BEFORE THE MARYLAND HEALTH CARE COMMISSION

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

MEDSTAR FRANKLIN SQUARE MEDICAL CENTER'S RESPONSE TO THE INTERESTED PARTY COMMENTS OF UMMC AND JHH

MedStar Franklin Square Medical Center ("MFSMC"), through undersigned counsel, hereby submits its response to the comments submitted by the University of Maryland Medical Center ("UMMS") and Johns Hopkins Hospital ("JHH") on MFSMC's updated needs analysis for its application for a kidney transplantation service.

I. INTRODUCTION

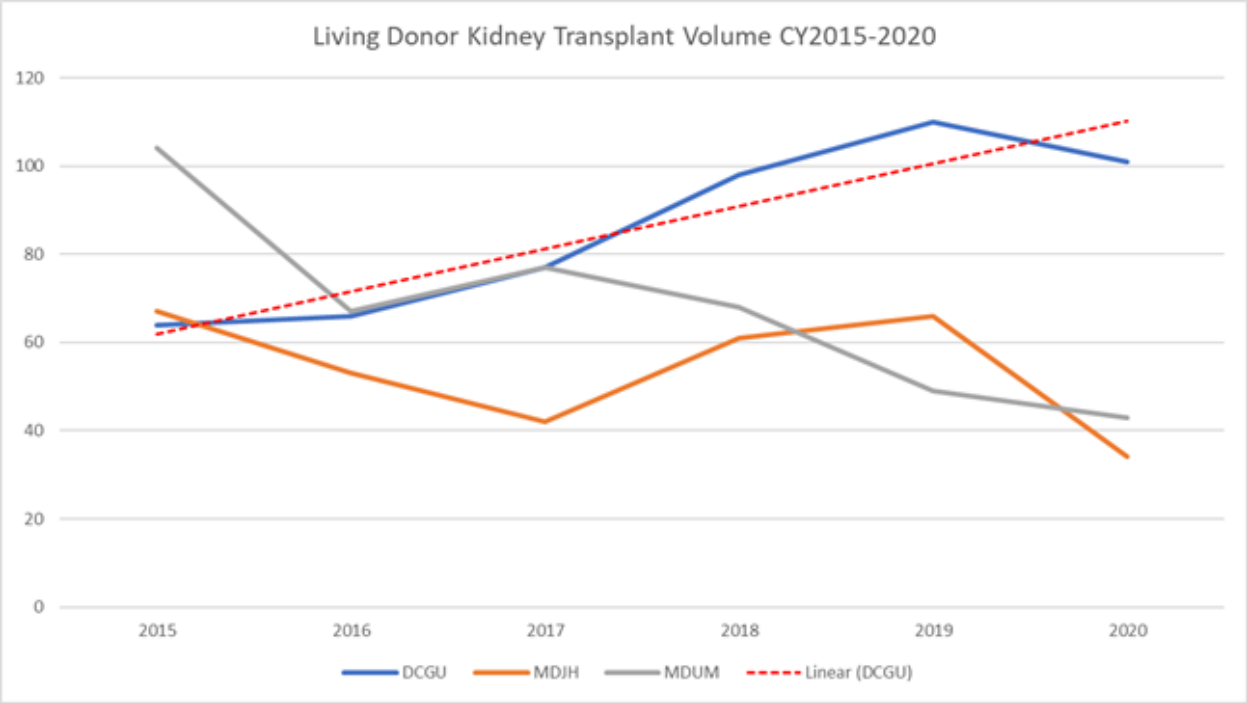
As commented in the original application, MFSMC, in partnership with MedStar Georgetown Transplant Institute (MGTI), believes that it can further support and augment the care of patients needing kidney transplantation in the Baltimore region. The brief narrative below addresses the specific concerns that were raised in the Interested Party Comments presented from both UMMS and JHH.

II. CREATING GREATER ORGAN AVAILABILITY TO MEET NEED[1]

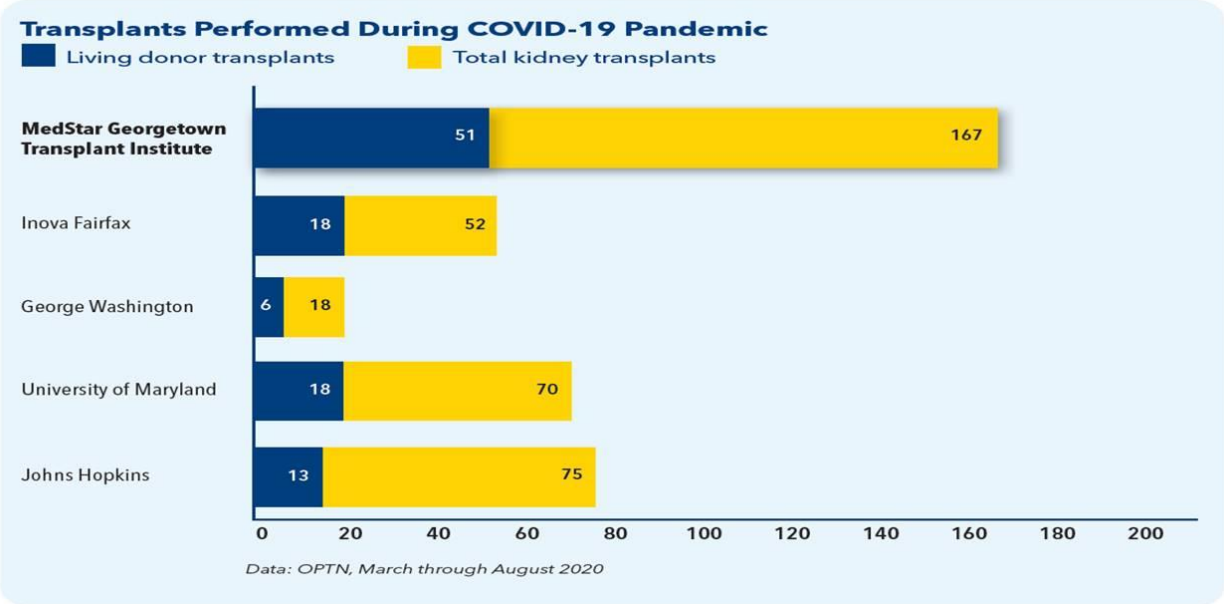
- **Living donor transplantation**. MGTI has a robust team and detailed processes in place that include extensive community outreach, individual patient/family education and the development of much collateral educational and public marketing materials directed toward promoting living donor transplantation wherever possible. Through these efforts, the program has experienced continued growth. The first graphic below compares the five-year volume trajectory of these procedures for MGTI, UMMS and JHH, with MGTI (blue line) leading substantially.

  Attention to this important strategy for increasing organ availability beyond the deceased donor pool has yielded great benefit to many patients who otherwise would be waiting years for an organ to be offered. MGTI operated services continuously through the peak of the COVID-19 pandemic (see second graphic below), through its strong commitment to telehealth services, while other Centers ceased operation entirely.

[1] *See* COMAR 10.24.15.04B(1)(a)



Source: SRTR



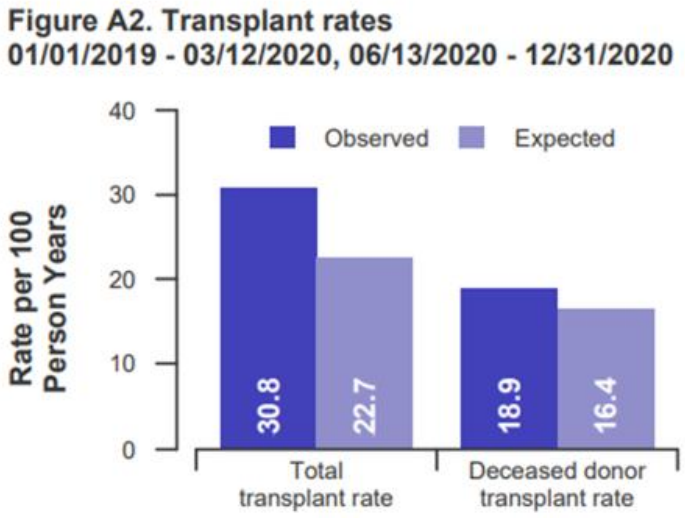
Source: SRTR

- **<u>Donor/Recipient "Swaps"</u>**. Related to the above paragraph, more living donor transplants can be achieved through the meticulous evaluation of the donor/recipient pool of individuals who are willing to participate in living donation. In this scenario, donor-

recipient pairs who present for living donation but may not match with one another, can be matched with unrelated individuals in a larger pool, hence achieving a greater number of successful transplants. MGTI performed "swap" procedures in as many as 53 pairs in CY 2020, with excellent outcomes for all.

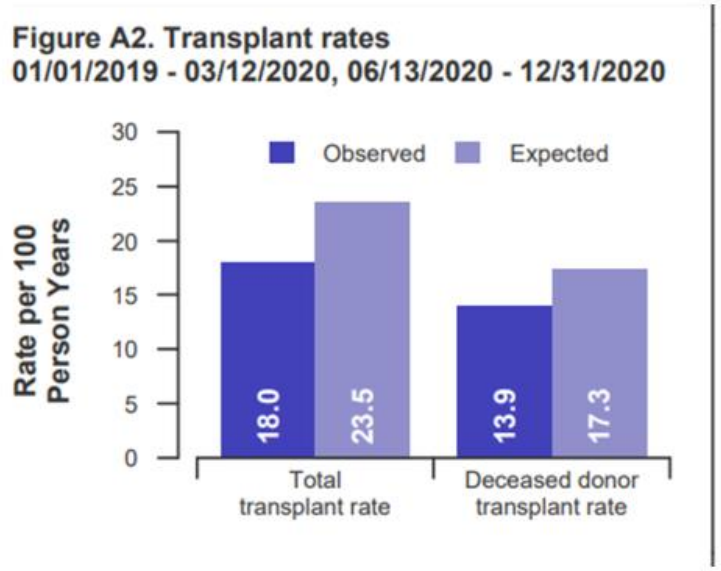
- **Desensitization Protocols**. Targeted toward individual patients on the waiting list who have sensitivity to human leukocyte antigens (HLAs), customized protocols have allowed numerous patients who otherwise would not be afforded matching opportunities with both deceased and living donors, to undergo transplantation. Desensitization to HLAs involves treatment with immunomodulating therapies designed to reduce levels of anti-HLA antibodies, thus expanding organ availability to more patients in need. MGTI has extensive experience in this area and will extend the expertise to MFSMC. This may also be coupled with swaps to identify more appropriate donors for which desensitization is believed to be more successful.
- **Effective Organ Utilization**. We found the narrative, as well as the graphic used by UMMS on pages 9-11 misleading. The accepted metric from the nationally recognized source -- SRTR -- to address this issue is the TRANSPLANT RATE, which is based upon a U.S. risk-adjustment model that considers not only the imports that were accepted but all offers - and allows comparison among programs. The graphic below, sourced from available SRTR data, shows that the observed MGTI Transplant Rate is greater than expected – versus UMMS and JHH which show lower than expected Transplant Rates.

Transplant Rate - MGTI



Source: SRTR

Transplant Rate - JHH



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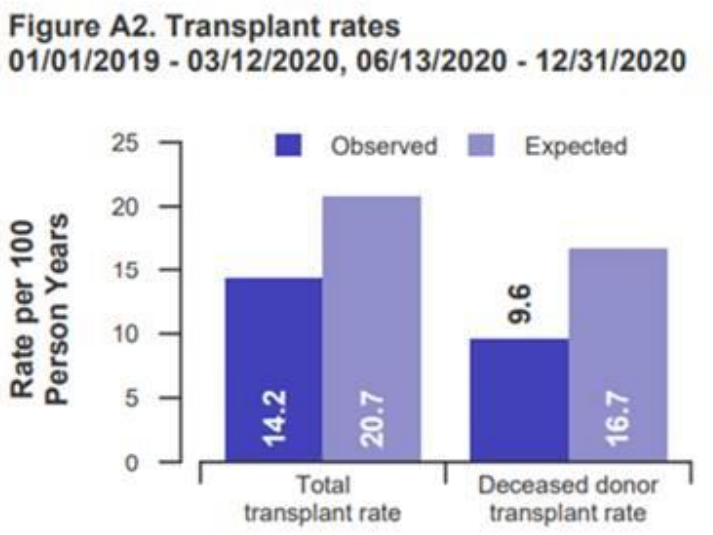


Source: SRTR

- **Clinical Research**. MGTI continues to pursue opportunities toward innovating treatment options in transplantation through its Center for Translational Transplant Medicine (a center within GUSOM/GUMC). In fact, although UMMS mentions MGTI's "conspicuous absence" from the APOL1 multi-center trial (footnote page 17), of even greater importance and practicality, MGTI is collaborating with Northwestern Medical School through an RO1 grant, awarded to look at increasing consent rates in achieving testing compliance. The Research Project (R01) grant is an award made to support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing the investigator's specific interest and competencies, based on the mission of the National Institutes of Health (NIH). These grants are extremely competitive.
- **Educational Resources Targeted at Awareness**. Over the last several years MGTI has conducted a variety of educational forums for physicians, patients, and the public toward

increasing awareness of the solution that transplantation offers to patients with advanced kidney disease. In addition, MGTI operates outreach clinics around the area, including five in Maryland, offering Maryland residents convenience and access to these needed services. These structural and educational activities have been ongoing despite MGTI's lack of a transplant facility in Baltimore.

- **Distributed Care Delivery Network**. MedStar Health believes that serving continuity of care in its own population of patients serves the greater good of the communities that we all serve. As transplantation has become more commonplace among the higher risk and minority populations in the state, the ability to align required lifelong transplant follow up care with cardiac, pulmonary, rehabilitation and other specialties for continuity of patient care is essential to the mission of an accountable organization. Satisfying our "internal need" is not in conflict with serving community need, as the commentors seem to imply.

III. DE NOVO ALLOCATION POLICY IMPACT[2]

As has been discussed, the CMS determined that it could no longer defend the use of the Organ Procurement Organizations (OPO) as the central basis for organ allocation. This realization led to modeling and implementation of a new system of organ allocation.

- **Impact of New Allocation Policy.** Although both UMMS and JHH criticize MFSMC's failure to adequately address how the new OPO allocation policy impacts the need for the proposed program, JHH inadvertently reveals its genuine opinion in stating: "the policy change that the Commission has directed MedStar to address did not go into effect until **March 15, 2021.** … Indeed, the new policy has been in effect for too brief a period for anyone to draw meaningful conclusions about volume shifts. The fact that the policy came

[2] *See* COMAR 10.24.15.04B(1)(b)

into operation during the COVID pandemic heightens the uncertainty of the effects of the policy on any possible need for an additional kidney transplant program in the Baltimore/Washington region." JHH Comments at 10 (emphasis in original). Given this concession that the policy is too new to draw meaningful conclusions, it is unclear what data JHH and UMMS suggest should be relied upon. We prefer to maintain conservative volume projections for a new program at MFSMC until such time as the current observed trends in organ allocation to the region become predictable over a longer time frame.

- **Import/Export Discussion by UMMS**. Since the OPO basis for importing or exporting organs has been discarded as of the implementation of the new allocation algorithm, this entire section on pages 10-12 of the UMMS Comments lacks current relevance. It has been observed thus far that the new allocation system has made available more kidneys from outside traditional DSA boundaries to all programs within the newly circumscribed geographical area around the Baltimore-Washington region.[3] Given the geographical boundaries that have been circumscribed by the CMS, neither the formula nor its effects will change through the addition of a new program.[4]
- **Loss of available organs from UMMS and JHH through addition of a program.** The existing programs in Baltimore are actively transplanting at volumes that far exceed the minimal volume thresholds prescribed by MHCC and effects from the new allocation methodology, on either existing program would be insignificant, even if MFSMC exceeded its projections.

[3] *See, e.g.*, Exhibit 1, September 22, 2021 Letter from Lori E. Brigham to Michael O'Grady at 2.

[4] As an aside regarding data accuracy as reported by UMMS in its narrative (page 10) on the import/export of organs, the MGTI import rate of 29% exceeded the UMMS rate of 13%.

The evaluation and listing of more patients, and recruitment of more potential live donors (as discussed in the Need section) serve to benefit all Maryland residents seeking organ transplant. Moreover, more listings means that additional kidneys will accrue from surrounding areas and be offered to Baltimore residents.

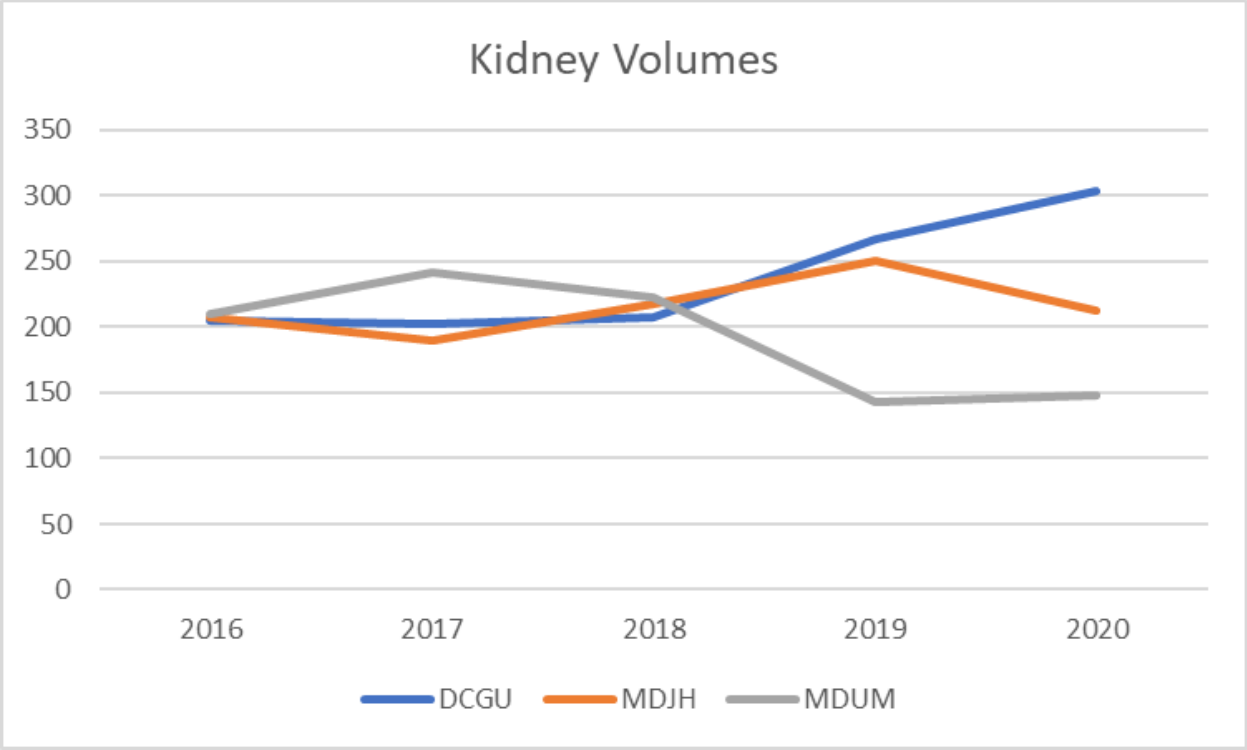
IV. SIMULTANEOUS LIVER KIDNEY (SLK) TRANPLANT

We are puzzled by the assertions made by JHH regarding volume and severity of SLK transplants. JHH states on page 3 that SLK is their "most common form of multi-organ transplant" and presents a combined volume (JHH and UMMS) of 24 procedures performed annually. Later, on page 13, JHH states that SLK is an "uncommon" and a high-risk procedure. MedStar Health's interest is in maintaining continuity of care among its patients needing both organs. MGTI performs many multi-organ procedures of different varieties of which SLK is neither the most common, the most complicated nor the highest risk. As an expansion of the team at MGTI, MFSMC will be able to perform these procedures comfortably and safely.

V. INITIATION OF A SUCCESSFUL EXPANSION OF MGTI AT MFSMC

- **MGTI Performance Success is Transferrable**. MGTI is entirely confident in its ability to achieve its objectives at MFSMC despite the UMMS assertion on page 2 that the experience, skills and overall performance of the MGTI program are not transferrable to MFSMC and JHH's criticisms of the program at pages 14-16. The MGTI record speaks for itself; as the trend line shows on the volume graphic below, the upward trajectory in volume at MGTI over the last ten years has been steady and significant. The growth shown is attributable to strong and consistent leadership and to the directed focus of a large and motivated team. The same leadership and team will have principal oversight of the

MFSMC site. Based on experience, the expectation of a successful operation at MFSMC is entirely realistic.



Source: SRTR

- **MedStar Franklin Square Medical Center**. MFSMC has benefitted from a number of sophisticated improvements in facilities and service offerings over the time frame of the pendency of this Application. A new surgical pavilion opened and is operational. A new helipad was constructed last Spring on the roof of the emergency room to facilitate critical transfers to the facility. A neurovascular intervention program, inclusive of a dedicated interventional suite, new CT scanner and neuro ICU, has been established and is fully functional. These additions overlay an existing platform of superb gastrointestinal, critical care and cancer care, the state's largest emergency department and many primary and secondary services to serve the entire community need. Contrary to the assertion by UMMS

that MFSMC is unprepared to host a program (page 20), it is, in fact, an ideal site for a new, competitive program for transplantation in the Baltimore region.

VI. CONCLUSION

MGTI is well prepared to meet the needs and provide additional access for Maryland patients in and across the Baltimore region at one of MedStar's most sophisticated tertiary care facilities. The program at MFSMC will be fully integrated with MGTI, the longstanding stellar performance of which is indisputable. As supported by available and objective SRTR data, MGTI's volume of living donor transplants, high utilization of deceased donor organs and creative protocols for enabling previously deemed non-candidates to receive kidneys augments the transplantation options - hence fulfilling needs that have not been optimized in the Baltimore community. As well, the data speak volumes in terms of the quality of services that can be added to the Baltimore community. We stand ready to take on the challenge and welcome the opportunity through award of the CON.

Dated: October 1, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing was served by electronic mail on the following this 1st day of October, 2021:

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I hereby declare and affirm under the penalties of perjury that the facts stated in the foregoing Response to Interested Party Comments are true and accurate to the best of my knowledge, information and belief.

09.30.21

Date

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Vice President
MedStar Health Corporate Services

DONATE LIFE
BeADonor.org

WRTC
WASHINGTON REGIONAL
TRANSPLANT COMMUNITY

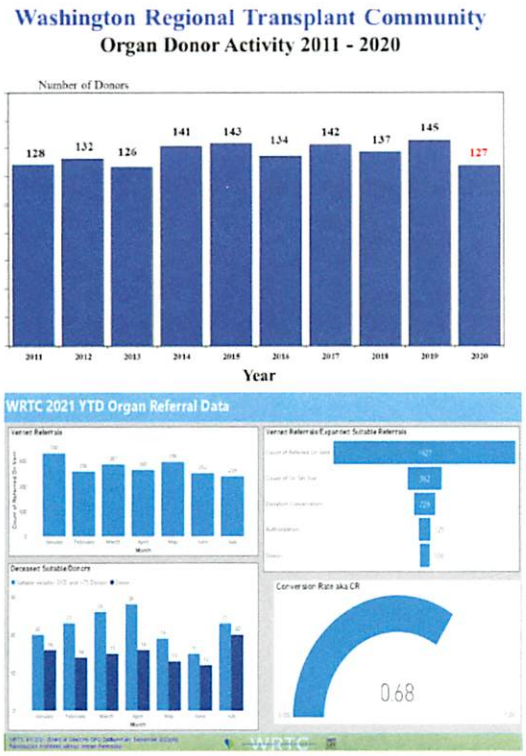
September 22, 2021

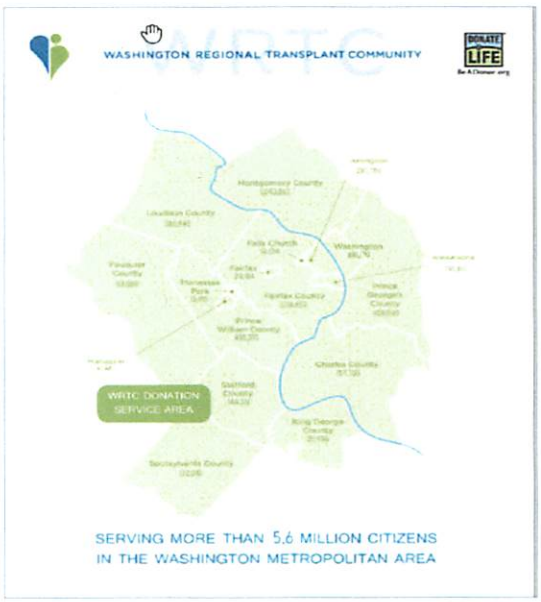
Michael O'Grady, Ph.D.
Commissioner/Reviewer
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

Dear Commissioner Grady:

I am writing in reply of the letter requesting data and information regarding organ donation related to your evaluation of the application of MedStar Franklin Square Medical Center to establish a kidney transplant program.

As background information Washington Regional Transplant Community is the federally designated organ procurement organization (OPO) for the Washington, D.C. Metropolitan area. WRTC provides organ and tissue recovery services to all hospitals in the District of Columbia, Northern Virginia and three counties in Maryland (Prince George's, Charles, and Montgomery counties). The population base is approximately 5.6 million people and WRTC provides recovery services to over 40 hospitals. WRTC's five-year average for organ donors is 137 donors annually. During 2020 we experienced decreases in organ donor suitability due to COVID. I have attached a chart below for the information pertaining to organ donors.





3190 FAIRVIEW PARK DRIVE | SUITE 700 | FALLS CHURCH, VA 22042 | 1-866-232-3666 | BEADONOR.ORG

Questions:

Regarding the change in UNOS' policy approved in December 2019 (Policy) that moves from a distribution system based on donation service areas to a system based on acuity circles, which was implemented on March 15, 2021:

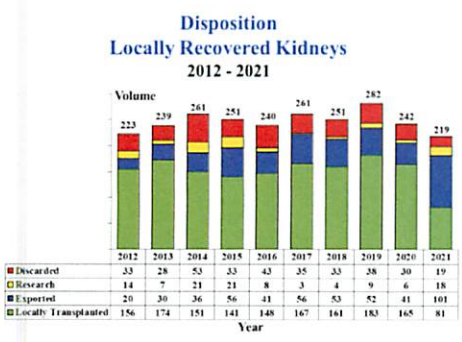
(a) Describe both the Policy's impact to date and its anticipated future impact on kidney transplant patients (particularly in Maryland). Please explain.

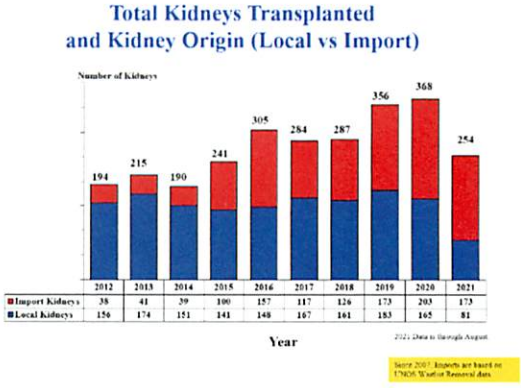
(b) Describe both the Policy's impact to date and its anticipated future impact on the number of kidneys available for transplant in each of the organ procurement organizations (OPOs) responsible for the evaluation and procurement of deceased donor organs for hospitals in Maryland (Living Legacy Foundation and the Washington Regional Transplant Community). Please explain.

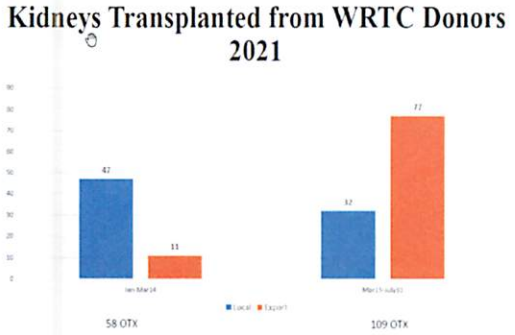
The data below is based on the transplantation of kidneys at transplant centers located in the WRTC donation service area (DSA). These kidney transplant centers include MedStar Georgetown Hospital, Inova Fairfax Hospital, Children's National Medical Center, George Washington University Hospital and The Walter Reed National Military Medical Center.

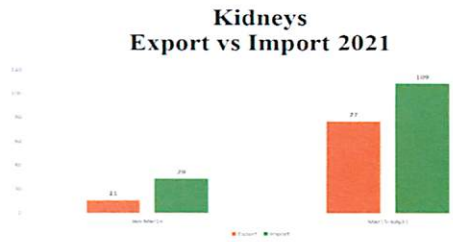
"Locally" transplanted kidneys refer to kidneys that came from donors that WRTC recovered from hospitals in our DSA. "Exported" kidneys are kidneys that WRTC sent to transplant centers outside our DSA. "Research" refers to kidneys that were not accepted for transplant, but the family authorized the kidney to be sent for Research. "Discarded" means the organ was not accepted for transplant and discarded (no research authorization).

The kidney allocation system went into effect in March 2021. The 2021 data available is only through July in the 1st graphic but note the dramatic difference in the kidney imports for transplant (at one of the five centers in WRTC's DSA) vs. those kidneys exported outside the DSA prior to 2021. The five-year average for kidneys exported outside our DSA for transplant is 41, with a five-year average of 164 kidneys annually being transplanted at one of the transplant centers in the WRTC DSA. The shift in kidneys being imported into the WRTC service area for transplant and those being transplanted locally has radically shifted. Annualizing the 18-week data, we see kidney imports to transplant centers in the WRTC DSA potentially reaching over 220 kidneys. Instead of match sequencing relying on donation service area (DSA) and OPTN Region, kidney allocation is now based on geographical distance between donor and recipient. We anticipate this trend to continue.









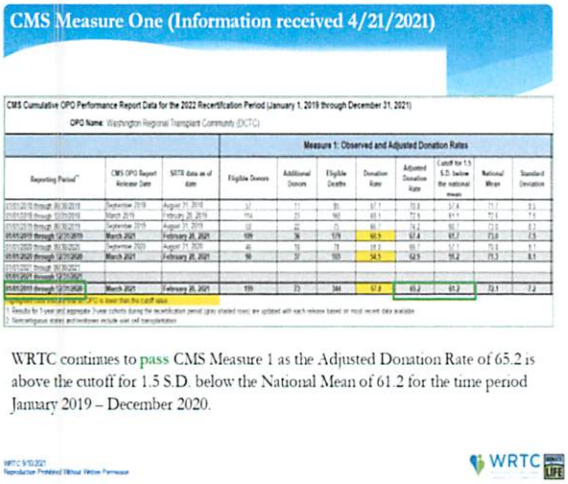
2. What do you view as the most effective ways to increase the number of *kidney donations* in the jurisdictions covered by the Washington Regional Transplant Community (WRTC)? In addition to the WRTC, which other organizations or infrastructure would you say have historically had an impact in increasing the number of kidneys available? Please explain.

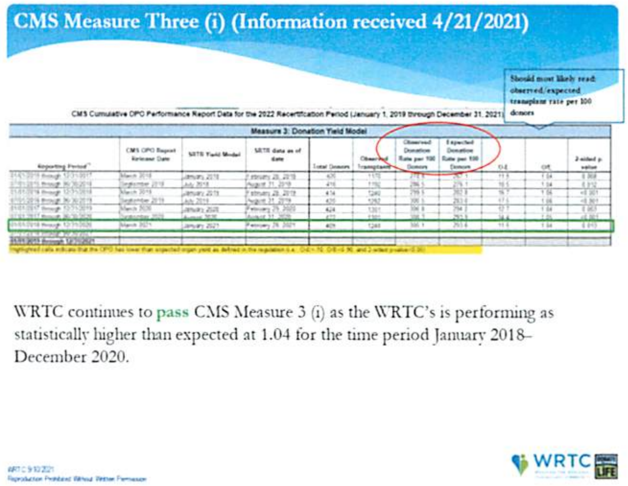
The most effective way to increase the number of kidney donations is to increase organ donation. The most effective way to increase organ donation is to encourage more individuals to designate themselves as organ donors, whether on their driver license or by registering to be a donor in an on-line registry. All decisions to be an organ donor are legally honored by WRTC at the time a patient dies if the patient is medically suitable.

There is still a large percentage of individuals that are not designated to be organ donors and in those cases the family must authorize donation at the time death. The **only** individuals that are medically suitable to be organ donors are those that die of some type of neurologic insult or injury and are in the intensive care unit on a ventilator. These potential cases are traditionally sudden and unexpected deaths, and the end-of-life discussions with family are stressful and traumatic. These cases require sensitive coordination between the clinical care team and the WRTC team to optimize the family donation conversations. The commitment of the hospital to organ donation, and to family centered care will provide the optimal outcome to this family dialog. This collaboration requires education, resources, and teamwork to ensure the donation process moves forward.

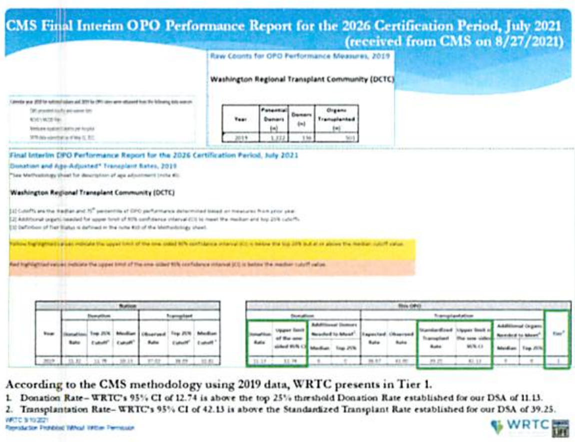
3. What metrics or outcome measures have customarily been used to measure the success of an organ transplantation program?

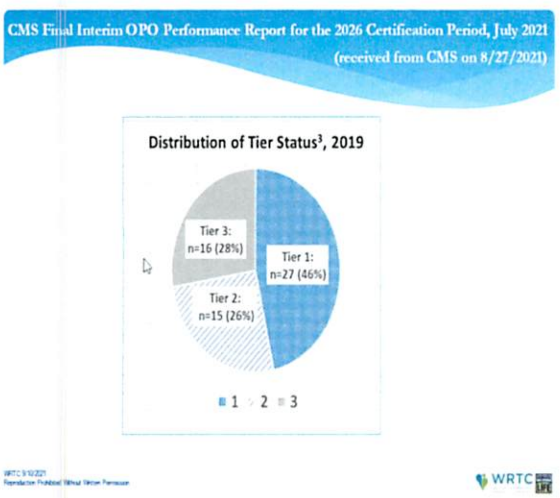
CMS certifies OPOs and the current metrics (1 & 3) are shown below. Recertification and designation for OPOs will occur again in 2022 cycle. WRTC currently meets both CMS metrics.

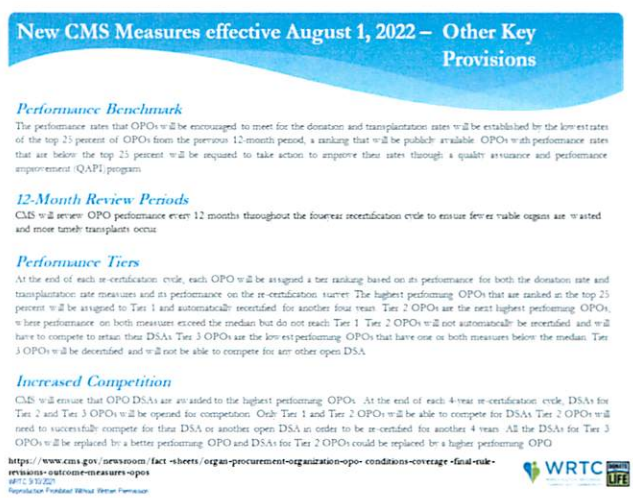




Effective August 1, 2022, CMS will use new metrics for OPOs, and I have also provided below the graphic where WRTC stands on the new CMS metrics. WRTC is considered a Tier One OPO.







4. What metrics or outcome measures do you view as appropriate to measure the effectiveness of organ transplantation services in a state or region? If these measures are not currently in use by oversight agencies or authorities, please explain why, if known.]

WRTC uses a variety of metrics to assess performance. The key metrics include total organ donors compared to the medically suitable potential for all hospitals in the DSA. We measure the organ donation authorization rate, donor designation rate, and the organs recovered per donor and transplanted (which is measured by CMS metric three or referred to as the "Yield Metric").

5. From your perspective, what are the likely benefits, if any, of establishing an additional kidney transplantation program in the WRTC's designated service area? Please also discuss and explain likely drawbacks, if any.

WRTC currently has five kidney programs in its DSA. The application is for a kidney program in the Donation Service Area assigned to The Living Legacy Foundation. WRTC has no comment on any likely benefits. Increasing the number of transplant programs will not increase the number of organ donors.

6. From your perspective, what evidence or information would strongly indicate that a hospital has the ability to increase the supply or use of donor organs for patients served in Maryland? Please explain.

WRTC currently performs death record audits at every one of the hospitals to which we provide donation services. We are aware of every death at our designated hospitals that is medically suitable for organ donation by performing this routine review (monthly in some hospitals, quarterly in others). Hospitals are required by regulation to notify the OPO of every death. If the hospital does not notify WRTC when the established clinical trigger is reached, then we are aware of the missed donation opportunity through the record review. We will work with the hospital to develop a performance improvement plan to ensure every donation opportunity is referred timely to the OPO. It is very rare for a hospital in our DSA to not properly contact WRTC when the clinical triggers are reached. If there is any opportunity for a hospital to increase donation it would be related to the donor authorization rates at the hospital. Increasing authorization requires teamwork with the OPO, donor preservation, process management and family centered care to ensure that a non-designated donor converts to a donor with family authorization.

7. Is there a source for the most current and accurate registered organ donor rate in Maryland, its neighboring states, and the United States?

The information for Maryland is available from Donate Life Maryland the rates are:
The current donor designation rate in Maryland is 45%.
The current donor designation rate in Virginia is 66%.
The current donor designation rate in D.C. is 61%.
The current donor designation rate nationally is 46.5%.

8. Is there useful information on what the future will bring?
a. Do you expect demand for kidney transplants to grow or decline, depending on the trends in the risk factors and conditions that lead to kidney failure?
b. What is the growth rate trend line?

c. Are there future projections?

WRTC has no comment on the clinical demand for kidney transplants in the future.

9. Are there non-surgical remedies for kidney failure in the pipeline that would be expected to halt its progression short of the need for a transplant?

WRTC has no comment on the non-surgical remedies for kidney failure in the pipeline.

10. Will you provide us with data on the number and percent of patients who die waiting for an organ? Any detail is appreciated such as race/ethnicity, time on the waiting list, etc.

I contacted the Organ Procurement and Transplantation Network (OPTN) and was told by the research department at UNOS that the information you are requesting is not readily available. To obtain this data you would need to submit a data request to UNOS. The data request team will be able to help narrow down your search and get you the information are asking about. The Data Request process is outlined on the OPTN website: https://optn.transplant.hrsa.gov/data/request-data/ .

If you require any further data or clarification, please feel free to contact me at 703-641-0100 or by email at Lori@WRTC.org.

Sincerely,

Lori E Brigham
President & CEO