



second chances. INFINITE HOPE.

October 1, 2021

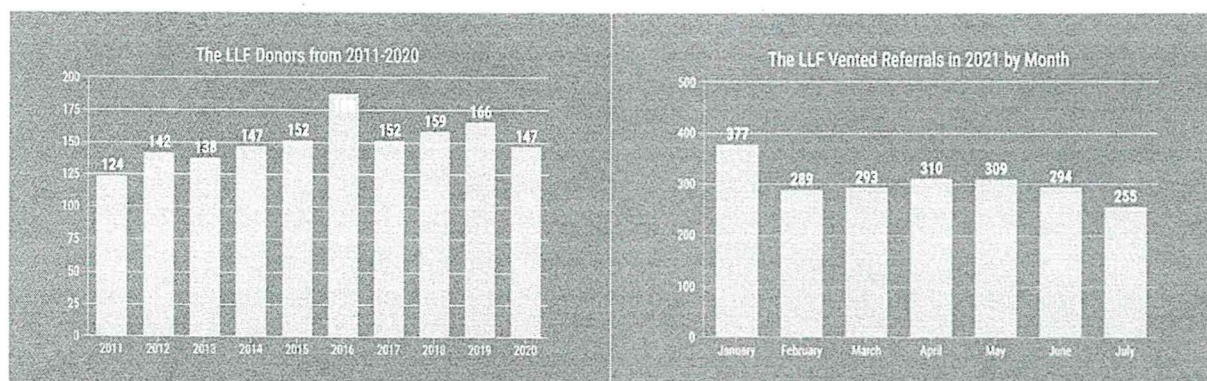
Michael O'Grady, Ph.D.
Commissioner/Reviewer
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

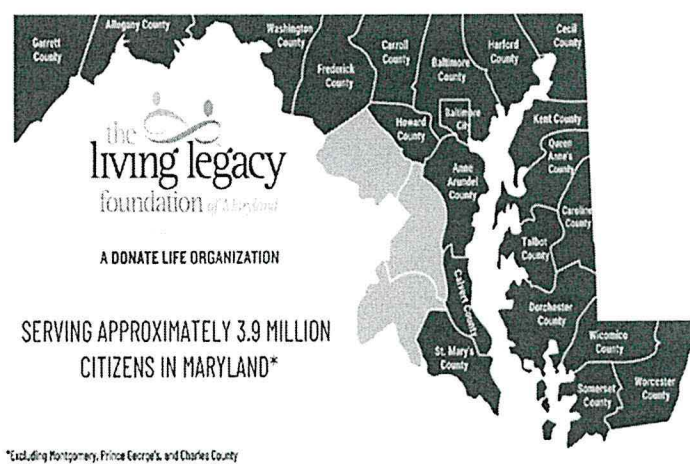
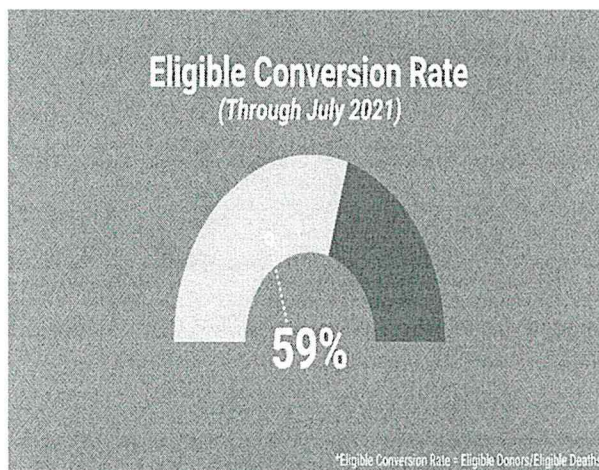
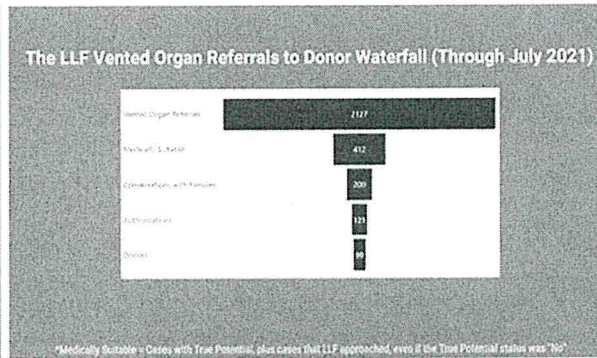
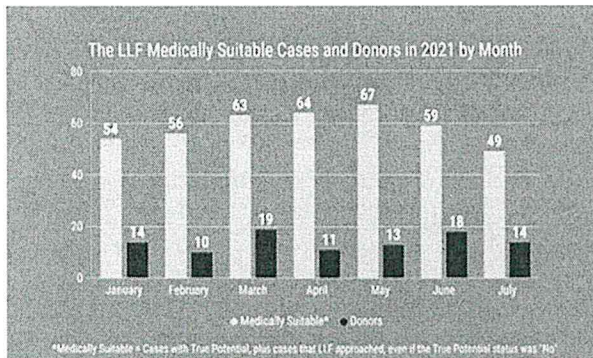
Dear Commissioner Grady:

This letter is in response to your request for 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, The Living Legacy Foundation of Maryland (The LLF) is the federally designated organ procurement organization (OPO) for Maryland, except for Montgomery, Prince George's, and Charles Counties. The LLF facilitates donation and transplantation in area hospitals, provides donor family support, and educates hospitals and the public about the life-saving power of organ, eye, and tissue donation. The population base is approximately 3.9 million people, and The LLF provides recovery services to over 34 hospitals. The LLF's five-year average for organ donors is 152 donors annually. During 2020, we experienced decreases in organ donor suitability due to COVID-19.

I have attached a few charts below for information pertaining to organ donors, year-to-date organ referral data, and our donor service area.





Questions:

1. 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 (The Living Legacy Foundation and the Washington Regional Transplant Community). Please explain.

(c) Please address any other anticipated impacts of the Policy of which I should be aware.

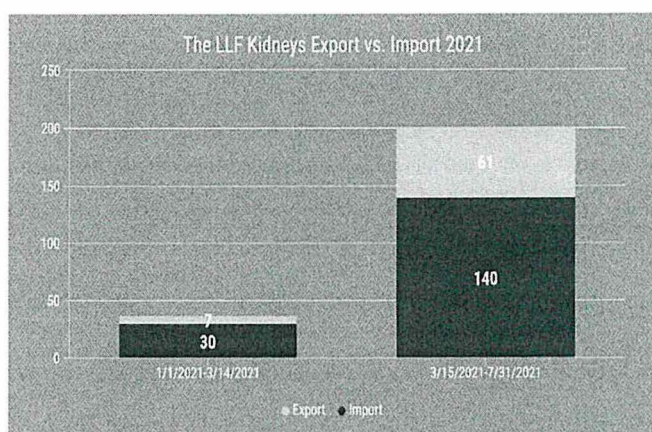
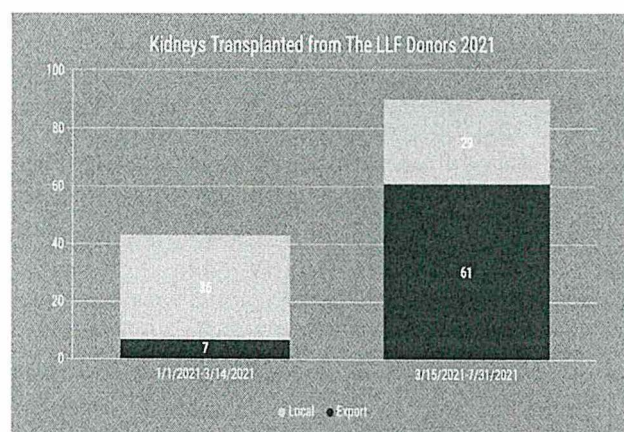
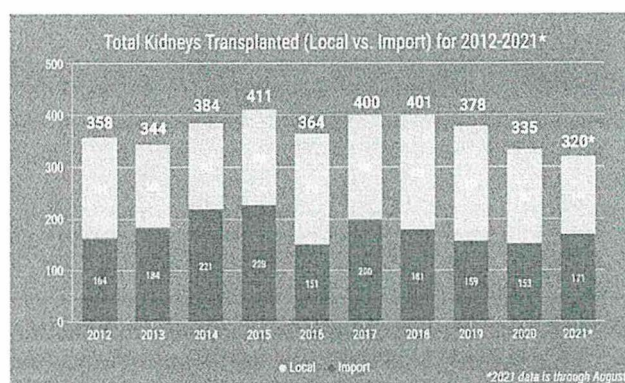
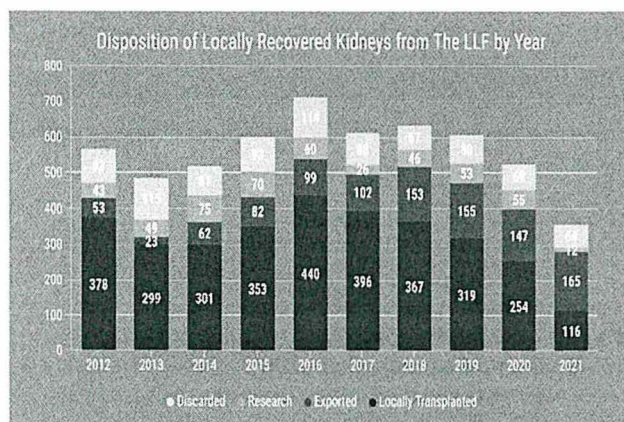
The data below is based on the transplantation of kidneys at transplant centers located in The LLF donation service area (DSA). These kidney transplant centers include The Johns Hopkins Hospital and the University of Maryland Medical Center.

"Locally" transplanted kidneys refer to kidneys that came from donors that The LLF recovered from hospitals in our DSA. "Exported" kidneys are kidneys that The LLF 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 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 the two transplant centers in The LLF DSA transplanting an average of 326 kidneys per year. The shift in kidneys being imported into The LLF service area for transplant and those being transplanted locally has changed radically. Annualizing the data, we see kidney imports to transplant centers in The LLF DSA potentially reaching over 400 kidneys.

Instead of match sequencing relying on DSA and Organ Procurement and Transplantation Network Region (OPTN), 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 Living Legacy Foundation (The LLF)? In addition to The LLF, 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's license or by registering to be a donor in an on-line registry. All decisions to be an organ donor are legally honored by The LLF at the time a patient dies if the patient is medically suitable.

There is still a large percentage of individuals who are not designated to be organ donors, and in those cases, the family must authorize donation at the time of 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 LLF 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 dialogue. This collaboration requires education, resources, and teamwork to ensure the donation process moves forward.

3. (a). What do you view as the most effective ways to increase the number of *kidney transplants* in the jurisdictions covered by The LLF? In addition to The LLF, which other organizations or infrastructure would you say have historically made an impact in increasing the number of kidneys transplants? Please explain.

Anything that can be done to incentivize the transplant hospitals to accept and transplant all transplantable kidneys would help. Too many kidneys are not used due to outcome measures and metrics applicable to transplant centers that are too restrictive. If we could redefine "what a successful transplant is," we could transplant more kidneys. Our efforts in connection with education, community outreach, and the efforts of Donate Life Maryland to increase donor designation rates are our most effective tools.

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

CMS certifies OPOs. The current metrics are Observed & Adjusted Donation Rates and the Donation Yield Model. Recertification and designation for OPOs will occur again in the 2022 cycle. Effective August 1, 2022, CMS will use new metrics for OPOs. The LLF 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.

The LLF 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 and is 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 LLF's designated service area? Please also discuss and explain likely drawbacks, if any.

The LLF currently has two kidney programs in its DSA. The application is for a kidney program in the DSA assigned to us. The LLF does not feel qualified to discuss 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.

The LLF 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 The LLF 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 The LLF 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?**

The utilization of kidneys is not within our purview. How organs are utilized is within the hands of the transplant hospital.

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?

This question is outside our area of expertise, and we do not feel qualified to answer.

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.

Ms. Lori Brigham, President & CEO of WRTC, contacted the OPTN and was told by the research department at UNOS that the information you request 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 you require. The Data Request process is outlined on the OPTN website: <https://optn.transplant.hrsa.gov/data/request-data/>.

Dr. O'Grady
October 1, 2021
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If you require any further data or clarification, please contact me at 410.961.0114 or by email at calexander@thellf.org.

Sincerely,

A handwritten signature in black ink, appearing to be 'CA' or 'Charles Alexander' in a stylized, cursive script.

Charles Alexander
President & CEO