, it has increased access generally in the State. MedStar Letter 2. MedStar does not explain why this statement is relevant, let alone “notable.” *Id.* Washington, D.C. has a population of approximately 690,000. Maryland’s population, meanwhile, exceeds 6 million—2 million of whom live in the two Maryland counties that surround D.C.—Montgomery and Prince George’s. It’s no surprise, then, that a specialty program in Washington, D.C. draws nearby Maryland residents. Indeed, it’s unlikely that there would be a need for a program at Georgetown if residents of the surrounding counties were not expected to use that program. But none of that suggests a lack of access for Maryland residents. Nor does MedStar contend otherwise.

**E. MedStar’s Self-Assessment of Georgetown’s Quality is Overblown, Fails to Demonstrate Need, and is Self-Defeating.**

Finally, MedStar touts its track record of kidney transplants at Georgetown. And it portrays its program at Georgetown as superior to the programs at the University of Maryland and Johns Hopkins. Indeed, MedStar goes so far as to claim that Johns Hopkins’ and the University of Maryland’s rate of waitlist mortality “reflect[s] poor care of patients waiting for transplant.” MedStar Letter Exhibit 9.

First, MedStar’s portrayals are overblown. To support its claims of “superiority,” MedStar points to Exhibits 1 and 2 to its submission. At first glance, the bar charts in those exhibits purport to show wide differences between the rates of one-year graft survival between Georgetown and Johns Hopkins on the one hand, and the University of Maryland on the other. But the bars *appear* to be significantly different because MedStar chose to present the data by beginning the y-axis at 91.5 and concluding it at 96.5. In reality, Georgetown’s rate of survival is nearly identical to Johns Hopkins’ and not meaningfully different from the University of Maryland’s. MedStar employed the same tactic in Exhibit 2. There MedStar began its bar chart of one-year survival rate at 95 and concluded it at 98.5 Again MedStar’s rate is nearly identical to Johns Hopkins and not meaningfully different from the University of Maryland. In short, distorting the appearance of data by manipulating the y-axis of a bar graph does not demonstrate “superiority.”

Contrary to MedStar’s claims of superiority, an analysis of *three-year* graft survival rate makes clear that both Maryland centers are high performing. Based on data available April 30, 2021, the metric “Adult (18+) 3-year survival with a

functioning graft” tracks single organ transplants performed between July 1, 2015 and December 31, 2017. Attached Exhibit (SRTR Program-Specific Report, released July 6, 2021). That metric allows for a much larger sample size: 469 for Johns Hopkins, 523 for the University of Maryland, and 481 for Georgetown. The centers respective graft survival rates were 89.92% for Johns Hopkins, 84.72% for the University of Maryland, and 85.60% for Georgetown. In attempting to identify a quality deficit in the Baltimore region, MedStar fails. No such quality deficit exists. *Id.*

Nor are MedStar’s accusations about waitlist mortality justified. For starters, Exhibit 9 appears to show that Georgetown’s and Johns Hopkins’ have the same rate in 2021 (the lines intersect). Any divergence, however, does not reflect quality of care by the transplant centers as MedStar contends. That is because many kidney transplant candidates are not directly cared for by the transplant programs with which they are waitlisted. As a result, MedStar’s attempt to portray a differential in rates in waitlist mortality as reflective of quality of care falters. Critically, MedStar has not shown that a new program at Franklin Square would attract anyone in Maryland that would not already be waitlisted at existing programs. And MedStar’s statements about race and socioeconomic status of patients transplanted at Georgetown tell us nothing about the hypothetical transplant population at Franklin Square.

Second, even if MedStar’s portrayals of survival rates were accurate, they do not help MedStar carry its burden of showing need. Pointing to a high-performing

program at one hospital does not demonstrate a need to replicate or “emulate” that program at another hospital. MedStar Letter 2. After all, MedStar seeks a Certificate of Need, not a Certificate of Emulation. If the standard were the one which MedStar perceives and its statements of superior quality were accurate, then it would mean that MedStar should be permitted to open kidney transplant programs at all of its affiliated hospitals. That clearly does not reflect the governing standard or reality.

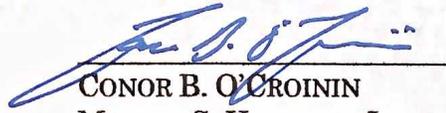
Third, MedStar’s decision to continue touting its program at Georgetown is self-defeating. Under the new allocation policy—the substance of which MedStar ignores—an additional high-volume program in the Baltimore/Washington area further lessens the possibility that there is any need for the low volume program it seeks to open. That is because the multiple high-volume programs in the Washington, D.C. Metropolitan area will now be competing from the same organs and MedStar’s own proposed low-volume program. In other words, by touting its program at Georgetown, MedStar itself has undermined the fundamental premise of its application.

### **Conclusion**

For these reasons, and the reasons Johns Hopkins articulated in its prior set of interested party comments, MedStar’s application fails to meet the fundamental requirements for a certificate of need. Accordingly, MedStar’s application must be denied.

Dated: September 16, 2021  
Baltimore, Maryland

Respectfully submitted,



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## Certificate of Service

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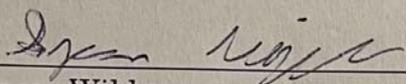
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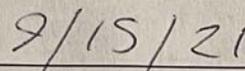
Conor B. O'Croinin

## AFFIRMATION

I hereby declare and affirm under the penalties of perjury that the facts stated in the Interested Party Comments of the Johns Hopkins Hospital in Response to the Updated Need for Assessment by Medstar Franklin Square Medical Center for an Additional Kidney Transplant Program in the Baltimore-Washington Area are true and correct to the best of my knowledge, information, and belief.



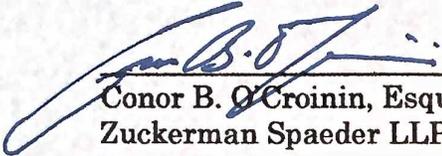
\_\_\_\_\_  
Spencer Wildonger  
Director of Health Planning  
Health Care Transformation and Strategic Planning  
Johns Hopkins Health System

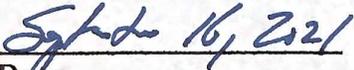


\_\_\_\_\_  
Date

**AFFIRMATION**

I hereby declare and affirm under the penalties of perjury that the facts stated in the Interested Party Comments of the Johns Hopkins Hospital in Response to the Updated Need for Assessment by Medstar Franklin Square Medical Center for an Additional Kidney Transplant Program in the Baltimore-Washington Area are true and correct to the best of my knowledge, information, and belief.

  
\_\_\_\_\_  
Conor B. O'Croinin, Esquire  
Zuckerman Spaeder LLP

  
\_\_\_\_\_  
Date

**AFFIRMATION**

I hereby declare and affirm under the penalties of perjury that the facts stated in the Interested Party Comments of the Johns Hopkins Hospital in Response to the Updated Need for Assessment by Medstar Franklin Square Medical Center for an Additional Kidney Transplant Program in the Baltimore-Washington Area are true and correct to the best of my knowledge, information, and belief.



9/15/2021

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Martin S. Himeles, Jr., Esquire  
Zuckerman Spaeder LLP

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Date



### C. Transplant Information

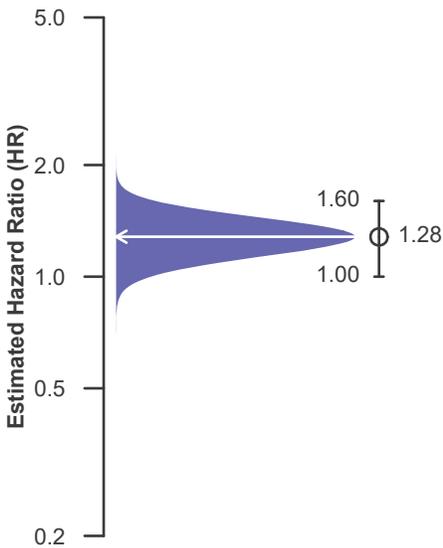
**Table C7. Adult (18+) 3-year survival with a functioning graft**  
**Single organ transplants performed between 07/01/2015 and 12/31/2017**  
**Deaths and retransplants are considered graft failures**

	DCGU	U.S.
Number of transplants evaluated	481	43,863
Estimated probability of surviving with a functioning graft at 3 years (unadjusted for patient and donor characteristics)	85.60%	90.02%
Expected probability of surviving with a functioning graft at 3 years (adjusted for patient and donor characteristics)	88.87%	--
Number of observed graft failures (including deaths) during the first 3 years after transplant	66	4,203
Number of expected graft failures (including deaths) during the first 3 years after transplant	51.06	--
Estimated hazard ratio*	1.28	--
95% credible interval for the hazard ratio**	[1.00, 1.60]	--

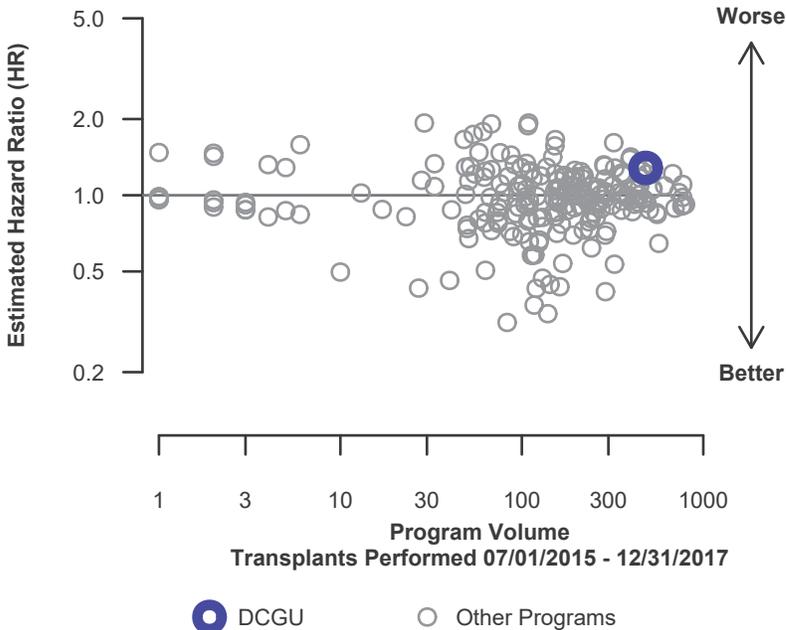
\* The hazard ratio provides an estimate of how Georgetown University Medical Center (DCGU)'s results compare with what was expected based on modeling the transplant outcomes from all U.S. programs. A ratio above 1 indicates higher than expected graft failure rates (e.g., a hazard ratio of 1.5 would indicate 50% higher risk), and a ratio below 1 indicates lower than expected graft failure rates (e.g., a hazard ratio of 0.75 would indicate 25% lower risk). If DCGU's graft failure rate were precisely the expected rate, the estimated hazard ratio would be 1.0.

\*\* The 95% credible interval, [1.00, 1.60], indicates the location of DCGU's true hazard ratio with 95% probability. The best estimate is 28% higher risk of graft failure compared to an average program, but DCGU's performance could plausibly range from 0% reduced risk up to 60% increased risk.

**Figure C5. Adult (18+) 3-year graft failure HR estimate**



**Figure C6. Adult (18+) 3-year graft failure HR program comparison**





## C. Transplant Information

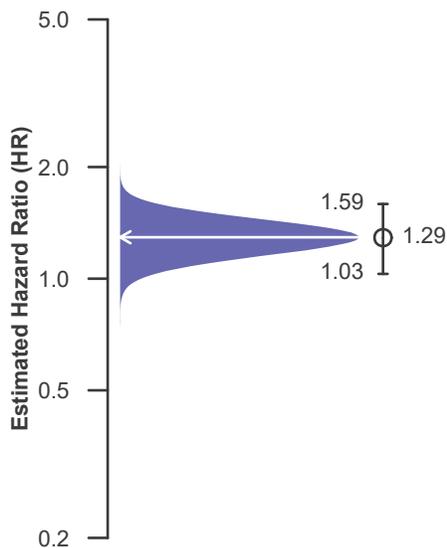
**Table C7. Adult (18+) 3-year survival with a functioning graft**  
**Single organ transplants performed between 07/01/2015 and 12/31/2017**  
**Deaths and retransplants are considered graft failures**

	MDUM	U.S.
Number of transplants evaluated	523	43,863
Estimated probability of surviving with a functioning graft at 3 years (unadjusted for patient and donor characteristics)	84.72%	90.02%
Expected probability of surviving with a functioning graft at 3 years (adjusted for patient and donor characteristics)	87.46%	--
Number of observed graft failures (including deaths) during the first 3 years after transplant	78	4,203
Number of expected graft failures (including deaths) during the first 3 years after transplant	59.86	--
Estimated hazard ratio*	1.29	--
95% credible interval for the hazard ratio**	[1.03, 1.59]	--

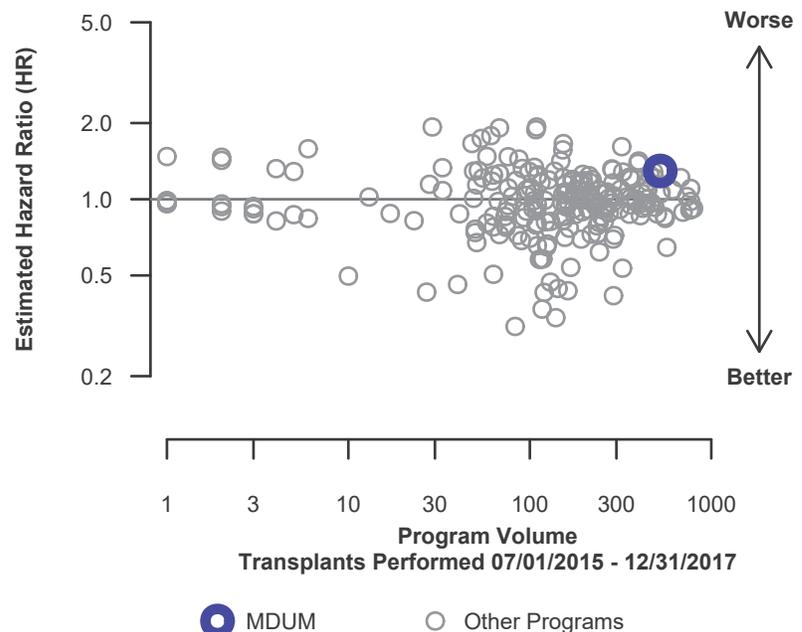
\* The hazard ratio provides an estimate of how University of Maryland Medical System (MDUM)'s results compare with what was expected based on modeling the transplant outcomes from all U.S. programs. A ratio above 1 indicates higher than expected graft failure rates (e.g., a hazard ratio of 1.5 would indicate 50% higher risk), and a ratio below 1 indicates lower than expected graft failure rates (e.g., a hazard ratio of 0.75 would indicate 25% lower risk). If MDUM's graft failure rate were precisely the expected rate, the estimated hazard ratio would be 1.0.

\*\* The 95% credible interval, [1.03, 1.59], indicates the location of MDUM's true hazard ratio with 95% probability. The best estimate is 29% higher risk of graft failure compared to an average program, but MDUM's performance could plausibly range from 3% increased risk up to 59% increased risk.

**Figure C5. Adult (18+) 3-year graft failure HR estimate**



**Figure C6. Adult (18+) 3-year graft failure HR program comparison**





## C. Transplant Information

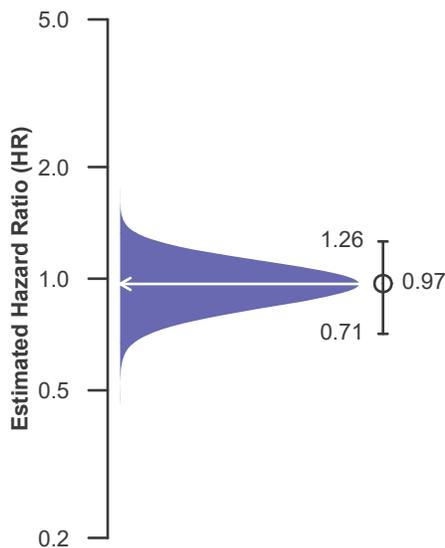
**Table C7. Adult (18+) 3-year survival with a functioning graft**  
Single organ transplants performed between 07/01/2015 and 12/31/2017  
Deaths and retransplants are considered graft failures

	MDJH	U.S.
Number of transplants evaluated	469	43,863
Estimated probability of surviving with a functioning graft at 3 years (unadjusted for patient and donor characteristics)	89.92%	90.02%
Expected probability of surviving with a functioning graft at 3 years (adjusted for patient and donor characteristics)	89.44%	--
Number of observed graft failures (including deaths) during the first 3 years after transplant	46	4,203
Number of expected graft failures (including deaths) during the first 3 years after transplant	47.60	--
Estimated hazard ratio*	0.97	--
95% credible interval for the hazard ratio**	[0.71, 1.26]	--

\* The hazard ratio provides an estimate of how Johns Hopkins Hospital (MDJH)'s results compare with what was expected based on modeling the transplant outcomes from all U.S. programs. A ratio above 1 indicates higher than expected graft failure rates (e.g., a hazard ratio of 1.5 would indicate 50% higher risk), and a ratio below 1 indicates lower than expected graft failure rates (e.g., a hazard ratio of 0.75 would indicate 25% lower risk). If MDJH's graft failure rate were precisely the expected rate, the estimated hazard ratio would be 1.0.

\*\* The 95% credible interval, [0.71, 1.26], indicates the location of MDJH's true hazard ratio with 95% probability. The best estimate is 3% lower risk of graft failure compared to an average program, but MDJH's performance could plausibly range from 29% reduced risk up to 26% increased risk.

**Figure C5. Adult (18+) 3-year graft failure HR estimate**



**Figure C6. Adult (18+) 3-year graft failure HR program comparison**

