September 22, 2021

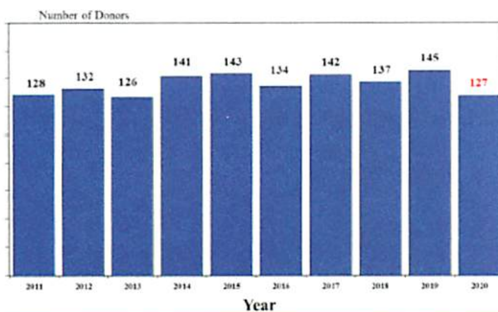
Michael O'Grady, Ph.D.
Commissioner/Reviewer
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

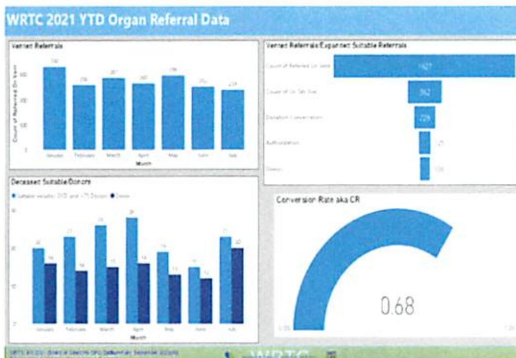
Dear Commissioner Grady:

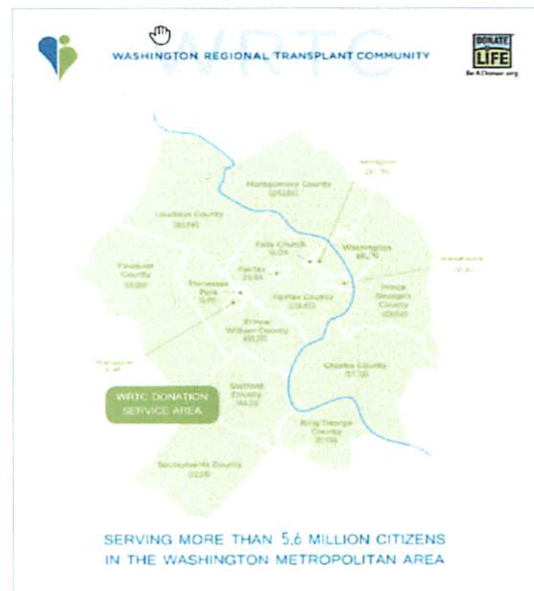
I am writing in reply of the letter requesting data and information regarding organ donation related to your evaluation of the application of MedStar Franklin Square Medical Center to establish a kidney transplant program.

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.

Washington Regional Transplant Community
Organ Donor Activity 2011 - 2020







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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:

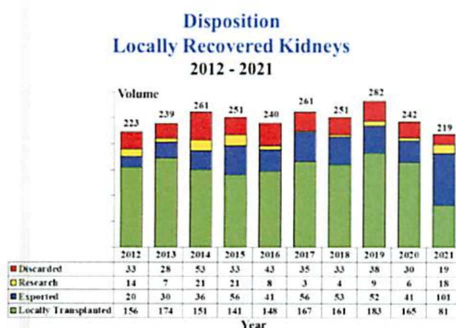
(a) Describe both the Policy's impact to date and its anticipated future impact on kidney transplant patients (particularly in Maryland). Please explain.

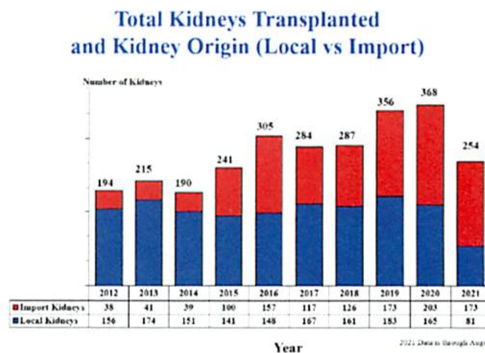
(b) Describe both the Policy's impact to date and its anticipated future impact on the number of kidneys available for transplant in each of the organ procurement organizations (OPOs) responsible for the evaluation and procurement of deceased donor organs for hospitals in Maryland (Living Legacy Foundation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

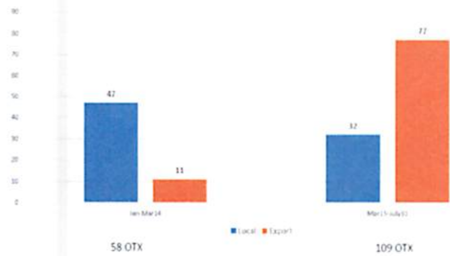
"Locally" transplanted kidneys refer to kidneys that came from donors that WRTC recovered from hospitals in our DSA. "Exported" kidneys are kidneys that WRTC sent to transplant centers outside our DSA. "Research" refers to kidneys that were not accepted for transplant, but the family authorized the kidney 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.





Kidneys Transplanted from WRTC Donors
2021



Kidneys
Export vs Import 2021

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 <u>on a ventilator</u>. 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.

CMS Measure One (Information received 4/21/2021)

CMS Cumulative OPO Performance Report Data for the 2022 Recertification Period (January 1, 2019 through December 31, 2021)

OPO Name: Washington Regional Transplant Community (DCTC)

Reporting Period[1]	CMS OPO Report Release Date	SRTR data as of date	Eligible Donors	Additional Donors	Eligible Deaths	Donation Rate	Adjusted Donation Rate	Cutoff for 1.5 S.D. below the national mean	National Mean	Standard Deviation
			Measure 1: Observed and Adjusted Donation Rates							
[illegible] through 06/30/2019	September 2019	August 31, 2019	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible] through 12/31/2019	March 2019	February 28, 2019	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible] through 06/30/2019	September 2019	August 31, 2019	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
01/01/2019 through 12/31/2019	March 2021	February 28, 2021	109	36	179	60.9	67.4	61.7	73.0	7.5
[illegible] through 06/30/2020	September 2020	August 31, 2020	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
01/01/2020 through 12/31/2020	March 2021	February 28, 2021	90	37	165	54.5	62.5	59.2	71.3	8.1
01/01/2021 through 06/30/2021										
01/01/2021 through 12/31/2021										
01/01/2019 through 12/31/2020	March 2021	February 28, 2021	199	73	344	57.8	65.2	61.2	72.1	7.2

Highlighted cells indicate that an OPO is lower than the cutoff value.

1 Results for 1-year and aggregate 3-year cohorts during the recertification period (gray shaded rows) are updated with each release based on most recent data available.

2 Noncontiguous states and territories include islet cell transplantation.

WRTC continues to pass CMS Measure 1 as the Adjusted Donation Rate of 65.2 is above the cutoff for 1.5 S.D. below the National Mean of 61.2 for the time period January 2019 – December 2020.

CMS Measure Three (i) (Information received 4/21/2021)

Should most likely read: observed/expected transplant rate per 100 donors

CMS Cumulative OPO Performance Report Data for the 2022 Recertification Period (January 1, 2019 through December 31, 2021)

Reporting Period[1]	CMS OPO Report Release Date	SRTR Yield Model	SRTR data as of date	Total Donors	Observed Transplants	Observed Donation Rate per 100 Donors	Expected Donation Rate per 100 Donors	O-E	O/E	2-sided p-value
			Measure 3: Donation Yield Model							
[illegible] through 12/31/2017	March 2019	January 2019	February 28, 2019	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible] through 06/30/2018	September 2019	July 2019	August 31, 2019	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible] through 12/31/2018	March 2019	January 2019	February 28, 2019	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible] through 06/30/2019	September 2019	July 2019	August 31, 2019	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible] through 12/31/2019	March 2020	January 2020	February 29, 2020	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible] through 06/30/2020	September 2020	August 2020	August 31, 2020	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
01/01/2018 through 12/31/2020	March 2021	January 2021	February 28, 2021	409	1248	305.1	293.6	11.5	1.04	0.013
[illegible] through 06/30/2021										
01/01/2019 through 12/31/2021										

Highlighted cells indicate that the OPO has lower than expected organ yield as defined in the regulation [illegible]

WRTC continues to pass CMS Measure 3 (i) as the WRTC's is performing as statistically higher than expected at 1.04 for the time period January 2018–December 2020.

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.

CMS Final Interim OPO Performance Report for the 2026 Certification Period, July 2021 (received from CMS on 8/27/2021)

Raw Counts for OPO Performance Measures, 2019

Washington Regional Transplant Community (DCTC)

Year	Potential Donors (n)	Donors (n)	Organs Transplanted (n)
2019	[illegible]	[illegible]	[illegible]

Final Interim OPO Performance Report for the 2026 Certification Period, July 2021

Donation and Age-Adjusted* Transplant Rates, 2019

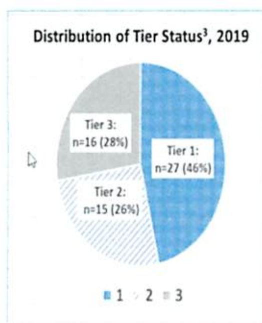
Washington Regional Transplant Community (DCTC)

Year	Nation: Donation Rate	Nation: Top 25% Cutoff[1]	Nation: Median Cutoff[1]	Nation: Observed Rate	Nation: Top 25% Cutoff[1]	Nation: Median Cutoff[1]	This OPO: Donation Rate	This OPO: Upper limit of the one-sided 95% CI	Additional Donors Needed to Meet[2]: Median	Additional Donors Needed to Meet[2]: Top 25%	Expected Rate	Observed Rate	Standardized Transplant Rate	Upper limit of the one-sided 95% CI	Additional Organs Needed to Meet[2]: Median	Additional Organs Needed to Meet[2]: Top 25%	Tier[3]
2019	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	12.74	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	42.13	[illegible]	[illegible]	1

According to the CMS methodology using 2019 data, WRTC presents in Tier 1.

1. Donation Rate– WRTC's 95% CI of 12.74 is above the top 25% threshold Donation Rate established for our DSA of 11.13.
2. Transplantation Rate– WRTC's 95% CI of 42.13 is above the Standardized Transplant Rate established for our DSA of 39.25.

CMS Final Interim OPO Performance Report for the 2026 Certification Period, July 2021 (received from CMS on 8/27/2021)



New CMS Measures effective August 1, 2022 – Other Key Provisions

Performance Benchmark

The performance rates that OPOs will be encouraged to meet for the donation and transplantation rates will be established by the lowest rates of the top 25 percent of OPOs from the previous 12-month period, a ranking that will be publicly available. OPOs with performance rates that are below the top 25 percent will be required to take action to improve their rates through a quality assurance and performance improvement (QAPI) program.

12-Month Review Periods

CMS will review OPO performance every 12 months throughout the four-year recertification cycle to ensure fewer viable organs are wasted and more timely transplants occur.

Performance Tiers

At the end of each re-certification cycle, each OPO will be assigned a tier ranking based on its performance for both the donation rate and transplantation rate measures and its performance on the re-certification survey. The highest performing OPOs that are ranked in the top 25 percent will be assigned to Tier 1 and automatically recertified for another four years. Tier 2 OPOs are the next highest performing OPOs, where performance on both measures exceed the median but do not reach Tier 1. Tier 2 OPOs will not automatically be recertified and will have to compete to retain their DSAs. Tier 3 OPOs are the lowest performing OPOs that have one or both measures below the median. Tier 3 OPOs will be decertified and will not be able to compete for any other open DSA.

Increased Competition

CMS will ensure that OPO DSAs are awarded to the highest performing OPOs. At the end of each 4-year re-certification cycle, DSAs for Tier 2 and Tier 3 OPOs will be opened for competition. Only Tier 1 and Tier 2 OPOs will be able to compete for DSAs. Tier 2 OPOs will need to successfully compete for their DSA or another open DSA in order to be re-certified for another 4 years. All the DSAs for Tier 3 OPOs will be replaced by a better performing OPO and DSAs for Tier 2 OPOs could be replaced by a higher performing OPO.

https://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos

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?

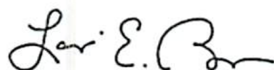
WRTC has no comment on the non-surgical remedies for kidney failure in the pipeline.

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