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April 30, 2018

**Via hand delivery and e-mail**

Mr. Kevin McDonald
Chief, Certificate of Need
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

**Re:** **Suburban Hospital** Docket Number 17-15-2400 – Interested Party Comments on behalf of MedStar Georgetown University Hospital

Dear Mr. McDonald:

On behalf of MedStar Georgetown University Hospital ("MGUH"), we offer these comments on the Certificate of Need ("CON") application from Suburban Hospital for a liver transplant program, Docket Number 17-15-2400. MGUH's physical address is 3800 Reservoir Road, N.W., Washington, D.C. 20007, located in the Metropolitan Washington health planning region.

MGUH requests that it be granted interested party status in this application. MGUH provides liver transplant services such as those sought to be provided by the applicant. MGUH is a wholly owned subsidiary of MedStar Health, Inc. ("MedStar"). MedStar is a non-profit, regional health care system in the Maryland-Washington D.C. Region. MGUH is the 11th largest transplant center in the United States, and the second largest transplant center in the Baltimore-Washington D.C. region, behind only the University of Maryland Medical System (based on 2016 data).

MGUH qualifies as a "person" under COMAR 10.24.01.01B(31) who would be "adversely affected" by the Suburban Hospital CON under COMAR 10.24.01.01B(2)(a) and B(20)(e) because MGUH is "authorized to provide the same service as the applicant, in the same planning region used for purposes of determining need under the State Health Plan." *Id.* at B(2)(a).

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For the reasons outlined below, MGUH opposes the Suburban application. Specifically, pursuant to COMAR 10.24.01.08F(1)(c), MGUH submits that the application fails to demonstrate a need for the program (COMAR 10.24.15.05B(1)) or that barriers to access exist (COMAR 10.24.15.05B(3)). As demonstrated in the attached comments, general concerns from MGUH can be summarized into the following categories:

- The data on transplant volumes does not support the claim that a new progam is needed;

- Scientific literature and actual experience do not support the claim that increased competition leads to increased numbers of transplants and improved patient survival; and

- The methodologies supporting the arguments regarding migration of patients and import/export of organs are inappropriate.

MGUH believes that a number of factual inaccuracies are present in the Suburban application that warrant response and clarification and accordingly requests either an opportunity to Present Oral Argument pursuant to COMAR 10.24.01.09A(3), or an evidentiary hearing pursuant to COMAR 10.24.01.10D.

As a result, the case made by Suburban for the need for a new liver transplant program based on barriers to access in the Washington region is neither objective nor valid, and accordingly should be denied. Detailed comments relating to specific language in the Suburban application are made in **blue**, following actual quotations from the Suburban application, shown in **grey**. COMAR Review Standards are **bolded**.

We appreciate the opportunity for review and comment.

Sincerely,

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## *COMMENTS FROM MEDSTAR HEALTH (Interested Party)*

**Surburban Hospital Certificate of Need Application for Liver Transplant (Applicant)**

**COMAR 10.24.15 ORGAN TRANSPLANT SERVICES CHAPTER**

**.05B PROJECT REVIEW STANDARDS**

**Standard .05B(1) – Need**

**An applicant shall demonstrate that a new or relocated organ transplant center is needed. An applicant shall address:**

**(a) The ability of the general hospital to increase the supply or use of donor organs for patients served in Maryland through technology innovations, living donation initiatives, and other efforts.**

**Suburban Hospital (summary of "Need" argument quoted from the application):**

"Data reflecting liver transplants performed and liver transplants received within these two DSAs reveal striking disparities in transplant volume, access, acuity, organ supply, and wait lists:

Volume: Despite serving a larger population, the single WRTC transplant facility performs fewer liver transplants than the two LLF facilities, and this gap is widening". (Application page 23).

***MedStar Georgetown University Hospital (MGUH) Response:***

*The data and discussion presented by Suburban Hospital in its attempt to demonstrate need for the proposed project based on an ability to increase the supply or use of donor organs lack validity and are misleading, on the grounds detailed below*

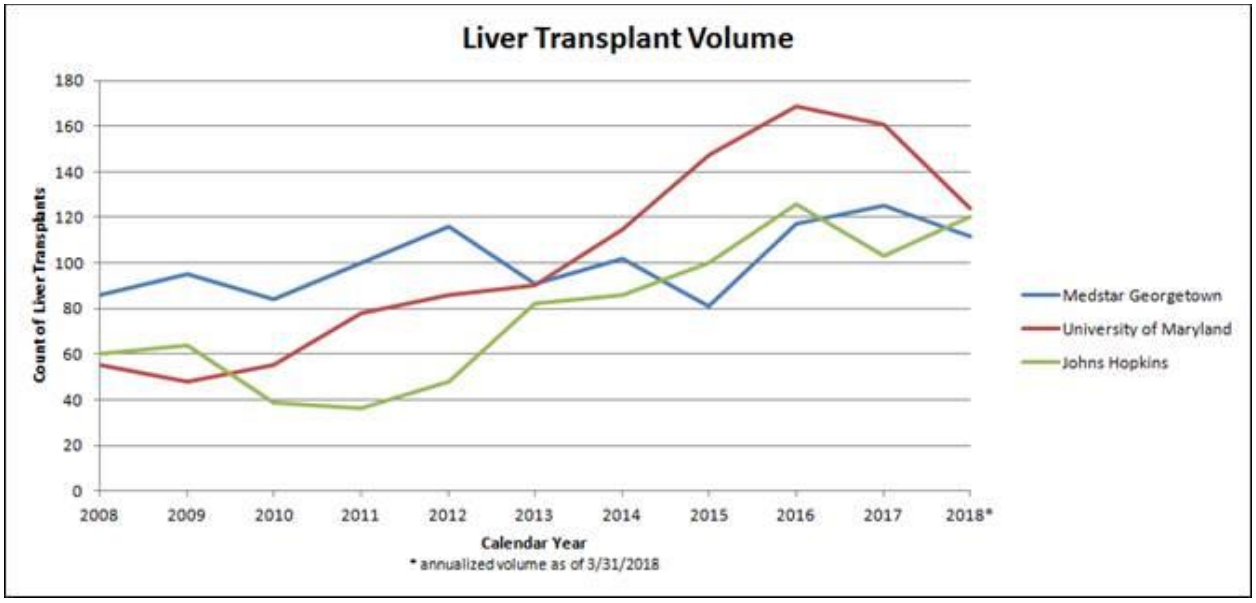
- *The impact of a new program can only be extrapolated from its current level of activity. By combining its data with that of a separate, unrelated entity (UMMS),*

*JHH's basic assumptions regarding a new program - as well as the projections for its future performance - are not realistic.*

- *Transplant volume cannot be tied specifically to population density but rather to many variables including the time that a program has been in operation, physician referral patterns (that fluctuate over time), patient and donor selection (that evolve over time), availability of organs (determined by a variety of factors) and allocation policy (governed by CMS/UNOS). Exhibit 1 demonstrates that volume among all programs varies over the decade, with gaps widening and narrowing, as a consequence of internal programmatic developments. One can observe decreases in volume at individual centers due to the program taking a more conservative position in terms of recipient and donor selection, in order to improve patient/graft outcomes. This phenomenon among programs is well known.*
- *Exhibit 1 also demonstrates that the JHH program historically has performed at a lower volume threshold than the MGUH program. A further decrease in JHH volume occurred several years ago when CMS sanctioned the program for poor outcomes, during which time the program admitted to temporarily adopting more conservative organ acceptance practices. This phase ended with the release of the program from CMS scrutiny, creating a reversal in activity over time. UMMS demonstrated a significant increase in volume associated with new surgical leadership of their program during the 2014-2016 years; volume has contracted somewhat more recently.*
- *MGUH volume also is seen to have fluctuated over time, though less markedly, due to stable programmatic and institutional leadership and outcomes.*

- *As clearly shown in Exhibit 1, the volume gaps are narrowing dramatically among all Centers.*

***EXHIBIT 1: 10 YEAR VOLUME BY PROGRAM[1]***




**Suburban Hospital:**

"Access: A similar discrepancy exists with regard to access. LLF residents are nearly four times more likely to obtain a transplant within their DSA than WRTC residents are to receive a transplant within their DSA." (Application page 23).

"There are multiple ways to assess barriers in access to liver transplantation, including center volume, transplant rates, migration of residents in order to access transplant, acuity of patients, and wait listing." (Application page 114).

"Access Disparity … A related explanation … is that a DSA with only one center is more vulnerable to disruptions that occur within the single transplant center than a DSA with multiple centers. For instance, when a single centers suffers an unexpected

[1] Source: UNOS.org/data. Transplants performed until March 31, 2018 as of April 10th, 2018.

loss of personnel (e.g., the loss of a surgeon, hepatologists, etc.) or experiences other operational issues (e.g. bed shortage, ICU shortage, infectious outbreaks), the adverse effects on patient access within the services area are immediately felt and can last for months. Such circumstances ultimately depress the ability of single-center DSA residents to obtain transplant services locally." (Application pages 31-32)

***MGUH Response:***

*As detailed below, a new program will not lead to increased access.*

*Migration and Wait-listing. Patient "migration" is not a phenomenon used in transplant parlance to describe the movement of individuals between geographical areas for evaluation for transplantation. Rather, wait-listing for transplant at one program or another is typically motivated by individual preference, referring physician recommendation, family support, perceived reputations of individual centers and many other variables that may change over time. Furthermore, 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. In light of the liver organ allocation policy mandated by CMS, "migration" based on "access" simply does not occur, and thus should be ignored.*

*Single-Center vulnerability. Potential operational disruption of a single transplant center is not a realistic concern. MGUH has six full-time liver transplant surgeons and 7 full-time hepatologists – thus, physician staffing is never an issue. MGUH has sufficient beds available - including critical care beds - and the capability to expand if demanded, as demonstrated by the recent opening of 12 intermediate beds earmarked for advanced liver disease patients specifically. (Note also that MGUH is in*

*the process of building a new pavilion that will house a variety of surgical services, and new state of the art operating rooms.) MGUH's transplant program has never experienced an operational problem that precluded patient access. To the contrary, when sanctioned by CMS due to poor outcomes, JHH was mandated to offer its patients' wait-listing at other nearby programs; patients were sent letters offering them MGUH as an alternative. MGUH had then, and continues to have, both capacity and capability. MGUH's program has never been sanctioned.*

**Suburban Hospital:**

Population Health Initiatives Suburban submits that Johns Hopkins will build a Regional Center of Excellence for Liver Disease, deploy trained nurse coordinators, increase access to experienced liver specialists, etc. (Application page 158).

***MGUH Response:***

*MGUH has seven established and functioning evaluation centers at sites distributed around the Baltimore-Washington area; volumes of patient visits and evaluations at MGUH sites have been growing steadily. Conversely, JHH has but two hospital-centric sites located at Suburban and Sibley hospitals. MGUH has a full cadre of nurse coordinators and social workers assigned on-site at its various locations as well as staff availability via telemedicine technology. While the applicant proposes to expand sites "if [the application is] approved", MGUH is already serving patients closer to their communities. As well, many patients from the Johns Hopkins sites at Sibley and Suburban continue to enjoy access to liver transplant services at MGUH.*

**Suburban Hospital:**

**"**Acuity: The average MELD score for patients receiving a transplant in the WRTC center is much lower than for patients receiving a transplant in the LLF centers, meaning that the single WRTC facility tends to perform transplants on healthier adult patients". (Application page 23).

***MGUH Response:***

*The data on which this argument is premised are outdated. More recent data demonstrate that the distribution of high MELD patients as a proportion of the transplant experience changes over time. No statistically significant differences have been presented in the Suburban application. Rather, the applicant makes a qualitative statement on the basis of a single SRTR reporting period.*

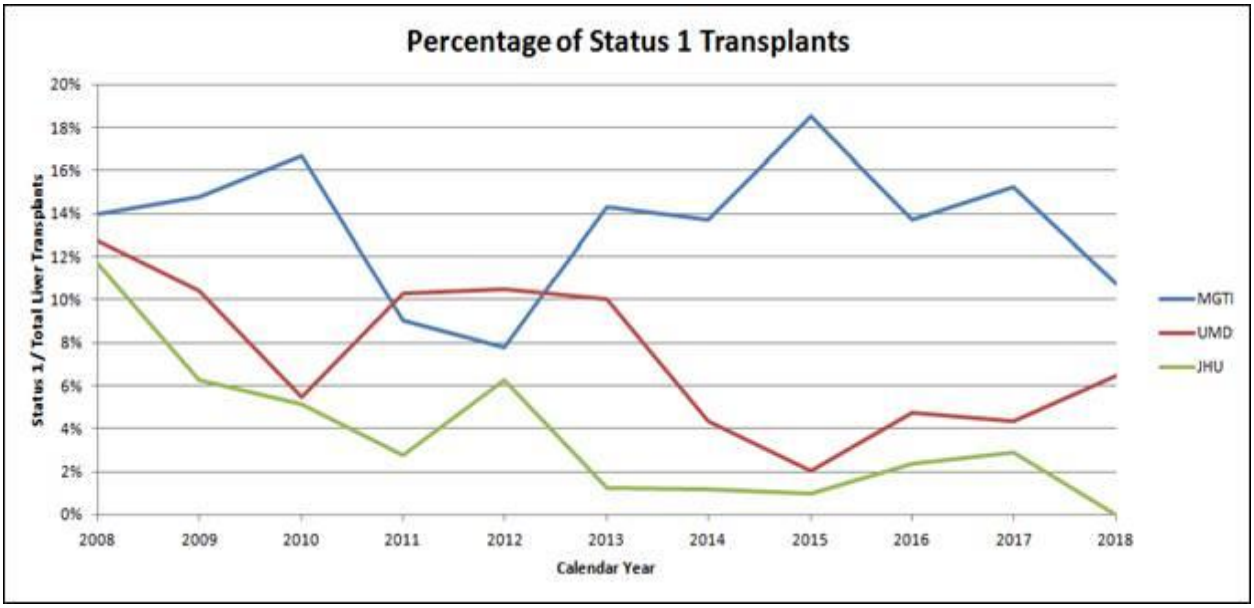
*In addition, the most seriously ill patients requiring liver transplantation are "Status 1" patients - those who will survive only hours without a liver transplant. MGUH performs many more transplants in this category than either the JHH or UMMS program. In fact, the Status 1 group, when combined with other high MELD score categories, represents a far higher proportion of acutely ill patients than that reported in the Suburban application, which selectively chose a limited cohort of patients to support its argument. As Exhibit 2 demonstrates, although a Center may present a large percentage of higher acuity patients in a given period of time, these levels fluctuate randomly as a consequence of changes in allocation policy and annual DSA OPO performance characteristics. Fluctuation in MELD scores does not necessarily reflect uniquely divergent medical practices at one center and certainly is not indicative of "access" issues.*

*Finally, a recent publication suggests that MELD profile differences exist at all levels of allocation, including within a single DSA.[2] MELD as a measure of acuity is not in itself an appraisal of access to transplant - and centers that are aggressive in utilizing higher-risk organs often demonstrate a broader range of MELD scores than more conservative centers. In other words, the greater the number of extended criteria donors that are accepted, the more likely it is that those organs will be utilized in patients with relatively lower MELD scores because the allocation system matches the presumed highest functioning organs preferentially (and appropriately) to the highest acuity recipients. Hence, a center that accepts less-than-ideal grafts for its relatively lower MELD patients (in whom those grafts are expected to be successful), effectively drives down its median MELD score. This approach, a standard practice at MGUH, actually reflects an efficient strategy that increases patients' overall access to transplant.*

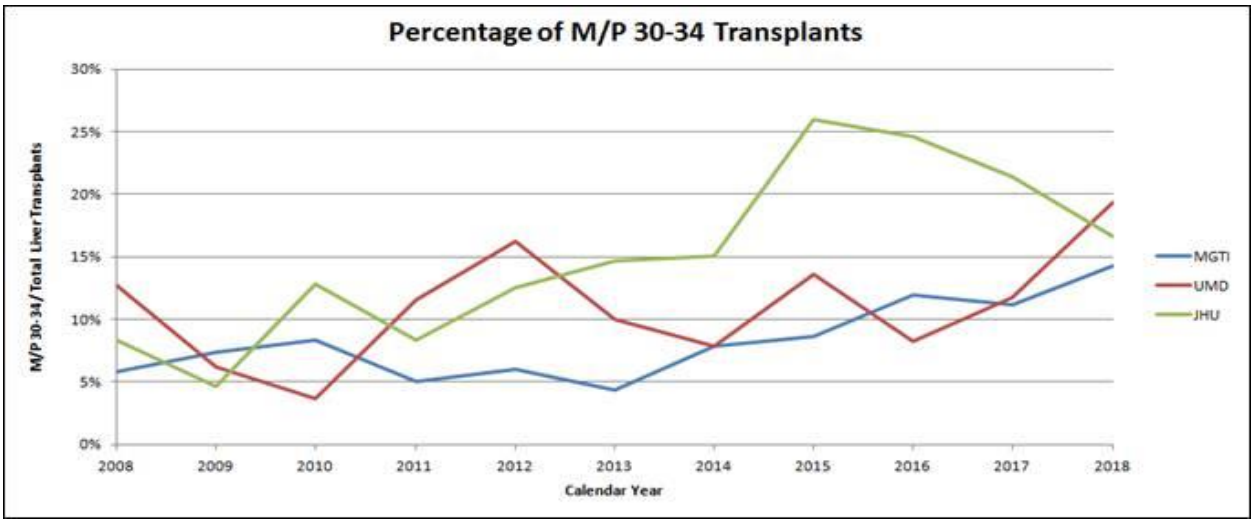
*Exhibit 2 shows the variability of patients at three levels of acuity over time: Status 1, MELD 30-34 and MELD >35. Note convergence of the lines in the second and third graphics for the most recent time frames.*

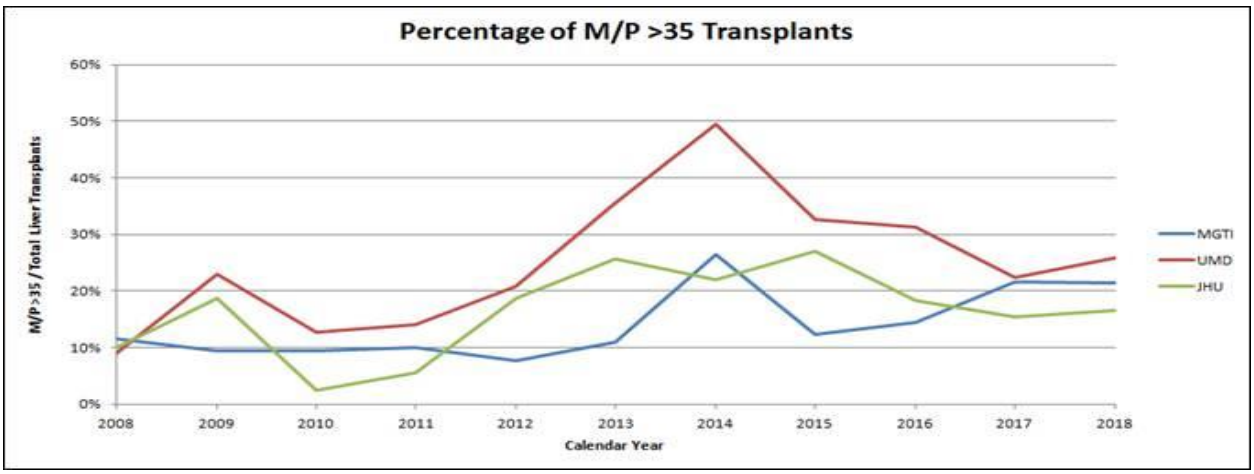
[2] Croome, *et al.* "Intraregional Model for End-Stage Liver Disease Score Variation in Liver Transplantation: Disparity in Our Own Backyard." *Liver Transplantation* 24, no. 4 (2018).

## *EXHIBIT 2: PATIENT ACUITY OVER TIME FOR THREE CENTERS* [3]




[3] Source: UNOS.org/data. Transplants performed until March 31, 2018 as of April 12th, 2018.




**Suburban Hospital:**

"Volume: Despite serving a larger population, the single WRTC transplant facility performs fewer liver transplants than the two LLF facilities, and this gap is widening." (Application page 23).

"Supply: WRTC procures fewer livers than the LLF and exports a higher proportion of the livers it procures. The WRTC center also imports fewer livers per year. This discrepancy is also growing". (Application page 23).

***MGUH Response:***

*Population. Although the WRTC DSA population is slightly larger than LLF, WRTC DSA has a lower number of deaths (not just eligible deaths). Exhibit 3 (SRTR.org) shows the number of deaths in the WRTC DSA (labeled DCTC DSA) where DCTC ranks 36/58. Concurrently, the death rate (the number of deaths per 1000 individuals) is shown at 5.61/1000; the DSA ranks 57/58, next to last. Exhibit 4 shows the LLF (labeled MDPC DSA) with the number of deaths ranking 35/58 and the death rate at 8.93/1000 at a rank of 21/58 - both values higher than DCTC. Hence, the MDPC has access to more organs than WRTC despite the slightly smaller population. Clearly, the addition of a transplant center will have no impact on the number of deaths – or death rate - within a DSA.*

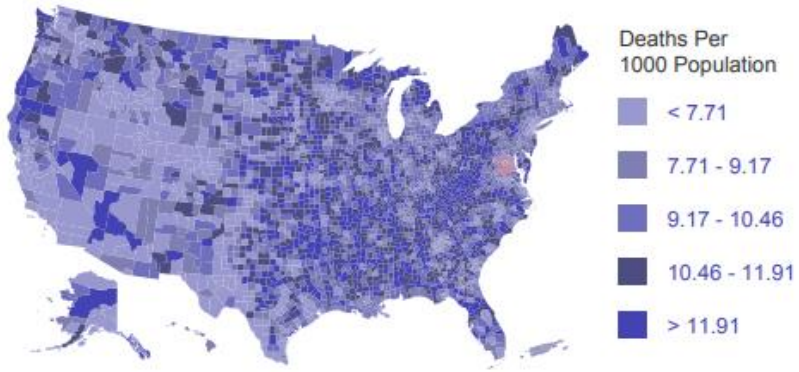
***EXHIBIT 3: WRTC (DCTC) DSA[4]***

**Figure B2. Deaths per 1000 population***

Deaths within DCTC's DSA: 30,639. This ranks 36th among the 58 DSAs (1st is the highest).

Death rate within DCTC's DSA: 5.61. This ranks 57th among the 58 DSAs (1st is the highest).

*US Census Bureau, 2015 projected death (includes all deaths, not limited to eligible deaths) and population




[4] Source: SRTR OPO Reports for DCTC and MDPC, Public Release Jan 5th, 2018 based on data as of Oct 31st, 2017.

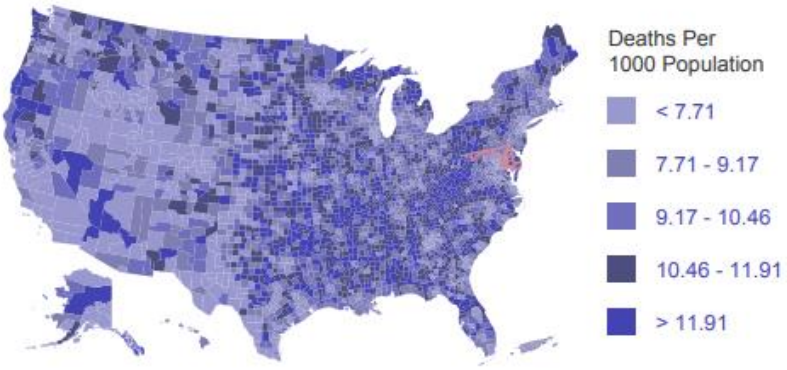
## *EXHIBIT 4: LLF (MDPC) DSA[5]*

**Figure B2. Deaths per 1000 population***

Deaths within MDPC's DSA: 34,829. This ranks 35th among the 58 DSAs (1st is the highest).

Death rate within MDPC's DSA: 8.93. This ranks 21st among the 58 DSAs (1st is the highest).

*US Census Bureau, 2015 projected death (includes all deaths, not limited to eligible deaths) and population




*Organ Procurement Organization (OPO) Performance . Although the Suburban application suggests that the WRTC OPO is "underperforming" in terms of the number of organs procured, SRTR.org data show that the WRTC is, in fact, performing slightly better than expected. Exhibit 5, WRTC PERFORMANCE, confirms an Observed donation rate 66.3/100 eligible deaths v. an Expected donation rate of 64.4/100 eligible deaths.*

[5] Source: SRTR OPO Reports for DCTC and MDPC, Public Release Jan 5th, 2018 based on data as of Oct 31st, 2017.

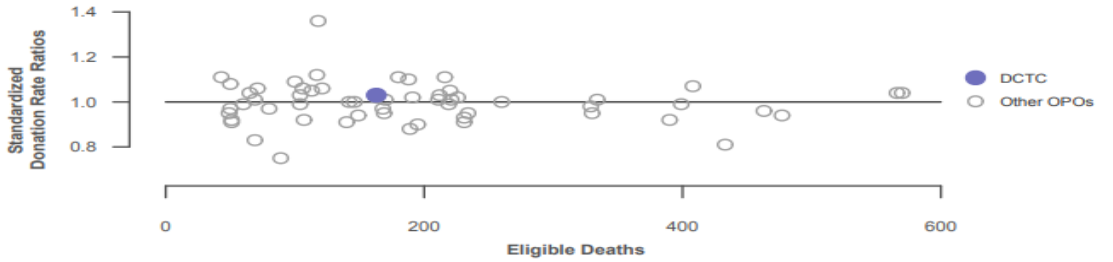
## EXHIBIT 5: WRTC PERFORMANCE[6]

**Table B1. Measures of donation rate*, 07/01/2016 to 06/30/2017**

| | | National | | |
|---|---|---|---|---|
| | DCTC | Min. | Average | Max. |
| Eligible Deaths | 163 | 43 | 195.17 | 570 |
| Deceased Donors (All) | 135 | 35 | 175.93 | 567 |
| Deceased Donors Meeting Eligibility Criteria | 108 | 29 | 137.71 | 428 |
| Observed Donation Rate Per 100 Eligible Deaths | 66.3 | 53.3 | 70.6 | 88.9 |
| Expected Donation Rate Per 100 Eligible Deaths | 64.4 | | | |
| Standardized Donation Rate Ratio (95% CI) | 1.03 (0.91,1.14) | | | |
| P Value | 0.630 | | | |

*The donation rate is calculated as the number of deceased donors meeting eligibility criteria per 100 eligible deaths.

**Figure B4. Standardized donation rate ratios (observed/expected), 07/01/2016 to 06/30/2017**




*Exports/Imports. All OPOs are subject to the national regulations (CMS/UNOS) governing organ allocation, which over time have resulted in increased regional sharing of organs. The self-created import-export equation methodology presented by Suburban presents no data suggesting that a new center would "increase the supply of organs in the WRTC [DSA]". Exhibits 6 and 7, sourced from the SRTR database, show the most recent import/export comparison between WRTC and LLF. Note that there is little difference in organs exported directly to one region over another. Organs travelling between centers do so because the allocation rules mandated by CMS require it.*

[6] Source: SRTR OPO Report for DCTC, Public Release Jan 5th, 2018 based on data as of Oct 31st, 2017.

## *EXHIBIT 6: EXPORTS FROM MDPC (LLF) TO ALL PROGRAMS*[7]

### E. Programs Transplanting Organs Procured by MDPC

**Figure E4. Programs transplanting livers procured by MDPC, 07/01/2016 to 06/30/2017***

● Location of OPO headquarters

* Transplants within the local area of the OPO are not always visible on the map due to scale. See Table E4 for full details.

**Table E4. Programs transplanting livers procured by MDPC, 07/01/2016 to 06/30/2017**

| Hospital Name (Code) | Geography* | Transplants |
|---|---|---|
| Johns Hopkins Hospital (MDJH) | Local | 60 |
| University of Maryland Medical System (MDUM) | Local | 73 |
| Albert Einstein Medical Center (PAAE) | Regional | 2 |
| Allegheny General Hospital (PAAG) | Regional | 3 |
| Children's Hospital of Philadelphia (PACP) | Regional | 1 |
| Children's Hospital of Pittsburgh of UPMC (PACH) | Regional | 2 |
| Geisinger Medical Center (PAGM) | Regional | 1 |
| Georgetown University Medical Center (DCGU) | Regional | 8 |
| Hospital of the University of Pennsylvania (PAUP) | Regional | 2 |
| Our Lady of Lourdes Medical Center (NJLL) | Regional | 1 |
| University Hospital (NJUH) | Regional | 4 |
| Children's Healthcare of Atlanta at Egleston (GAEH) | National | 1 |
| New York-Presbyterian Hospital/Weill Cornell Medical Center (NYNY) | National | 1 |

[7] Source: SRTR OPO Report for MDPC and DCTC, Public Release Jan 5th, 2018 based on data as of Oct 31st, 2017.

## *EXHIBIT 7: WRTC EXPORTS TO ALL PROGRAMS*[8]

### E. Programs Transplanting Organs Procured by DCTC

**Figure E4. Programs transplanting livers procured by DCTC, 07/01/2016 to 06/30/2017***

Location of OPO headquarters

* Transplants within the local area of the OPO are not always visible on the map due to scale. See Table E4 for full details.

**Table E4. Programs transplanting livers procured by DCTC, 07/01/2016 to 06/30/2017**

| Hospital Name (Code) | Geography* | Transplants |
|---|---|---|
| Georgetown University Medical Center (DCGU) | Local | 69 |
| Albert Einstein Medical Center (PAAE) | Regional | 5 |
| Allegheny General Hospital (PAAG) | Regional | 2 |
| Children's Hospital of Philadelphia (PACP) | Regional | 2 |
| Children's Hospital of Pittsburgh of UPMC (PACH) | Regional | 2 |
| Geisinger Medical Center (PAGM) | Regional | 1 |
| Hospital of the University of Pennsylvania (PAUP) | Regional | 3 |
| Johns Hopkins Hospital (MDJH) | Regional | 5 |
| Our Lady of Lourdes Medical Center (NJLL) | Regional | 1 |
| Penn State Milton S Hershey Medical Center (PAHE) | Regional | 1 |
| Thomas Jefferson University Hospital (PATJ) | Regional | 1 |
| University Hospital (NJUH) | Regional | 1 |
| University of Maryland Medical System (MDUM) | Regional | 7 |
| University of Pittsburgh Medical Center (PAPT) | Regional | 1 |
| Primary Children's Hospital (UTPC) | National | 1 |

[8] Source: SRTR OPO Report for MDPC and DCTC, Public Release Jan 5th, 2018 based on data as of Oct 31st, 2017.

*WRTC Exports: 33/102 (32%) were exported but only 5 went to JHH (and 7 to UMMS) versus other programs. For these reasons, the minor variations represented in the Suburban application can be seen to reflect evolving UNOS policy, which is intended - and continues - to improve access for the highest acuity patients. In other words, UNOS has determined that increased organ sharing, rather than more transplant centers, is the proper mechanism through which to address differences in OPO performance characteristics – and provide greater access to organs for the most severely compromised patients.*

*Finally, a note should be made of the potential for "artificially created need. JHH has two sites at which liver transplant evaluations are performed, and from which they refer all candidates to JHH for transplantation, despite the close proximity to MGUH. With that said, organs from the WRTC OPO will "follow" high acuity patients for which sharing is mandated under UNOS allocation policy - these livers are not leaving the DSA due to a lack of "access." In fact, as described earlier, MGUH will accept a less-than-ideal organ that may not suit a patient at the highest level of acuity, if it presents a reasonable and viable match for another patient on the waiting list who can benefit.*

**Suburban Hospital:**

"Wait List: The LLF waitlist currently has more than three times as many patients as the WRTC wait list…A likely contributor to some or all of these disparities is the absence of competition within the WRTC DSA". (Application page 23).

***MGUH Response:***

*Wait-list size is not, in itself, a true measure of need or transplant center performance. Criteria for wait-listing are center-dependent and change over time,*

*based on updated disease management standards and clinical protocol modifications, among other variables. Nor does careful review of the literature support the assertion that competition between programs effects improvement in OPO performance or increases the supply of available organs. Specific responses to other language and references in the Suburban application follow.*

**Suburban Hospital:**

Adler and Halldorson references regarding competition (Application pages 49-50).

***MGUH Response:***

*The current body of scientific literature does not support the argument that increased competition results in increased numbers of liver transplants or improved patient survival. The application of the Herfindahl-Hirshman Index (HHI) in this context is particularly problematic given the lack of inclusion of a variety of important variables particular to the geographical market, the specialized services and the highly detailed issues under consideration. In other words, critical variables that fit the issues being considered have been omitted. Following are specific limitations of the referenced studies:*

Adler, *et al*. "Is Donor Service Area Market Competition Associated with Organ Procurement Organization Performance?" *Transplantation* 100, no. 6 (2016).

*This paper has significant limitations which prevent the data from being applied to the current state of liver transplantation:*

- *Data used precede the implementation of Share 35. With Share 35 and increased regional sharing, the effect of center density within a DSA is reduced significantly. Future changes aimed at reducing geographic disparities in access to liver transplantation will reduce this effect further.*

- *The number of liver transplants performed in each strata of the Artificial Neuronal Network (ANN)[9] seems to follow population, as expected. ANNs with larger-served populations performed more transplants. This is not discussed in the paper.*
- *The most significant variable in increasing liver transplants - the Incidence Rate Ratio (IRR)[10] - is the number of donors; this factor is not discussed.*
- *Data is generalized from multiple DSAs and may not be specifically applicable to areas where access to liver transplant is not geographically restricted.*
- *The methodology of analysis is questionable. Novel measures of "competition" are used and multi-variate analysis is conducted using variables which were not significant on univariate analysis.*
- *Single center DSA ANN was unable to be calculated. This is problematic because many single center DSAs are still in close proximity to other centers.*
- *Competition was associated with increased graft failure (HR=2.17) but not associated with patient mortality. This suggests that competition within a DSA may lead to use of higher risk organs and increased costs related to performing repeat transplants in a single patient.*
- *As recognized by the authors, this paper looks at "clustering and dispersion, but it is sensitive to the area of a DSA, rather than the actual population served or the demand for liver transplantation. The DSA might not be perfectly representative of a market…"*

[9] Artificial Neural Networks **(**ANN**)** is the foundation of Artificial Intelligence (AI), solving problems that would be nearly impossible by human or statistical standards. In this context, ANN is a model for forecasting survival in liver transplant recipients.

[10] Rate ratio (IRR): A rate ratio (sometimes called an incidence density ratio) in epidemiology, is a relative difference measure used to compare the incidence rates of events occurring at any given point in time.

- *Like many studies looking at liver transplantation, this study cannot account for major determiners of liver transplant volumes: OPO performance, center performance, center listing practices and center acceptance of donor organs.*

Halldorson, *et al*. "Center Competition and Outcomes Following Liver Transplantation." *Liver Transplantation* 19, no. 1 (2013).

*The Halldorson paper overall is not applicable to liver transplantation in 2018 as the data presented (before 2009) preceded changes in organ allocation which resulted in increased regional sharing. Nonetheless, the paper highlights the following:*

- *Increased competition is associated with increased risk of graft failure.*
- *Increased competition is associated with increased risk of patient death after liver transplantation.*
- *Increased competition is associated with increased costs associated with transplant.*

*Actual Program Experience: OPO productivity versus competition. See the evidence provided in Exhibits 8 and 9 (source:SRTR.org) that program competition seems clearly to have no effect on OPO performance. Exhibit 8 shows that PADV (Philadelphia area) is the highest performing OPO in the country, with 8 highly competitive transplant programs. Exhibit 9 shows that NYRT (New York metro) is one of the lowest performing OPOs in the country with a comparable number of highly competitive programs (7). Both of these OPOs exist in a milieu of highly competitive transplant programs, both are located in the mid-Atlantic region of the U.S. with similar large urban populations, and yet the data reflect a marked disparity in livers produced for transplant. Thus, the theoretical argument for the benefits of competition is not reflected in the actual programmatic experience in our geographical area.*

## *EXHIBIT 8: PADV OPO DONATION RATES*[11]

*Note that PADV has an Observed donation rate of 75.1 per 100 eligible deaths, exceeding the expected donation rate of 72.0.*

**Table B1. Measures of donation rate*, 07/01/2016 to 06/30/2017**

| | | National | | |
|---|---|---|---|---|
| | PADV | Min. | Average | Max. |
| Eligible Deaths | 570 | 43 | 195.17 | 570 |
| Deceased Donors (All) | 567 | 35 | 175.93 | 567 |
| Deceased Donors Meeting Eligibility Criteria | 428 | 29 | 137.71 | 428 |
| Observed Donation Rate Per 100 Eligible Deaths | 75.1 | 53.3 | 70.6 | 88.9 |
| Expected Donation Rate Per 100 Eligible Deaths | 72.0 | | | |
| Standardized Donation Rate Ratio (95% CI) | 1.04 (0.99,1.09) | | | |
| P Value | 0.111 | | | |

*The donation rate is calculated as the number of deceased donors meeting eligibility criteria per 100 eligible deaths.

**Figure B4. Standardized donation rate ratios (observed/expected), 07/01/2016 to 06/30/2017**

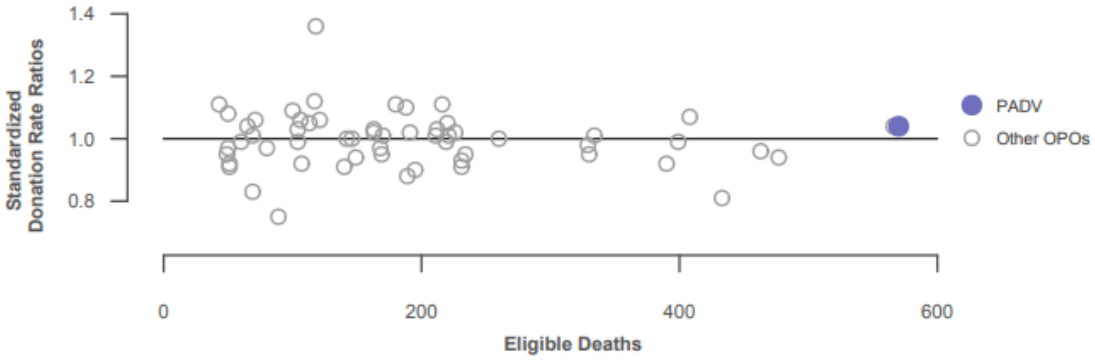



**Figure B5. Donations per 100 eligible deaths, 07/01/2012 to 06/30/2017**

[11] Source: SRTR OPO Report for PADV, Public Release Jan 5th, 2018 based on data as of Oct 31st, 2017.

## *EXHIBIT 9: NYRT DONATION RATES*[12]

*Note NYRT's observed donation rate of 53.3 per 100 eligible deaths, well under the expected rate of donation of 65.6.*

**Table B1. Measures of donation rate*, 07/01/2016 to 06/30/2017**

| | | National | | |
|---|---|---|---|---|
| | NYRT | Min. | Average | Max. |
| Eligible Deaths | 433 | 43 | 195.17 | 570 |
| Deceased Donors (All) | 290 | 35 | 175.93 | 567 |
| Deceased Donors Meeting Eligibility Criteria | 231 | 29 | 137.71 | 428 |
| Observed Donation Rate Per 100 Eligible Deaths | 53.3 | 53.3 | 70.6 | 88.9 |
| Expected Donation Rate Per 100 Eligible Deaths | 65.6 | | | |
| Standardized Donation Rate Ratio (95% CI) | 0.81 (0.74,0.89) | | | |
| P Value | <0.01 | | | |

*The donation rate is calculated as the number of deceased donors meeting eligibility criteria per 100 eligible deaths.

**Figure B4. Standardized donation rate ratios (observed/expected), 07/01/2016 to 06/30/2017**

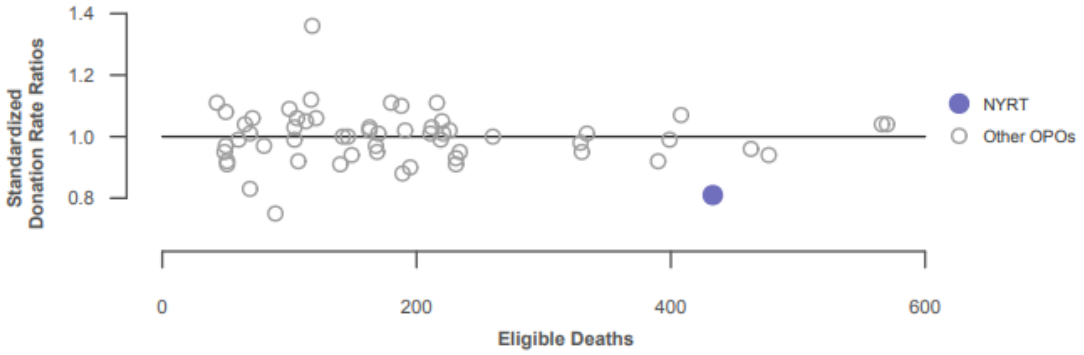



**Figure B5. Donations per 100 eligible deaths, 07/01/2012 to 06/30/2017**

*Additionally, WRTC had prior competition in the DSA, with 3 existing liver programs. Two of those failed, and one emerged as a strong, stable program over a long period of time (MGUH). During the time of competition, significantly lower total transplant volumes were evident, a phenomenon that has reversed under a single*

[12] Source: SRTR OPO Report for NYRT, Public Release Jan 5th, 2018 based on data as of Oct 31st, 2017.

*center with stable leadership. To summarize, the effect of competition on OPO performance is not substantiated by the relevant experience.*

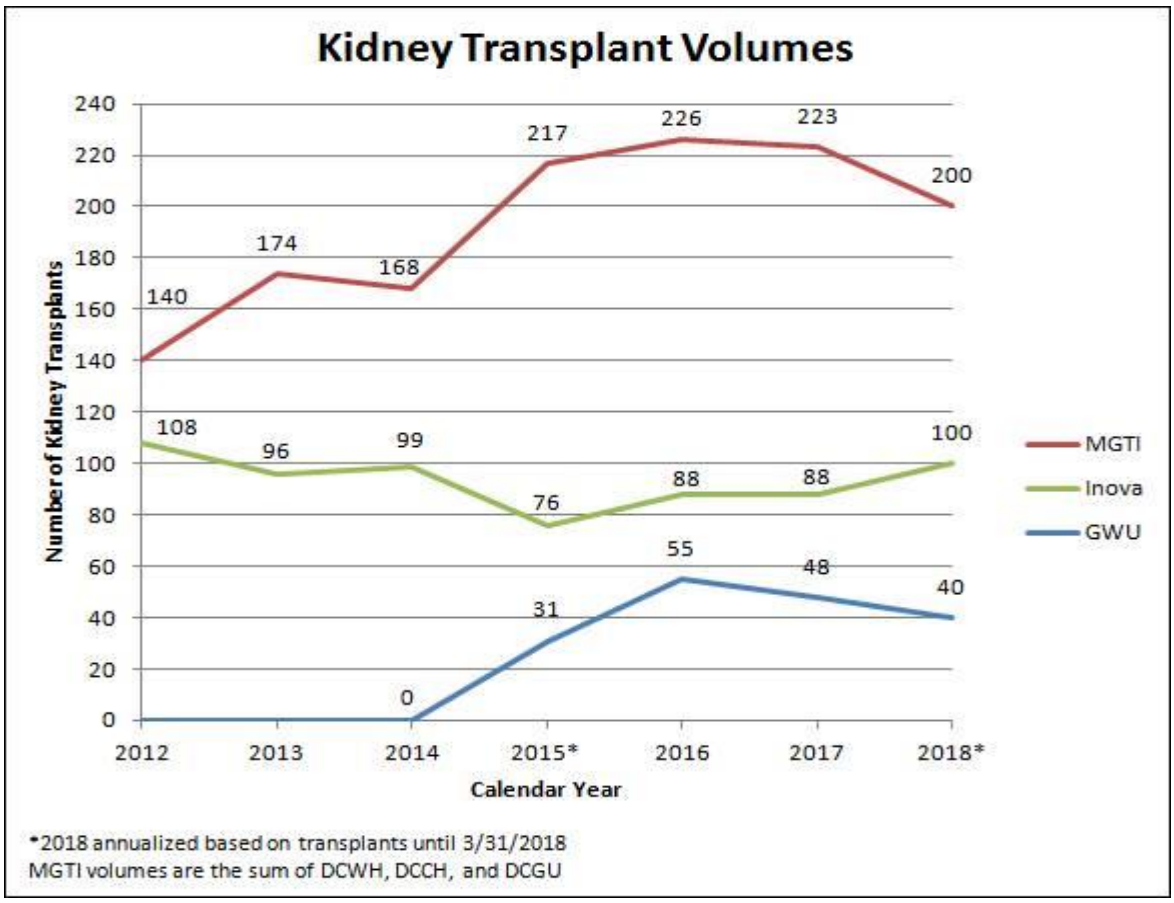
**Suburban Hospital:**

Suburban submits that increased competition will lead to increased transplant volumes, citing George Washington University's kidney transplant service. "There is every reason to believe that similar beneficial effects on transplant volume will result from increased competition for liver transplants in the WRTC". (Application pages 25-26)

***MGUH Response:***

*The reality is that GWU volume increases in 2016 (as well as virtually every other kidney transplant program in the country including MGUH) were attributable to the change in kidney allocation policy that went into effect concurrently with the inception of the GWU program. Exhibit 10 shows that the volume at GWU has not been sustained and is, in fact, declining.*

## *EXHIBIT 10: WRTC PROGRAM VOLUMES SINCE 2012[13]*




*Note also several other points relevant to the graphic:*

- *MGUH consolidated the volumes of its two programs (one at MedStar Washington Hospital Center) in July 2015. Aside from the increased volume, decreasing the competition between these programs resulted in greater efficiency in operations, volume growth overall and lower costs, all of which have been sustained. In our own experience, eliminating competition between programs has resulted in greater productivity.*

[13] Source: UNOS.org/data. Transplants performed until March 31, 2018 as of April 11th, 2018.

- *A decline in Inova Fairfax volume that occurred simultaneously with GWU program inception.*
- *GWU transplants are comprised of fewer than 50% DC residents, although a principal justification of "need" for this program was based on supporting the underserved in the DC community; a majority of GWU transplants come from the State of Maryland and a substantial number from Virginia, as confirmed by zip code data (Exhibit 11).*

### *EXHIBIT 11: GWU KIDNEY TRANSPLANT VOLUME BY YEAR AND ORIGIN[14]*

**Transplants by Donor Type**

U.S. Transplants Performed : January 1, 1988 - March 31, 2018

For Organ = Kidney, TXC = DCGW-TX1 George Washington University Hospital, Format = Portrait

Based on OPTN data as of April 11, 2018

Change Report (Optional) :

Organ: Kidney | Center: DCGW-TX1 George Washington University Hospital | Go

Add Field to Report : | Go

| | | To Date | 2018 | 2017 | 2016 | 2015 |
|---|---|---|---|---|---|---|
| All Donor Types | All Recipient States of Residence | 195 | 10 | 48 | 55 | 31 |
| | District of Columbia | 69 | 1 | 17 | 24 | 14 |
| | Maryland | 83 | 8 | 23 | 22 | 13 |
| | New York | 2 | 0 | 1 | 0 | 0 |
| | Ohio | 1 | 0 | 0 | 1 | 0 |
| | South Carolina | 1 | 0 | 0 | 1 | 0 |
| | Tennessee | 1 | 0 | 0 | 1 | 0 |
| | Virginia | 28 | 1 | 7 | 6 | 4 |
| | Unknown | 10 | 0 | 0 | 0 | 0 |

[14] Source: UNOS.org/data. Transplants performed until March 31, 2018 as of April 11th, 2018.

***SUMMARY from MGUH:***

*More programs does not equal more transplants. If it were so, then the large number of candidates on wait-lists nationally could be served easily by increasing the number of programs around the country. The WRTC region was once populated by three competing liver transplant programs at Howard University Hospital, Inova Fairfax Hospital and Georgetown University Hospital. The 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.*

*The application fails to present relevant data regarding volume, access, acuity, organ supply or center wait lists. The cited literature on competition in organ transplant programs does not support the argument for the many reasons enumerated. Therefore, the case made under review standard .05B(1) does not warrant approval of the application.*

**Standard .05B(3) – Access**

**(b) An applicant that seeks to justify the need for additional organ transplantation services on the basis of barriers to access shall:**

**(i) Present evidence to demonstrate that barriers to access exist, based on studies or validated sources of information, and**

**(ii) Present a credible plan to address those barriers. The credibility of the applicant's plan will be evaluated on whether research studies or empirical evidence from comparable projects support the proposed plan as a mechanism for addressing each barrier**

**identified, whether the plan is feasible, and whether members of the communities affected by the project support the plan.**

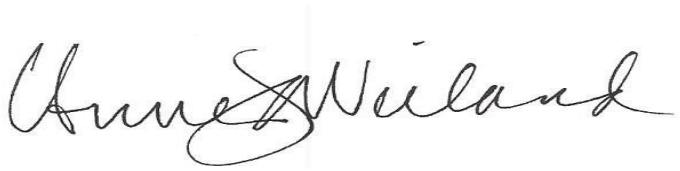
***MGUH response:***

*Neither objective nor validated evidence that barriers to access exist has been presented. Methodologies describing patient "migration" patterns have no basis in statistical data reporting mandated by national regulatory agencies – CMS, UNOS, SRTR.*

***CONCLUSION***

*As has been noted throughout this document, the applicant has failed to present credible evidence of Need or Access to transplantation services in the WRTC DSA, nor a credible plan to address these supposed barriers. The "Population-Health Initiatives" that are outlined on page 158 of the Suburban application outline additional steps to be taken by that program if the application is approved; MGUH is already serving the community in every way listed under the bulleted points underneath subparagraph b) of that section.*

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



***Anne P. Weiland,***
***Vice President, MedStar Health***
***on behalf of MedStar Health***
***Dated: April 30, 2018***