IN THE MATTER OF	*	BEFORE THE
MEDSTAR FRANKLIN SQUARE KIDNEY TRANSPLANT SERVICE	*	MARYLAND HEALTH
Docket No. 17-03-2405	*	CARE COMMISSION

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UNIVERSITY OF MARYLAND MEDICAL CENTER'S COMMENTS ON MEDSTAR HEALTH, INC.'S CON APPLICATION PROPOSING THE ESTABLISHMENT OF A KIDNEY TRANSPLANT SERVICE AT MEDSTAR FRANKLIN SQUARE HOSPITAL CENTER

University of Maryland Medical Center ("UMMC"), by its undersigned counsel and pursuant to COMAR § 10.24.01.08F, submits these comments addressing the Certificate of Need ("CON") Application and related materials filed by MedStar Health, Inc. ("MedStar") proposing to establish a kidney transplant service at Franklin Square Hospital Center d/b/a MedStar Franklin Square Medical Center ("MFSMC"). For the reasons described more fully below, UMMC respectfully asks that the Commission deny MedStar's Application. In the alternative, and as described more fully in the accompanying Motion for Stay of CON Review, UMMC requests that the Commission defer review of MedStar's application until the United Network for Organ Sharing finalizes its forthcoming changes to kidney allocation policy in December 2019, and require MedStar to update its analyses of its compliance with the applicable State Health Plan chapter and review criteria based on that new policy.

In addition to the following comments, and in an effort to avoid the review of duplicative information by the Commission and all parties, UMMC incorporates by reference as if fully set forth below: (i) UMMC's Motion for Stay, in full; and (ii) portions of the Interested Party Comments of The Johns Hopkins Hospital ("JHH") concerning MedStar's failure to demonstrate need for its proposed program or existing barriers to access for minority populations.

Statement of Interested Party Status

UMMC is an "interested party" within the meaning of COMAR § 10.24.01.01B(20) because UMMC 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. UMMC first opened kidney transplant services at its facility in downtown Baltimore since 1986. The State Health Plan Chapter for Organ Transplant Services, COMAR § 10.24.15, defines "the health planning regions for CON review of an application to establish or relocate organ transplant services in Maryland" to be "consistent with the OPO [Organ Procurement Organizations] designations." COMAR § 10.24.15.03, p. 8. MFSMC, JHH, and UMMC all fall within the Living Legacy Foundation service area designation, serving western and central Maryland, the Eastern Shore, Calvert, and St. Mary's Counties in southern Maryland. Id., pp. 7-8.

Introduction

The Maryland Health Care Commission (the "Commission") convened a Workgroup in October 2014 to recommend changes to the State Health Plan for Organ Transplant Services. The Workgroup engaged in a more than two year process involving the review of current organ transplant research, policies, and data. That process resulted in the current State Health Plan Chapter for Organ Transplant Services, COMAR § 10.24.15 (the "State Health Plan Chapter"), which the Commission unanimously voted to approve in January 2017. The State Health Plan Chapter recognizes that "[o]rgan transplantation is a specialized tertiary-level health service that requires clinical expertise and a hospital setting with the most advanced diagnostic, surgical, and monitoring equipment." COMAR § 10.24.15.03, p. 8. As a result, the Commission determined "the public is best served if a limited number of general hospitals provide specialized services to

a substantial population base." Id. The limitation of organ transplant services to high volume hospitals offering specialized care is associated with high quality of care, efficient scale of operation, and better patient outcomes. Id., pp. 8-16.

Despite the policy goals of the State Health Plan Chapter, MedStar proposes to create a low-volume kidney transplant program at a community hospital, MedStar Franklin Square Medical Center ("MFSMC"), within close proximity to two existing high volume programs, and within 50 miles of MedStar's high-volume MedStar Georgetown Transplant Institute ("MGTI") and adult kidney transplant programs at Inova Fairfax Hospital, George Washington University Hospital ("GWUH"), and Christiana Care Health Services.[1] MedStar's proposed low-volume program does not meet the policy goal of the State Health Plan Chapter to concentrate services at a limited number of high volume programs.

McdStar justifies its proposed low-volume program on the basis of several incorrect assumptions.

- MedStar's assertion that it will be able to increase the availability of organs in Maryland is based on generalized statements and lacks meaningful projections to support its volume assumptions.
- Despite MedStar's assertions in its application, the minority population in Maryland is well served by existing programs.
- MedStar underestimates the cost of its program, and improperly compares the cost effectiveness of its program to UMMC and JHH rather than to MGTI. MedStar projects

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[1] Source: https://srtr.org/transplant-centers/, search for programs within 50 miles of MFSMC Zip Code 21237. Walter Reed National Military Medical Center is also within 50 miles of MFSMC program.

shifting the majority of its volume from MGTI, which has lower Medicare and Medicaid charges than the projected charges for MFSMC.

Even if MedStar had complied with the State Health Plan Chapter, the Commission should still delay review of MedStar's application because national kidney allocation policy will fundamentally change in fourteen months in a way that will undermine much of the analysis in MedStar's application and related filings. The current organ allocation policy and the forthcoming changes are described in greater detail in UMMC's Motion for Stay of CON Review. As discussed more fully in UMMC's Motion, the Organ Procurement and Transplantation Network ("OPTN") has formed a working committee to evaluate and propose changes to kidney allocation policy in order to comply with a directive from the Health Resources Service Administration to eliminate geographic Donation Service Areas ("DSAs") and regional barriers from organ allocation policies. Motion for Stay, pp. 3-5, 10; see also Exhibits A and D to Motion for Stay. OPTN projects that a final policy changes will be submitted to the OPTN Board for approval in December, 2019. Id.

The removal of geographic barriers in organ allocation policy will not only render MedStar's analysis in its application out-of-date with forthcoming the policy changes, but will also undermine the unstated purpose of MedStar's application – MedStar will not need a hospital in the Baltimore area DSA in order for its patients to benefit from MedStar's purported ability to increase the availability of donated organs in the Baltimore area. MedStar's efforts, under the new allocation policy, should benefit MedStar patients on MGTI and MFSMC kidney transplant waiting lists equally, because any organ donated in the Baltimore area will be in close proximity to both MGTI and MFSMC, and the current DSA barrier between the two facilities will no longer exist.

When stripped of unsupported assumptions and viewed in light of the forthcoming changes to kidney allocation policy, MedStar's application has little support other than the desire to reduce travel time for MedStar patients through the creation of a low-volume program that will, according to MedStar, rely on the expertise and efficiency of its high-volume affiliate. The Commission should reject this as an inadequate showing of need for a new transplant program, as such justification would open the door for every Maryland community hospital affiliate of an academic hospital with high-volume transplant programs to establish satellite organ transplant programs for patient convenience. Such a result is not only unneeded in Maryland, but is in direct contradiction with the State Health Plan Chapter's stated policy goals for these highly specialized services.

ARGUMENT

I. MEDSTAR CANNOT DEMONSTRATE THAT ITS PROPOSAL TO ESTABLISH A KIDNEY TRANSPLANT SERVICE COMPLIES WITH THE NEED STANDARD, COMAR § 10.24.15.04B(1).

MedStar claims that it will be able to increase the use and supply of donor organs in Maryland in by summarizing a variety of efforts in place at MGTI aimed at increasing organ use and donation. MedStar CON Appl. 48-78. However, MedStar has not made any effort to quantify the impact these various efforts will have in Maryland – that is, MedStar does not project the "new" organ volume any one effort will create. Without any such projection, it is impossible to determine whether the proposed increase in supply is worth the operational costs and other risks of adding a new program.[2]

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[2] The State Health Plan Chapter notes that several studies examining the relationship between competition among organ transplant centers and patient outcomes "indicate that increasing competition may have both positive and negative consequences for patients." COMAR §10.15.15.03, p. 21. One such study found that "a greater number of transplant centers was associated with a greater number of transplants, but greater competition was associated with

MedStar has also not demonstrated that it will be able to increase the organ supply in Maryland at all. As MedStar itself recognized in opposing GWUH's recent CON Application in the District of Columbia, CON #12-2-8 (the "GWUH CON Review"), a new program cannot "somehow generate a sudden spike in organ donations." MedStar April 5, 2013 Letter submitted in GWUH CON Review, attached as Exhibit 1, p. 2. "The fact is … that there is no basis to believe that there is such an untapped, hidden source of organ donors." Id. (emphasis in original). In commenting on the CON Application of Suburban Hospital, Docket No. 17-15-2400, MedStar recognized that "[m]ore programs do not equal more organs," and rejected Suburban Hospital's suggestion that the opening of the new kidney transplant program in the WRTC resulted in increased organ supply in the DSA. MedStar April 30, 2018 Comments on Suburban CON Appl. ("MedStar Comments on Suburban CON Appl."), p. 24. MedStar argued that recent increase in kidney transplant rates in the WRTC were instead attributable to changes in kidney allocation policy. Id., p. 21.

MedStar relies heavily on its ability to increase the supply of living donor organs through various efforts. MedStar CON Appl. pp. 48-55. UMMC performed more living donor transplants than MGTI in a 30 month time frame, and MedStar has not demonstrated that it will be able to improve upon the considerable success of UMMC and JHH in facilitating living donor transplants in the Baltimore area.

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higher patient mortality and worse graft outcomes." Id., p. 22. (For study cited, see SHP p. 22, n.84).

Table 1
Adult Living Donor Transplants
Period Evaluated: 1/1/2015 to 6/30/2017

Program	Transplants
UMMC	210
JHH	133
MGTI	164

Source: SRTR PSRs for MGTI, JHH, UMMC, Kidney Program, Oct. 9, 2018, Table C5L, C6L.

MedStar also touts its hospitals' participation within their DSAs' OPO as a means of improving organ donor rates. MedStar CON Appl. pp. 43-44. This participation, however, is not tied to the existence of an organ transplant service at MFSMC. It is a requirement included in CMS Conditions of Participation. 42 C.F.R. § 482.45. MedStar hospitals will continue to participate in donor programs with OPOs with or without approval of the proposed project.

While MedStar relies upon the success of MGTI to support its assumptions that it can create more transplant volume, MedStar noted in the Suburban Hospital CON review that kidney transplant volume at MGTI has been decreasing since 2016. Id. at p. 22. MGTI's 2017 volume decreased by 3 cases from its 2016 volume, from 226 to 223 cases, and MGTI projects that its 2018 kidney transplant volume will be 200, 26 cases fewer than its 2016 kidney transplant volume. MedStar April 30, 2018 Comments on Suburban CON Appl., p 22. In contrast, UMMC's kidney transplant volume increased by 50 cases from 2016 to 2017 (223 to 273 cases). OPTN database, annual kidney transplant volume by center. MedStar's suggestion that it can create new organ supply by opening a second program at a time when its existing program is currently experiencing volume decline is not credible.

B. MedStar Does Not Need a New Program to Increase the Supply of Organs in Maryland.

MedStar's argument that it will be able to increase the use and supply of organs in Maryland is premised on the assumption that much of Maryland is in the LLF, while MedStar is in the WRTC, as whatever efforts MedStar is currently capable of should already be benefiting patients on waitlists for hospitals in WRTC. As described more fully in UMMC's Motion for Stay, OPTN expects to change kidney allocation policy by December, 2019 to remove the geographic boundaries of DSAs. See Motion for Stay, pp. 3-5, 10. Given the relative proximity of MGTI to the Baltimore area, if MedStar can increase the number of donor kidneys available in the current Baltimore-area DSA, this increase will likely benefit patients waitlisted at MGTI to the same extent it would benefit patients waitlisted at the proposed MFSMC program. Simply put, MedStar need not open a new transplant program in the Baltimore-arca DSA in order to increase the number of donor kidneys available to that DSA and benefit MedStar patients, because DSAs will soon no longer exist.

II. MEDSTAR DOES NOT DEMONSTRATE EXISTING BARRIERS TO ACCESS.

While MedStar concedes that the access standard, COMAR § 10.24.15.04B(3), does not apply because MedStar "is not seeking to justify the need for an additional transplant program on the basis of barriers to access," (MedStar CON Appl., p. 67), MedStar makes statements throughout its application attempting to justify its program based on various access-related issues, including access for minority patients, access to a program with high quality and acceptance rate measures, and geographic access. The Commission should reject these based on MedStar's concession that it is not seeking to justify its program based on access.

Furthermore, no access barriers exist. Patients in the LLF, including minority patients, have access to two high-quality kidney transplant services. Adding a third program would

contradict the Commission's express recognition that "the public is best served if a limited number of general hospitals provide specialized services to a substantial population base." COMAR § 10.24.15.03, p. 8.

A. Minority Patients Have Appropriate Access to Kidney Transplant Services in the Baltimore Area.

MedStar's assertion that its program "provides greater access to minority populations...than any program in the region or nation" must be rejected. UMMC has a strong record of access for minority patients. As detailed in JHH's Comments, minority populations receive transplants at a higher rate within the LLF, served by JHH and UMMC, than in the WRTC, served by MedStar and a low-volume at George Washington. In addition, SRTR's most recent Program Specific Reports demonstrate UMMC performs kidney transplants on a significantly larger population of minority patients than MGTI.

Table 2
Candidates with Deceased Donor Transplants[1]
Candidates registered between 1/1/2012 and 12/31/2014

	Asian	African-American	Hispanic/ Latino	Race Other	White
UMMC	78	885	35	5	534
JHH	65	570	42	1	547
MGTI	39	286	32	2	137

Note 1: Table based on deceased donor organ transplants only. Living donor organ transplants result from a patient's pairing with a willing, suitable donor, and are not as meaningful a marker for access.

Source: SRTR PSRs for MGTI, JHH, UMMC, Kidney Program, Release Date Oct. 9, 2018, Table B7

UMMC also provides high-quality care to its patients, including minority patients. CareChex, a medical quality rating system, ranks UMMC the #2 kidney transplant program in United States for Patient Safety for 2019, based on three years of recent data.

Table 3
CareChex, America's Top Quality Hospitals, 2019
Patient Safety – Nation
Transplant of Kidney

Rank	Hospital Name	City	State
1	**Indiana University Health**	**Indianapolis**	**IN**
2	University of Maryland Medical Center	Baltimore	MD
3	**Ronald Reagan UCLA**	**Los Angeles**	**CA**
4	Medical College of Virginia Hospitals	Richmond	VA
5	**Methodist Hospital**	**San Antonio**	**TX**
6	New York-Presbyterian Hospital	New York	NY
7	**Mayo Clinic Hospital Rochester**	**Rochester**	**MN**
8	Northwestern Memorial Hospital	Chicago	IL
9	**Mayo Clinic Hospital**	**Phoenix**	**AZ**
10	University of Alabama Hospital	Birmingham	AL

Source: CareChex 2019 Rankings, Data Time Period: October 2014 – September 2017

B. Driving Distance to MGTI is not a Barrier to Access.

MedStar proposes a new program less than ten miles away from two existing high-volume programs and within 50 miles of its existing MGTI.[3] The State Health Plan Chapter provides that "travel to an organ transplant center located in a health planning region other than where the organ transplant recipient resides is not, in and of itself, considered a barrier to access, if the drive time in less than three hours one-way." COMAR § 10.24.15.04B(3). Even if improving drive time were a permissible justification, establishing a new program just ten miles away from two existing programs does nothing at all to promote geographic access to organ transplant services in Maryland.

To the extent that MedStar intends to improve access based not simply on driving time, but by expansion into a new DSA, that goal will be rendered irrelevant when OPTN adopts new allocation policy in December of 2019 that will no longer include the geographic barriers of

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[3] See Note 1, supra.

DSAs in allocation procedures. See Motion for Stay, pp. 1-5, 10. Furthermore, as MedStar appropriately comments in the review of the Suburban Hospital's CON Application to establish liver transplant services, "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." MedStar Comments on Suburban CON Appl., p. 4.

Finally, MedStar does not need a new program at MFSMC to improve its post-surgical treatment of Baltimore area patients, and may make use of its existing network of providers. MedStar states that it has been building its infrastructure in the Baltimore area to support transplant patients:

> Since 2015, MedStar has been laying the groundwork to provide the full range of transplant-related services to those patients in need in the Baltimore region. To date, in anticipation of expanded services, MGTI has extended all services required for referral, triage, evaluation, and listing of transplant candidates to MFSMC. MGTI has also extended follow up services required for the long-term maintenance of patient and organ health after transplantation.

MedStar CON Appl., p. 16. In its comments on the Suburban CON Application, MedStar similarly touted that it "has seven established and functioning evaluation centers at sites distributed around the Baltimore-Washington area" and that "volumes of patient visits and evaluations at [MedStar] sites have been growing steadily." In the GWUH CON Review, MedStar noted that it had "kidney transplant facilities and clinics in Annapolis, Baltimore, Clinton, and Frederick in Maryland" and that it "assures seamless geographic coverage to its entire service area." MedStar February 17, 2017 Additional Testimony and Information in GWUH CON Review, Exhibit 2, p. 5. "Before and after the transplantation procedures, [MedStar] patients have access to a broad range of services and staff at [the previously mentioned] locations to serve their needs." Id.[4]

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[4] MedStar also "provides free Uber car service to patients who have an inability to attend appointments or secure reliable transportation for financial reasons." Id.

To the extent that MedStar desires to achieve more accessible, local care for its Baltimore-area transplant patients, there is no reason MedStar cannot provide that care without opening a new transplant program at MFSMC.

III. MEDSTAR'S PROGRAM IS NOT COST EFFECTIVE AND THERE ARE MORE COST EFFECTIVE ALTERNATIVES THAT WOULD ACCOMPLISH MEDSTAR'S PURPOSE (COMAR § 10.24.15.04(4); COMAR 10.24.01.08G(3)(c).

A. MedStar Recognizes that Increased Competition Results in Increased Costs

As noted above, less than four months prior to submitting its Application, MedStar opposed the Suburban Hospital CON application to establish a new liver transplantation service. MedStar relied principally on three arguments, among these that "[s]cientific literature and actual experience do not support the claim that increased competition leads to increased numbers of transplants and improved patient survival." Medstar Comments on Suburban CON Appl., Enclosure Letter, p. 2.

Of note, MedStar indicated that its own quality and costs improved when it consolidated its two programs:

> [MGTI] 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.

Medstar Comments on Suburban CON Appl., p. 22. MedStar further summarized with endorsement studies finding that increased competition led to various risks, including increased graft failure and increased costs. Id., pp. 16-18.

Similarly, in the recent GWUH CON review, the Medical Director of MGTI's Kidney and Pancreas Transplant Program, Basit Javaid, M.D., "cautioned that the addition of a new transplant center in [D.C.] would, in light of the limited organ donor pool, destabilize existing

area transplant centers by diluting their clinical expertise, thereby risking degrading their surgical outcomes and weakening their financial viability." MedStar May 9, 2014 Request for Reconsideration, GWUH CON Review, Exhibit 3, p. 5. MedStar further argued that the "existence of a low-utilization transplant program in [MedStar's] service area raises concerns regarding cost, quality, and duplication of services." MedStar Feb. 24, 2017 Additional Comments to Public Hearing Record, GWUH CON Review, Exhibit 4, p. 7.

Having recently touted the increased efficiency and quality MedStar achieved through consolidation in one recent CON review, and condemned the addition of a new, low-volume transplant program in another, MedStar should not be eager to open a new low-volume program, and thus risk both undermining its newfound cost-saving efficiency and volume gains at MGTI, and imposing greater costs and quality risks on Maryland's existing high-quality, high-volume providers.

B. MedStar's Projected Staffing Costs are Understated and do not Comply with OPTN By-laws.

MedStar's projected operational costs fail to account for the considerable staffing needs required to operate a kidney transplantation program. "A general hospital awarded a Certificate of Need to establish an organ transplant service shall be certified by United Network for Organ Sharing ["OPTN"] within the first year of operation." COMAR § 10.24.15.04B(6)(a). OPTN bylaws require transplantation programs to be fully functioning as stand-alone programs. That is, MedStar may not simply run MFSMC as a satellite of MGTI, but must meet each staffing requirement of the OPTN bylaws.

OPTN bylaws require each transplant center to have surgeons and transplant physicians available 365 days a year, 24 hours a day, 7 days a week to provide program coverage. OPTN bylaws, available at: https://optn.transplant.hrsa.gov/governance/bylaws/ (last accessed

10/13/2018). MedStar's proposed staffing of just three total physicians is impractical, especially at the relatively low average salary of $333,333.[5] MedStar March 1, 2018 Completeness Response, Table L. According to OPTN bylaws, A transplant surgeon must be readily available in a timely manner to facilitate organ acceptance, procurement, and transplantation, and a transplant surgeon or transplant physician may not be on call simultaneously for two transplant programs more than 30 miles apart unless the circumstances have been reviewed and approved. OPTN Bylaws. Without an exemption for specific reasons, the primary surgeon or primary physician cannot be designated as the primary surgeon or primary physician at more than one transplant hospital unless there are additional transplant surgeons or transplant physicians at each of those facilities. Id. Additional transplant surgeons must be credentialed by the transplant hospital to provide transplant services, and be able to independently manage the care of transplant patients, including performing the transplant operations and organ procurement procedures. Id. Additional transplant physicians must be credentialed by the transplant hospital to provide transplant services and be able to independently manage the care of transplant patients. Id.

In addition, the proper care and management of transplant recipients require both physicians and ancillary health professionals. The transplant program must show proof of collaboration with experts in anesthesia. Id. MedStar makes no mention of transplant anesthesiology in its proposed staffing plan, and does not describe its staffing plan with any sufficient detail to demonstrate that its extremely lean staffing model could meet all staffing requirements. MedStar March 1, 2018 Completeness Response, Table L. A transplant center requires, in addition to surgical and aesthesia staffing, collaboration with experts

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[5] Not only is this salary relatively low, but MedStar fails to project any amount of benefits for any staffing level. MedStar March 1, 2018 Completeness Response, Table L.

in histocompatibility and immunogenetics, immunology, infectious disease, pathology, physical therapy and rehabilitation medicine, pulmonary medicine, including respiratory therapy support, and radiology. OPTN Bylaws.

MedStar also fails to include any pharmacy staffing in its staffing model. MedStar March 1, 2018 Completeness Response, Table L. OPTN Bylaws require a transplant program to identify at least one Clinical Transplant Pharmacist on staff who will provide pharmaceutical expertise to transplant recipients. OPTN Bylaws. The Clinical Transplant Pharmacist should be a member of the transplant team, providing comprehensive pharmaceutical care to transplant recipients. Id. The Transplant Pharmacist must be a licensed pharmacist with experience in transplant pharmacotherapy, and must work with patients and their families, and members of the transplant team, including physicians, surgeons, nurses, clinical coordinators, social workers, financial coordinators, and administrative personnel. Id.

The Commission should require MedStar to submit additional detail regarding its staffing plan, and should evaluate the sufficiency of the staffing model in light of OPTN bylaws. MedStar should also be required to add benefits, which often comprise significant proportion of staffing costs, to its projection.

C. The Majority of MedStar's Proposed Patients Will Pay More, Not Less, for Transplant Services at MFSMC.

MedStar estimates that it referred an annual average of 15 kidney cases to UMMC and JHH for the past four years, and estimates that that referral volume will decline to an annual average of 10 cases in the first three years of a new program at MFSMC. MedStar March 1, 2018 Completeness Resp., p. 23. The majority of the volume shift will be from MGTI, which MedStar indicates has a current waitlist of 129 patients from Maryland who "orient to Baltimore." Id., p. 24.

MedStar misleadingly frames its program as a more cost efficient alternative by comparing its projected charges to those of UMMC, JHH, and MGTI based on each program's average charge per kidney transplant case. Unlike UMMC and JHH, however, MGTI does not charge all payers the same rates. Thus, an appropriate cost comparison must consider MGTI's projected payer mix. MedStar expects that, by the third year of operation, its program volume will have a payer mix that includes 41.9% Medicare patients and 25.3% Medicaid patients. March 1, 2018 Completeness Resp., Table K. Because of Maryland's Total Cost of Care Model State Agreement with CMS, Medicare and Medicaid charges are actually significantly higher in Maryland than nationally. MedStar's proposed charges exceed MGTI's CMS reimbursement rates for Medicare transplant recipients, and likely Medicaid transplant recipients as well. CMS FY 2019 IPPS Impact File, Correction Notice Tables 1A-1E for Labor, Non Labor and Capital Rates and Other Adjustments. As a result, 67.2% of the patients MedStar shifts from MGTI will likely pay more, not less, for kidney transplant services

D. There are Cost-Effective Alternatives to MedStar's Proposed Program.

As discussed throughout these Comments, MedStar may implement its proposed efforts to increase organ use and supply in the Baltimore area without establishing a new program at MFSMC. To the extent that MedStar may not have done so under the existing allocation policy because such efforts would not directly benefit patients on MedStar's MGTI waitlist, the forthcoming changes to the kidney allocation policy will eliminate the DSA barrier. As a result, MedStar's efforts will likely benefit its patients to the same extent they would benefit patients waitlisted at MFSMC.

In addition, as set forth more fully in the JHH Comments, UMMC and JHH are adequately serving the needs of the MedStar's targeted service area. To the extent that a handful of patients a year may prefer to have surgery at a location closer to Baltimore, those patients are

able to join waitlists for UMMC and JHH programs as well as MGTI – and in fact may already be on those waitlists. MedStar has not supported the operation of a new program at a cost of $5.5 million a year simply for a few dozen patients annually to avoid 60 minutes of driving.

Conclusion

For the reasons set forth above, UMMC respectfully asks that the Commission deny MedStar's Application proposing to establish a kidney transplant service at MedStar Franklin Square Medical Center.

Respectfully submitted,

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October 15, 2018

Table of Exhibits

Exhibit	Description
1	2013-04-05 MedStar Letter regarding Analysis of GWUH CON Application, GWUH CON Review (Letter and Exhibit A only; Exhibits B-C excluded)
2	2017-02-17 MedStar Additional Testimony, GWUH CON Review (Letter only, exhibits excluded)
3	2014-05-09 MedStar Request for Reconsideration of Issuance of CON, GWUH CON Review
4	2017-02-24 MedStar Additional Comments to Public Hearing Record, GWUH CON Review

CERTIFICATE OF SERVICE

I hereby certify that on the 15th day of October 2018, a copy of University of Maryland Medical Center's Comments on MedStar Health, Inc.'s CON Application Proposing the Establishment of a Kidney Transplant Service at MedStar Franklin Square Hospital Center was sent via email and first-class mail to:

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

October 15, 2018
Date

Scott Tinsley-Hall
Director, Strategy & Market Intelligence

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

October 15, 2018
Date

Rolf Barth, MD
Professor of Surgery

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

October 15, 2018
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Anahita Masoumi, DNP, MBA, RN
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EXHIBIT 1

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April 5, 2013

VIA ELECTRONIC MAIL
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Re: MedStar Georgetown University Hospital – Analysis of George Washington University Hospital CON Application Seeking Approval of a Kidney/Pancreas Transplant Service - CON # 12-2-8

Dear Mr. Selassie:

The George Washington University Hospital ("GWUH") Certificate of Need application to re-open its once-failed kidney transplant program raises the bedrock health planning issues of need, financial feasibility, and quality of care – and fails to justify its Certificate of Need approval on any ground. Following its previous failure in the operation of a renal transplant program, GWUH has now offered a proposal that provides no compelling reason for approval. Specifically – and beyond any doubt – it is clear that:

- There is no "unmet need" or demand for an additional transplant program to serve the District of Columbia area.
- Existing transplant programs currently have abundant additional capacity were any increase in demand to occur.
- Previous additional transplant programs – including one at GWUH – have opened and closed due to low utilization.

- The addition of a new, unneeded transplant program would lead to low utilization and a reduction in quality of care for all transplant programs.

- The proposed GWUH transplant program itself would suffer from low utilization and would fail.

In the final analysis, the GWUH application is built upon two obviously mistaken propositions:

First, that the number of organ transplants is a function of organ transplant waiting lists. It is not. Rather, organ transplant volume is driven by the number of actual donors. This true demand barometer shows no need for additional transplant programs in the area.

Second, GWUH suggests that if only its kidney transplant program were approved, GWUH itself could somehow generate a sudden spike in organ donations – apparently enough to fully utilize its own center. We understand that these "new donor" numbers would occur through exhortations to GWUH employees and staff.

Were this truly possible, not only MedStar Georgetown University Hospital ("MGUH"), but numerous potential recipients of these organ donations, now on waiting lists, would gladly welcome the additional donors GWUH asserts it would be able to generate – but apparently it is only if GWUH had its own program that such efforts could be undertaken.

The fact is, however, that there is no basis to believe that there is such an untapped, hidden source of organ donors. This proposition is not supportable.

The path to a SHPDA decision in this case is straightforward. This application should be denied. The applicant has failed to meet its burden of demonstrating compliance with any of the key CON review criteria, and instead proffers a proposal that will meet no unmet public need. The GWUH program would inappropriately duplicate existing services, and lead to low utilization and possible quality concerns at all programs. As was the case with GWUH's previous kidney transplant program, this service, too, would be underutilized and is not financially feasible.

MGUH asks that SHPDA Staff, the Project Review Committee, the Statewide Health Coordinating Council, and the SHPDA Director deny this application. The decision is simple.

In support of our position, we have attached a more detailed analysis of the multiple reasons for CON denial. We also redirect your attention to our previously submitted scientific evidence of the correlation between low-volume kidney transplant centers and less than optimal health outcomes for patients. The protection of the health of District residents warrants the SHPDA's careful consideration of this irrefutable data.

Sincerely,

John T. Brennan, Jr.
John T. Brennan, Jr.

Kathleen M. Stratton
Kathleen M. Stratton

Enclosures

cc (via electronic mail/with enclosures):

Phillip Husband, Esq.
Kerry M. Richard, Esq.

George Washington University Hospital
Certificate of Need Application
Registration No. 12-2-8
Establish Kidney and Pancreas Transplant Service

Table of Contents

TAB A

George Washington University Hospital
Certificate of Need Application
Registration No. 12-2-8
Establish Kidney and Pancreas Transplant Service

Analysis of GWUH CON Application

Prepared by:

Dean Montgomery

I. There is No Need for the Proposed District Hospital Partners, LLP/George Washington University Hospital Renal Transplant Service

District Hospital Partners, LLP and George Washington University Hospital (GWUH) seek Certificate of Need (CON) authorization to establish an unneeded and unnecessary kidney and pancreas transplant service. Following are the comments of Dean Montgomery, a health services planning expert, who has been retained to evaluate the application and offer his expert opinion on the reasons why this application should not be approved. In Mr. Montgomery's opinion, the data and information presented in the application does not justify approval of the project. In his opinion, examination of the application, of end stage renal disease incidence and prevalence trends, and of the market in which a new service would be developed indicates that the application does not address a number of important considerations and does not present a compelling community oriented argument for an additional transplant program in the Washington metropolitan area.

II. Overall Context of ESRD Transplant Demands

The incidence and prevalence of end stage renal disease (ESRD) is expected to continue to increase as the population ages and the prevalence of underlying contributing chronic conditions such as hypertension and diabetes remain high. Most ESRD patients necessarily rely on long-term kidney dialysis to treat their condition as they await a more permanent solution, a kidney transplant.

The principal obstacle to obtaining a transplant nationwide, and in the Washington metropolitan areas, is the longstanding shortage of donor kidneys. Organ donation levels are relatively flat and the list of those waiting for a transplant continues to grow. Transplant rates for adult candidates are decreasing.
The state of kidney transplantation may be summarized as follows:[1]

- Nationally, the number of active candidates on the waiting list for a transplant increased from 7,404 in 2003 to 32,501 in 2011 and continues to grow,

- The waitlist population continues to age, with transplant candidates $\geq$ 50 years representing an increasing percentage of those on the lists,

- Consistent with increasing age of candidates on waiting lists, the number of transplants performed annually in patients aged 50 years or older has increased steadily for more than a decade, with the number in patients aged 65 years or older tripling between 1998 and 2011,

[1] OPTN/SRTR 2011 Annual Data Report, pp. 12-15

- Relatively flat kidney donation rates have resulted in steady decreases in transplant rates for more than a decade, and

- Many kidneys recovered for transplant are discarded. The discard rate has increased steadily from 2002 to 2011.

These problems are longstanding and well known. Efforts are being made to address them, but resolution is not expected soon.

National patterns and trends are evident in Network 5 and in the Washington metropolitan area. They result from a number of enduring complex interrelated social circumstances and factors. There is no indication that they relate in any meaningful way to the number of transplant programs, nationally or locally.

III. The GWUH Argument for Re-Opening Another Transplant Center is Not Convincing

A. *There is No Apparent Community Need*

GWUH points to the high incidence of end stage renal disease (ESRD) in the District of Columbia, the large number of ESRD patients waiting for a kidney transplant, the number of ESRD patients treated by GWUH faculty, and the expectation that GWUH will be able to increase the number of organs available for transplant as evidence of a public (community) need for the service proposed. The applicant states:

> "Community Need: Patients in GW Hospital's market have one of the highest rates of ESRD. According to the Transplant Management Group, as of January 1, 2010, within the area encompassing the District of Columbia (Network 5) there are 6,781 patients with ESRD. Of that 6,781, there are more than 1,000 patients in Washington D.C. who are on the waiting list for kidney transplants. Of those, only 177 received kidney transplants.
>
> GW Hospital Patient Demand: At the GW Medical Faculty Associates more than 200 End Stage Renal Disease patients are being managed for chronic kidney disease along with 81 GW patients on waiting lists elsewhere for transplant surgery. The division of renal diseases and hypertension provides care for more than 500 patients in various stages of chronic kidney disease (CKD) in the outpatient clinics located at the 2150 Pennsylvania Avenue and Greenbelt, MD offices." p. 13
>
> ". . . GW Hospital has the capability to grow the number of organs procured

demonstrated by recent recognition from the U.S. Department of Health and Human Services (HHS) for the Hospital's leadership role in organ donation (2008 with the Medal of Honor, 2009 and 2010 with the Silver Medal). As part of the HHS Organ Donation Breakthrough Collaborative, the Hospital has achieved an organ donation rate of 75%; the national average rate is 60%." p. 14

"Patients wait longer to receive a kidney transplant in our region than elsewhere in the United States. Nationally, 13.6% of all ESRD patients on the approved waiting list receive a kidney transplant within 12 months. Within the local "Donor Service Area", which includes The George Washington University Hospital, known as the Washington Regional Transplant Community (ESRDs Network 5) only 8.6% of patients receive kidney transplants within 12 months.

Finally the dialysis population in DC is continuing to grow. It is anticipated that over the next five years, the population of patients undergoing dialysis will grow by another 2.7%." p. 15

At first glance (facially) these circumstances may be interpreted to suggest that an additional transplant service, at GWUH or elsewhere, has substantial inherent merit. When examined closely and in context it is far less clear that they support establishing an additional transplant service.

ESRD Incidence and Prevalence

The District of Columbia population has had high End Stage Renal Disease (ESRD) incidence and prevalence rates for many years (Exhibits 1, 2). High ESRD incidence and prevalence produce a substantial pool of patients, a large percentage of whom would benefit from a kidney transplant. This circumstance does not, in and of itself, mean that additional transplant programs are needed.

Exhibit 1
End Stage Renal Disease (ESRD) Incidence
Newly Diagnosed Chronic ESRD Patients by State of Residence, 2004 -2011

Jurisdiction	2004	2005	2006	2007	2008	2009	2010	2011	Incidence Rate (2010)
District of Columbia	425	433	436	390	420	426	419	419	0.000696
Maryland	2,297	2,504	2,523	2,388	2,454	2,533	2,449	2,435	0.000423
Virginia	2,671	2,684	2,913	2,809	2,777	2,904	2,953	2,845	0.000367
West Virginia	673	655	707	675	692	752	672	761	0.000361
Other	387	189	143	155	145	175	165	199	
Mid-Atlantic Renal Coalition, Network 5	6,453	6,465	6,722	6,417	6,488	6,790	6,658	6,659	0.000409

Though District of Columbia ESRD rates are high, the absolute number of ESRD patients waiting for a kidney transplant, historically and currently, is substantially smaller than the numbers waiting for transplants in neighboring Maryland and Virginia. With their larger populations, Maryland and Virginia had 8,834 and 10,554 ESRD patients, respectively, in 2011 compared with 1,921 ESRD patients in the District of Columbia (Exhibit 2). The numbers of patients awaiting transplants also are substantially higher in Maryland and Virginia than in the District of Columbia.

These data and circumstances, in and of themselves, do not indicate or suggest the number of transplant programs needed to meet community need or to ensure a larger number of organ donations or transplants. Over most of the last decade Maryland has had two kidney transplant programs, Virginia has had six, and the District of Columbia four. With this service delivery network, Maryland with two centrally located transplant programs has performed significantly larger numbers of kidney transplants and has relatively fewer patients waiting for transplants. Maryland's programs have much higher (two to four times higher) average transplant volumes than average volumes among programs in Virginia and the District of Columbia.

Exhibit 2
End Stage Renal Disease (ESRD) Prevalence
Active Dialysis Patients by State of Residence, 2004 -2011

Jurisdiction	2004	2005	2006	2007	2008	2009	2010	2011	Prevalence Rate (2010)
District of Columbia	1,728	1,679	1,778	1,809	1,793	1,867	1,897	1,921	0.003153
Maryland	7,038	7,375	7,621	7,823	8,106	8,281	8,580	8,834	0.001482
Virginia	8,674	8,848	9,087	9,332	9,546	9,798	10,185	10,554	0.001267
West Virginia	1,625	1,701	1,761	1,794	1,821	1,860	1,858	1,912	0.000999
Other	346	280	264	283	263	248	243	272	
Mid-Atlantic Renal Coalition, Network 5	19,411	19,883	20,511	21,041	21,529	22,054	22,763	23,493	0.001397

Source: Network 5, Network SIMS Database, 2012

The Maryland model appears to hold considerable promise. It suggests that fewer higher volume programs are preferable to a larger number of lower volume programs.

There is no necessary connection between the number of transplant programs, the number of transplants, or likelihood of transplantation. Both the District of Columbia and Maryland have had a number of "start up" transplant services over last two decades. Shady Grove Adventist Hospital (Montgomery County, Maryland) established a kidney transplant service in 1994. The service was closed in 1998, performing a total of 15 transplants over five years (Exhibit 3).

Exhibit 3. Shady Grove Adventist Hospital
Kidney Transplants, 1994-1998

Year	1998	1997	1996	1995	1994
Transplants	3	3	5	2	2

Source: OPTN & SRTR Transplant Data, 2012

The District of Columbia had two kidney dialysis programs which are no longer operational. George Washington University Hospital established a transplant program in the 1980s. The program was not successful. It was closed in 1996 after performing a total of 51 transplants (Exhibit 4).

Exhibit 4. George Washington University Hospital
Kidney Transplants, 1988-1995

Year	1996	1995	1994	1993	1992	1991	1990	1989	1988
Transplants	1	1	7	3	4	13	6	6	10

Source: OPTN & SRTR Transplant Data, 2012

Howard University also established a kidney transplant service more than two decades ago. Transplant volumes were never high, decreasing gradually from the late 1980s to 2010. The program was closed in 2010, after performing a total of 219 transplants over the last 23 years (Exhibit 5).

Exhibit 5. Howard University Hospital
Kidney Transplants, 1988-2010

Year	2011	2010	2009	2008	2007	2006	2005	2004	2003	2002	2001	2000
Transplants		1	13	8	4	13	11	9	9	6	4	5
Year	1999	1998	1997	1996	1995	1994	1993	1992	1991	1990	1989	1988
Transplants	10	9	6	7	7	10	14	14	15	11	15	18

Source: OPTN & SRTR Transplant Data, 2012

The history and patterns of development and use at these unsuccessful programs are instructive. New programs should not be undertaken unless there is a compelling need for additional capacity or a purpose that only a new service can address. Locating in an area with high ESRD incidence and prevalence is no guarantee of long-term stability or success.

B. *Local Hospital Kidney Donation Experience and the Fallacy of the "New Donations" Theory as Support for the Program*

GWUH obtained six kidneys for transplant in 2011. This was the fourth highest in the metropolitan area, behind Washington Hospital Center, Inova Fairfax Hospital, and Prince Georges General Hospital. GWUH ranked lower in terms of its standardized donation ratio (the ratio of actual donations to the number of expected donations). With an observed (actual) donation ratio of 60%, GWUH ranked 8th among metropolitan area hospitals with multiple donations in 2011.[2] Its standardized ratio (0.95) also was the 8th highest among metropolitan area hospitals with multiple donations in 2011. Five of the hospitals with higher standardized ratios than GWUH do not have (and do not seek) transplant services.

These data show that it is not necessary that a hospital have a transplant program to obtain substantial numbers of organs for transplantation and to contribute meaningfully in meeting the needs of ESRD patients.

IV. Local Capacity and Service Volumes Do Not Support Approval of the GW Project

Excluding military services, the Washington metropolitan area now has four kidney transplant programs, several also perform pancreas transplants. Three of these programs (Washington Hospital Center, Georgetown University, Children's National Medical Center are located in the District of Columbia) and one in Fairfax, VA (Exhibit 5, Map 1). All of these programs have substantial transplant volumes, but none is functioning at high capacity. All are operating at service volumes that are less than half of the well established transplant programs in nearby Baltimore, MD, Johns Hopkins University Hospital and University of Maryland Medical Center (See Exhibits 6-10).

Moreover, all of the metropolitan area transplant programs currently have service volumes well below their highest annual caseload within the last three years (Exhibits 6, 7, 10). Washington Hospital Center's 2011 transplant case volume (81 transplants) was about 32% below its average case volume of the previous two years (119 transplants). Similarly, though its case volume is trending higher, Georgetown University Hospital's 2011 case volume (59 transplants) was more than 6% below the average case volumes of the previous two years (63 transplants). With the exception of the University of Maryland Medical Center, transplant case volumes also were lower at neighboring transplant programs (Inova Fairfax Hospital, Johns Hopkins University Hospital) in 2011 than in 2010 (Exhibits 6-10).

Current market conditions and trends do not argue for or support adding additional transplant capacity. There is substantial unused capacity and capability in the region. It is

[2] See Scientific Registry of Transplant Recipients (SRTR), Table 3a, 7/13/2012 at www.srtr.org.

likely the service volumes at the region's existing kidney transplant services would be affected negatively (reduced) at least marginally if a new transplant program were opened.

V. The Experience of District Hospital Partners' 80% Owner - Universal Health Services - At McAllen Medical Center Does Not Support the Need for the Project

Universal Health Services, the principal owner of GWUH, has a kidney transplant service at McAllen Medical Center (MMC) in McAllen, Texas. The history and operation of that program may be indicative of how a GWUH program would perform. Data from the 2011 Scientific Registry of Transplant Recipients (SRTR) report on Universal's MMC program include these findings:

> "At McAllen Medical Center (TXMA), 83.78 percent of adult patients were alive one year after transplant, compared to the 95.05 percent that would be expected based on the characteristics of these patients. Moreover, the p-value of 0.008 indicates that this difference is statistically significant." [Overview]
>
> "The patients on the waiting list at this program experienced a transplant rate of 0.05 per year spent on the waiting list for any person(s) on the waiting list. Compared to the expected rate of 0.12, the difference is unlikely to have occurred by random chance ($p<.01$) and probably represents a real difference from the expected rate." [p.3]
>
> "At this program, 6.7% of patients had received a transplant by 6 months after being placed on the waiting list, compared with 13.4% in the nation (Table 4). At 6 months, 2.9% had died (compared to 1.5% nationally) and 89.4% were still on the waiting list (83.3% nationally). Note that these figures are not adjusted for patient characteristics." [p.3]
>
> One quarter of the patients placed on the waiting list at this program had received a transplant as of 45.5 months after listing; in the nation it took 13.7 months to reach the same fraction." [Table 6]

Universal's McAllen transplant program has operational characteristics and deficiencies, e. g., low transplant rates and long waiting list, similar to those the applicant argues would be addressed in the Washington metropolitan area by a GWUH transplant program. It is difficult to credit these arguments given

Universal's failure to resolve them at its other kidney transplant service. MMC had a low transplant rate (Exhibit 11) in both 2010 and 2011.

Exhibit 11
McAllen Medical Center
Kidney Transplant Experience, 2010-2011
Transplant Rate among Waitlist Patients

Year	*Transplants (Number)*	*Waitlist (Number)*	*Observed Rate*	*Expected Rate*[2]	*Ratio of Observed/ Expected Rate*	*Comparison with Similar Programs*
2011	22	308	0.071	0.17	0.40	Signficantly Lower[1]
2010	14	287	0.049	0.18	0.27	Signficantly Lower[1]

Source: Scientific Registry of Transplant Recipients, Center-Specific Reports, McAllen Medical Center, 2011, Table 3.

[1]The difference between the McAllen Medical Experience and that of similar transplant programs nation wide is statistically significant. The difference "is unlikely due to random chance and probably represents a real difference from the expected rate". McAllen Medical Center, SRTR Report, Table 3.

[2]The expected transplant rate is adjusted for age, blood type, previous transplantation, time on the waiting list, peak panel reactive antibody (PRA), and the interaction between previous transplantation and peak PRA.

The McAllen hospital also had long wait times for those on its transplant wait list (Exhibit 12). It is not evident how Universal will achieve in the Washington metropolitan area what it has failed to achieve or correct in McAllen.

Exhibit 12
McAllen Medical Center
Kidney Transplant Experience, 2006-2011
Time (Months) to Transplant for Waitlist Patients

Percentile	McAllen Medical Center	Donation Service Area	Region	U.S.
		Months to Transplant		
5th	4.2	2.4	2.1	1.9
10th	10.7	5.9	4.4	4.0
25th	45.5	35.9	14.7	13.7
50th	>72	>72	60.6	53.0
75th	>72	>72	>72	>72

Source: Scientific Registry of Transplant Recipients, Center-Specific Reports, McAllen Medical Center, 2011, Table 6.

VI. The Narrow Proprietary Focus of the Application Does Not Reflect Public Need

The GWUH application is deficient in a number of additional respects. There are a number of substantive planning questions that should be addressed directly by the applicant, and weighted carefully by the SHPDA, before the application is considered seriously for approval.

Questions and concerns that are not addressed meaningfully (outside of assertions and assumptions) include:

- There is essentially no consideration of the metropolitan area context and how a GWUH transplant program would fit in the existing network of transplant programs. There is no substantive discussion or analysis of the potential impact on existing transplant services. Given the lack of success of an earlier George Washington University Hospital kidney transplant program and the failure of at least two other transplant programs in the metropolitan area, these questions warrant the fullest consideration.

- The application contains no substantive discussion of the ESRD patient and kidney transplant market, or of kidney transplant patient origin and destination patterns in the metropolitan area. It is unclear, for example, how GWUH expects to relate to the kidney transplant populations of nearby Maryland (Montgomery and Prince Georges County).

- There is no discussion of Universal's kidney transplant experience at McAllen Medical Center.

- There is no discussion or explanation of GWUH's kidney transplant experience in the 1990s and how the problems encountered then would be avoided going forward.

The GWUH application focuses more on the institutional needs of GWUH than it does on justification of a public need for an additional transplant program. The GWUH application is not well developed. It should be denied or at minimum deferred until unanswered questions and concerns can be addressed.

VII. Conclusions

The GWUH application does not contain data or other information that demonstrate there is a community or public need for an additional kidney transplant program in the metropolitan area or in the District of Columbia.

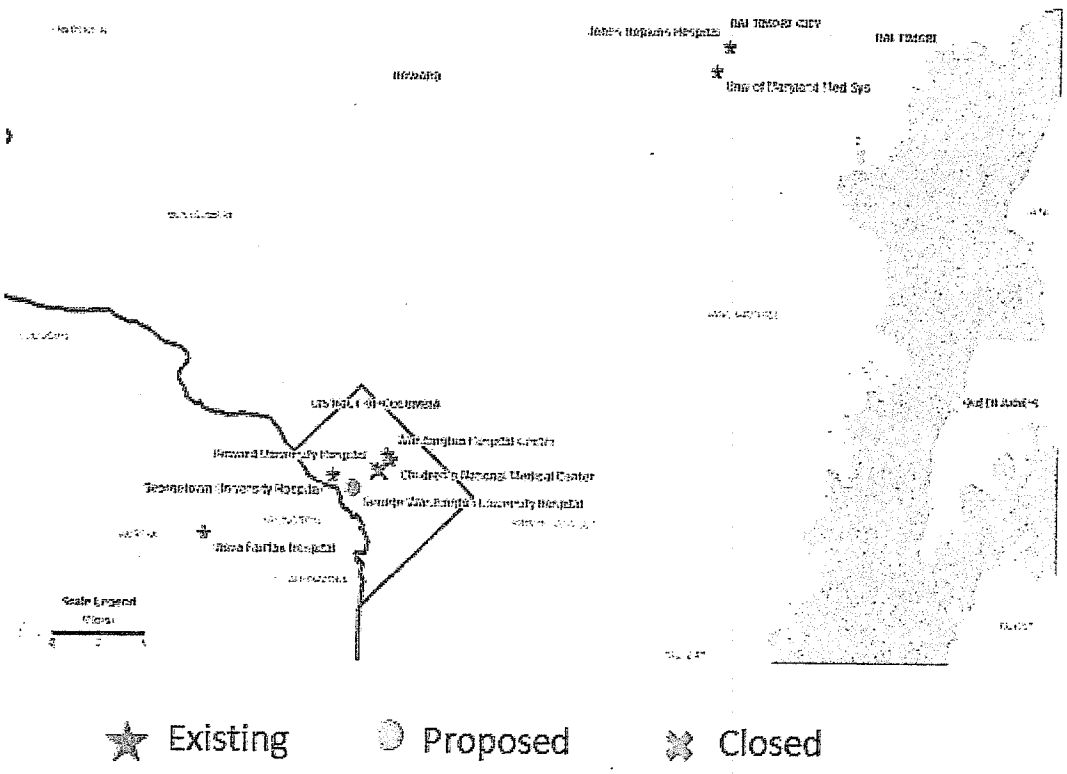
There is no analysis, qualitative or quantitative, showing the need for additional transplant capacity or programs. Excluding military services, the Washington metropolitan area has four kidney transplant programs, three of which are in the District of Columbia. None of the programs are operating near capacity. All are operating at service volumes that are less than half of the transplant caseloads of Johns Hopkins University Hospital and University of Maryland Medical Center.

The operational characteristics and experience of Universal Health Service's only kidney transplant service, McAllen Medical Center, are problematic. This subject is not addressed by the applicant. It necessarily raises the question of whether authorizing a kidney transplant service at a second Universal medical center is in the public interest.

Absent a public need for the proposal, approval of a transplant program which would likely be underutilized, and for which "new demand" is contrived, is inappropriate. The applicant's assistance in growing current organ donor rolls would be welcome; adding to the supply of transplant programs, however, is misplaced and inappropriate.

Exhibits

Exhibit 5. District of Columbia and Neighboring Kidney Transplant Services



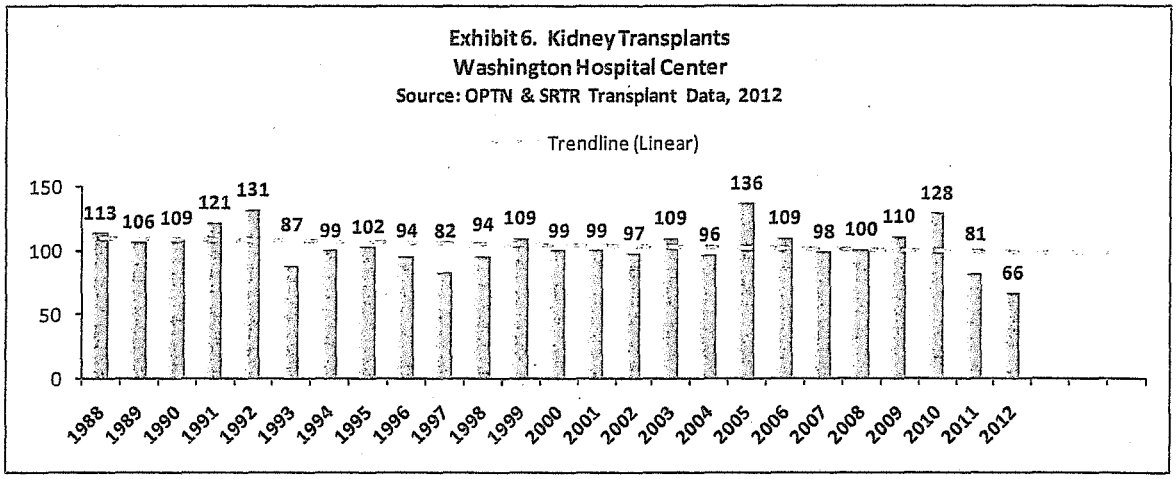


Exhibit 6. Kidney Transplants
Washington Hospital Center
Source: OPTN & SRTR Transplant Data, 2012
Trendline (Linear)
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113 106 109 121 131 87 99 102 94 82 94 109 99 99 97 109 96 136 109 98 100 110 128 81 66
1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012

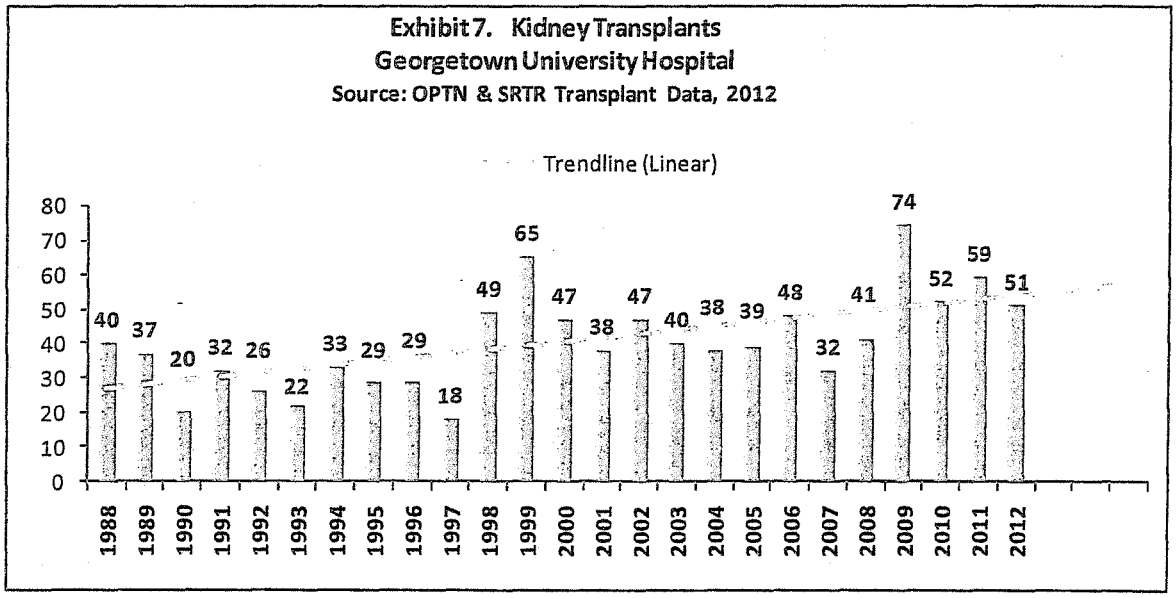
Exhibit 7. Kidney Transplants
Georgetown University Hospital
Source: OPTN & SRTR Transplant Data, 2012
Trendline (Linear)
80
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1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012

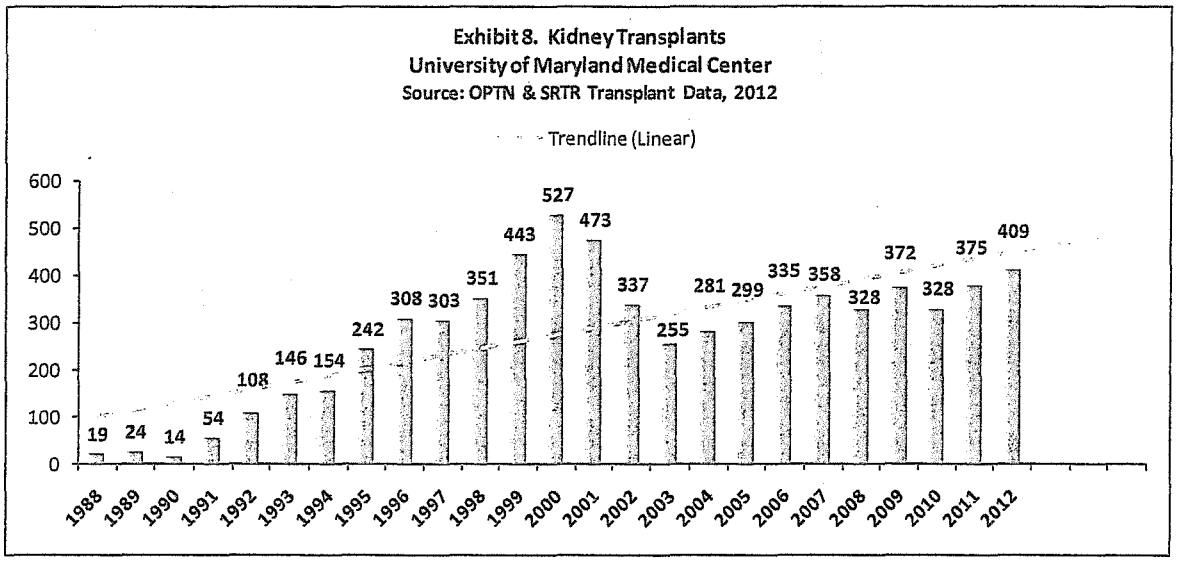
Exhibit 8. Kidney Transplants
University of Maryland Medical Center
Source: OPTN & SRTR Transplant Data, 2012
Trendline (Linear)
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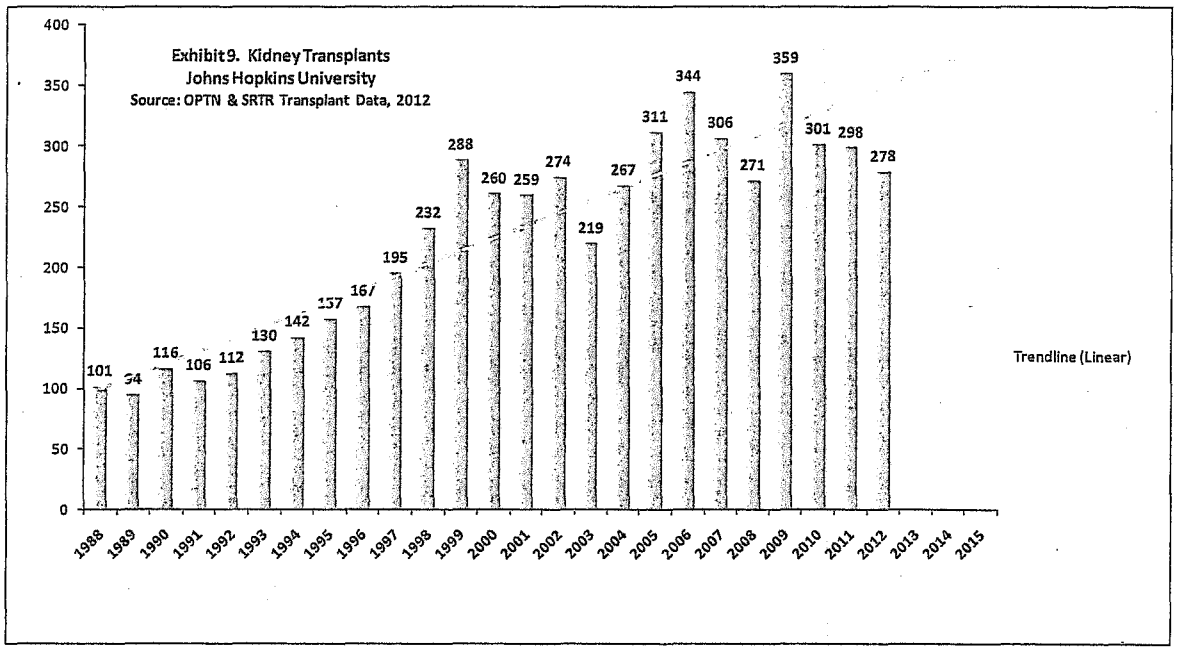
Exhibit 9. Kidney Transplants
Johns Hopkins University
Source: OPTN & SRTR Transplant Data, 2012
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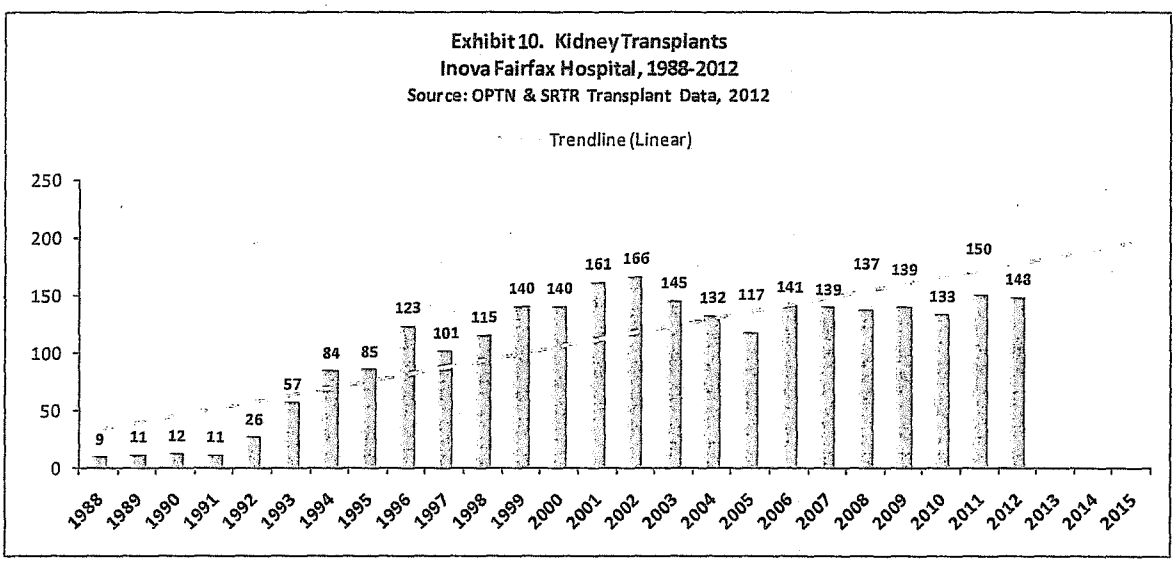
Exhibit 10. Kidney Transplants
Inova Fairfax Hospital, 1988-2012
Source: OPTN & SRTR Transplant Data, 2012
Trendline (Linear)
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EXHIBIT 2

1001 Pennsylvania Avenue, N.W., Washington, DC 20004-2595 ▪ p202 624-2500 ▪ f202 628-5116

crowell moring

John T. Brennan Jr.
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February 17, 2017

VIA EMAIL & HAND DELIVERY

CON # 12-2-8

Mr. Amha Selassie, Director
State Health Planning and Development Agency
899 North Capitol Street, N.E.
2nd Floor
Washington, D.C. 20002

Re: Additional Testimony and Information for Public Hearing Record Regarding District Hospital Partners, L.P.'s Transplant Services

Dear Mr. Selassie:

This letter provides additional testimony and information from MedStar Health, Inc., ("MedStar") on behalf of MedStar-Georgetown University Hospital ("MGUH") for inclusion in the public hearing record concerning your determination as to whether to "modify" or "retract" District Hospital Partners L.P.'s' Certificate of Need to operate a kidney and pancreatic transplant service and close that service. Your authority in this matter has been defined by the D.C. Court of Appeals Order and Judgment dated September 16, 2016. A copy of the Court Order directing the SHPDA's actions is included and attached hereto as Exhibit A. Having now considered "current circumstances," your authority to act remains the same, as set forth in the Order. Based on the testimony and submissions made at the February 6th public hearing, DHP has not argued, and has made no showing, either legally or factually that its approach can or should be "modified" in any way. Thus, under the Court Order, the Certificate of Need issued by the SHPDA against its will must be retracted and the transplant service closed.

Under the rule of law, of course, the DHP transplant program should never have opened. DHP chose to rely on an interim decision while the CON review and appeals process was still being undertaken. DHP knew full well how the CON appeals process worked and that its case was not over – DHP itself took advantage of the appeals process at the Office of Administrative Hearings ("OAH"). Then, when the SHPDA sought Reconsideration of the OAH decision in this case, DHP tried to bootstrap the fact that it had voluntarily spent a few dollars opening the program into an argument that the case was moot. However, the SHPDA's Request for Reconsideration was not "moot," as OAH ruled. Next, DHP followed this strategy to ignore the

CON appeals process by claiming before the D.C. Court of Appeals that the appeal filed was also "moot" – an argument the Court explicitly dismissed in its decision.

In short, DHP has consistently acted as if the CON laws were optional. However, the CON process does not run that way. DHP knew that it risked losing its CON when it and opened its service early. Now, DHP ought to be instructed to "start over" in the CON process and to close its service. At this time, the SHPDA should and must honor and adhere to the rule of law by abiding by the Court Order and revoking the Certificate of Need, as invited to by the Court of Appeals. Permitting DHP to benefit from its risky decision to ignore the CON appeals process would reduce the District of Columbia's health planning laws and the SHPDA's authority and integrity to a shambles.

DHP cannot overcome this first hurdle, that is, to convince the SHPDA that it should be permitted to remain open despite the D.C. Court of Appeal ruling that SHPDA's original decision was correct, and entitle to deference. However, DHP also cannot argue that "current circumstances" would warrant any other result. DHP has not delivered to D.C. residents. Shockingly, in its two years of operation, only slightly over one D.C. resident per month has received a kidney transplant at DHP. And none have received a pancreatic transplant. At the same time, MGUH performed over 205 transplants last year, and even more capacity remains. MGUH could –at all times – have accommodated one more patient per month. MGUH has shown it can increase its transplant services as organs become available, and is nowhere near its capacity. If a full substantive CON review of the DHP application were required, DHP would not be able to prove its services were needed or that two programs operating below capacity are financially appropriate or efficient.

In addition to the Court Order, MedStar submits at this time the following additional information, including information requested by the SHPDA at Exhibits A through C. MedStar reserves the right to augment its legal argument and/or testimony on or before February 24th, as the SHPDA has permitted.

Sincerely,

John T. Brennan, Jr.

Enclosures

MEDSTAR ANALYSIS OF DHP'S FAILURE TO ENHANCE ACCESS TO D.C. RESIDENTS AND RESPONSE TO SHPDA INQUIRIES

I. DHP's Transplant Service Has Provided Minimal Additional Access to D.C. Residents.

Since opening in January 2015, DHP has had little impact on affording D.C. residents access to transplant services. Over the two years since program inception, DHP has provided no pancreatic transplant services, and 38 kidney transplant services to District residents – only a little over one transplant per month.

DHP has not delivered on its Certificate of Need application promise to enhance access to D.C. residents. Rather, DHP's recipients have come from the DC suburbs (Montgomery County, Fairfax County, Arlington, and Alexandria. (Montgomery County, Fairfax County, Arlington, and Alexandria), for which well over half of DHP's transplant services have been provided. Specifically, 48 of the 86 transplants that GW reportedly performed in 2015-2016 (56%) benefited residents not living in the District of Columbia.

II. MedStar-Georgetown Transplant Institute Continues to Provide Access to D.C. Residents in Growing Numbers

Even with DHP's positive opinion of its transplant service, MedStar Health, Inc., through the MedStar-Georgetown Transplant Institute ("MGTI") has continued to enhance access to minorities, and especially to D.C. residents. In 2016 alone, MGTI provided transplants to 205 individuals. This reflects a growing trend in serving D.C. residents. Below, we provide tables showing overall transplant patient counts at MGTI between 2012-2016, and for 2015-2016 by living/deceased donor status.

TABLE 1. NUMBER OF TRANSPLANTS PERFORMED AT MGTI ON DISTRICT OF COLUMBIA RESIDENTS (2015-2016)

	2015	2016	2015-2016
Living Donors	6	8	14
Deceased Donors	25	34	59
Total District Resident Transplants (Living & Deceased)	**31**	**42**	**73**
Total Transplants (District and Non-District Residents)	**201**	**205**	**406**
Percentage of Total Transplants From the District	**15.4%**	**20.4%**	**17.9%**

TABLE 2. DISTRICT OF COLUMBIA TRANSPLANT PATIENT COUNTS (2012-2016)

DC Quadrant	Kidney & Simultaneous Pancreas/Kidney Transplants	Pancreas Transplants Only
	(2012-2016)	(2012-2016)
NW DC	72	0
SE DC	42	0
NE DC	37	0
SE/NE DC	29	1
SW DC	3	0
Total:	**183**	**1**

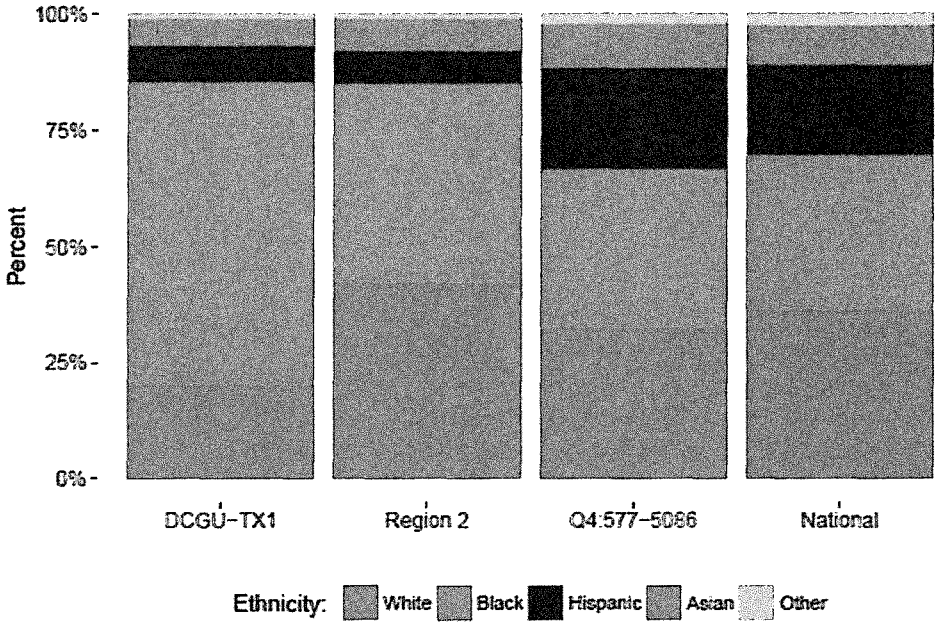
MGTI has regularly reached out to D.C. residents in numerous ways, as shown in the outreach efforts undertaken by MGTI. **Exhibit A**. MGTI anticipates this growth in D.C. resident access to continue as more organs become available. MGTI also leads the nation in transplants to minorities. Having generated a waiting list that is 79% comprised of minorities, which is over 25% more than the national average,[1] MGTI expects this trend to continue, and is committed to continuing to serve minorities in a meaningful way. MGTI's current waitlist is comprised of the demographic groups set forth in Table 3, below.

TABLE 3. CURRENT MGTI WAITLIST DEMOGRAPHICS

	Kidney	Pancreas	Kidney / Pancreas	All K or K/P	% of Total
MGTI Current Waitlist					
All Ethnicities on K, K/P wailtist	934	25	15	974	100%
White	189	10	4	203	21%
Black	606	12	9	627	64%
Hispanic	79	1	1	81	8%
Asian	56	1	1	58	6%
American Indian/Alaska Native	1	0	0	1	0%
Pacific Islander	1	0	0	1	0%
Multiracial	2	1	0	3	0%

[1] Organ Procurement and Transplant Network ("OPTN"), Kidney Benchmark Report (Jan. 2017). DCGU-TX1 is the identifier assigned to MedStar-Georgetown University Hospital. Region 2 includes Delaware, the District of Columbia, Maryland, New Jersey, Pennsylvania, and West Virginia.

TABLE 4. KIDNEY TRANSPLANT CANDIDATE ETHNICITY ON DECEMBER 31, 2016 (AS OF JANUARY 6, 2017)



Ethnicity (%)

	DCGU-TX1	Region 2	Q4:577-5086	National
White	20.32	42.38	32.62	36.42
Black	65.00	42.78	34.31	33.32
Hispanic	8.19	7.18	21.65	19.60
Asian	5.96	6.93	9.59	8.46
Other	0.53	0.72	1.84	2.20
Total	100.00	100.00	100.00	100.00

The distribution of ethnicity for candidates who were waiting for a kidney transplant on December 31, 2016 is shown in Figure 11. Overall, White candidates were the majority, followed by Black, Hispanic, and Asian candidates. Other ethnic groups accounted for 2.20% of the wait list.

MEDSTAR ANALYSIS OF DHP'S FAILURE TO ENHANCE ACCESS TO D.C. RESIDENTS AND RESPONSE TO SHPDA INQUIRIES

Based on the data provided in Table 5, between 2012-2016, MedStar has provided kidney transplants to 652 minority patients (78%), simultaneous kidney/pancreatic transplants to 30 minority patients (67%), and pancreatic transplants to 23 minority patients (53%). These statistics demonstrate that MedStar has been a national leader in this effort to serve the needs of minorities.

TABLE 5. DEMOGRAPHICS OF TRANSPLANT RECIPIENTS AT MGTI PROGRAMS (2012-2016).

Kidney Transplants	2016	% of total 2016	2015	% of total 2015	2014	% of total 2014	2013	% of total 2013	2012	% of total 2012
All Ethnicities	205		201		156		163		131	
White	51	25%	45	22%	37	24%	41	25%	30	23%
Black	124	60%	127	63%	96	62%	100	61%	83	63%
Hispanic	19	9%	23	11%	13	8%	11	7%	9	7%
Asian	11	5%	6	3%	9	6%	9	6%	9	7%
American Indian/Alaska Nat	0	0%	0	0%	0	0%	0	0%	0	0%
Pacific Islander	0	0%	0	0%	0	0%	1	1%	0	0%
Multiracial	0	0%	0	0%	1	1%	1	1%	0	0%

Kidney/Panc Transplants	2016	% of total 2016	2015	% of total 2015	2014	% of total 2014	2013	% of total 2013	2012	% of total 2012
All Ethnicities	21		3		11		4		6	
White	7	33%	0	0%	2	18%	2	50%	3	50%
Black	12	57%	2	67%	9	82%	2	50%	2	33%
Hispanic	1	5%	0	0%	0	0%	0	0%	0	0%
Asian	1	5%	1	33%	0	0%	0	0%	1	17%

Pancreas Transplants	2016	% of total 2016	2015	% of total 2015	2014	% of total 2014	2013	% of total 2013	2012	% of total 2012
All Ethnicities	14		9		8		7		5	
White	5	36%	3	33%	3	38%	6	86%	3	60%
Black	7	50%	4	44%	4	50%	1	14%	2	40%
Hispanic	2	14%	2	22%	1	13%	0	0%	0	0%
Asian	0	0%	0	0%	0	0%	0	0%	0	0%
Pacific Islander	0	0%	0	0%	0	0%	0	0%	0	0%
Multiracial	0	0%	0	0%	0	0%	0	0%	0	0%

III. MedStar Continues to Afford Its Patients Geographic, Financial, Physical, and Clinical Accessibility

A. Geographic Accessibility

MedStar's primary service area is the District of Columbia. As stated in Table 1 above, MedStar has provided 183 kidney and pancreatic transplants within the District in the past two years, 45 of which were provided to residents in Southeast and Southwest Wards.

As part of the broader MedStar Health System, MGTI links its transplant service capabilities to the Washington Hospital Center and the seven other MedStar hospitals in the Baltimore-Washington area. In fact, MedStar Washington Hospital continues to provide a wide array of preoperative and postoperative transplantation services. With additional kidney transplant facilities and clinics in Annapolis, Baltimore, Clinton, and Frederick in Maryland, and in Annandale, Virginia, MedStar assures seamless geographic coverage to its entire service area. Since July 1, 2016, MGTI has completed 233 evaluations for kidney transplants at four of these off-campus locations. Of these, 69 patients have been listed for kidney transplant at MGTI, proving the benefit of outreach to the communities that we serve. Before and after the transplantation procedure, patients have access to a broad range of services and staff at these locations to serve their needs.

B. Financial Accessibility

MedStar treats all patients, regardless of ability to pay. MedStar contracts with virtually all third-party payers, and routinely enters into "single case agreements" in order to ensure that no transplant candidate is deprived of the option to receive services at MGTI. Currently, MedStar Health's Managed Care Division is completing a comprehensive contracting initiative with Amerihealth Caritas District of Columbia and Trusted Health Plan, the District's Medicaid managed care organizations ("MCOs"). **Exhibit B.** While negotiations are ongoing, MedStar continues to serve members of these health plans through the aforementioned single case agreements. Nearly 300 single case agreements for pre-transplant, transplant, and post-transplant services have been signed with non-contracted payers in the last year, including nearly a third for Medicaid members. This is in addition to the patients MedStar serves through MedStar Family Choice, a Medicaid HMO that enrolls 55,354 individuals in the District of Columbia.

C. Physical Accessibility

MGTI does everything possible to provide its patients with easy physical access to transplant services. While not on a Metro line, MGTI's surgical facility at MedStar-Georgetown University Hospital provides free Uber car service to patients who have an inability to attend appointments or secure reliable transportation for financial reasons. All of MGTI's services are accessible by bus and through private transportation.

D. Clinical Practice Access

MedStar must dispel the notion created at public hearing that its transplant services are not available to "high-risk" patients. While clinical assessments may differ, MedStar has demonstrated consistently that it is capable of, and successful at, providing transplants to "high-risk" patients. For example, MGTI performs more transplants for patients who received a previous transplant, for patients who are more immune-sensitized, and for more diabetic patients than DHP. These patients are provided high-quality, successful care by MedStar's team of transplant surgeons, who must confer as a group to assess potential efficacy and risk in individual cases. Our decision to go forward with a particular transplant is consistent with established national guidelines and standards of practice. The collective experience of these surgeons assures high quality of care and ethical outcomes.

Prior to 2014, a patient's position on the kidney transplant prioritization was primarily determined by the time a patient was actively listed at an OPTN-approved transplant center. In other words, patients who had been on a waiting list for the longest period of time were at the top of the list. In December 2014, after a decade of debate among invested parties both within and outside the transplant community, the United Network of Organ Sharing ("UNOS"), under the authority of the OPTN, changed the kidney allocation policy to assign priority to patients who had been on dialysis for many years (a surrogate measure for disease severity), regardless of when they were actually listed for a kidney transplant. This change meant that patients who had been on dialysis for many years were immediately elevated to the top of the list and became immediately eligible for the next organ(s).

UNOS allows for patients to present, be evaluated, and listed at more than one program, including within the same donor service area ("DSA"). If a patient is listed at two centers within the same DSA served by one organ procurement organization ("OPO"), the referring neprhology is required to designate a "primary" center to avoid confusion when an organ becomes available. Under these circumstances, a kidney would be designated for a particular recipient regardless of the center at which the recipient is listed (i.e., the same kidney could go to either center).

E. MedStar has Significant Additional Capacity

MedStar provided 205 transplants in 2016, or approximately 1.3 transplants per week. This number could easily grow to two per week, or about three hundred procedures per year, fully covering the small number of transplants provided by the single surgeon at DHP over the past two years. Other hospital systems of equivalent size perform even more transplant procedures than MGTI, demonstrating the expandability of resources for transplant services. MGTI can easily absorb greater volume. For example, in 2016, University of Maryland Medical Systems performed 297 kidney transplants.[2] This would be easily achievable at MGTI. As has been expressed on many other occasions, the only factor limiting expansion of transplantation services is the availability of donor organs. The addition of another center in the Washington D.C.-metropolitan area has resulted only in a redistribution of the already limited supply of

[2] Sources: Kidney Link,

available organs, which has been static over the last 10 years from the local OPO. In fact, DHP's volume of transplants, particularly in the first year of DHP's existence is directly correlated with the loss of volume by Inova Fairfax.

TABLE 6. INOVA FAIRFAX VOLUME DIFFERENCE FROM 2012-2015

Inova Statistics	2012	2015	Difference	Percentage Change	GW 2015
All	**108**	**76**	**32**	**29.6**	**31**
Caucasian	38	28	10	26.3	8
African American	37	22	15	40.5	22
Living Donor	48	36	12	25.0	8
Deceased Donor	60	40	20	33.3	23

IV. Data Requested by the SHPDA

In addition, MedStar provides the following data to the SHPDA as requested at the public hearing.

- **Exhibit C**. Number of kidney and pancreatic transplants performed in last five (5) years by Zip Code and District quadrant (accounting for pre- and post-consolidation of service at MedStar-Georgetown)

V. Conclusion

DHP's Certificate of need must be retracted for DHP's failure to comply with the rule of law, and for opening its transplant service "at its own risk" while the CON review and appeal process was still pending. DHP should be required to close its service and begin the CON process anew on this basis alone.

Even if the DHP application were to be considered on its merits, however, the "current circumstances" are that DHP has not enhanced access to kidney or pancreatic transplant services to D.C. residents. In fact, DHP has provided no pancreatic transplant services whatsoever. MGTI has continued to offer accessible services to D.C. residents, and has far greater capacity to do so in the future. The DHP transplant service should be closed and its CON application revoked.

Even if the DHP application were to be considered on its merits, however, the "current circumstances" are that DHP has not enhanced access to kidney transplant services to D.C. residents, and has not performed any pancreatic transplants. On a clinical performance level, MGTI is among the top ten quality transplant institutions in the country. It continues to offer comprehensive services to any patient eligible for transplantation, regardless of payor. It serves more minority patients than any other center in UNOS Region 2 or nationally. It continues to offer accessible services to the residents of the District of Columbia, through the primary site at

MedStar-Georgetown University Hospital and through multiple other access points around the Washington D.C.-metropolitan region. It has capacity to expand volume as needed for the community that it serves. The DHP program is duplicative and inefficient both from an available organ distribution standpoint and from a health planning efficiency perspective. Therefore, DHP transplant service should be closed and its CON application revoked.

EXHIBIT 3

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May 9, 2014

VIA HAND DELIVERY

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Amha Selassie, Director
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Development Agency
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Re: MedStar Health, Inc.'s Request for Reconsideration of the Issuance of Certificate of Need Registration No. 12-2-8 for the Establishment of Kidney and Pancreas Transplant Services

Dear Mr. Selassie:

Pursuant to D.C. Code § 44-412, and as provided in the April 11, 2014 letter from the State Health Planning and Development Agency ("SHPDA"), MedStar Health, Inc. ("MedStar") hereby requests reconsideration of the decision awarding a Certificate of Need ("CON") to District Hospital Partners, LP ("DHP") for the establishment of kidney and transplant services. MedStar's request is timely, and, as detailed below, MedStar has demonstrated "good cause," as defined in D.C. Code § 44-412(b) and 22 DCMR § 4312.3, in support of this request.

I. Summary of Relevant Procedural History

Following an extensive review, on May 31, 2013, the SHPDA denied DHP's application for a CON to establish a new kidney and pancreas transplant program in the District of Columbia because DHP had failed to demonstrate a need for the proposed project. *See* SHPDA's Certificate of Need Review Findings in the Matter of: District Hospital Partners, LP, George Washington University Hospital, Certificate of Need Registration No. 12-2-8 at pp. 3-16 (May 31, 2013) (hereafter "SHPDA's Denial of CON").

After SHPDA denied its request for reconsideration of the CON decision, DHP appealed to the OAH on August 8, 2013. On January 27, 2014, the OAH reversed the SHPDA's decision, finding, based on "new evidence" submitted by DHP, that the SHPDA's determination as to the need for a new transplant program was "unreasonable," "an abuse of discretion," and "no longer [supported by] substantial evidence." *See* OAH's Final Order in *District Hospital Partners, LP v. District of Columbia Department of Health, State Health Planning and Development Agency* at 25, 28 (Jan. 27, 2014) (hereafter "Final Order"). The OAH then ordered the SHPDA to issue the CON to DHP. *Id.* at 29. SHPDA subsequently requested reconsideration of the OAH's reversal and moved the OAH for a stay of its Final Order pending reconsideration. *See*

SHPDA's Motion for Reconsideration and for Stay Pending Reconsideration and Appeal in *District Hospital Partners, LP v. District of Columbia Department of Health, State Health Planning and Development Agency* (Feb. 6, 2014). The OAH denied SHPDA's motion as to both requests. *See* OAH Order Denying Respondent's Motion for Reconsideration and Motion for Stay Pending Reconsideration and Appeal (Feb. 28, 2014). Thereafter, on April 11, 2014, the SHPDA, without conducting any further review, reviewing any other evidence, or reaching any other findings on which the CON decision was based, issued the CON to DHP.

II. MedStar's Request for Reconsideration Demonstrates Good Cause

D.C. Code § 44-412(a) provides that "any person[1], for good cause shown," may "request reconsideration of a certificate of need decision at a public hearing before the SHPDA." A person may demonstrate good cause by presenting evidence of any of the following:

(1) "[S]ignificant and relevant information not previously considered by the SHPDA";

(2) "[A] significant change in a factor or circumstance relied upon in reaching the decision";

(3) "[A] material failure to follow SHPDA review procedures"; *or*

(4) "[A]nother basis for a public hearing such as when the SHPDA determines that a hearing is in the public interest."

See D.C. Code § 44-412(b); *see also* 22 DCMR § 4312.3. MedStar need present evidence of only *one* of the aforementioned circumstances in order to demonstrate "good cause" in support of its request for reconsideration.

A. New Information, Not Previously Considered, Is Now Available Regarding Transplant Outcomes, Which Information Is Significant and Relevant to SHPDA's Decision to Issue the CON.

On March 20, 2014, the Scientific Registry of Transplant Recipients ("SRTR"), an ever-expanding national database of transplant statistics, released new transplant outcomes data for transplant centers in the Washington metropolitan region. *See* Scientific Registry of Transplant Recipients Report for the Washington Regional Transplant Community (2014) (hereafter "SRTR Report for the Washington Region") and SRTR Reports for Georgetown University Medical Center and Washington Hospital Center (2014) (hereafter "SRTR for MGTI"), Exhibit A.

According to this highly reliable source and these data, patients who received organ transplants at the MedStar Georgetown Transplant Institute ("MGTI"), which is owned and

[1] The definition of "person" includes a corporation, such as MedStar Health, Inc. *See* D.C. Code 44-401(16).

operated by MedStar, enjoy excellent transplant outcomes equal or superior to the outcomes of patients who received transplants in other area programs. *See* SRTR for MGTI (2014); *see also* Declaration of Matthew Cooper, M.D. (May 8, 2014) (hereafter "Cooper Declaration"), Exhibit B. For example, these data demonstrate that MGTI patients experienced low mortality rates, low first year graft failure rates, and optimal patient survival rates, as compared to patients transplanted at other centers. *See* Cooper Declaration at ¶ 13.

Further, Table F5 in the SRTR Report for the Washington Regional Transplant Community includes data reflecting the increased utilization of kidneys supplied by expanded criteria donors ("ECDs") for transplants in this region. *See* SRTR Report for the Washington Region at 27. However, because organs from ECDs pose a greater risk of complication and graft failure than organs procured from other donors, low-volume transplant centers tend to discard ECD organs in order to maintain a high patient survival rate, prevent the loss of Medicare funding, and avoid being placed on probation. *See* Cooper Declaration at ¶ 10. In contrast, the data for transplant centers in the District of Columbia show an *increase* in the number of kidneys utilized, from 29.9% in 2012 to 35.5% in 2013, a utilization rate significantly above the national average of 14.8%. *See* SRTR Report for the Washington Region at 27. These data are especially significant because they mean that area transplant centers, and primarily MGTI, are taking an aggressive and progressive stance concerning organ utilization and making certain that every transplantable organ available is used for District of Columbia transplant patients. *See* Cooper Declaration at ¶ 11.

These newly reported data demonstrating excellent outcomes in this region can be attributed partly to MGTI's current transplant volumes. *Id.* at ¶ 14. As explained in great detail below (*see* Section C, *infra*), the diversion of some transplant patients to a new transplant center in the District would cause MGTI to suffer a decline in clinical volume, thereby risking a negative impact on its patients and on its stellar transplant and patient survival rates. *Id.* at ¶ 15. The data presented in the SRTR Report are significant and relevant to this matter and were not previously considered by the SHPDA. In light of these new data which illustrate the potential impact of a new transplant program on the quality of care in the District, reconsideration by SHPDA of its decision to issue DHP's CON is warranted.

B. SHPDA's Decision Resulted From a Material Failure to Follow its Own Review Procedures.

1. The SHPDA decision to issue DHP's CON was not based on the appropriate process or standard for determining need for transplant programs.

When reviewing CON applications, the SHPDA must consider the "defined priorities, goals, objectives, and criteria and standards of the [District of Columbia] State Health Plan." *See* 22 DCMR § 4050.3. Concomitantly, the SHPDA must evaluate whether "[t]he project shall be needed to meet service and/or facility levels required for the District as specified in the D.C. State Health Plan." *Id.* at § 4050.6(a). If, as here, the State Health Plan ("SHP") does *not* specify a method for determining need for new transplant programs, "the project shall be found

to be needed *by the SHPDA Director* on the basis of a special analysis of District or larger area service and facility needs [including] the appropriateness of utilization rates of the same or similar services of the applicant and other providers." *Id.* at § 4050.6(b) (emphasis added). Such a special analysis may be proffered by the applicant or undertaken by the Director himself.

SHPDA abided by these clearly established procedures when initially reviewing DHP's CON application. The SHPDA Director concluded that the need for transplant programs was a function of organ availability, not the product of disease incidence. SHPDA's Denial of CON at 12-13. With this need methodology established, it then failed to use this method for determining transplant program need, as developed by the SHPDA Director pursuant to § 4050.6(b), in issuing its April 11, 2014 decision. Instead, in granting the CON, the April 11, 2014 SHPDA decision improperly relies on an irrelevant portion of the State Health Plan to find that a new transplant program is needed in this area. *See* Final Order at pp. 4-5, 27-28 (referencing provisions in the State Health Plan simply addressing disparities in access to kidney dialysis and transplants without regard to any assessment of *the availability of donor organs* which is the methodology established by the SHPDA Director for determining transplant program need, pursuant to § 4050.6(b)). Indeed, the information in the SHP on which OAH based its order to grant the CON is premised are not probative *in the least* on the issue of whether DHP demonstrated *need* for a new kidney transplant program on the basis of donor availability. Accordingly, the April 11, 2014 decision granting the CON is not based on the appropriate standard of need methodology for demonstrating a need for a new transplant program.

2. The April 11th CON was issued without the requisite review by SHPDA.

In issuing a CON to DHP without applying its own specialized competence and expertise to the "new evidence" on which the OAH Final Order was based, SHPDA failed to follow its own procedures for issuing a CON. Final Order at 29. While "new evidence" may be considered at the OAH stage of CON proceedings, *see* DC Code § 44-413(b), the OAH does not have the specialized expertise to assess the "new evidence." Instead, the D.C. Code is equally clear that "due account" must be given to the "experience" and "specialized competence" of the SHPDA in evaluating the multiple and complex factors that go into a determination to issue a CON for new services or facilities. *Id.* In a situation such as this, where new factual evidence has been adduced which SHPDA has not been able to review and weigh based upon its special expertise, remanding the matter to SHPDA for consideration of the new evidence is consistent with the D.C. Code's recognition of the "presumption of...regularity...experience, and specialized competence" afforded SHPDA's decision-making process with respect to CONs. *Id.*

Evaluating the "new evidence" in light of SHPDA's assessment of the need for a new transplant program in this area requires the application of SHPDA's specialized competence and experience with respect to the requirements and operation of successful transplant programs. Issuing a CON to DHP without such analysis is inconsistent with the statutory role accorded the SHPDA in reviewing CON applications, and its overall regulatory responsibility for the CON process in the District of Columbia. At a minimum, a public hearing should be held to permit the

SHPDA this opportunity. Accordingly, reconsideration of the SHPDA April 11, 2014 decision is warranted.

C. Reconsideration is in the Public Interest.

The public interest would be served by reconsideration of the April 11, 2014 grant of the CON. Allowing DHP to proceed with establishing an unnecessary transplant center would risk adversely impacting the quality of patient care and destabilizing other critical transplant programs in the area. Specifically, the integrity of patient care offered at existing transplant programs in the Washington metropolitan area – including that offered to patients served by Inova Fairfax, Walter Reed, Children's National Medical Center, and MGTI – would be compromised if a surplus transplant center were established.

The Medical Director for MGTI's Kidney and Pancreas Transplant Program, Basit Javaid, M.D., cautioned that the addition of a new transplant center in the District would, in light of the limited organ donor pool, destabilize existing area transplant centers by diluting their clinical expertise, thereby risking degrading their surgical outcomes and weakening their financial viability. *See* Statement of Basit Javaid, M.D., Medical Director of the Kidney and Transplant Program for MGTI, SHPDA Information Hearing Transcript (Feb. 19, 2013) at pp. 84, 92. Dr. Javaid's statements are buttressed by the new evidence, outlined in Section A, *supra*, regarding transplant outcomes in the District. Adding an unnecessary transplant center could jeopardize these positive outcomes and risk patient safety. *See* Cooper Declaration at ¶ 16.

The SHPDA itself has acknowledged that other transplant centers serving the District of Columbia are underutilized and recognizes that an additional transplant center would exacerbate this underutilization, thereby potentially affecting the quality of care at all centers. *See* SHPDA's Denial of CON at 11-12 ("The number of organ donors is down nationally, regionally, and locally. Current caseloads at most transplant services are well below volumes of two or three years ago[.] Literature suggests that high volume transplant centers usually have better (higher) time specific survival rates and lower unit operating costs."). Therefore, potential adverse impact on the public in terms of patient care and the integrity of existing area transplant centers necessitate reconsideration of the decision to grant a CON for a new transplant program.

Additionally, given the SHPDA's responsibility of administering, operating, and enforcing the CON program, *see* D.C. Code § 44-402(b)(3), allowing a decision that was granted improperly or otherwise without adequate expert review to stand would risk undermining the District's CON regulatory framework.

In short, reconsideration of the April 11, 2014 decision clearly would serve the public interest.

III. Conclusion

For these reasons, MedStar respectfully requests that the SHPDA grants its request for reconsideration.

Respectfully submitted,

John T. Brennan, Jr.
On behalf of the MGTI

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EXHIBIT B

DECLARATION OF MATTHEW COOPER, M.D., IN SUPPORT OF MEDSTAR HEALTH INC.'S REQUEST FOR RECONSIDERATION

I, Matthew Cooper, M.D., do hereby declare as follows:

1. I am over twenty-one years of age and competent to make the following statements.
2. I have personal knowledge of the facts set forth in this Declaration and, if called to testify as a witness, I can and will testify to these facts in a court of law.
3. I am currently the Director of the Kidney and Pancreas Transplant Program at the MedStar-Georgetown Transplant Institute ("MGTI") and have been a transplant surgeon for 12 years.
4. I also serve as a member of the Board of Directors for the United Network of Organ Sharing ("UNOS"), an organization that has contracted with the federal government to oversee the allocation of transplantable organs.
5. Additionally, I am a member of the Board of Directors for the Washington Regional Transplant Community (DCTC), which is the organ procurement organization for this service area and oversees the local distribution of deceased donor organs.
6. I submit this Declaration in support of MedStar Health Inc.'s Request for Reconsideration of the State Health Planning and Development Agency's letter awarding a Certificate of Need to District Health Partners, L.P. for a new kidney and pancreas transplant program.
7. The Scientific Registry of Transplant Recipients (SRTR) released a report containing data about the operations and performance of the DCTC on January 14, 2014.
8. Only 10% of the kidneys transplanted between July 2012 and June 2013 in the DCTC service area were exported outside of the service area.

9. 35.5% of kidneys used in the DCTC service area during this time period were from Expanded Criteria Donors ("ECDs"), up from 29.9% in the previous year. This percentage far exceeds the national average of 14.8%.
10. Organs from ECDs pose a greater risk of complication and graft failure compared to organs from other donors. Low patient or graft survival rates may lead to probation or a loss of Medicare funding. Accordingly, low volume transplant centers tend to discard organs from ECDs.
11. These data underscore the aggressive approach that MGTI and other transplant programs within the DCTC service area take toward organ utilization and the fact that there is enormous capacity among existing providers to perform more transplants.
12. The SRTR released outcomes data for kidney transplant programs within the Washington, DC and Baltimore areas on March 20, 2014.
13. These data show that MGTI patients experience outcomes, including yearly transplant rates, waitlist mortality rates, first year graft survival rates, and first year patient survival rates, that are on par with or superior to other programs in the region.
14. These excellent outcomes are due in part to current transplant volumes.
15. A new transplant program will lead to redistribution of patients and a decline in clinical volume, which will have a negative impact on patient outcomes.
16. These new data demonstrate that another transplant program is unnecessary and will lead to worse outcomes for patients in Washington, DC.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on May 8th, 2014

Matthew Cooper, M.D.

EXHIBIT 4

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February 24, 2017

VIA EMAIL AND HAND DELIVERY

Mr. Amha Selassie, Director
State Health Planning and Development Agency
899 North Capitol Street, N.E.
2nd Floor
Washington, D.C. 20002

Re: MedStar Georgetown University Hospital's Additional Comments to Public Hearing Record – District Hospital Partners Kidney and Pancreas Transplant Services, CON Registration No. 12-2-8

Dear Mr. Selassie,

MedStar Georgetown University Hospital, ("MedStar") submits these additional comments as part of the public hearing record related to the District Hospital Partners, L.P. ("DHP") Certificate of Need ("CON") for kidney and pancreas transplant services at George Washington University Hospital ("GWUH"). For both legal and factual reasons, the DHP CON must be revoked and its service closed. Additional information has arisen during the course of this public hearing further strengthening the need to revoke this CON.

The SHPDA now knows the following "current circumstances" about the GWUH kidney and pancreas transplant services:

- DHP has failed to demonstrate that GWUH has met a need for kidney transplant services for D.C. residents, providing only about one transplant per month to D.C. residents over two years, and only twenty in the past six months, or less than one a week.

- DHP has failed to provide any evidence that it is meeting a need for pancreatic transplant surgeries, having performed none in its two years of operation since GWUH "opened" the transplant service.

In fact, DHP's recent testimony effectively admits to DHP's failure to carry out the CON as awarded in April 2014.[1] In the 34 months since receiving the CON, GWUH has failed to establish a kidney and pancreatic transplant service as authorized. As a result of this failure alone, the DHP CON should be revoked.

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[1] Attachment A.

I. There Is No Public Need for the DHP Kidney and Pancreas Transplant Service at GWUH

MedStar does not believe that the SHPDA has any authority in this case but to revoke the DHP CON, pursuant to the D.C. Court of Appeals' Order issued September 15, 2016.[2] While DHP would wish that the Court granted the SHPDA broader authority – such as to "affirm" the CON – preceding its 34-page Opinion, the Court issued a simple Judgment and Order to the SHPDA: to either "modify" or "revoke" the DHP CON. For reasons mentioned in our previous comments,[3] revocation and closure of the GWUH service is the only option available to the SHPDA. Even if you consider standard CON review criteria as if DHP had filed a de novo application, only one result may arise.

The prematurely opened kidney and pancreatic transplant service would not demonstrate that it is fulfilling a public need that would be otherwise unmet. DHP has particularly failed to meet its promise to D.C. residents. Only 38 D.C. residents have received kidney transplants at GWUH in two years – about one a month.

At the same time, MedStar continues to grow its transplant services at MGUH to D.C. residents, making clear it can accommodate those needs. In the past two years, MedStar provided kidney transplants to 73 D.C. residents and to over 183 D.C. residents in the past five years.[4] This reflects a steady increase in the transplants provided to the D.C. population, and MedStar has capacity to provide many more such transplants, subject to expansion of the organs available. DHP cannot identify an "unmet public need" for D.C. residents.

More importantly, DHP has failed to demonstrate that there exists an "unmet public need" for the GWUH pancreatic transplant service. Surprisingly, DHP admitted at public hearing, when questioned by the SHPDA that it has not in fact instituted a kidney and pancreatic transplant service as authorized by the CON.[5] In fact, it has yet to provide a single pancreatic transplant – now about three years after receiving its CON approval.

This failure to demonstrate or meet a public need for pancreatic transplants presents a two-fold problem for DHP. First, it obviously proves that such a service is unnecessary. Second, it makes clear that DHP has not fulfilled its promises with respect to the CON it received, nor did it previously advise the SHPDA of its failure to do so. In no Progress Report submitted prior to opening its service did DHP notify the SHPDA that the second part of its CON approval – the pancreatic transplant service – was not opening or that it would be delayed,

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[2] Attachment B.

[3] Memorandum, "Legal Issues and Process Recommendations to the SHPDA for Determining whether District Hospital Partners' Transplant Services Certificate of Need Should be Retracted and The Service Closed," (Dec. 19, 2016) (on file with agency).

[4] MedStar Analysis of DHP's Failure to Enhance Access to D.C. Residents and Response to SHPDA Inquiries pgs. 2 and 4, (filed Feb. 17, 2017) (hereafter, the "MedStar Analysis").

[5] Attachment C. Hearing Transcript, State Health Planning and Development Agency, (Feb. 6, 2017) pages 157-158 (hereafter, "Transcript").

nor did DHP so notify the SHPDA following the opening of its kidney transplant component in January 2015.[6]

In addition, DHP at no time sought SHPDA's approval for changes in the approved project, as required under the D.C. CON statute for alterations in a project of this magnitude. MedStar submits, therefore, on an independent basis, that DHP's CON should be revoked for failure to abide by the specifications set forth in the CON itself and based on violations of 22-B DCMR §§ 4005.1 *et seq.*[7]

Finally, DHP has failed to demonstrate that GWUH is meeting a general unmet public need for kidney transplant services. In January 2017, GWUH provided but a single transplant – one transplant. In the past six months, GWUH has provided a total of only twenty transplants – less than one a week. Therefore, GWUH's data actually shows a recent decline in its number of transplants and its projected 12-month average will be only forty based on the last six months – down 20% from the number GWUH reportedly performed in calendar year 2016.

MedStar submits that whatever volume GWUH's program has generated is based on two key strategies: (1) the importation of organs from outside of the Organ Procurement Organization ("OPO"); and (2) performing transplants for non-D.C. residents. Specifically to the latter point, GWUH has achieved its minimal volume by attracting patients from Maryland and Virginia – not D.C. In fact, since January 2015 until the end of 2016, 56% of its transplants went to non-D.C. residents.

In contrast, MedStar maintains and grows its transplant services using traditional, scientifically proven assessments, clinical guidelines, and standards. From 2015 to 2016, the number of kidney and pancreas transplants performed at MedStar rose from 213 to 240. As we discuss below, with four full-time kidney and pancreas transplant surgeons and five additional surgeons on staff with the requisite training to perform kidney transplants,[8] MedStar's capacity to provide additional transplants is significant – far in excess of the transplants reported by GWUH over its first two years. For instance, any one of MedStar's existing four dedicated surgeons could certainly have performed the single transplant conducted at GWUH in January 2017 reported in the most current Organ Procurement and Transplantation Network ("OPTN") data.

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[6] July 11, 2014 Progress Report provided as Attachment D, and October 8, 2014 Progress Report provided as Attachment E.

[7] Attachment F.

[8] The dedicated kidney/pancreas transplant surgeons are: Matthew Cooper MD, Director Kidney/Pancreas Transplantation; M. Reza Ghasemian MD; Jennifer Verbesey MD; and Peter Abrams MD. The additional surgeons fully-trained in multi-organ transplant are: Thomas Fishbein MD, Exec. Director, MedStar Georgetown Transplant Institute; Rafael Girlanda MD; Cal Matsumoto MD; Jason Hawksworth MD; and Alexander Kroemer MD.

II. SHPDA Can Make No Finding as to the Quality of Care Provided at the GWUH Transplant Program

Under the standard CON review process, an applicant has the burden to demonstrate that its proposal will result in the provision of quality health care services. 22-B DCMR § 4012.16.[9] No such finding can be made on the record in this case.

The Scientific Registry for Transplant Recipients ("SRTR"), which is the organization contracted by the federal government to regulate transplantation, has established time frames for reporting patient and graft survival after these procedures. The outcome data are reported for one- and three-year periods, usually with a lag of at least six months. While GWUH has shown acceptable one-year outcomes in a very small number of patients, it is premature to extrapolate these data as a measure of quality of program success overall. The safety, efficiency, and quality of a kidney transplant program is not measurable only two years into operation as is the current circumstance with the GWUH program. GWUH has only undertaken 86 kidney transplants and no pancreatic transplants in that period of time. [10]

Long-term success after transplantation requires judicious consideration of many factors including co-existing conditions, psychological readiness, family support structure and more. The overall management of these factors is critical to the optimal timing of transplantation and achieving the most successful long-term outcome after transplantation. What is known with respect to the GWUH patients treated thus far is that its transplant program management is not opposed to accepting "high risk" patients – for example, a patient with multiple myeloma only recently in remission. Quality and success cannot be properly assessed in a complex clinical field such as organ transplantation by the number of transplant procedures that a particular surgeon elects to perform. Long-term patient and graft (organ) outcomes are the only objective measures of quality in this clinical context.

Therefore, given the lack of long-term data regarding GWUH's transplant program, SHPDA can make no finding on the record as to the quality of services provided at GWUH.

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[9] This regulation reads, "[e]ach applicant shall satisfy the criterion for assurance that the care to be provided is of acceptable quality. The standard for satisfying this criterion is by providing evidence and assurances that it will meet professional and community standards of quality care. The applicant shall document compliance with this standard by showing that the project conforms to the requirements of District and federal regulatory agencies and recognized accreditation bodies including the Joint Commission on the Accreditation of Health Care Organizations and the Commission on Accreditation of Rehabilitation Facilities."

[10] "SRTR currently evaluates transplant outcomes at three time points: 1 month, 1 year, and 3 years after transplant. In addition, SRTR evaluates two different outcomes: 1) survival with a functioning transplanted organ, and 2) survival regardless of whether the organ continues to function. SRTR uses complex statistical methods to perform these evaluations. These methods attempt to adjust for the case mix at the transplant program so programs that perform transplants in sicker patients, or accept higher-risk donors than other programs, are not penalized in their evaluations." SRTR, "Understanding SRTR's outcome Assessment," http://beta.srtr.org/about-the-data/guide-to-key-transplant-program-metrics/txguidearticles/5-tier-outcome-assessment/ (last visited Feb. 23, 2017).

III. Unnecessary Duplication of Services

MedStar's transplant staffing and other resources far exceed those at GWUH. This does not make for a "monopoly," but predisposes to a more cost efficient, effective and generally higher quality operation. It is a fact described in the medical literature that higher volume transplant programs perform more favorably than small volume programs; they have greater experience with a myriad of conditions and presentations and an ability to make optimal use of the available resources, avoiding redundancy. At its basis, the DHP program at GWUH is duplicative of an already accessible and proven excellent service; as such, the unnecessary resources expended for its operation pose an added cost burden to our local healthcare community.

In contrast to GWUH's operation of a one- or two-surgeon transplant service, MedStar's far more active, high-quality transplant program is staffed with four dedicated kidney transplant surgeons and five additional surgeons trained in multi-organ transplantation (nine in total); all of these surgeons have expertise in kidney transplantation and combined operations involving the kidney with the liver or pancreas. The transplant program at MedStar currently performs approximately 240 transplants per year (or about 50 transplants for each of its four specialized surgeons). MedStar has existing personnel resources to easily perform many more additional procedures. Thus, the MedStar program could absorb the current transplant volume at GWUH without any additional recruitment of surgeons. In contrast, GWUH has limited surgeon back-up, an issue that we believe jeopardizes the delivery and quality of patient care.

As an organization, MedStar manages its cost structure prudently so as to be able to fund new technologies and bring advanced clinical practices to patients. MedStar in particular manages its transplant services with sufficient resources that enhance productivity while keeping the operation as "lean" as possible without any concession in quality of care or patient experience. Most importantly, because of our volume and resources, MedStar has longstanding experience with, and capability for, the care coordination of very complex patient populations, particularly those likely to have multiple co-morbid conditions such as patients requiring organ transplantation. MedStar's skill in managing these patients has resulted in a long history of facilitating high-quality care for, and effective cost management of, this fragile population.

IV. MedStar's Transplant Services are Highly Accessible – Especially to D.C. Residents

As previously stated, MedStar Georgetown prides itself on being highly accessible to patients, including those residing in its primary service area – the District of Columbia.

In 2015-2016, MedStar performed transplants on 73 D.C. residents (31 in 2015 and 42 in 2016), many of whom live in the Southeast and Northeast areas of the District, which includes Wards 5, 6, 7, and 8.[11] MedStar treats patients from all payor sources, including Medicaid, and

[11] MedStar Analysis at 2.

facilitates free transportation – by Uber or otherwise – to patients who cannot pay for those services.[12]

GWUH data show that it has been primarily "accessible" to the population of the D.C. suburbs rather than a majority of District of Columbia residents, although its original CON application promised otherwise.[13] MedStar has a demonstrated record of serving D.C. residents over the many years of its operation.[14]

V. The Provision of Transplant Services to District of Columbia Residents Will Not Be Negatively Affected By The Closure of Transplant Services at GWUH

A. GWUH Has Provided No Pancreatic Transplants Since Issuance of the CON Three Years Ago

As stated previously, pancreatic transplant services are non-existent at GWUH; "closure of the pancreatic transplant program" would therefore not impact service delivery or access to pancreatic transplant patients in any way. In the meantime, MedStar's pancreatic transplant service delivery remains available and growing in volume.

B. *Kidney Transplant Recipients All Participate in a Single, Unified "Waiting List"*

While GWUH may have a list of patients who have designated it as their "primary" hospital, GWUH cannot alter the placement of the patient on the organ transplant waiting list. What GWUH has done, however, is to take more clinical risks with its patients – risks whose long term outcome cannot be predicted in a year or two post-transplant. In its zest to build up volume in order to justify its existence, GWUH has ignored sound medical judgment appropriate to its listing of high-risk candidates for transplant.

Closure of the GWUH program would enable patients on its waiting list to immediately transition, without jeopardizing waiting time, to a larger program with proven efficiency in accommodating patients, even those at higher risk for transplant. No patients will be disadvantaged, and listing protocols, driven by United Network for Organ Sharing ("UNOS") the outside arbiter of organ allocation, will remain the same. In fact, MedStar submits that its experienced clinical decision-making expertise will result in ensuring that patients receive the best-functioning kidney for them and the most advantageous outcome over the long term.

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[12] MedStar Analysis at 5.

[13] DHP, Attachment A to Post-Remand Hearing Submission Regarding Kidney and Pancreas Transplant Services at George Washington University Hospital, CON No. 12-2-8, at 4 (Feb. 17, 2017) (relevant excerpts provided as Attachment G.)

[14] MedStar Analysis at 2-5.

C. All Patients Who Have Received Transplants at GWUH Could Have Been Accommodated At MedStar

The GWUH transplant service is not needed. It is duplicative of existing services, and offers no unique access or treatment to any specific patient population. Its closure would have no effect on the provision of transplant services to D.C. residents. As stated throughout this submission, the data are clear that GWUH's program is not fulfilling any deficit in the availability of kidney or pancreatic transplant services. GWUH has only provided kidney transplants to only 38 D.C. residents in two years. In January 2017, GWUH provided a single transplant in the entire month (a fact not brought to the SHPDA's attention at the February 6, 2017 public hearing or in subsequent submissions to the agency). In contrast, MedStar at MGUH provided 240 total transplants, including 35 pancreatic transplants in 2016, an almost 200% increase in the latter over the prior year; this program is viable and growing rapidly. Further, as opposed to the limitations presented by GWUH's limited surgeon transplant staff, MedStar's transplant team consists of four transplant specialists and five additional surgeons. Based on these resources, were GWUH's transplant service to close, there would be no lack of transplant service capability in the District.

D. MedStar Has Significant Experience in the Consolidation of Less Cost Effective Transplant Programs

The existence of a low-utilization transplant service program in our service area raises concerns regarding cost, quality, and duplication of services. As a reminder, the District of Columbia was the locale of two such inefficient transplant centers in the past – at Howard University Hospital ("HUH") and, importantly, the earlier program at GWUH. These programs closed due to their inability to maintain sufficient volume to support the cost structure. From a health planning perspective, this experience should not be repeated.

In 2015, MedStar, recognizing the value of consolidation of expertise, skills, staff, equipment, and costs, transitioned the surgical component of its transplant program at MedStar-Washington Hospital Center ("MWHC") to a single transplant surgery program at MedStar Georgetown University Hospital. Integral to the consolidation was ensuring convenience and continuity of care for its patients, and for these reasons, MedStar maintains all pre-transplant evaluation services and post-operative follow-up transplant services at MWHC. MedStar conducted this consolidation with no adverse impact whatsoever on patient care, access, or waiting lists. In fact, the consolidation of the program resulted in great operational efficiency accompanied by greater flexibility in matching donors with recipients from the larger, consolidated waiting list. MedStar has experienced an overall increase in the number of transplant procedures performed at the centralized location of its transplant surgery services, while enhancing patient care. Based on this specific experience with absorbing, in the case of MWHC, a large volume program, MedStar anticipates no issues related to the capacity to accommodate a greater volume of patients, should GWUH be closed.

VI. Conclusion

Based on the September 15, 2016 Judgment and Order of the D.C. Court of Appeals, the SHPDA is bound to either "modify" or "revoke" the CON that it was ordered against its will to issue to DHP on April 11, 2014. While the appeal of that CON was pending, DHP took a business and clinical gamble in prematurely opening a kidney transplant service that may not be sustainable (it has never opened its pancreatic transplant service). Along the way, DHP failed to advise the SHPDA that it would not be performing as required by that CON, and failed to conform its actions to its approval.

At its core, the District's CON program as administered by SHPDA is a well-conceived, important statutory and regulatory framework that must be respected and followed; it is not acceptable that individuals ignore the rule of law. Indeed, DHP has done little throughout the course of this CON review to demonstrate its respect for the "rule of law:"

- it opposed the SHPDA's request for reconsideration at the Office of Administrative Hearings ("OAH") on the basis it had already spent a few dollars, making the SHPDA request "moot;"

- it then argued to the D.C. Court of Appeals that the Court's review was "moot" – because it had "at its own risk" decided to open its service; and

- it ignored CON requirements to comply with the specifications of a CON and request from the SHPDA authority to vary its actions.[15]

Moreover, the CON law requires that an applicant demonstrate a "public need" for its proposed service – an unmet need that could not otherwise be accommodated by existing providers. *See* D.C. Code § 44-406(a). Short duration of its operation aside, DHP cannot demonstrate that its transplant service at GWUH has closed a gap in public need – there is no need.

For the reasons set forth above, MedStar requests that the SHPDA revoke the CON DHP was forced to grant to DHP on April 11, 2014, and commence the process of closing the GWUH transplant service, under SHPDA's direction.

Sincerely,

John T. Brennan, Jr.

Enclosures

[15] Respondent District Hospital Partners, LP's Supplemental Brief Regarding OAH Decision Reversing Agency Decision Below at 15-18, (Oct. 15, 2015) (excerpts provided at Attachment H).