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May 15, 2018

VIA E-MAIL AND HAND DELIVERY

Mr. Kevin McDonald
Chief, Certificate of Need
MARYLAND HEALTH CARE COMMISSION
4160 Patterson Avenue
Baltimore, MD 21215

Re: Suburban Hospital Application for Certificate of Need — Liver Transplant Service

Dear Mr. McDonald:

This firm represents Suburban Hospital, the Applicant in the above-referenced matter. In conformance with COMAR 10.24.01.08 (F)(3), we have enclosed by email Suburban's Response to Interested Party Comments of MedStar Georgetown University Hospital. The original and four hard copies will follow by hand delivery.

Please do not hesitate to contact me if I can be of assistance.

Very truly yours,

Conor B. O'Croinin

cc: Ms. Eileen Fleck (Eileen.fleck@maryland.gov)
Dr. Travis Gayles (hhsmail@maryland.gov)
Ms. Ruby Potter (ruby.potter@maryland.gov)
David C. Tobin, Esq. (dtobin@tobinoconnor.com)
Anne S. Langley, Esq., Senior Director, Health Planning and Community Engagement, Johns Hopkins Health System
Spencer Wildonger, Director of Health Planning, Health Care Transformation and and Community Engagement, Johns Hopkins Health System
Martin S. Himeles, Jr., Esq.

BEFORE THE MARYLAND HEALTH CARE COMMISSION

IN THE MATTER OF	*	
	*	
THE APPLICATION OF	*	
SUBURBAN HOSPITAL, INC.	*	**Docket No. 17-15-2400**
FOR A CON TO ESTABLISH A	*	
LIVER TRANPLANT SERVICE	*	
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RESPONSE TO INTERESTED PARTY COMMENTS OF MEDSTAR GEORGETOWN UNIVERSITY HOSPITAL

In accordance with COMAR 10.24.01.08(F), MedStar Georgetown University Hospital ("MedStar") has requested interested party status and submitted comments in response to Suburban Hospital, Inc.'s ("Suburban's") application for a certificate of need to open a second liver transplant program in the Washington Regional Transplant Center Donor Service Area ("WRTC DSA"). Suburban submits this response.

Introduction

In its comments, MedStar does not contend that Suburban's proposal is not viable or that there is a more cost-efficient alternative to introducing a second liver transplant program in the WRTC DSA. *See* COMAR 10.24.01.08(G)(3)(c) & (d). Nor does MedStar contend that Suburban's proposed program would have an adverse impact on its existing program at Georgetown or, for that matter, any other health care provider. Instead, MedStar contends that Suburban has failed to demonstrate the need for a second program in the WRTC DSA, that intra-DSA competition is neither useful nor desirable, and that Suburban has not demonstrated that there are barriers to access ((COMAR 10.24.15.05B(3)).

But in its application, Suburban documented the historical access disparities in the two DSAs serving Maryland residents. It is on this basis—evidence of sustained and, in fact, growing disparate access in the two DSAs—that Suburban has demonstrated need. Suburban's proposed solution to bridging this access divide is to introduce a second center where there is only one, cultivate a competitive

environment in a service area where competition doesn't exist, and apply the same practices, procedures, and organizational structure that has allowed The Johns Hopkins Hospital Comprehensive Transplant Center to become a national leader and innovator in the field of liver transplantation.

Hard data establishes undeniable disparities between the Washington Regional Transplant Community Donation Service Area ("WRTC DSA"), in which MedStar is the sole center that performs liver transplants, and the Living Legacy Foundation Donation Service Area ("LLF DSA"), in which there are competitive centers at The Johns Hopkins Hospital ("Hopkins") and the University of Maryland Medical System ("UMMS"). As Suburban showed in its application, there are disparities in the volume of transplants performed, access for DSA residents, the number of residents transplanted locally, the willingness of the DSAs to perform transplants on sicker patients, the organ supply, and wait-listing practices.

Competition is the key to erasing these harmful disparities. A second center in the WRTC DSA will have the added benefit of providing a safety net to counteract any disruptions to the sole existing liver transplant program.

I. There Are Clear Disparities Between The Two DSAs Serving Maryland.

By employing separate data sets, MedStar attempts to draw attention away from the disparities between the LLF DSA and the WRTC DSA. And it invites the Commission to conclude that introducing competition will not improve access or better meet the needs of WRTC DSA residents. But MedStar's efforts to distract from the problems in the WRTC DSA by repackaging data sets fall flat. In fact, the

identified disparities are significant and enduring. And as a result, real people experience real harm.

A. The Disparity in the Volume of Adult Liver Transplants.

The WRTC DSA covers a lot of people—5.5 million, including 2.1 million Maryland residents—but it is served by only a single liver transplant center. The LLF DSA, by contrast, covers 3.9 million people, but has two highly functioning and competitive centers. The single center in the WRTC DSA performs far fewer transplants than the two centers in the LLF DSA. This pattern is consistent. Every year from 2011 through 2017, the centers in the LLF DSA performed more adult liver transplants than the center in the WRTC DSA. In 2015, the LLF DSA centers performed 241 transplants on adult patients. The lone WRTC DSA center (MedStar's program at Georgetown) managed to perform only 49.

Adult Liver Transplants						
DSA	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**
LLF	127	169	199	241	291	260
WRTC	98	76	79	49	84	97

MedStar attempts to explain away this persistent volume gap by contrasting Hopkins', MedStar's, and UMMS's volumes—ignoring the fact that Hopkins and UMMS share a service area. MedStar Comments ("Cmts.") at 2. Quantifying access disparities between the two DSAs requires consideration of the volume of transplants performed in the LLF and WRTC DSAs—not the volume in each center. In other words, a comparison of transplant volumes at MedStar to either UMMS or

Hopkins, as opposed to a comparison of MedStar to UMMS and Hopkins, tells us nothing about the access disparities between the two DSAs.

MedStar makes the same mistake when it contends that "volume gaps are narrowing dramatically among all Centers." MedStar Cmts. at 1-3. First, there remain volume gaps in adult liver transplants among the centers. In 2017, MedStar performed 97 adult liver transplants. Hopkins performed 99 and UMMS—which operates within two miles of Hopkins—performed 161. Second, while comparing MedStar's 97 adult liver transplants separately to Hopkins' 99 adult liver transplants or UMMS's 161 adult liver transplants in isolation may create the misimpression that the DSAs function at a similar level, holding up the 97 adult liver transplants performed in the WRTC DSA to the 260 performed in the LLF DSA reinforces the striking disparities in adult liver transplant volumes between the two DSAs. It is that comparison—260 to 97—that matters.

Suburban does not intend to perform pediatric transplants; it will increase access to liver transplants for adults. Adult transplant volumes in the LLF DSA and the WRTC DSA for each year from 2012 through 2017, shown in the chart above, reflect the disparity in access for adult patients in the two DSAs.

MedStar's attempt to suggest that the widening trend shown originally in the chart on page 25 of Suburban's application will vanish in 2018 is equally misguided. As an initial matter, data for the first three months of 2018 is no basis for an annual volume projection. Worse yet, MedStar's data for that three-month period is unreliable, as it is unlikely that complete data for all three centers for the first

quarter of 2018 is available yet—and even less likely that it was available as of April 10, 2018, the date MedStar obtained the data in MedStar Exhibit 1. MedStar Cmts. at 3 n. 1. The full-year data for adult transplants from 2012 to 2017 shown above reflects that the widening gap did not materially change in 2017, when the number of adult transplants in the LLF DSA was almost three times the number in the WRTC DSA.

In short, MedStar's attempt to explain away the striking volume disparities between the two DSAs by comparing MedStar's volumes in isolation with UMMS or Hopkins, rather than with UMMS *and* Hopkins, fails. The simple reality is that even though the WRTC DSA population is 40% larger, the centers in the LLF DSA perform far more adult liver transplants each year than the single WRTC DSA center. This occurs despite the fact that the liver disease burden in the WRTC DSA is comparable to the liver disease burden in the LLF DSA—and certainly there are no differences that would explain volume differences of this magnitude. For adults in the WRTC DSA in need of liver transplants, these disparities are far more than statistics.

B. The Difference in Patient Access for Maryland Residents.

In its application, Suburban showed that in 2015, per capita, LLF DSA adult residents were nearly twice as likely as WRTC DSA adult residents to obtain a liver transplant. Application at 30. And in 2015, LLF DSA adult residents were more than five times as likely as WRTC adult residents to obtain that transplant locally, that is, within their DSA. Application at 31. This access disparity between

neighboring DSAs also is evident in the travel patterns of those patients with the means to travel outside of their DSA to obtain a liver transplant. Left out of the equation are those patients who lack the means to engage in inter-DSA travel. *See* Dzebisashvili, Nino, *et al.* "Following the organ supply: assessing the benefit of inter-DSA travel in liver transplantation." Transplantation 95.2 (2013): 361-371 (explaining the effect of socioeconomic status on a patient's ability to migrate outside of a DSA to obtain a liver transplant).

MedStar does not dispute the accuracy of the data that Suburban has presented. It does not dispute, for instance, that 66% of adult patients residing in the WRTC DSA who received a liver transplant in 2015 left the WRTC DSA to do so. Yet only 6% of patients residing in the LLF DSA who received a liver transplant in 2015, did so outside of the LLF DSA. Application at 36.

Instead, MedStar pleads with the Commission to ignore this disparity. MedStar posits that residents who live in close proximity to another DSA should be expected to travel outside of their DSA. MedStar Cmts. at 4. MedStar also contends—without support—that "'migration' based on 'access' simply does not occur[.]" *Id.* MedStar is wrong.[1]

While it is not unreasonable to suggest that patients in adjoining DSAs may engage in inter-DSA travel, the data do not reflect comparable movement among adult liver patients between the two DSAs. To the contrary, the data show adult

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[1] MedStar is unfamiliar with the concept of patient migration. It incorrectly suggests that "'migration' is not a phenomenon used in transplant parlance." MedStar Cmts. at 4. *But see* P. Croome *et al.*, *Patterns and Outcomes Associated with Patient Migration for Liver Transplantation in the United States*, PLoS ONE 10 (2015) (available at http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0140295).

liver patients from the WRTC DSA flocking to the LLF—migrating in 2015 at more than ten times the rate of LLF DSA residents migrating to the WRTC DSA. Application at 37. This migration pattern is unmistakable evidence of a lack of access in the WRTC DSA. The reality is that migration based on access does occur, and in the WRTC DSA, it is occurring at alarming levels. And while migration is one way to overcome a lack of access in one DSA, it not a viable option for all transplant candidates. For again, patients with lower socioeconomic status are less likely to engage in inter-DSA travel. Dzebisashvili, *supra*, 361-371. Instead, they will forego transplantation altogether.

C. The Acuity Difference Based on Misaligned Incentives.

Suburban has proven that MedStar—the only center in the WRTC DSA—is not serving relatively sicker transplant patients. Application at 39. This is demonstrated by the difference in median MELD scores at the time of transplant over the course of five OPTN/SRTR Annual Reports from 2011 to 2015. Suburban Answer to Completeness Question 1 at 44-47.

MedStar does not dispute this data or resist the conclusion that the data Suburban has presented in its application show that the programs in the LLF DSA perform transplants on patients with higher median MELD scores than patients who received transplants in the WRTC DSA. Rather, MedStar contends that more recent data show a change in this trend, that such disparities occur "randomly," and that MedStar performs more transplants on Status 1 patients than *either* UMMS *or* Hopkins. MedStar Cmts. at 6.

To begin with, Status 1 patients have no relevance in determining the access of adults with chronic liver disease to transplants. Status 1 includes Status 1A and Status 1B. Status 1B patients, included in MedStar's Status 1 figures, are irrelevant. Status 1B is assigned only to pediatric patients. Because Suburban will only perform liver transplants on adult patients, Status 1B patients are not at issue.

Status 1A patients are also irrelevant. These patients do not have chronic liver disease; they are patients whose livers were healthy until they suffered acute and severe onset liver failure. Status 1A patients have not been assigned MELD scores and have not been on waiting lists; they have experienced sudden liver failure from a cause *other than* liver disease, and their life expectancy is less than seven days. Such patients are generally in much better overall health than patients with high MELD scores, and although their need is urgent, they do not pose the same challenges as transplants to high MELD score patients, whose health has badly deteriorated.

And even if Status 1A transplant volumes were relevant, MedStar's analysis again is based on its incorrect comparison of centers rather than DSAs. If the comparison is by DSA and limited to adult Status 1A transplants, the numbers are as follows:

Status 1A Liver Transplants (Adults)					
DSA	**2013**	**2014**	**2015**	**2016**	**2017**
LLF	10	6	3	10	10
WRTC	5	2	1	2	6

Considerably fewer adult Status 1A patients have received liver transplants in the WRTC DSA than in the LLF DSA every year for the past five years, notwithstanding the larger population in the WRTC DSA. This is a very different picture than the one presented by MedStar in MedStar Exhibit 2. MedStar Cmts. at 8. The reason for this is two-fold. First, as discussed, MedStar's comparison is not at the DSA-level—a more appropriate comparison when two of the three centers share a service area, while the third center is in a different service area. Second, the charts report the percentage of each center's volume, rather than the actual number of transplants. Reporting figures as a percentage of the whole masks the fact that the percentages are of vastly different numbers. In 2015, for example, 241 adults were transplanted in the LLF DSA as compared to only 49 in the WRTC DSA.

And if the analysis is limited to adult transplant recipients with high MELD scores, the disparities are even greater. As shown in Suburban's answer to completeness question number 36, in 2016, the centers in the LLF DSA performed transplants on 75 adult patients whose MELD scores were 35 and above—MedStar performed only 8. More recent data now available reflects that in 2017, the LLF DSA centers performed 51 cases in this category, versus only 21 for MedStar. Similarly, for patients with MELD scores in the range of 30 to 34, the centers in the LLF DSA in 2016 performed 45 transplants, while the single center in the WRTC DSA performed only 11. In 2017, the LLF DSA centers performed 40 cases in this category, versus 11, again, for MedStar. When these values are reported as counts at the DSA-level, MedStar's suggestion of comparable performance disappears.

MedStar's own comments make clear the reasons for these disparities. MedStar concedes that, as the only center in the WRTC DSA, it assigns marginal organs to patients with lower MELD scores. MedStar Cmts. at 7. In a single-center DSA, if a liver is not allocated to a patient in the Region that is Status 1A, Status 1B, or has a MELD score of 35 or greater, the liver is first matched locally—to a patient listed at a center within the same DSA—in the case of the WRTC, a patient listed at MedStar. Because it operates without competition, MedStar can make the unilateral determination that a liver is not suitable for any of its patients with higher MELD scores, and accept the liver for a patient with a lower MELD score. In this single-center environment, its incentive is to make conservative use of each liver, since it is not at risk of losing the liver to a competing center within the DSA.

In the LLF DSA, however, if Hopkins has the highest MELD score patient to match with an available liver, the organ is offered to Hopkins. If Hopkins doesn't accept the organ offer, and the patient with the next highest MELD score to match is listed at UMMS, the liver is then offered to UMMS. In short, as long as there is no competing center in the same DSA, a center may choose to pass over higher acuity patients in favor of "patients with relatively lower MELD scores." MedStar Cmts. at 7. This may allow the single center to enhance its probability of higher outcomes at the expense of individual sicker patients who are passed over. If there are competing centers, on the other hand, each has an incentive to use a liver for the sickest patient for whom the liver would be suitable. The result in the single center DSA is the use of livers for patients with lower MELD scores.

D. The Supply Imbalance and the WRTC DSA's Import/Export Deficit.

Suburban has explained that the supply of livers in a DSA is equal to the number of livers procured plus the number of livers imported minus the number of livers exported. Application at 91-95. Suburban explained further how the WRTC DSA exports far more livers than the LLF DSA and imports far fewer livers than the LLF DSA. The result is a supply imbalance.

Suburban will increase outreach efforts to potential donors in the WRTC DSA, and it expects its increased efforts will increase the number of livers procured in the WRTC DSA. But Suburban's principal contention is *not* that its application should be granted because of those anticipated efforts. Rather, Suburban's principal position is that it will help increase supply because competition will lead to better use of available organs, as well as increased liver imports. *See* Suburban Answer to Completeness Question 28.

MedStar ignores this point, and instead attempts to explain the supply imbalance by pointing to the difference in death rates in the two DSAs. MedStar Cmts. at 10. MedStar cites an unusually low death rate in the WRTC DSA as the sole reason for the supply imbalance. Put simply, MedStar contends that more eligible donors die in the LLF DSA than in the WRTC DSA, and this creates an abundance of locally-procured organs. *Id.*

Yet if differing death rates have any relevance, they are relevant only to the number of locally-procured organs. They cannot account for differences in import and export rates. Suburban has demonstrated that a far greater percentage of

organs were exported from the WRTC DSA than the LLF DSA.[2] And the difference has been growing. Application at 93. Similarly, the number of livers imported into the LLF DSA has far exceeded the number imported into the WRTC DSA—and that difference has been increasing as well. In a DSA with competing centers, livers that MedStar is now allowing to be exported will more often be used within the DSA. A competing center at Suburban will also increase the number of imported livers, just as occurs in the LLF DSA. Application at 94.

E. The WRTC DSA's Shorter Waitlist and Fewer Waitlist Additions.

Suburban explained in its Application that since 2011, MedStar's waitlist has lagged behind the Hopkins/UMMS waitlist. As of 2017, the number of patients on the WRTC waitlist was one-third the number waitlisted in the LLF. The difference matters to patients simply because being on a waitlist is an essential step toward obtaining a liver transplant. Application at 46-47.

Rather than dispute the point, MedStar asserts that "waitlist size is not, in itself, a true measure of need or transplant performance." MedStar Cmts. at 15. True enough, but the disparity reflects a barrier to access and is all the more indicative of a problem given that the WRTC DSA has 40% higher population than the LLF DSA.

[2] MedStar offered Exhibits 6 and 7 in its Comments to show that export rates are comparable. But in fact, these exhibits show exactly the opposite. From July 1, 2016 to June 30, 2017, only 16 % of livers procured in the LLF DSA were exported (26 of 159 livers). During the same period, 32% of livers procured in the WRTC DSA were exported (33 of 102 livers).

Furthermore, on page 48 of its application, Suburban reports waitlist additions by year. The table below updates these figures and adds figures for 2017[3]:

OPO	2011	2012	2013	2014	2015	2016	2017
LLF OPO	197	320	435	534	453	421	464
WRTC OPO	140	160	171	194	141	209	216

Waitlist additions reflect the degree to which the centers in a DSA are identifying, evaluating, and listing transplant-eligible patients. In this regard, the single transplant center in the WRTC DSA lags far behind the centers in the LLF DSA. A second center is the best option for bridging this gap.

II. Competition is the Key to Erasing Harmful Disparities.

A second center in a DSA can guard against disruptions. Introducing competition will improve performance at both centers. In its application, Suburban cites peer-reviewed scientific literature examining the effects of competition among centers within a DSA on volume, access, supply, and waitlists. Application at 49-53. The disparities observed between the competitive LLF DSA and the non-competitive WRTC DSA are consistent with these findings: intra-DSA competition is associated with more transplants, more listings, more marginal donors, greater use of available organs, and higher MELD at transplant. These benefits have been substantiated by the experience of George Washington University's recent addition of a kidney transplant program in the WRTC DSA.

[3] Organ Procurement and Transplantation Network. These figures are subject to change based on future data submission or correction.

A. Multi-Center DSAs Minimize the Impact of Disruptions.

A single-center DSA is at risk for a major disruption. The risk of disruptions is illustrated by the experience of both Hopkins and MedStar—notwithstanding MedStar's proclamation that it has never experienced an operational disruption, and its belief that it is impervious to one. MedStar Cmts. at 4-5.

CMS establishes outcome thresholds for each center, and it reports the performance of each center at six-month intervals. If a center's outcomes fall below those thresholds for two successive intervals, it must enter into a Systems Improvement Agreement (SIA) before it can be recertified. An SIA requires a center to show significant improvement before it will be recertified.

Nine years ago, in 2009, Hopkins' outcomes fell slightly below the threshold, and it entered into an SIA with CMS. During the SIA, Hopkins transplanted patients with lower MELD scores, without HIV infection, and without acute liver disease. It referred listed patients who did not meet its criteria to other centers.

Hopkins then conducted a root cause analysis and made changes to address the findings. These changes improved Hopkins' outcomes to the sixth best in the country.

MedStar points out that Hopkins experienced a period of lower volumes during this period. But MedStar misses the point. Because there was a second center in the LLF DSA—UMMS—Hopkins was able to undertake its root cause analysis and develop protocols to restore its excellence in outcomes with minimal impact on DSA volumes and transplant candidates. Hopkins' volumes were at their lowest in 2010-

2011, but LLF DSA volumes remained steady during this period, dipping only slightly in 2010, and increasing in 2011. Volumes during this period are shown below.

LLF Transplant Volumes						
	2008	2009	2010	2011	2012	2013
JHH	60	64	39	36	48	82
UMMS	55	48	55	78	86	90
LLF Total	**115**	**112**	**94**	**114**	**134**	**172**

Because there were two centers in the LLF, one was able to increase its volume and minimize the impact of the disruption at one of the centers.

In the WRTC DSA, however, when MedStar encountered similar problems, there was no other center to pick up the slack. For adult patients transplanted in 2012 through 2014, MedStar's outcomes deteriorated, and approached the threshold at which CMS would have required an SIA. MedStar's adult, 1-year survival with a functioning graft hazard ratio was 1.47 in the June 2015 report, and 1.50 in the December 2015 report. At the time, two consecutive reports of 1.50 would have required an SIA. *See* Exhibit 1 (SRTR Report).

As a result of these problems, MedStar's transplant volumes decreased. As noted, MedStar performed only 49 adult liver transplants in 2015, down from 79 the year before and 100 three years earlier. Had there been a second program in the WRTC DSA, the reduction in volume could have been mitigated. But because there was no other program in the DSA, residents of the WRTC DSA saw their access to transplants within the DSA further decline.

MedStar's insistence that disruption of its operations "is not a realistic concern," MedStar Cmts. at 4, is no more convincing than its assertion that it "has never experienced an operational problem that precluded patient access," *id.* at 5. A second center is in everyone's interest.

B. GW's Experience Proves the Benefits of Competition.

The addition of a second transplant program can increase volume for both the DSA and the existing center, as shown by GW's recent development of a kidney transplant program and the resulting growth in kidney transplants performed in the WRTC DSA. The GW program was launched in 2013. In the period of 2013 to 2016, the total kidney transplant volume performed in the WRTC DSA increased from 293 to 417. Additionally, the kidney transplant volume specifically at MedStar centers in the WRTC DSA increased from 163 to 205. Application at 26. This growth in volume occurred concurrently with the addition of a competitive program in the DSA.

MedStar's attempt to challenge the suggestion that competition may have contributed to this growth in volume relies on 2018 data annualized using only three months of actual data. MedStar Cmts. at 22, Exhibit 10. As explained above, this type of extrapolation is unreliable, and data for the most recently available calendar year support's Suburban's conclusions.

Furthermore, GW's Chief Executive Officer Kimberly D. Russo explained her firsthand experience with the benefits of competition. Exhibit 2 (GW Letter of Support). She explained the effect that GW's new liver transplant program had on

the sole existing kidney transplant program in D.C. The existing program hired a new surgeon and increased its outreach efforts. That center then performed more transplants than it had in years.

Accordingly, it is unsurprising that Ms. Russo predicts similar benefits from Suburban's program in the WRTC DSA.

C. The Relevant Scientific Literature Confirms the Benefits of Intra-DSA Competition.

In its application, and in responses to the Commission's completeness questions, Suburban explained that scientific research has shown that in a non-competitive DSA, the single program in that DSA is less likely to make proper use of marginal organs. Suburban Application at 49-51 & Suburban's Answer to Completeness Question 28 (citing Adler, Joel T., *et al.* "Is Donor Service Area Market Competition Associated With Organ Procurement Organization Performance?" Transplantation 100.6 (2016): 1349-1355, at 1353). MedStar has confirmed the accuracy of this model. As noted, MedStar has explained that its "standard practice" is to avoid using marginal organs (which it terms "less-than-ideal grafts") with sicker patients. MedStar Cmts. at 7. That is precisely what the Adler article predicted would occur in a non-competitive DSA.

In response, MedStar contends that this paper has "significant limitations." MedStar Cmts. at 16. First, MedStar argues that the Adler analysis should not be applied because it predates Share 35. But MedStar's standard practice applies to patients with MELD scores below 35, and it is those patients that Suburban intends to serve. Second, MedStar faults the authors for failing to discuss "liver transplants

performed in each strata of the Artificial Neuronal Network," and for failing to discuss the Incidence Rate Ratio. *Id.* at 17. But MedStar doesn't apply these concepts either, let alone explain how either could alter the authors' conclusions.

MedStar also points to the Halldorson paper's identification of potential negative effects of competition within a DSA. MedStar Cmts. at 18. But these negative effects have not been seen in the LLF DSA, and MedStar offers no persuasive prediction that they will occur in the WRTC DSA. Instead, MedStar relies on an inflated assessment of its own performance in an attempt to mask the effect of the lack of competition in the WRTC DSA. The data reflects the problems in the WRTC DSA that the cited literature associates with a lack of competition. In a DSA in which the relationship between outcomes and competition is consistent with the literature, there is every reason to expect that the introduction of a competing center will have the beneficial effects described in the literature.

D. While a Second Center May Enhance the Local OPO, DSA Performance is What Matters.

MedStar contends that introducing competition into the WRTC DSA will have no effect on the productivity of the OPO (as distinct from the centers within the DSA). MedStar Cmts. at 11, 18. The OPO works closely with the transplant programs within a DSA. The introduction of a second center, including a new team of surgeons, staff, and physicians, will likely enhance the operations of the OPO. But, as discussed, the real benefits of competition are at the center level.

E. The Bygone Programs at Howard and Inova Are Irrelevant.

MedStar argues that "the effect of competition on OPO performance is not substantiated by the relevant experience" of the WRTC DSA. Medstar Cmts. at 20. While mentioning these programs by name, Howard University Hospital (Howard) and Inova Fairfax Hospital (Inova), MedStar elides the fact that one program has been shuddered for more than a decade and the other for more than two decades. Indeed, Howard has not performed a liver transplant since 1997, while Inova has not performed a liver transplant since 2006.

MedStar's claim that "[t]he former programs failed while the latter has sustained steady growth over and above volumes achieved historically, while maintaining superior outcomes, i.e., total liver transplant volume has increased steadily in the setting of less competition within the DSA," might be compelling if weren't for the simple fact that volumes across the country have increased significantly since 1997 and since 2006. MedStar Cmts. at 24. This line of argument —that Inova and Howard's liver transplant programs are relevant even though they closed 12 and 21 years ago—is inconsistent with MedStar's earlier claim that data used in the Halldorson paper is "not applicable to liver transplantation in 2018" because the data predates 2009. MedStar Cmts. at 18.

In sum, MedStar has offered no reason why competition will not cure the disparities between the LLF DSA and WRTC DSA.

III. MedStar's Position Conflicts with its Franklin Square Application.

Soon after Suburban submitted its liver transplant application, MedStar submitted applications to establish both kidney and liver transplant programs at MedStar Franklin Square in Baltimore. In its application to open a third liver transplant program in the LLF DSA, MedStar contends that a new liver program at Franklin Square will increase access for MedStar patients. MedStar Franklin Sq. Liver Application at 55. And yet, the crux of MedStar's comments regarding the Suburban application is that a new program will not increase access. MedStar Cmts. at 25.

Also in its application, MedStar describes the distance from Baltimore to Georgetown as a "geographic challenge for many." MedStar Franklin Sq. Liver Application at 55. In that context, MedStar acknowledges the benefits of having a transplant program closer to patients' homes. *Id.* at 62. It also recognizes the benefits to patients to list in centers located in both DSAs. *Id.* at 61. Yet in its comments regarding Suburban's proposal, MedStar resists even the idea of patient "migration." MedStar Cmts. at 4. Further, MedStar argues that "in areas of close geographic proximity, there should not be an expectation that residents of a DSA with arbitrary borders should be transplanted within that same DSA." *Id.*

But MedStar can't have it both ways. The inconsistency in its positions further undermines its comments regarding Suburban's application.

Conclusion

For these reasons, MedStar's comments fail to diminish the force of Suburban's showing that its proposed project at Suburban Hospital has met all of the applicable review criteria. In short, approving this application will further the Commission's desire to "safely and effectively meet the health care needs of appropriate patients." SHP Organ Transplant Services Chapter, Policy 1.

Respectfully submitted,

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Baltimore, Maryland 21202

Counsel for Suburban Hospital

AFFIRMATION

I solemnly affirm under the penalties of perjury that the facts stated in Applicant Suburban Hospital's Response to Interested Party Comments of MedStar Georgetown University Hospital are true and correct to the best of my knowledge, information and belief.

Dated: May 15, 2018

Benjamin Philosophe, MD, PhD
Surgical Director
Comprehensive Transplant Center
Johns Hopkins Medicine

CERTIFICATE OF SERVICE

I certify that on May 15, 2018, I caused a copy of Applicant Suburban Hospital's Response to Interested Party Comments of MedStar Georgetown University Hospital to be mailed, postage prepaid, to:

David C. Tobin, Esq.
TOBIN O'CONNOR & EWING
5335 Wisconsin Avenue, N.W.
Suite 700
Washington, DC 20015

Conor B. O'Croinin

Exhibit 1

SRTR Program-Specific Reports
Adult (18+) 1-Year Survival With Functioning Graft

Georgetown University Medical Center

C. Transplant Information

Table C6. Adult (18+) 1-year survival with a functioning graft
Single organ transplants performed between 01/01/2012 and 06/30/2014
Deaths and retransplants are considered graft failures

	DCGU	U.S.
Number of transplants evaluated	195	13,353
Estimated probability of surviving with a functioning graft at 1 year (unadjusted for patient and donor characteristics)	83.55%	88.62%
Expected probability of surviving with a functioning graft at 1 year (adjusted for patient and donor characteristics)	88.77%	--
Number of observed graft failures (including deaths) during the first year after transplant	30	1,442
Number of expected graft failures (including deaths) during the first year after transplant	19.75	1,442
Estimated hazard ratio*	1.47	1.00
95% credible interval for the hazard ratio**	[1.01, 2.02]	--

* 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, [1.01, 2.02], indicates the location of DCGU's true hazard ratio with 95% probability. The best estimate is 47% higher risk of graft failure compared to an average program, but DCGU's performance could plausibly range from 1% increased risk up to 102% increased risk.

Figure C3. Adult (18+) 1-year graft failure HR estimate

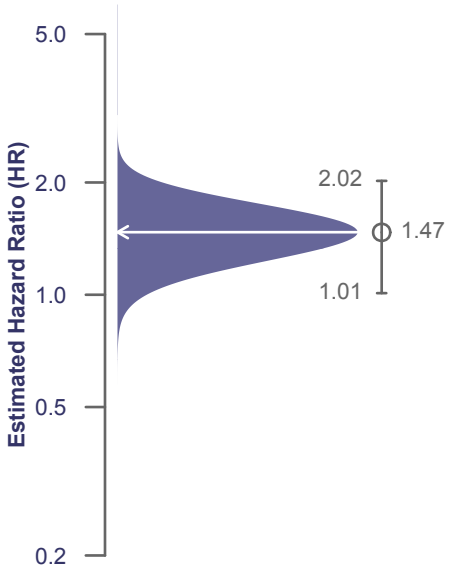
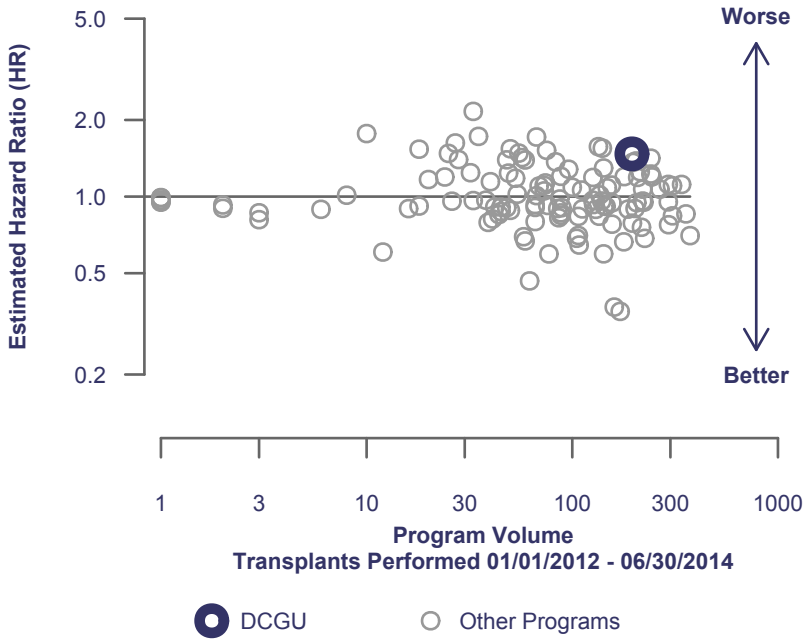


Figure C4. Adult (18+) 1-year graft failure HR program comparison



C. Transplant Information

Table C6. Adult (18+) 1-year survival with a functioning graft
Single organ transplants performed between 07/01/2012 and 12/31/2014
Deaths and retransplants are considered graft failures

	DCGU	U.S.
Number of transplants evaluated	186	13,612
Estimated probability of surviving with a functioning graft at 1 year (unadjusted for patient and donor characteristics)	83.59%	88.61%
Expected probability of surviving with a functioning graft at 1 year (adjusted for patient and donor characteristics)	88.62%	--
Number of observed graft failures (including deaths) during the first year after transplant	29	1,466
Number of expected graft failures (including deaths) during the first year after transplant	18.67	1,466
Estimated hazard ratio*	1.50	1.00
95% credible interval for the hazard ratio**	[1.02, 2.07]	--

* 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, [1.02, 2.07], indicates the location of DCGU's true hazard ratio with 95% probability. The best estimate is 50% higher risk of graft failure compared to an average program, but DCGU's performance could plausibly range from 2% increased risk up to 107% increased risk.

Figure C3. Adult (18+) 1-year graft failure HR estimate

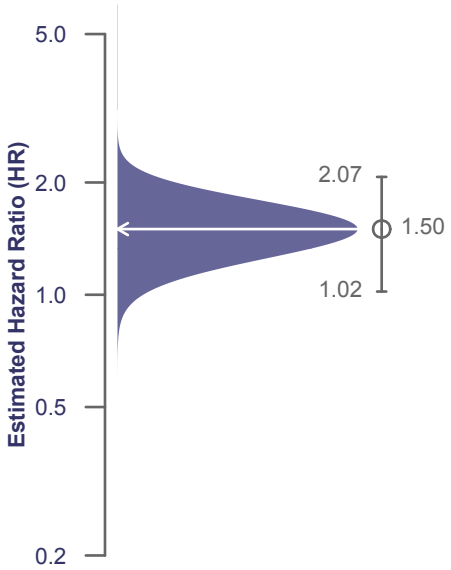


Figure C4. Adult (18+) 1-year graft failure HR program comparison

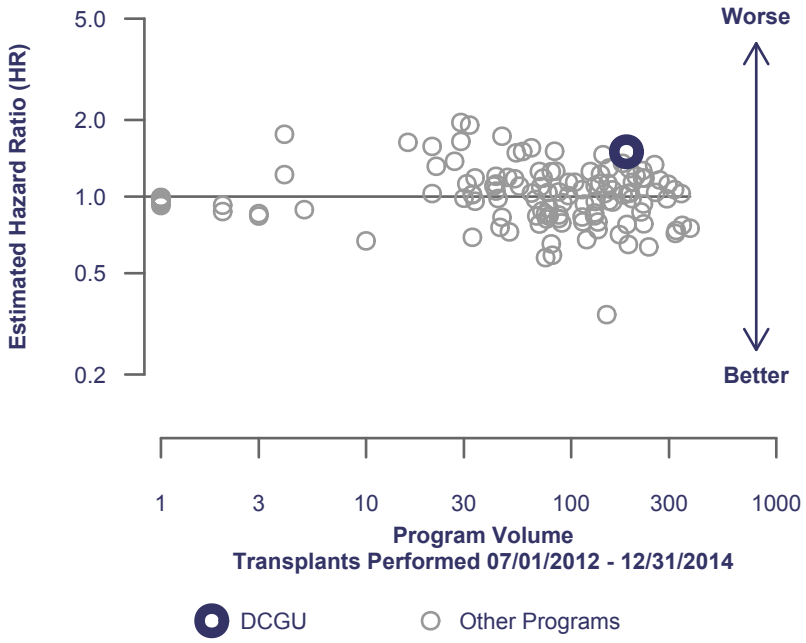


Exhibit 2

Letter of Support

George Washington University Hospital: Chief Executive Officer, Kimberly D. Russo, MS, MBA

THE GEORGE WASHINGTON
UNIVERSITY HOSPITAL

900 23rd Street, NW
Washington, DC 20037
(202) 715-4000
www.gwhospital.com

April 12, 2017

Mr. Ben Steffen
Executive Director
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland
21215-2299

RE: Suburban Hospital's CON Application to Establish a Liver Transplant Program

Dear Mr. Steffen,

I write on behalf of George Washington University Hospital ("GWUH") to support Suburban Hospital's proposal to establish a liver transplant program in Montgomery County in order to improve accessibility to transplant services in the state. I am the Chief Executive Officer of GWUH and have witnessed firsthand the importance of providing transplant services in the place where they are needed and the tremendous benefits that market competition, particularly centered on community outreach, can have on a transplant community.

In 2015, GWUH opened the GW Transplant Institute, offering a second kidney transplant option for adult, non-military patients in the District of Columbia. The Institute was projected to perform 7 and 23 kidney transplants in its first and second years of operation, respectively. Due to our talented surgeons and tremendous outreach efforts, the Institute performed 31 and 55 kidney transplants – nearly tripling those early projections. We found that through aggressive community outreach, we were able to identify those patients in greatest need of kidney transplants and improve awareness of living donor opportunities, increasing the number of transplantable organs within and imported to the District. And due to the expertise of our physicians, the Institute frequently transplants high risk patients who previously were rejected by other area programs. Because the sole existing kidney transplant program (i.e., adult, non-military) in the District was suddenly faced with competition, that hospital hired a new surgeon and increased its own outreach efforts. As a result, that existing program has actually performed more kidney transplants since our Institute opened than it had in many years. In short, it was forced to "up its game."

After stagnant rates of kidney transplants performed annually in the District, the addition of a second kidney transplant program at GWUH increased transplant volumes by 66% from 2014 to 2016. This increase greatly benefitted the overall D.C. community, particularly certain low income areas of the city, which you may know has the highest rate of kidney disease in the nation.

We believe our experience – and the resulting benefits for area kidney transplant patients – foreshadows the likely positive impacts of Suburban Hospital's proposed liver transplant program. Existing Maryland liver transplant programs exclusively transplant patients in Baltimore, as would the program proposed in another pending CON application. There remains a critical need for access for those patients who reside elsewhere – notably in the densely populated Maryland suburbs of D.C. Such patients must currently choose between utilizing the single liver transplant option in the District or commuting to Baltimore to be transplanted. Given our recent experience in the kidney transplant arena, we suspect strongly that the provision of liver transplant services in Montgomery County – and the introduction of liver transplant program competition in the D.C. area – will benefit Maryland and D.C. residents alike and greatly improve access for those Maryland residents for whom Baltimore is not an viable option.

We fully support Suburban Hospital's efforts to serve liver transplant patients who reside outside of Baltimore, and we urge you to approve the hospital's proposed liver transplant program.

Sincerely,

Kimberly D. Russo, MS, MBA
Chief Executive Officer