

February 1, 2022

Chiquita Brooks-LaSure
Administrator
Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3409-NC
P.O. Box 8010
Baltimore, Maryland 21244-8010

Submitted electronically via <http://www.regulations.gov>

Dear Ms. Brooks-LaSure:

On behalf of the American Society of Transplantation (AST), representing over 4,000 medical professionals engaged in the field of solid organ transplantation, we applaud your leadership and continuous efforts to improve the nation's organ donation and transplant system. We welcome the opportunity to respond to this request for information.

In addition to our Society's professional membership, we support a Transplant Community Advisory Council (TCAC) that includes transplant recipients and living donors. As the RFI directly requested responses from patients and donors, we felt it was important that TCAC members respond independently to the RFI.

We used the general themes outlined in the RFI's introductory section as a framework for our response. Our intent in doing so is to provide a more cohesive, comprehensive response that incorporates direct, and some indirect, answers to the specific questions posed. As we are unsure of how this information will be used, we have provided mostly high-level conceptual responses and welcome the opportunity for ongoing engagement to clarify or expand on our comments.

Before responding to the RFI, we wish to bring to attention the status of communication between responsible governmental agencies and the various stakeholders involved in the care of patients with end organ failure. The Advisory Committee on Organ Transplantation (ACOT) was an effective mechanism for engagement with Department of Health and Human Service. We applaud this first effort at enhancing communication between key stakeholders. We further submit that establishing a single entity for consistent communication between the organ donation and transplant community, including representation from the families we serve, and all responsible governmental agencies would ensure alignment of priorities and efforts. According to its website, the ACOT last met in April 2020. The AST received requests from HRSA in both 2020 and 2021 to submit ACOT nominees but has received no updates on this process and the [ACOT roster](#) provided on HRSA's website until just this week stated that all current members' terms have expired. We appreciate your recent efforts to repopulate this important group and look forward to its reanimation or another mechanism to bring clear lines of communication and discussion to focus at this critical time.

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I. Way to improve systems of care for all patients in need of a transplant

A. Minimize race related inequities¹

Inequities in organ donation and transplantation warrant special consideration because of the high burden of end organ failure in ethnic minority groups which exacerbates racial inequities in access to organ donation and transplantation.

Disparities in transplant access begin at the entry level of the transplant process, with lower rates of referral (including pre-emptive referral), lower rates of kidney transplant evaluation and delays in completion of transplant candidate evaluation among minority groups, all of which culminate in delays in waitlisting and transplantation.

A shortage of health care resources relative to patient need is not unique to the field of organ transplantation. However, unlike other areas of medicine the discrepancy between the need and supply for transplantable organs cannot be alleviated by a simple increase in funding. The organ supply is inherently dependent on volunteer donations from the public. Therefore, ensuring public trust and fairness in the organ donation and transplant system is of paramount importance. The U.S. is a highly pluralistic society, and the organ donation and transplant system must support the diverse needs of its inhabitants who not only rely on the system for life saving transplants but are the source of the organs that are transplanted.

Systemic racism must be eliminated from the organ donation and transplantation system.

The AST is committed to removing persistent racial inequities that contribute to disparity in opportunities, physical health, psychological wellbeing, healthcare access, and quality of life in the organ donation and transplantation communities. Through the AST's Inclusion, Diversity, Equity, and Access to Life (IDEAL) Committee, we have committed resources to:

- Establish and sustain a pipeline for increased diversity within our professional field
- Sponsor research grant opportunities dedicated to increasing equity and reducing racial disparities in transplantation
- Eradicating policies and practices in transplantation that are discriminatory
- Accelerate advocacy efforts to promote legislation to advance equitable transplantation access and outcomes for patients of color.
- Educate our members about the negative ramifications of systemic racism and the benefits of diversity through targeted educational activities.

We provide the following observations related to inequities to vulnerable populations in the organ donation and transplantation (ODT) system:

Inequities are far greater in vulnerable populations gaining access to the waiting list than in receiving an organ transplant after wait-listing.

Major contributors to disparities after wait-listing include biological and geographic factors which can be addressed with policy changes. The impact of such policy changes can be reliably assessed.

¹ <https://pubmed.ncbi.nlm.nih.gov/25883072/>

Inequities in gaining access to the waiting list are more challenging to overcome. This is due to the fact that access to transplant evaluation and wait-listing is a shared responsibility between non-transplant care providers (community physicians, dialysis providers and other health care services), transplant centers and transplant care providers. In addition, the evaluation of wait-list candidates is dependent on services that are utilized by the general patient population and are therefore vulnerable to larger health system-based inequities and inefficiencies, creating challenges for patients with limited health literacy to navigate.

The RFI specifically highlights race-based difference in organ donation. Such differences are confounded by a myriad of factors (e.g., health literacy, inability to access and/or navigate the healthcare system). We do not support the promulgation of race specific metrics for living or deceased donation, as they do not address the underlying factors that contribute to such differences. As an example, we point to work demonstrating that race-based differences in living donation are heavily confounded by differences in socioeconomic status. We support research to understand the basis of these differences so that effective strategies to overcome these disparities can be advanced.

We provide the following considerations to address racial inequities in the ODT system:

We applaud the OPTN for its regular review of organ allocation policies and encourage rapid integration and evaluation of new policies to improve fairness in access to transplantation after wait-listing.

Clear articulation of the responsibilities of transplant and non-transplant care providers prior to wait-listing. The assignment of roles should be determined by provider expertise. Accordingly, transplant professionals should have a **primary role** in the design and implementation of patient education and counseling regarding organ transplantation to ensure that it is accurate, appropriate, and current. Further, we support advancement of metrics to ensure that these pre-transplant responsibilities are being effectively executed.

Ensuring culturally safe care for deceased donor families to make an informed decision about organ donation

Removal of financial disincentives to living donation that disproportionately impact ethnic minority groups based on the principal of financial neutrality

Ensuring living kidney donors are provided lifelong care for health conditions that may compromise their post donation kidney function, including conditions not directly related to the donor surgery. We believe that this is a societal responsibility. Because living donors are selected based upon their health, the cost of ensuring that donors maintain a high level of post-donation health and appropriate treatment of kidney health conditions that may develop as they age and may compromise their post-donation kidney function is likely to be small relative to the health care savings provided by their act of donation².

**B. Reorganization of the Medicare ESKD Program to a Value Based CKD Program –
CONCEPTUAL**

² Am J Transplant 2017 May;17(5):1176-1181.doi: 10.1111/ajt.14147. Epub 2017 Jan 9

- C. The ESKD program is unique within Medicare. It is the one of less than a handful of programs in which the diagnosis of a categorical disease provides the basis for an entitlement for persons of all ages.

The potential benefits of the ESKD Medicare program are limited by several factors:

1. The entitlement begins at end stage disease. As a result, prevention of end-stage disease and pre-emptive transplantation are not prioritized and CKD patients with limited or no insurance lose the opportunity to accrue valuable time on a kidney waiting list towards future transplantation.
2. For kidney transplant recipients, the entitlement ends three years after transplantation-compromising the longevity of kidney transplants. This is only partially addressed by the passage of the Immuno-Bill and even then, patients will have significant co-pays. The requirement for long-term posttransplant care remains a gap in the ESKD Medicare Program.
3. Absence of a comprehensive long-term care program. Kidney transplantation is a form of kidney replacement therapy not a cure for ESKD. It is one of three ESKD treatment choices, including dialysis or palliative care. Long-term kidney allograft survival in the U.S. is inferior to that in other developed countries due to the absence of a long-term multi-disciplinary care strategy. As a result, transplant failure is now one of the leading causes of dialysis initiation.
4. Fragmentation of care – the ESKD program for transplant recipients is not patient centered, Rather it is payer/provider-centered leaving patients vulnerable to the priorities and policies of these stakeholders.

We propose reorganization of the system to create the most value, where value is defined as outcome / cost². A new value-based CKD program would prioritize therapies that maximized value especially prevention of end stage disease, and transplantation over other therapies that provide lower value.

In a value-based CKD program, value would be maximized by:

- Prevention of kidney failure to limit end stage kidney disease (ESKD)
- Pre-emptive transplantation and rapid transplantation for those who progress to ESKD
- Dialysis would ideally be a bridge to transplant and maintenance dialysis would be reserved for those with absolute contraindications to transplantation or those with limited life expectancy in who the value of transplantation will not be realized
- Advancement of long-term after-transplant care models focused on maximizing long-term kidney transplant survival to avoid return to dialysis/need for repeat transplantation
- For those requiring dialysis – modalities that optimized self-care, independence, functionality, and quality of life would be optimized (i.e. Peritoneal Dialysis)
- Optimal end of life care for those not wanting dialysis or transplantation

A value-based CKD system would align the interest of all stakeholders to maximize value. We believe that such a model is also more transparent and clearer to both patients and providers. This would include alternative payment models that link payment to value, replacing the silos of pre-dialysis CKD, dialysis, transplant, and even OPOs with an integrated model that provides a continuum of CKD care focused on maximizing overall system value. In this model overarching metrics of value would include the population rates of CKD progression and ESKD, the rate of pre-emptive transplantation, rates of living and deceased donor transplantation, rates of home-

based dialysis, the proportion of incident and prevalent ESKD patients treated with transplantation, and duration of post-transplant patient and allograft survival^{3,4}.

D. Explore creation of a new two stage pre-transplant evaluation process

We believe that it is critical that transplant professionals have a primary role in the design and implementation of patient education regarding organ transplantation to ensure that it is accurate and appropriate. To ensure all patients with CKD that will progress to kidney failure receive optimal education, counseling, and support about transplantation we propose exploration of a new two-stage transplant evaluation process to triage these individuals to better serve their individual needs.

Stage 1: Virtual or telehealth - based education and counselling by the transplant center.

The goal of this health encounter is to ensure all patients without absolute contraindications (we can specify these) to transplantation are provided individualized information about transplantation and opportunities for transplantation prior to the need for dialysis irrespective of their place of residence. This would require all patients to have ABO Blood Group and determination of sensitization to anti-HLA antibodies (cPRA) determination and obtainment of the patient's medical and social history but would not require other consultations or specialized tests.

The encounter would exclude patients who will not benefit from transplantation from further evaluation and provide potentially suitable patients counselling about their realistic opportunities for transplantation including identifying patients who might only be candidates for living donor transplantation (i.e., those who survival is shorter than waiting), patients who are suitable for transplantation with high KDPI kidneys and acceptance of increased viral risk donor kidneys. Optimal end of life care for those not wanting dialysis or transplantation is also important here.

Stage 1 would include education about living donor transplant and provide patients with resources and skills to assist with the identification of a living donor.

Stage 1 would also identify additional tests and consultations to be completed prior to stage 2. This would ensure timely completion of the pretransplant evaluation. Further, we believe that this process will be enhanced by a central repository for all testing related to transplant evaluation (e.g., the OPTN). This will eliminate costly redundancy of testing done by multiple healthcare providers including the community nephrologist, the dialysis center, and the evaluating transplant program.

We are confident that a virtual encounter will help mitigate geographic disparities, enable better coordination of testing, and eliminate redundancies and duplication of efforts in the evaluation process. For patients with limited broadband access, this initial virtual evaluation could take place from the office of a local nephrologist or dialysis unit. Implementation of this practice will require investment in telehealth and the creation of a centralized pre-transplant data system by the OPTN.

³ Porter - N Engl J Med. 2010 Dec 23;363(26):2477-81. doi: 10.1056/NEJMp1011024. Epub 2010 Dec 8

⁴ Sylvia Burwell NEJM <https://www.nejm.org/doi/full/10.1056/nejmp1500445>

Stage 2: In person multi-disciplinary transplant assessment

Patients screened through stage 1 as being potentially suitable transplant candidates would be required to complete a standard comprehensive multi-disciplinary transplant candidate assessment. The efficiency of this assessment would be improved by the triage process and organization of tests in the stage 1 evaluations. Patients declined by a given transplant center could be referred to another center through the system.

E. Increase communication with wait-list candidates

Currently, there is little emphasis on re-evaluation of transplant options after wait-listing. Patients may identify new potential living donors or develop new health conditions that impact their eligibility for and or acceptance of certain types of deceased donor kidneys.

The RFI called for increased transparency with regard to organ offers for wait-list candidates and new strategies to increase the utilization of deceased donor kidneys.

While the idea of informing wait-list candidates of deceased donor organ offers in real time seems a laudable goal, the considerations around accepting or declining an organ offer is extremely nuanced. We believe it would be difficult to implement and would not necessarily lead to increased offer acceptance, and thus, do not endorse this specific proposal.

However, educating patients about waiting times for comparable patients (i.e., patients of similar age, ABO, cPRA, region of residence) would inform patient decision making regarding their transplant options. This education would be provided during the Stage 1 Education/ Counselling session described above. In addition, periodic wait-list status reviews of transplant waiting times along with a discussion of current transplant opportunities may be considered. Periodic WL status reviews may add value to the management of CKD patients if the reviews lead to new opportunities for LD transplantation or enabled appropriate candidates to make informed decisions regarding the acceptance of high KDPI or increased infectious risk donor kidneys. Improved communication during wait-listing may increase transplant center acceptance of kidney offers for individual WL candidates because transplant centers will have a better understanding of the patients health status and priorities. Whether periodic WL status reviews improve system value by improving the outcomes including QOL of wait-list candidates warrants further research.

Increased patient communication and medical oversight of WL candidates is currently an unfunded activity. Without living donors, patients may remain on a waiting list for 6-8 years. During this time, health status deterioration commonly occurs. Data indicates that 30-40% of waitlisted kidney patients will die or be delisted within 5 years of listing. The care of wait-listed kidney candidates is fragmented. The bulk of their care is delivered by their local care team, including community nephrologists and dialysis units. Sharing of information between these entities and the transplant team is rudimentary. From the standpoint of the transplant center, patients are expected to be in a state of "transplant readiness" at all times in the event an organ offer materializes, but also because the proportion of patients in active status at centers is publicly available data. Development of more robust information systems that improve communication between stakeholders and that may impact kidney candidate transplant readiness should be a priority and should be set up to gather data that helps to better understand some of the barriers to transplantation of waitlisted patients. Ongoing care of

patients on the waitlist should be sufficiently reimbursed and it may have long-term fiscal benefits.

The value of an investment in this work would be assessed by additional metrics including organ utilization, perioperative transplant complications, living donor transplantation in patients without a prior identified living donor and WL candidate satisfaction. The promulgation of metrics of wait-list mortality without necessary investment in resources to ensure appropriate monitoring of the medical fitness of wait-list candidates or advancement of uniform delisting criteria is of uncertain value and may have unintended consequences of decreasing patient access to transplantation.

II. WAYS TO INCREASE THE NUMBER OF ORGANS AVAILABLE FOR TRANSPLANTATION

A. Deceased Donation

Words Matter:

The focus of the deceased donation system should be to provide all potential donors and donor families with the opportunity to make an informed donation decision, and to ensure that all donated organs that can be safely transplanted are utilized to their maximum benefit.

We are sensitive to the promulgation of terms that fail to recognize that donated organs as societal gifts. While the use of pejorative terms such as “cadaver” and “organ harvest” is now infrequent, the use of terms such as marginal, poor quality, and discard that are equally depreciative is increasingly common and should be replaced with terms that do not diminish the value of these gifts. Further dialogue on appropriate terminology would ensure communication was respectful of donors and donor families.

Metrics of deceased donor services:

While we support the use of valid indicators of the effectiveness of organ donation services, we are concerned with the focus on “OPO performance” in the RFI that likens the complex process of deceased organ donation to a simple work product.

While convenient, the limitations of metrics based on administrative data should be acknowledged and investment in additional indicators of the quality of deceased donor services is essential. We do not believe the metrics adopted by CMS are sufficient to fully evaluate the effectiveness of organ donation services provided by an OPO. The validity of metrics based on administrative data not collected for the dedicated purpose of monitoring the quality of deceased donor services should be regularly monitored using the gold standard of hospital chart reviews and or comparison with novel methods to identify potential donors (i.e., AI). Further, this metric should be supplemented with implementation of process measures that will inform specific steps in the donation process in need of quality improvement and provide insights into the importance of factors not related to the quality of deceased donor services provided by the OPO that influence whether a potential deceased organ donor is an actual organ donor.

In addition to process measures, continued investment in qualitative assessments of deceased donor services, including surveys of donor families who do and do not consent to donation, as

well as health care providers such as ICU, ED, and OR staff who interact with OPO staff should be implemented.

As highlighted above, a paramount consideration is the provision of culturally safe care and support to deceased donor families. This starts with ensuring the diversity of OPO staff reflects that of the communities they serve. A national comprehensive investment in deceased donor services including initiatives to increase donor registrations in the community, and initiatives to enhance the identification and support of potential donors and donor families should be considered.

The importance of sharing of best practices between rather than the creation of a competitive environment is stressed.

Living Kidney and Liver Donation:

We provide the following considerations to increase living kidney donations:

- a. Reciprocity based strategies to promote living donation including providing priority for deceased donor transplantation for the donor's family members should be evaluated.
- b. Removing disincentives for living donation including full reimbursement for lost wages and out of pocket expenses (through programs like the National Living Donor Assistance Center and the AST's Living Donor Circle of Excellence as examples). We see this as a first step. Ideally, we believe that achieving financial neutrality is not solely for those who have been "means-tested," but appropriate for all living donors.
- c. Provision of appropriate post donation care to prevent and treat conditions that might compromise post donation kidney function. This may allow potential donors with some medical considerations to be safely accepted as donors.

Increasing the transplantation of recovered deceased donor organs:

Considerations applicable to all organs:

Advancement of new metrics that are more consistent with patient values is necessary to increase transplantation. Continued emphasis on post-transplant outcomes alone will limit efforts to increase organ utilization for transplantation. It is important to recognize that some transplants will be favored by patients if they improve patient access to transplantation (i.e. shorter waiting time) even though may provide a shorter duration of allograft survival). Therefore, such transplants should be evaluated by more comprehensive metrics that take into account the impact on the patient before and after transplantation.

Optimal management of deceased donors prior to organ recovery surgery is essential to maximize the number of transplants enabled by each donor. Standardization of donor management protocols together with implementation of relevant metrics of donor management should be considered.

Advancement of specific organ allocation criteria that enable the use of safely transplantable organs at risk for non-use to be transplanted in medically appropriate and consenting wait-list candidates

Sharing of best practices between transplant centers that safely transplant higher risk organs and higher risk patients and centers that do not

Sharing of information about the outcomes of transplants using organs declined by some centers that were subsequently accepted for transplantation by another center

Advancement of strategies to enable more widespread use of ex vivo preservation technologies during organ transport. A national strategy to enable more widespread use of these devices is needed.

Establishment of standards for DCD time outs may increase donations and help ensure planning for appropriate resources at donor hospitals

Considerations to specifically increase the use of deceased donor kidneys:

The 2014 Kidney Allocation System prioritized the top 20% kidneys by KDPI for placement in patients with the top 20% EPTS but did not change allocation of high KDPI kidneys. We support implementation of an allocation policy that prioritizes patients for transplantation with a high KDPI deceased donor kidney in return for shorter waiting time in accordance with published information about which patients will and will not benefit from these kidneys. Access to high KDPI kidneys would be limited to candidates who would benefit from transplantation with a high KDPI kidney. Eligible consenting patients could be prioritized for a high KDPI kidney up until the time that they would no longer derive a survival benefit from such kidneys. Thereafter the patient would only be offered a lower KDPI kidney. The success of this policy would be measured by the utilization of high KDPI kidneys and the time to transplantation among patients who consent to receive high KDPI kidneys.

Transplant center organ acceptance is influenced by the regulatory environment. Metrics that reward high organ offer acceptance practices are inconsistent with metrics that discourage acceptance of high KDPI kidneys and transplantation of candidates with a high burden of comorbid diseases. Clarification of the system goals is essential to ensure the most relevant metrics are used. If maximization of the number of transplants is the system objective, this must be coupled with articulation of a minimal acceptable outcome. In the context of a value-based CKD system, a minimal acceptable outcome would be defined in relation to the alternative treatment of dialysis rather than a continued focus on comparisons between transplant centers.

Sharing of information about the outcome of mate kidney transplants

Transplant hospitals are generally not reimbursed more for a kidney transplant if hospitalization is prolonged due to delayed graft function or other organ/recipient complications. Removal of financial disincentives that limit performance of more complex transplants should be considered.

Considerations to increase the use of extra-renal organs:

Further research of donor lung characteristics that are not transplanted and their impact on lung transplant outcomes is needed. Related to this is consideration of a standardized donor risk score.

Advancement of unified criteria for non-use of donor lungs or lungs at risk for non-use along with increased flexibility in lung allocation to allow centers to utilize donor lungs at risk for non-use in selected patients is suggested.

Ex vivo perfusion and organ treatment are increasingly valuable ways of managing and improving the function of deceased donor organs that may not have otherwise been transplantable.

Donation after cardiac death (DCD) continues to expand the number of organ donors beyond those meeting brain death criteria. The use of DCD hearts is growing, in particular. The use of normothermic regional perfusion will continue to help expand the use of these hearts. This does not rely on the use of ex vivo perfusion devices and is within reach for all transplant programs to perform, potentially increasing the donor heart pool by up to 30%. This expansion of the donor pool is already seen in the United Kingdom.

III. Ensuring policies that incentivize the creation and use of future new treatments and technologies

We are delighted by recognition of the importance of fostering innovation in the RFI. Both the patient and the professional community are eager to see advances in the field, both from a clinical and a pharmaceutical perspective.

The transplant community voices frustration of the “same old same old” treatments and the expectation that they must live with skin cancers and other by-products of the medications they must take regularly. They do not believe that this is acceptable and are eager to see advances that improve both the quantity and quality of life for transplant recipients.

We believe the transplant ecosystem in the United States represents an unparalleled opportunity to advance the concept of learning health system that allows the identification and testing of new policies, programs, innovations and therapies. A major enabler is the existence of a comprehensive data system that could be used much more purposefully to support innovation and encourage new investment in transplantation. We believe many of the barriers to creation of such a system including data privacy, need for consent and the cost of data acquisition can be addressed by increased engagement of donor families and patients, investment in data sciences and creation of opportunities for outside investment in the system.

Advancement of policies to enable research in deceased donors both before and after organ recovery surgery consistent with recommendations from the National Academy of Sciences Engineering and Medicine Consensus Study Report, Opportunities for Organ Donation Intervention Research

Specific examples include:

- Leveraging existing data systems to support post approval collection of safety and efficacy data for new therapies. This would allow more rapid regulatory approval of new treatments and long-term outcome assessment.
- Leveraging existing data systems to enable conduct of pragmatic trials, observational control groups, and accumulation of real-world evidence
- Development of IT infrastructure to enable conduct of virtual trials that would enable enrolment of patients living at a distance from the transplant center or in community or rural settings that are typically excluded from clinical trials to participate in clinical trials.

This is especially relevant for conduct of research to improve long-term outcomes in prevalent transplant recipients where U.S. outcomes fall short of those in other countries.

Evaluation of the impact of regional organ donation centers:

These centers should be linked to allow pooling of data, advancement of standards, establish and standardize resource requirements, understand public support, provide oversight, governance and enhance public trust.

Metrics and Innovation:

Existing metrics do not take into account the totality of the patient experience which do not include timely access to transplantation and only focus on post-transplant outcomes limit innovation.

Outcome metrics that thwart innovation should be eliminated. Research performed with appropriate patient consent, research oversight (i.e., DSMB) should be exempt from inclusion in outcome metrics with the proviso that the research outcomes must be made public.

Again, we thank you for this opportunity to address the questions posed and would be pleased to offer further assistance or input by email or in a meeting with our professional and transplant community representatives. Please let us know how we may be of further assistance in this important decision-making process.

Sincerely,

The AST Executive Committee, on behalf of the AST Board of Directors



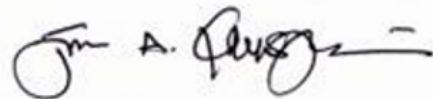
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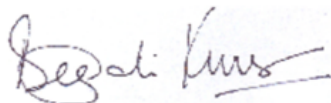
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