



American Society of Nephrology

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Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3409-NC, RIN-0938-AU55
P.O. Box 8010
Baltimore, MD 21244-8010

Re: CMS-3409-NC: Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities

Administrator Brooks-LaSure:

On behalf of the more than 37,000,000 Americans living with kidney diseases and the 21,000 nephrologists, scientists, and other kidney health care professionals who comprise the American Society of Nephrology (ASN), thank you for the opportunity to respond to the Request for Information (RFI) issued by the Centers for Medicare and Medicaid Services (CMS) related to transplant programs, organ procurement organizations, dialysis facilities, joint ventures, and related issues. ASN applauds CMS' efforts "seeking public comment that will help to inform potential changes that would create system-wide improvements, which would further lead to improved organ donation, organ transplantation, quality of care in dialysis facilities, and improved access to dialysis services." In this letter, ASN provides an Executive summary followed by detailed point-by-point feedback on the questions posed by CMS related to transplantation, home dialysis, and quality of care in dialysis facilities.

Executive Summary

ASN strongly agrees that increasing access to transplantation and home dialysis is the best next step to improve care for many individuals with kidney failure, and it must be done equitably. Black Americans, Latinx Americans, Native Americans, and Native Hawaiian/Pacific Islanders as well as individuals with lower educational and socioeconomic status face disparities in nearly every step of the process for kidney transplantation. For example, Black Americans are less likely than White Americans to be identified as transplant candidates, referred for evaluation, placed on the kidney transplant waitlist or receive kidney transplants, especially living donor kidney transplants, while also being more likely to receive lower quality kidneys, have organ offers declined for them and have poorer transplant graft survival. Critically, similar disparities exist in home dialysis utilization. For example, Black patients with kidney failure are 31% less likely to receive home dialysis compared to White patients with kidney failure. Developing system-wide improvements that address inequitable access to kidney transplantation and home dialysis could have a strong and lasting positive impact for patients with kidney failure.

The following is a summary of ASN's recommendations found in this comment letter.

A. Transplant Programs

- 1. For patients and their families: Are transplant programs meeting your specific needs and are you satisfied with the care that you have received? Specifically, what type of information are you receiving from your transplant program or transplant surgeon?**

Patient-centered communication

- i) Standardize communications to patients.
- ii) Provide process measure data like "time to transplant."
- iii) Make web-based information patient friendly and understandable.
- iv) Ensure patient selectivity and transplant center thresholds are transparent.
- v) Provide real-time updates for waitlisted patients:
 - a. Notify patients of organ declines when possible.
 - b. Improve communications between all stakeholders regarding a patient's death.
 - c. Notify patients about pauses or deactivation.
 - d. End "internal holds" at centers.
 - e. Establish transparency around bypass filters.
 - f. Study impact of centers that pass on offers due to the offer occurring on a weekend.

- 2. How can the current transplant program Conditions of Participation (CoPs) be improved in order to incentivize and ensure performance quality in organ transplantation?**

System-wide alignment

The Conditions of Participation (CoPs) for dialysis facilities and transplant centers are not aligned and do not recognize the role of both in facilitating a smooth transition of care for patients.

- i) Reverse OPTN Board approval of a new policy combining pretransplant (offer acceptance, waitlist mortality) and posttransplant (90-day graft survival and conditional one-year graft survival) indicators.
- ii) Align measures in ESRD Treatment Choices (ETC) model and the ESRD Quality Incentive Program (QIP).
- iii) Incentivize maximum access to waitlists, optimal organ use, and transplant rates, while maintaining post-transplant outcomes.
- iv) Support patient-centered CoPs through robust pre and posttransplant care.

Alternatives for ensuring quality and oversight

- i) Examine changes in allocation system for impact on increased discard rates.
- ii) Increase process measures for patient communications.
- iii) Align OPO and transplant center operations to improve equity.
- iv) Study impact of decision to decline a waitlist candidate due to a lack of social support.
- v) Compare deceased donation practices in other countries to the United States.
- vi) Increase hospital quality related activities in transplantation.
- vii) Address the data gap with increasing Medicare Advantage participation.
- viii) Increase resources allocated to and development of advanced CKD and kidney failure care management programs with the specific aim to facilitate transplantation.

3. Are there additional requirements that CMS could implement that would improve the manner, effectiveness, and timeliness of communication between OPOs, donor hospitals, and transplant programs?

- i) Encourage minimum requirements to adequately staff transplant programs including the pretransplant coordinator and living donor teams, staff that are reviewing organ offers, and staffing models for posttransplant care.
- ii) Increase communications efforts between OPOs and transplant centers.
 - a. Improve communication between patients, transplant center and dialysis providers about patient preferences and priorities.
 - b. Help patients appreciate the tradeoff between increased selectivity for organs and wait times for those organs. This may help patients recognize the benefits of organs that they have not opted into such as high Kidney Donor Profile Index (KDPI), public health service increased risk (PHS-IR) or hepatitis C virus positive (HCV+) organs.
- iii) Increase accountability of transplant centers for organs that are declined on the behalf of patients when these organs are of excellent organ quality. Address issues of technology and infrastructure impacting the following:
 - a. DonorNet
 - b. Organ Center
 - c. Bypass Filters
 - d. Decline Codes
 - e. Inadequate oversight of process measures as evidenced by out of sequence offers
 - f. Data Quality

4. Addressing discard rates.

- i) Labeling effect of the KDPI
- ii) Continued flagging by the Membership and Professional Standards Committee (MPSC) for 1-year outcomes
- iii) 5-Star Rating

- iv) Hospital Commitment
- v) Measures addressing declines

5. Additional performance measures for transplant centers.

6. Transplant recipient patient rights

7. Equity in transplant

B. Kidney Health and End-Stage Renal Disease Facilities.

CMS's questions for section B of this RFI fall into 2 broad categories – care delivery for chronic kidney disease and kidney failure. We have summarized our suggestions below.

1. How can we improve equitable care for patients with chronic kidney disease to slow the progression to kidney failure?

Patients with chronic kidney disease could benefit from new guidelines and strategies to improve screening, education, care coordination, and affordability of medications; these guidelines and strategies could help identify patients at high risk for progression to kidney failure and could help slow the progression of chronic kidney disease. Briefly, we recommend the following:

Screening

- i) Screen patients with tools such as the Kidney Failure Risk Equation.
- ii) This screening can identify patients who are at high risk for progression to kidney failure and offer an opportunity to prevent them from “crashing” into dialysis.
- iii) Screening could occur at the point of entry to Medicare and annually afterwards, using serum creatinine and/or cystatin C measurement in combination with urine albumin-to-creatinine ratio.

Education

- i) Modify Medicare's Kidney Disease Education (KDE) program to expand eligibility, improve affordability, and encourage utilization of the program:
 - a. Expand the scope of who can provide training to include advanced practice providers (i.e., physician assistants, nurse practitioners, and clinical nurse specialists).
 - b. Expand beneficiary eligibility to include patients with CKD stage 3b – stage 5.
 - c. Allow dialysis facilities to provide kidney disease education services.
 - d. Include dietary consultations at all stages of CKD.
 - e. Adjust the reimbursement for the KDE benefit, which has remained unchanged for 30 years.
 - f. Waive the 20% copay for KDE.

- ii) Develop explicit national content guidelines to help ensure that all treatment options and decision-points are clear and accessible to patients.

Care coordination and telehealth

- i) Fund care coordination programs for patients with advanced chronic Kidney disease.
- ii) These care coordination programs could focus on slowing progression of chronic kidney disease, reduce unnecessary inpatient utilization, and ensure patients have an optimal start to dialysis when needed (i.e., avoid the highly morbid and expensive “crash start” dialysis).
- iii) Provide additional funding or incentives to support programs for populations at risk for kidney health disparities (i.e., Black Americans, Latinx Americans, Native Americans, and Native Hawaiian/Pacific Islanders as well as individuals with lower educational and socioeconomic status). These programs could include recruiting community health workers, or patients with kidney disease and their caregivers to serve as patient navigators. Patient navigators could help address barriers to self-management, streamline care, ensuring patients see their nephrologists, receive their medications, and understand how chronic kidney disease might impact them.
- iv) Maintain reimbursement for telehealth services beyond the public health emergency and expand them to cover educational outreach efforts recommended in this letter.
- v) Fund research on how care coordination programs and telehealth services impact all patients with chronic kidney disease while monitoring the impact of these programs on historically underserved communities.

Affordability

- i) Reduce cost-related barriers to access to medications that are proven to slow the progression of chronic kidney disease, such as SGLT2 inhibitors, and finerenone.
- ii) Encourage each US state to offer a Medigap plan. Dialysis patients in the 22 states without the option to buy a supplemental Medigap plan face steep co-pays, and often must spend down assets to become Medicaid-eligible, a nonsensical and financially devastating choice.
- iii) Waive the three-month waiting period for Medicare eligibility for people with kidney failure who elect to undergo in-center hemodialysis. Currently Medicare coverage only begins in the first month for patients who elect to undergo training for home dialysis. Patients undergoing in-center hemodialysis without other insurance experience delays in obtaining lifesaving arteriovenous fistulas or grafts before obtaining Medicare coverage, increasing cost and risk of death. Given that there are numerous social determinants of health that prevent equitable access to home dialysis (such as access to stable housing), this policy only further exacerbates disparities for individuals whose default option is in-center hemodialysis.

2. How can we improve equitable access to home dialysis so that more patients have the option to safely choose home dialysis?

Patients with kidney failure face several barriers to home dialysis, including limited support at home, shortages in qualified personnel who can educate and train patients, lack of empowerment, and a healthcare system that favors in-center hemodialysis. Patients with kidney failure could benefit from strategies that improve assistance and remote monitoring at home, address shortages in home dialysis staff, empower patients to pursue self-care dialysis, and encourage providers to provide high quality home dialysis care through innovations such as new payment models and alternative care models.

Briefly, ASN recommends the following:

Assisted home dialysis and remote monitoring.

- i) Create a reimbursement mechanism for assisted home dialysis. This could allow providers to provide temporary assistance at the patient home during high-risk periods where patients are at high risk for complications such as modality transfer peritonitis, technique failure, burnout, or death.
- ii) Assistance could be provided for eligible patients during the initiation phase of home dialysis, during periods of transition/complications, or for respite care.
- iii) Reimburse caregivers for home dialysis costs, including utilities and caregiver time.
- iv) Evaluate the role of telemonitoring to provide virtual assistance and support for patients.

Address shortages in home dialysis staff. There is a critical shortage of home dialysis nurses. To address this shortage, CMS should strongly consider the following:

- i) Leverage the skills of members of the multidisciplinary care team for home dialysis training. Similar to in-center hemodialysis, allow registered nurses to supervise home dialysis patient training conducted by other team members, such as certified patient technicians and licensed practical nurses.
- ii) Expand the scope of patient training such that the registered nurse does not need to conduct all aspects of the training, provided that other members of the multidisciplinary care team are conducting aspects of training and that the patient is in the line of site of any registered nurse if dialysis is being provided at the same time (often a facility nurse manager).
- iii) For training nurses to become home dialysis nurses, provide competency-based training as an alternative to the time-based training requirement for home dialysis nurses. This could be strengthened through peer and Medical Director sign off to ensure competent care delivery.

Empower patients to pursue self-care dialysis.

- i) Redefine “self-dialysis” for in-center hemodialysis to include the list of activities that patients should engage in to build towards independence. Sample activities could include:
 - a. Take and record weight and vital signs, as relevant.
 - b. Set up the equipment required for treatment.
 - c. Have the machine set up for favorable orientation toward the patient.
 - d. Touch the machine during treatment and respond to alarms.
 - e. Manage the access site pre- and post-treatment, with or without self-cannulation.
- ii) Once patients can perform self-dialysis, provide clarification to allow self-dialysis patients to dialyze outside of the view of staff during treatment. This could allow patients to perform self-dialysis at their own schedule and preference without being restricted by the availability and timing of nursing staff.

Encourage innovations in payment models and alternative care models.

- i) Modify one-on-one training requirements. Some of the training on the machine and basics of dialysis may be done in a classroom style learning setting with multiple patients, as opposed to only one-on-one training. This could allow more patients to train on home dialysis and interact with their peers.
- ii) Allow training for dialysis to be done in the home so that the patient is trained in the setting where they will be dialyzing.
- iii) Reduce the administrative burden associated with medical justification requirements for increased frequency of treatments more than 3-4 per week.
- iv) Reduce the administrative burden associated with temporary changing dialysis modalities to allow for respite care and maximal flexibility.
- v) Improve reimbursement for home dialysis so that it has the same or better reimbursement compared to in-center dialysis.
- vi) Create incentives for alternative programs, such as transitional care units and self-care dialysis.
- vii) Patients receiving dialysis at home should have the ability to choose whether to participate in initial and annual care planning via teleconference (via audio or audio and video communication) with the multidisciplinary care team at home or face-to-face in the clinic.
- viii) If the patient chooses and if permitted according to the FDA’s labeling of the medications, self-administration of medications at home should be permitted (including by a care partner)

C. Organ Procurement Organizations (OPOs)

ASN re-affirms its support for the Organ Procurement Organizations (OPOs) Conditions for Coverage Final Rule issued on November 20, 2020.

Briefly, ASN recommends the following:

OPO Assessment and Recertification and Competition

- i) Create continuous improvement plans using data analytics.
- ii) Support Task 5 efforts.
- iii) Expand NIDDK program on improving organ donation.
- iv) Establish transparency guidelines for OPO data.
- v) Allow due diligence of OPO information for potential bidders of a designated service area (DSA).

Organ Transport and Tracking

- i) Increased support for transport of organs.
- ii) Use of appropriate tracking devices.
- iii) Improve organ tracking technology, logistics, and provide greater investment in donor staff at OPOs to make organ loss a rare or “never” event.

Donor Referral Process

- i) Clinical triggers for potential donor referral.
- ii) Increased use of APIs.
- iii) Use of best practices information sharing.

Organ Recovery Facilities

There is growing evidence that a broader use of organ recovery centers could result in more organs procured per donor, at lower cost to public and private payors, and organ procurement can transpire in a manner that is more convenient, and safer for surgical recovery teams. CMS needs to avoid financial losses for other stakeholders.

D. Joint Ventures

CMS needs to collect and analyze information about existing joint ventures first, then those relationships can be studied and compared to non-joint ventures to help answer these questions. Disclosure of joint ventures between dialysis organizations and University systems, healthcare organizations, hospitals, physician groups and individual physicians should be disclosed to patients and publicly available.

CMS Questions/ASN Responses

The remainder of ASN's comments in this letter follow the same order as the questions posed in the RFI.

A-1. Transplant Programs

2. Transplant Program CoPs

- 1. For patients and their families: Are transplant programs meeting your specific needs and are you satisfied with the care that you have received? Specifically, what type of information are you receiving from your transplant program or transplant surgeon?**

ASN strongly advocates for CMS to implement transparent guidelines, including clear presentation of eligibility criteria for listing and transplantation, to ensure clear, useful, and easily accessible data so the patient, their nephrologist, their dialysis facility, and transplant center can coordinate the care and communications necessary to identify the right transplant center fit for a patient and to keep the patient on the path to transplantation.

Regulations mandate that patients receive information on the transplant center's 1-year graft and patient survival based on Scientific Registry of Transplant Recipients (SRTR) data updated every 6-months and notify patients of significant changes. However, current requirements focus on too much information of limited discrimination provided by these outcomes and not enough information on elements that patients highly value. Not only is it burdensome for centers to maintain current written disclosure of data that are of limited value to patients, but there are also several other challenges to these communications:

- The communication is not standardized. ASN recommends standardizing how information is shared with the patient, similar to how financial information sharing has been standardized by the Consumer Financial Protection Bureau (CFPB). This is an important step in assuring clarity, objectivity of data and providing patients the ability to compare centers based on their results. Instead, the current system which allows centers to use different formats makes it difficult for patients to understand the information they are seeking. Even information shared by transplant centers on their websites is not standardized and difficult for patients to follow in order to make informed choices (PMID: 33353493).
- The information shared by centers is driven by data produced by SRTR that do not correspond to the information that patients want while they are on the wait list. This was described by Husain SA et al. (PMID 29945305), where patients clearly indicate their preference for process measures such as time to transplant, ease of waitlisting, and whether a center will accept patients like them on the transplant wait list. Critically, emphasis on less important or insufficiently adjusted

measures without full context also incentivizes transplant centers to only list and subsequently transplant patients with the fewest barriers to transplant, thus exacerbating disparities in access to transplant.

- While patients clearly prefer to get information from their providers, there is a limited understanding of the allocation system or the processes of the local transplant programs among dialysis staff, especially those at the patient bedside. (PMID: 29471303 and PMID: 29650714) Websites from UNOS and SRTR are not seen as primary sources of information by patient communities. The SRTR website, in particular, is difficult to use even by well-educated and informed patients.
- Serial changes in the SRTR rating of transplant centers over time add to the confusion over the value and meaning of the current 5-star rating system. The overall score does not sufficiently reflect the process measures in which patients are more interested. (PMID: 29316241). Providing a single 5-star rating for both access to transplant and post-transplant outcomes leads to confusion for patients about the more important measures. In addition, the repeated change in ratings while the patient is waitlisted is both confusing and anxiety provoking.
- Patient selectivity and transplant center thresholds are not publicly shared with patients, dialysis providers, or referring nephrologists, making it unclear if patients are candidates for transplant at a given center. Large variations in the thresholds for accepting patients make it difficult for patients to identify centers that would be willing to accept them as candidates. As a result, regional studies in the US demonstrate significant variation in the proportion of referred patients who are subsequently waitlisted (PMID: 31981441)
- In the last two decades, there has been an increase in selectivity by transplant centers and rapid delisting of patients from waitlist, both of which have a direct negative impact on access to transplant but have no associated transparency. (PMID: 30019832) As a result, the median survival of transplant candidates AFTER they are removed from the waitlist (for reasons other than transplant) is now approximately 5 years. (PMID: 33565145) while waitlist mortality has steadily dropped to approximately 5% annually compared to an overall annualized mortality rate of 20% for ESRD patients.
- Patients on the waitlist are frequently unaware of their status on the waitlist and receive little or no information from the transplant centers. This paucity of communication among patients, their dialysis facilities, and transplant centers results in several troubling facts:
 - a) Patients typically are unaware that organ offers are being declined on their behalf without their knowledge (PMID: 31469394). These offers are often for organs that patients would have accepted had they been asked.

- b) The waitlists are poorly curated and maintained due to insufficient communication between transplant centers, dialysis facilities, and patients or their caregivers. As a result, nearly one in 5 kidneys is now offered to a deceased person still on the waitlist because the transplant center is unaware that the patient is deceased (PMID: 30091841). Deceased candidates receive a median of 4 organ offers before they are removed from the waitlist.
- c) Patients must be informed if their centers either pause doing transplants or inactivate patients on the waitlist. Rapid inactivation of large numbers of patients was only recently introduced and the system desperately needs to leverage any communication tools the OPTN can provide.
- d) Almost all centers use an unofficial status of “internal hold” for patients who remain active on the waitlist and continue to receive offers but are not eligible to receive transplants. This practice is detrimental to the efficiency of the allocation system, often leads to confusion on the part of the patient and may be abused by centers. Patients on internal hold can continue to attract organ offers and be used to move organs to different Donor Service Areas (DSAs) by transplant centers before they are then declined forcing a local reallocation of that organ in a different part of the country than where it ought to have been used.
- e) Patients must be informed of the criteria used by a transplant center for accepting offered organs. These criteria are not currently shared with the patients. Knowledge of these criteria would give patients the choice of which center would suit them best. Bypass filters are used by transplant centers to automatically screen out offered kidneys from donors with certain clinical characteristics. For example, donor age criteria can be set such that centers are not offered national organ offers from donors above a prespecified age. While these filters were designed initially to help accelerate allocation, there use needs to be monitored and researched by CMS to determine the impact (PMID: 32479923). These bypass criteria often can result in dramatic changes in the probability of transplantation because it shrinks the pool of donor organs to which patients at a given transplant center have access.
- f) Centers appear to be less willing to use organs for transplantation on the weekend, including for organs that are eventually accepted by other transplant centers. How this impacts the probability of transplantation is not currently understood nor shared with patients (PMID: 31015260 and 27182001).

All of these processes/events occur without transparent, patient-centered communications that accurately convey what is happening within the process.

2. **Do transplant programs adequately protect the health and safety of living donors and transplant patients? Please provide data, research, studies, or firsthand accounts that would be illustrative of how transplant programs are performing with regards to adequately protecting patient health and safety.**

Transplant Patient Safety: Among patients selected for transplant organs, 1-year post transplant graft survival is excellent, averaging ~ 97% (PMID: 33595191). The critical issues are the organ shortage, discard rate, and lack of transplant access for many patients who could benefit from increased uptake of transplantation (resulting in a shrinking waitlist), which would require improving the discard rate and organ shortages. Expanding practices to procure and utilize all usable organs, even those that are deemed not of the highest quality, requires a system-wide perspective that is framed around a comparison of the benefits of the patient receiving that organ versus continuing on dialysis. The current regulatory penalties incite transplant centers to reject less than ideal organs even if these organs would still greatly improve the quality of life and longevity of transplant recipients when compared to dialysis. The Kidney Donor Profile Index (KDPI) is a measure of organ quality relative to other organs that does not adequately reflect the value that organ provides to a specific recipient. As such, the KDPI is a seriously flawed guide for clinicians, and it should never replace the quality-of-life perspective of the patient. While the idea of using a composite measure of organ quality to reduce cognitive load is a good one, alternative strategies need to be considered along with ongoing research to improve kidney allograft quality measures. ASN recommends that the KDPI be withdrawn immediately, and the Kidney Donor Risk Index (KDRI) be used without the KDPI.

Living Donor Safety: The OPTN has several mandates directed at living donor safety. Policy 14 defines minimal criteria that must be included in the living donor evaluation and informed consent. Policy 18 defines clinical and laboratory parameters that must be collected at 6 months, 1 year, and 2 years post donation. CMS has considered this policy to reflect data collection rather than medical care, and therefore has disallowed these efforts from reimbursement through the Medicare Cost Report or the recipient's insurance (including Medicare), even though post-donation follow-up is critical for monitoring safety. These data are summarized in SRTR Program Specific Reports, and complications (national level) in the Annual Data Report, although these reports are directed at professionals and are unlikely to be accessed by most patients.

Under its contract with HRSA, the SRTR has recently started a project to create a lifelong living donor registry, the Living Donor Collective (<https://livingdonorcollective.org/>). The first phase of data has been published (PMID: 33912656) with updated reporting appearing in a new Annual Data Report, and participating programs receive Program Specific Reports. Under this model, transplant centers register donors and the SRTR conducts follow-up. At this time, participation is voluntary and transplant centers cite concerns for costs as a barrier to participation.

To ensure a meaningful commitment to living donor safety, CMS could partner with the OPTN and SRTR to reimburse the costs of follow-up as necessary post-donation care and incentivize donor registration in the Living Donor Collective. ASN notes that there is very little long-term data on the outcomes following kidney donation, particularly among racial and ethnic minorities, which has impeded the growth of living donation. More recent advances in genetics of kidney disease, including the APOL1 alleles, raises new concerns and questions for the long-term risk of potential donors with genetic markers of kidney diseases. These questions need to be answered in order to ensure optimal and equitable access to living donation and reassure potential donors and optimize their safety.

3. How can the current transplant program CoPs be improved in order to incentivize and ensure performance quality in organ transplantation?

Systemwide alignment: Currently, the CoPs for dialysis facilities and transplant centers are not aligned and do not recognize the role of both in facilitating a smooth transition of care for patients. As a result, there are silos of care that occur in the nephrology clinic, dialysis unit, and the transplant center that increase challenges faced by patients in achieving optimal patient care.

- In 2019, CMS recognized how regulatory focus on post-transplant outcomes, such as graft and patient survival, in isolation could lead to unintended consequences including increased risk aversion in transplant centers and barriers to transplant access; accordingly, CMS eliminated the data, clinical experience, and outcome requirements for re-approval of transplant programs.
- Recently, the OPTN Board approved a new policy combining pretransplant (offer acceptance, waitlist mortality) and posttransplant (90-day graft survival and conditional one-year graft survival) indicators to motivate attention to all phases of care by transplant centers. ASN does not support that new policy and hopes this RFI will lead to the reversal of that approval. This is in part because of the inclusion of a waitlist mortality measure which would only encourage selective and delayed waitlisting of ESRD patients who continue to accrue waitlisting time from the time that they initiate dialysis. ASN notes that the OPTN has moved forward with new measures while being fully aware of the effort from the SRTR to develop new metrics for transplant centers. This failure to coordinate is going to result in another compilation of a variety of quality measures from different agencies that will create confusion among transplant centers – much to the disadvantage of patients. The confusing array of quality measures from different agencies also creates confusion for hospital leadership which adversely impacts their willingness to invest and support transplant programs and the much-needed quality improvement resources.
- Systemwide alignment is not present. CMS rewards dialysis providers and nephrologists for waitlisting patients in the ESRD Treatment Choices (ETC) model and the ESRD Quality Incentive Program (QIP) with the PPPW measure

(and is exploring referral metrics). However, the quality program incentivized dialysis facility goal of attaining higher listing for transplantation contrasts with the motivation of a transplant center to guard against higher rates of waitlist mortality due to the new OPTN policy on 90-day graft survival and on conditional one-year graft survival. Although these metrics are “risk adjusted”, there are well-known limitations to adjustment based on registry data. Further, the SRTR Transplant Rate includes inactive patients in the waitlisted denominator. This metric is used by some commercial payors as well. Centers may reduce their denominator by declining to list patients or by delisting patients to increase their transplant rate.

- Ensuring that centers are performing quality improvement activities on an ongoing basis requires the establishment of a robust effort in the form of a quality specialist focused on continuous improvement and monitoring of process and outcomes measures of the transplant center. This needs to be seen as a necessary investment on the part of hospitals with transplant centers.
- Incentivizing maximum access to waitlists, optimal organ use, and transplant rates, while maintaining post-transplant outcomes requires a harmonized, system-wide perspective. Published research shows that net survival benefit conferred by even the ‘lowest performing’ centers is far superior to dialysis (PMID 25237071). **To avoid risk aversion, recertification should focus on achievement of an absolute survival benefit over dialysis.**

Finally, transplant centers are not currently equipped to handle a deluge of patient referrals should dialysis facilities decide to indiscriminately refer all of their patients immediately for evaluation for transplantation. It is clear that improvements are needed in pre-referral evaluation and in communication between dialysis facilities and transplant centers to optimize the pre-transplant evaluation process and eliminate disparities. Currently, reimbursement policies do not incentivize the adequate staffing of pretransplant programs to appropriately expand and manage transplant center waitlisting. The current policies are exacerbated by the absence of any meaningful reimbursement from private payers for pretransplant related coordination of care and other activities to maintain patients active on the waitlist.

Patient-centered CoPs: The current CoPs are also focused almost exclusively on short-term patient outcomes. While short term outcomes have improved considerably, these improvements have come at the expense of selective access to transplantation and a rapid increase in organ discard rates. The current CoPs do not promote patient-centered care given the absence of requirements related to processes of care. CoPs related to process measures rather than merely outcome measures would encourage improved communications across silos of care (dialysis units, referring nephrologists, and transplant centers), encourage transplant centers to provide increased and timely access to evaluation and related testing, and encourage greater communication about waitlisted candidates among transplant centers and current care teams.

In order for transplant programs to function optimally and to increase access to transplant, transplant programs require robust, adequately funded pre-transplant teams that will aid patients in navigating the multistep evaluation process and will keep patients informed of changes in a timely manner; additionally, these pretransplant teams also must ensure regular communication with dialysis units and nephrologists so that changes in health status that require either temporary inactivation or delisting (when truly indicated) happen in a timely manner.

Making the patients' experience of pretransplant evaluation easier is an important goal (that will require adequate funding) that should help to address some of the barriers to transplant that disproportionately affect patients who do not live in close proximity to a transplant center. Some transplant centers seek to perform much of the pretransplant testing locally at their center. However, in the age of electronic medical records, efforts should be made to allow much of this testing to happen in a location that is of most convenience to the patient and their families, obviating the need for travel costs, time off from work, and other challenges that may inadvertently create barriers to consideration for transplant.

Pretransplant testing is a significant source of revenue for many transplant centers. Maintaining the financial stability of transplant centers is clearly a crucial objective in order for them to remain open to provide transplants. Accordingly, if patient-centered changes are made to baseline pretransplant testing, it will be necessary to understand and mitigate any deleterious impacts on the financial viability of transplant centers so that they can, in turn, continue to serve patients.

ASN notes that, while the Medicare program pays for a portion of pretransplant costs through organ acquisition cost center, pre-transplant costs related to coordination of care and monitoring activities for patients with private insurance are not reimbursed at this time. While transplanting privately insured patients is often associated with higher reimbursement, the activities for patients who fail to get a transplant are a source of significant unreimbursed costs.

The majority of patients are clinically stable after transplantation and could be managed by referring nephrologists in partnership with transplant centers. Improved partnerships require the creation of systems that allow for easy referral back to centers in the event of complications, with a significant resource investment into coordination of care activities.

At present, interest in taking care of transplant recipients (and living donors) in the long-term plummets on the part of transplant programs after one-year post-transplant and there is no clearly established pathway to community care, to the detriment of patients. It would be beneficial to establish—as well as provide reimbursement to support—a pathway for these individuals to receive skilled care from professionals. A variety of approaches could be undertaken to achieve this goal, and the care would not necessarily have to be provided at the transplant center itself.

Telemedicine may be an ideal venue to provide these patients access to long-term, post-transplant or post-donation care. It may also be possible for transplant centers and transplant nephrologists to forge connections with internists with knowledge about transplant or general nephrologists to provide this care at the community level.

Continuing education opportunities offered by societies such as ASN or primary care societies to help clinicians keep current about management of transplant recipients and donors may facilitate the provision of this care. The absence of reimbursement for long-term, post-transplant care and the lack of long-term outcomes evaluations hinders the provision of this care at present and would need to be established in order to support the work. The first step is for CMS and the kidney community to collectively acknowledge that the transplant ecosystem has a long-term commitment to the care of these patients that it does not currently meet. ASN encourages CMS to address the misalignment of the goal of increased opportunities for transplant with this payment policy.

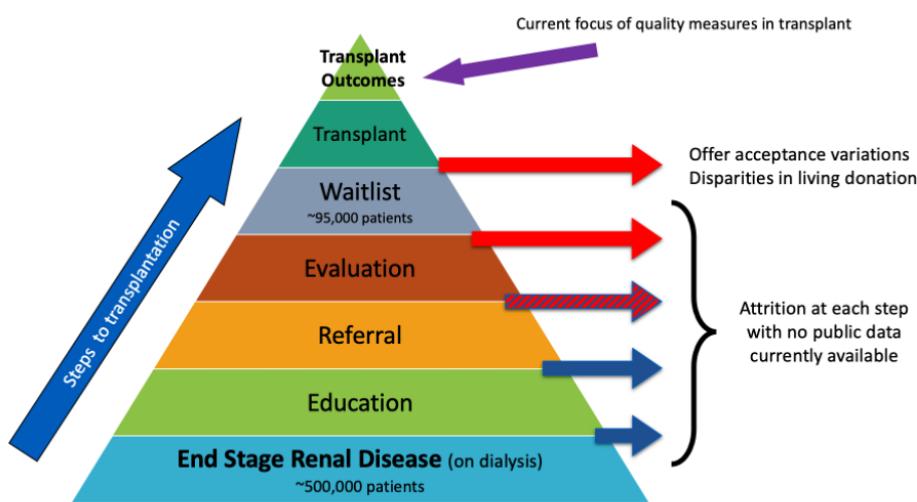
CoP accountability should extend to referring dialysis centers and nephrologists, especially if referrals prior to dialysis initiation are to be encouraged. Transplant programs do not currently have the ability to evaluate all patients who would potentially benefit from transplant in a timely manner, creating a significant bottleneck in the process. Adequate staffing of the pretransplant program and recognition of the significant amount of time committed to nonbillable activities, such as data capture, proactive identification of patients, coordination of care, selection conferences, and quality improvement processes, are critical to the development of robust processes. The absence of support/funds for these necessary direct patient related activities that are not currently reimbursed as well as the administrative activities associated with establishing and running a transplant program and its individual components (pretransplant, living donor and posttransplant) is a challenge and needs to be addressed.

Patient related activities performed by transplant nephrologists include coordination of care between dialysis units, referring physicians, transplant centers and consultants, review of regular testing to maintain candidates in a transplant ready status, review of potential candidates and their potential donors at selection conferences as well as the completion of quality assurance activities that are required by different agencies. These activities consume significant amounts of time and are not currently reimbursed in any form which then limits the ability of programs to support an adequate number of physicians which in turn adversely impacts transplant access by creating resource bottlenecks for the timely evaluation of patients referred for transplantation.

Similarly, referring nephrologists and transplant centers need to increase coordination when providing a continuum of care for patients post transplantation. The majority of patients are clinically stable after transplantation and could be managed by referring nephrologists in partnership with transplant centers. Improved partnerships require the creation of systems that allow for easy referral back to centers in the event of complications, with a significant resource investment into coordination of care activities.

While not necessarily part of the CoPs, there is a need for physician practices, transplant centers, dialysis units, and independent laboratories to share patient results in a seamless manner, particularly if the care of these patients will be co-managed by two or more sets of clinicians in partnerships or transform patient care silos to integrated care along a continuum.

Currently the quality measures are focused almost exclusively on post-transplant outcomes. This singular focus has created several negative unintended consequences and encouraged increasing selectivity. Overcoming this will require recognition that we should be assessing care along the continuum of patient experience in the steps to transplantation. This would mean creating quality measures (process or outcomes measures) for each step in the process.



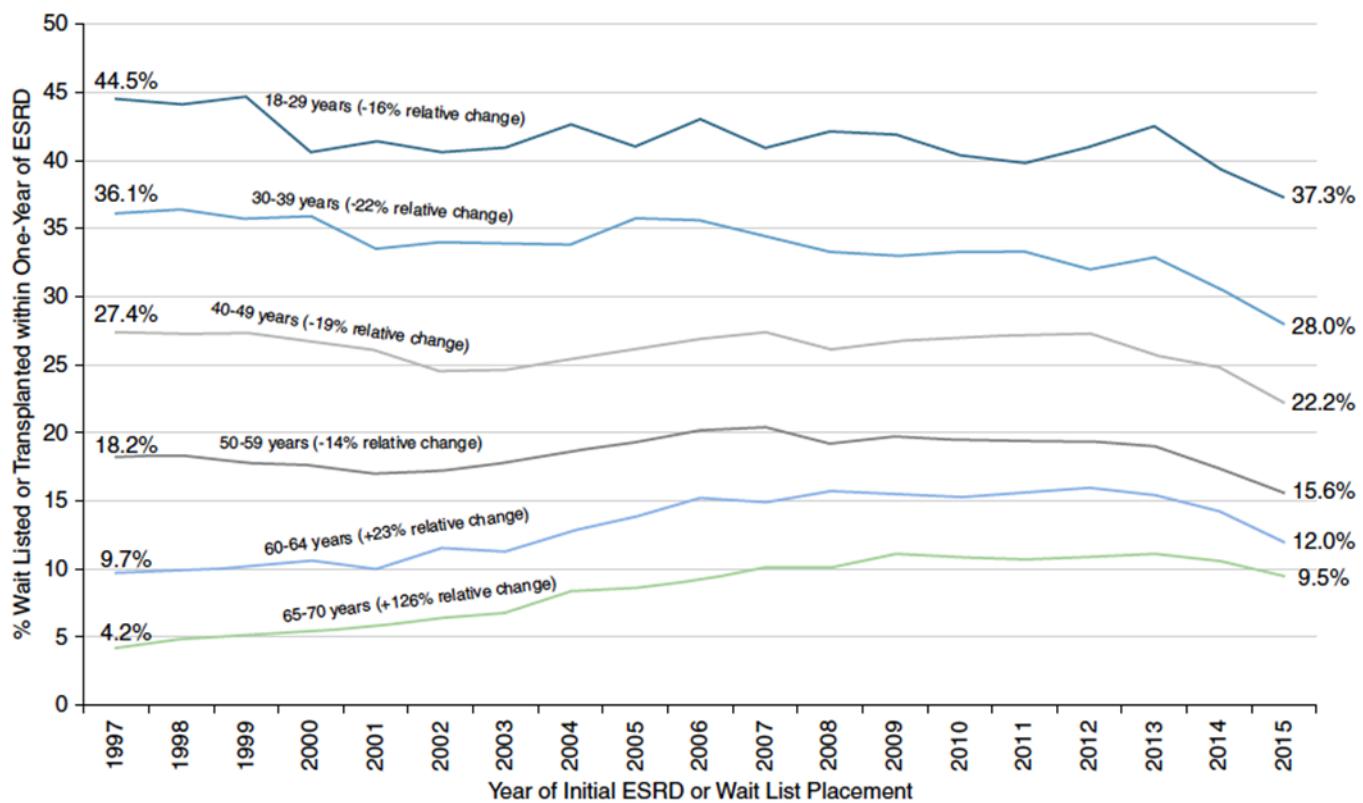
One method to potentially avoid unintended consequences is to calculate quality measures in such a way that considers the spectrum of the process from dialysis to transplant at any given time, so as to leverage the multistep nature of the process of education, referral, evaluation, waitlisting, transplantation, and post-transplant outcomes. Specifically, measures of quality should use the numerator from the prior step as the denominator for the next step along this continuum to discourage gaming of metrics or a singular focus on just one step of the process.

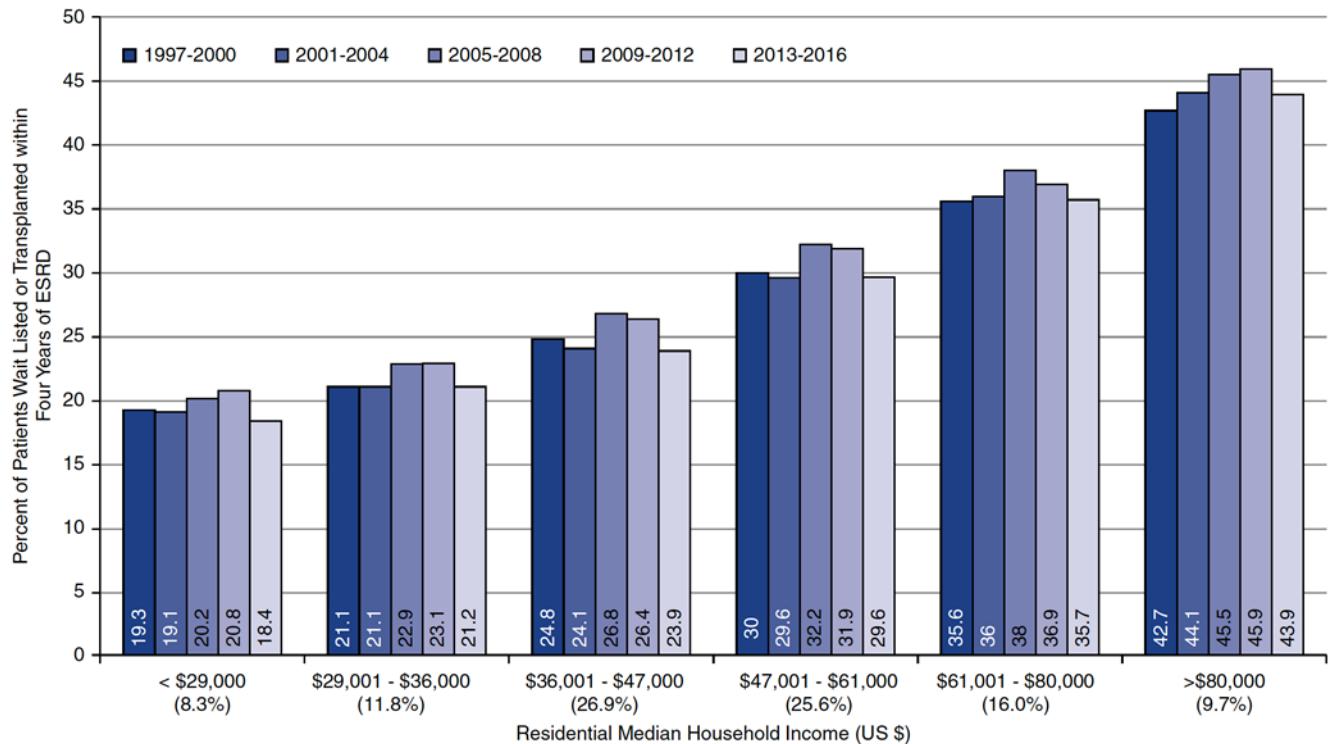
For example, the proportion of patients referred should be based on the number of patients who completed the education step, while the proportion of patients evaluated should be reported as a fraction of those patients who were referred for transplantation. This multistep process, however, spans different stakeholders – and would require that CoPs for transplant centers are aligned with Conditions for Coverage for dialysis facilities and with value care programs in which nephrologists are currently participating.

Post-transplant outcome measures currently focus on very short-term outcomes of graft survival and patient death but fail to account for the impact on quality of life. For example, patients who receive a transplant that is complicated by a prolonged hospital course, multiple readmissions, multiple complications with poor allograft function but is

dialysis independent at the end of a year would be considered a success by the current CoPs but has potentially resulted in a significantly worse quality of life for the patient. Similarly, from an access and health equity perspective, focusing on short-term, time-limited outcomes post-transplant limit the opportunity to spur growth in transplantation.

Finally, CoPs should be aligned with the primary goal for kidney transplantation in the United States, which is to increase access to kidney transplantation to the maximum number of patients with kidney failure while improving longer term post-transplant outcomes (particularly among our younger recipients) and quality of life (particularly among older recipients where long-term survival may not be the paramount goal). ASN believes it is particularly important to note that over the past two decades, the proportion of our younger dialysis patients being added to the waitlist has actually been declining for unclear reasons, while the racial and socioeconomic disparities in access to the waitlist has been largely unchanged.





4. Do the initial approval requirements at § 482.80 create barriers to the establishment of new transplant programs?

- Do they require an excessive amount of hospital resources at program launch, resulting in hospitals retaining lower performing transplant programs?

New transplant programs, particularly for kidney transplantation, are resource intense endeavors that require large teams to be able to establish a waitlist and provide true access to transplants. It is in the interest of existing transplant centers to have fewer competing centers because the established centers will have greater ability to be increasingly selective in the patients evaluated, waitlisted, and transplanted and in the organ offers that they are willing to accept. Recent analyses have demonstrated the impact of increased competition between transplant centers on transplantation rates. (PMID: 26574684) However, ASN notes that the increased complexity of the allocation system with KAS250 and the move towards continuous allocation has been associated with dramatic reductions in efficiency of organ allocation with centers becoming more selective for their high priority patients. This has now resulted in a sharp uptick in the discard rate in 2021 to nearly 24% and an increase in cold ischemia time even for kidneys that were procured and transplanted within the geographic boundaries of the DSA.

- What alternatives for ensuring quality and oversight should be considered?

Discard rates: As outlined earlier, quality and oversight should include patient-centered process measures. In addition to requiring a greater recognition of the silos of care among dialysis providers, referring nephrologists, and transplant programs, there needs to be greater shared oversight of OPO – transplant center interactions in order to promote shared accountability. A rapid increase in organ procurement that resulted from increased attention to OPO performance has been coupled with a rapid increase in the national discard rate. This discard rate has further increased following the introduction of the new allocation system that prioritizes centers within 250 nautical miles of the donor hospital, with a concomitant increase in the cold ischemia time experienced by kidneys that are transplanted. CMS needs to invest in research and analysis of these events to see how, and if, they are interrelated. This increase in cold ischemia time has also been seen among kidneys that are transplanted within the original donation service area (DSA) boundaries underscoring the need to understand the operational impact of changes in the allocation system – especially as we move towards continuous allocation. (PMID: 33037131)

Process measures: Process measures, such as measuring the proportion of referrals and waitlisting prior to dialysis initiation, can help incentivize early referrals from nephrology clinics and timely waitlisting of these individuals. Measures that focus on the time it takes patients to transition from referral to evaluation to active waitlisting would be another example of focus on process measures that patients and referring clinicians care about when selecting a transplant center. However, ultimately patients care most about whether they are actively waitlisted and subsequently transplanted.

Equity: A focus on increasing transplantation rates i.e., the utility of a procured organ by the system cannot happen without continued need to ensure equity in transplantation. While OPOs are increasingly vocal about the need to increase utility of organs even if it comes at the expense of equity, we believe that this argument represents a false choice. A fair allocation system has to prioritize equity, and this does not have to come at the expense of maintaining high utility. The socioeconomic determinants of access to transplantation, post-transplant outcomes, and the extent to which these are the result of active choices by transplant centers and referring clinicians need to be better understood. (PMID: 33574159 and 34140398 and 31503308).

Increased pressure on OPOs for organ procurement and transplantation without recognition that transplant centers need to be more willing to accept organs has resulted in unintended consequences, including ‘list-diving’ (centers choosing to skip over patients on their waitlist in order to be able to give the organ to a different patient on their waitlist), open offers (organs being offered to the transplant center with no requirement to follow the allocation prioritization of patients), and a rise in out of sequence organ placements (organs being offered to certain transplant centers out of sequence defined by the match run. (PMID 35000284) These processes undercut the principles built into the prioritization of the allocation system and risk exacerbating existing disparities.

Social support: Transplant centers frequently decline to waitlist patients due to the absence of “adequate social support” using arbitrary thresholds that may disproportionately affect individuals from lower socioeconomic groups and racial and ethnic minorities. The extent of this as a challenge to waitlisting and subsequent transplantation is not clear. Exclusion of patients without social support not only limits access to transplantation and exacerbates existing disparities, but it also ignores an opportunity to invest resources in supporting patients and expanding transplantation rates while saving CMS money in the long run. CMS and HHS need to fund research to better understand how this dynamic plays out, how impactful it is, and what are the steps along the way to avoid an over emphasis on “adequate social support.” ASN encourages CMS to leverage the ESRD Treatment Choice Learning Collaborative (ETCLC) to collect pilot data on process measures and information on pretransplant processes to improve our understanding of the factors at play.

Comparing systems: Deceased donor transplantation systems outside of the United States are achieving significantly better outcomes with organs from significantly older donors. Studies that can help understand the reasons for these differences are urgently needed. There is a large difference in discard rates and at least some of these differences stem from the labelling of less-than-ideal organs and the additional consenting process associated with these organs. A distinct step in organ discards was seen with the introduction of the extended criteria donor (ECD) label and this further increased with the introduction of the KDPI system. The use of a percentile scoring system for organ quality which results in organs being identified as the lowest quality organs procured creates cognitive biases – and fails to acknowledge the fact that other systems use significantly lower quality organs with good outcomes. Creation of additional hurdles such as a second consent for KDPI > 85% kidneys decreases the ability of centers to accept these organs appropriately and further disincentivizes the use of these organs

Hospitals: Currently, the investment into quality related activities is left to the discretion of the hospitals. As a result, transplant quality efforts are often severely underfunded and not adequately integrated into the overall quality efforts of the hospital in general. This works to the detriment of transplant programs that have limited bandwidth to have prospective monitoring of processes and outcome measures. This lack of investment by hospitals often works to the disadvantage of patients.

Data gap: ASN notes that a significant advantage of kidney transplant compared to other solid organs has been the ability to accurately identify the total population of patients with kidney failure receiving dialysis in the United States, with sufficient administrative and claims data to enable epidemiologic studies to understand the needs of this population as well as the challenges associated with equity in access to care and subsequent outcomes. The loss of information for the US Renal Data System (USRDS) that will occur with the movement of patients to Medicare Advantage is likely to result in an enormous challenge that significantly hobbles our ability to evaluate and monitor organ allocation, especially with respect to issues of equity. This inability to parse data is already apparent in the current structure of organ acquisition cost reports that limit the

ability of health care services researchers and others to adequately study the pretransplant processes across centers.

5. We are seeking ways to harmonize policies across the primary HHS agencies (CMS, the Health Resources and Services Administration (HRSA), and the Food and Drug Administration (FDA)) that are involved in regulating stakeholders in the transplant ecosystem so that our requirements are not duplicative, conflicting, or overly burdensome. Are there any current requirements for transplant programs, ESRD facilities, or OPOs that are unnecessarily duplicative of or in conflict with OPTN policies or policies that are covered by other government agencies?

- **What are the impacts of these duplicative requirements on organ utilization and transplant program/ESRD facility/OPO quality and efficiency?**

Duplicative and divergent requirements from different sources and authorities create a network of requirements that are hard to understand and even harder to communicate effectively to hospital leadership.

It is important to recognize that, while kidney transplant candidates currently constitute the vast majority of the national organ transplant waitlist and that the number of kidney transplants far exceed the number of other solid organ transplants performed in the United States, transplant centers and hospitals are much more focused on the transplantation of other solid organs.

Current financial reimbursement models for kidney transplant are geared towards the reimbursement of transplant surgery, leaving efforts to ensure that patients are healthy and appropriately optimized while on the waitlist to ensure a successful transplant beyond the purview of the transplant team with very heterogeneous results. Similarly, the care of extremely complex patients post-transplant is similarly marginalized in the reimbursement strategy. While many would draw attention to the small increases in the length of stay associated with the use of less-than-ideal organs, there is a dramatic increase in the amount of effort required to ensure that these organs recover and perform well. This frequently requires the coordination of care with outpatient dialysis facilities post transplantation for the management of delayed graft function, more frequent communication with patients for appropriate titration of medications, increased risk of rejection and the need for closer monitoring for rejection and other complications. In addition to increased clinical activity, this frequently also increases the extent to which social workers, financial coordinators and other members of the team need to engage with these patients in the post-transplant setting.

As a result, ensuring adequate staffing of pre/post-transplant care teams that include nephrologists is currently a challenge which in turn discourages the use of less-than-ideal organs – a problem that is exacerbated by the silos of care that patients experience.

ASN recommends that CMS undertake an in-depth review of reimbursement policies along the transplant line and their effects on the creation and maintenance of robust programs for pretransplant and posttransplant comprehensive care.

6. Are there additional requirements that CMS could implement that would improve the manner, effectiveness, and timeliness of communication between OPOs, donor hospitals, and transplant programs?

Staffing

We recommend establishing and funding minimum staffing requirements for transplant programs. These requirements should include and support for pretransplant coordinator and living donor teams, staff that review organ offers, and staffing models for posttransplant care. These requirements, coupled financial coverage of these services, will help ensure that hospitals adequately staff transplant programs for a given waitlist size rather than linking this merely to the number of transplants that are performed. The new allocation system KAS250 appears to have dramatically increased the number of organ offers that transplant centers are fielding and the communication burden on OPOs to get organ offers out to a larger number of centers to place the organs procured. This increased complexity of the system needs to be recognized and requires a rethinking of the current staffing models for pretransplant teams, OPO donor desk teams, and the center teams that are responsible for reviewing these offers. Increased pressure is forcing centers to turn to commercial vendors to review organ offers. That practice often results in the implementation of rigid organ offer acceptance criteria that risks more organ offers being declined.

Financial planning on the part of the hospitals determines the level of support for transplant programs by estimating a target number of transplants performed for the year since this provides an estimate for revenue and determines the annual operating budget for the transplant program. These sorts of targets are thought of as being beneficial since they give the transplant program something to work towards but come with several downsides. An absolute number of transplants may not be reflective of the needs of waitlist or reflect the variations in the deceased donor organ supply from year to year. Also, exceeding targets frequently results in unrealistic recommendations for subsequent years and risks creating budget shortfalls if there is a drop in the number of transplants performed leading to a reduction in staff thus creating obstacles to increasing the transplant volume in subsequent years. Adding physicians, surgeons, and staff to a program requires programs to be confident that they can meet transplant and revenue targets and that are right sized which then disincentivizes changes in sizes of the program from year to year. A predetermined goal number of transplants results in centers attempting to “right size” their waitlist to that goal rather than tailoring it to needs determined by the local/regional prevalence of ESRD.

Communication among Transplant Centers, OPOs, and OPTN

Improved communication between OPOs and transplant centers requires both organizations to have adequately staffed and trained teams that are responsible for

communicating organ offers rapidly and effectively. As transplant centers are increasingly outsourcing their organ offer screening to outside vendors, there is an increased risk that one-size-fits-all set of criteria are applied to all patients on the waitlist, which will also disadvantage patients who would benefit from accepting a less than ideal organ rather than waiting for a better offer in the future. When centers are using these criteria, ASN supports the center be required to share that information with the public, patients, and OPOs in order to help expedite organ placement.

The failure of the OPTN contractor to invest in technologies and infrastructure that can help patients and their transplant programs identify which organs they would or would not be willing to accept has been a true disservice to patients, transplant programs and OPOs. This failure encompasses several areas including the failure to communicate in an effective and timely manner with transplant centers and OPOs:

1. DonorNet

This repository of clinical information for donors that is used to communicate information to transplant centers remains a poorly organized system with manual data entry and little attention to the user interface for prioritization of the data required by programs to make rapid and informed choices. The fact that this system is a proprietary product that belongs to the contractor creates some unique challenges to the quality of the data, incentives for updating the system or the integration (via APIs or FHIR messaging) with other systems or even with TEIDI data collection forms. The complete absence of any efforts to leverage the OPTN dataset to create any clinical decision support tools over the past two decades is a clear example of the underinvestment in the allocation infrastructure. ASN urges HHS to reconsider whether the IT infrastructure contract should be separate from the rest of the OPTN contract similar to how the SRTR contract is an independent contract.

2. Organ Center

The UNOS organ center is required to participate in the allocation of all organs when we reach national allocation. These are mostly the hard-to-place organs and require both a good grasp of the clinical issues as well as robust relationships with centers. Unfortunately, there is widespread concern that the organ center is inadequately resourced to be able to adequately support all the organs that need to be allocated. The Organ Center's inadequate staffing and strained relationships with the transplant centers urgently needs to be addressed.

3. Bypass Filters

Currently, centers are able to set bypass filters for organs that are allocated nationally. However, there is little research into how these filters are used or implemented or whether they are effective at improving allocation efficiency. Given that these filters do not correspond to data released by the OPTN, it is not currently possible for centers to determine to what extent a given filter would shrink the available pool of kidneys for their patients thereby precluding the ability to make informed risk/benefit decisions. Further, these centers do not share this

information with patients or how these choices might adversely impact their probability of transplantation (PMID 33037131).

4. Decline codes

The inadequacy of existing decline codes for providing meaningful granular information on the reasons that a deceased donor organ was declined was well established for over a decade. For example, a recent analysis demonstrated that there were essentially no meaningful differences in the reasons for organ offer decline across the entire spectrum of KDPI (PMID 31469394). Revised codes were finally implemented in December 2021. Of note, this implementation occurred only after extensive pressure from the external parties to allocate adequate and timely information technology resources. Despite these, several suboptimal choices and compromises were implemented as a result of limited IT resources underscoring the failure of the OPTN contract to prioritize a key element of the Advancing American Kidney Health executive order that highlighted the need to lower the discard of deceased donor kidneys in the United States.

5. Inadequate oversight of process measures as evidenced by out of sequence offers

Currently, the Membership and Professional Standards Committee (MPSC) requires notification of all instances where an organ is placed out of sequence. However, what, if anything, the MPSC has done in response to this requirement remains unclear. CMS needs to verify if the information is being tracked or not and what is the reason for out-of-sequence offers.

6. Data Quality

The OPTN registry has not received the attention that such a critical dataset needs. Researchers have demonstrated inconsistencies within the dataset with respect to elements that are critical to allocation (time on dialysis). This particular set of errors is now being addressed with a passive system of data correction that puts the onus on transplant centers to self-verify. Similarly, there are no limits on data related to biological plausibility in any of the data entry forms. This has resulted in significant data errors that has forced SRTR to return data to the centers to re-evaluate those values that are outside of biological plausibility. This situation needs study and review.

These post-hoc corrections raise important questions about the validity of the data entered, the need for guardrails in place to prevent abuse of the system, and the implications of erroneous data for quality and regulatory purposes. There also appear to be inconsistencies in the data available in DonorNet and the OPTN data registry for reasons yet to be understood. Finally, the data definitions provided for the reported data elements are often broad and open to interpretation which creates further opportunity for confusion and inconsistency between centers. These inconsistencies have serious implications for the risk adjustment models used by regulatory agencies to monitor center outcomes.

- a) Dialysis dates: Allocation time is the primary factor that determines priority for allocation of a deceased donor kidney. For this time calculation, an accurate capture of the ESRD initial date is essential, yet there are large discrepancies in the ESRD dates reported on two different forms to the OPTN (PMID 31550418). Despite this being brought to their attention, there is no apparent effort to alert centers when there is a data discrepancy. CMS could investigate the acquisition of data having a mandatory “pull” function using APIs to link EHRs with the CMS database. Perhaps more egregious is the fact that the OPTN receives this information directly from CMS but DOES NOT attempt to validate these data in any form. When brought to their attention, they have reluctantly provided this information back to transplant centers via the data portal; this requires a passive check and puts the onus of verification back on centers.
- b) The donor’s terminal serum creatinine is a key clinical element that is used in organ offer decisions since it is part of the calculation of the KDPI, and a high terminal serum creatinine level is a significant unfavorable characteristic that is associated with organ discard. Although large data discrepancies exist between creatinine concentrations in DonorNet and the data reported on the deceased donor registration form (DDR), there has been no effort to reconcile these data elements or any quality assurance process for any of these data elements to date.
- c) Mortality and graft failure data reported by the OPTN contract significantly underestimate the true mortality of patients and graft failure given the failure of OPTN to incorporate data from external sources into its data sets or provide any communication back to centers in a timely manner when they become aware of an adverse event. There are consequences associated with the failure to use all mortality data that OPTN receives from CMS; specifically, some deceased candidates are remaining active on the waitlist. As a result, 18% of kidneys were offered to at least one deceased candidate and a median of four organ offers were received by deceased candidates on the waitlist. (PMID 30091841) These avoidable errors result in inefficiencies, and waste of resources in allocating an organ to an appropriate recipient, and like contribute to prolonged cold ischemia time.

Communication among Patients, Transplant Centers, Referring Providers and Dialysis Facilities

Most patients are currently unaware of organ offers that are declined on their behalf. This is particularly concerning given that 85% of all kidneys are declined at least once. While real time notifications are likely not feasible, asynchronous communication of these offers are a potential option for improving patient engagement.

For example, informing patients at regular intervals (every three or six months) could help by:

1. Improving communication between patients, transplant center and dialysis providers about patient preferences and priorities.
2. Helping patients appreciate the tradeoff between increased selectivity for organs and wait times for those organs. This may help patients recognize the benefits of organs that they have not opted into such as high KDPI, public health service increased risk (PHS-IR) or hepatitis C virus positive (HCV+) organs.

There are potential downsides to informing patients of these organ offers including:

3. Increasing patient anxiety by providing this information. These are also complex decisions and may result in cognitive overload for some patients who may prefer to have their programs make these choices for them and only inform them of offers that they would be willing to accept.
4. Impacting, negatively, the relationship between patients and centers. This can result if there is the perception that centers are not working towards the best interests of the patient.
5. Diminishing the value of the information provided to patients when inaccurately or imprecisely conveying the rationale for the decline.
6. Increasing legal liability associated with organ offer declines.

ASN believes that informed patients are activated patients and recognizes that most patients want more rather than less information. Accordingly, ASN recommends CMS research the value of providing organ offer decline information to patients with the following considerations:

1. Standardized communication that predefines the information included, the formatting of the communication, and ensuring that a patient-centered presentation is used to help patients engage in communications and subsequent shared decision making.
2. Patients may have the option of either opting out of these communications or having these communications sent only to their current nephrologist who can help them participate in shared decision making.
3. Nephrologists should receive aggregated information for their patients (either at the level of the provider or the practice or both) to help them understand transplant center preferences and whether those align with their patients.
4. Improved decline offer codes have been recently implemented by the OPTN. Whether these codes are being used appropriately and can be used to create informative communications needs to be studied but represents a unique opportunity to improve patient communication.

5. Greater clarification from CMS and HRSA would help transplant centers understand the legal considerations around the decline of an organ offer on behalf of a patient.

In addition to these reforms, ASN also supports the development of a centralized network to help match “complex” patients seeking a kidney transplant match with a program that has the expertise to accept them would be highly valuable. There is a subset of kidney patients in the United States who would be good candidates at certain transplant centers—but not at all transplant centers. Patients who live near a transplant center and/or have resources to travel to multiple transplant centers around the country significantly increase their odds of getting a kidney, whereas many people who do not have these options are effectively left with dialysis as their only choice.

For example, a patient who lives in an area with a single transplant center that is not particularly high-volume may be turned down at that center and not have the ability—for reasons related to factors such as transparency, communication, personal finances, and/or geography as described elsewhere in this letter—to seek out care at another center elsewhere in the country that would readily take them on. That patient’s journey to a transplant has effectively ended.

A centralized system to which kidney patients and their nephrology care teams could turn to upload baseline patient information that then helps to match or guide that patient to an appropriate program would generate more equitable access to consideration for transplant. Such a system could borrow concepts from the National Kidney Registry, which exists to match potential transplant recipients and living donors across the country.

7. **Are there additional data, studies, and detailed information on why the current number of organ discards remains high, despite CMS’ decision to eliminate the requirements for data submission, clinical experience, and outcome requirements for re-approval?**

Reasons for the continued high discard rate can be summarized as:

- The labeling effect of the KDPI creates cognitive biases favoring kidneys at the higher end of the scale and prevents OPOs from procuring organs from older donors – or expanding the donor pool to include older donors.
- Continued flagging by the MPSC for 1-year outcomes – and a frequent failure by transplant programs to understand the differences between the MPSC and CMS measures.
- Public ratings on the SRTR website are driven at least in part by 1-year measures and most programs do not have a clear sense of how much of the 5-star rating is dependent on early outcomes
- Use of 1-year patient and graft survival rating by private payors has not changed.

- Increased organ supply has facilitated increased selectivity on the part of transplant programs who have a predetermined target number of transplants for the year. In order for transplant programs to be elastic with respect to size and transplant numbers, hospital leadership needs to demonstrate a stronger commitment to these programs.
- Transplant programs are accountable for performance post-transplant but are not accountable for the consequences of declining an organ for a patient or any subsequent untoward consequences.
- The high variability of probability of transplantation within DSA boundaries underscores the variation in the willingness of transplant centers to accept organs. Increased reluctance to accept organs on evenings and weekends, to the detriment of patients is part of the problem (PMID 31015260 and 30444802) and likely persists in the absence of any process measures.

One potential strategy to improve organ utilization and decrease discards is to actively incentivize the use of more marginal organs for transplantation. Incentives, even if done in a time limited manner, could potentially include:

1. Exemption of these less-than-ideal kidneys from quality/regulatory measures of performance
2. Increased reimbursements for the index hospitalization given the increase in length of stay often seen with the use of these organs
3. Increased reimbursement for subsequent outpatient care given the often more complex care needed and the increased care coordination that is often required especially in instances where patients remain dialysis dependent for some duration post discharge.
4. Measuring and reporting the impact that the use of marginal organs has on the probability of transplantation at a given center. This direct recognition of the ability to improve patient outcomes with less-than-ideal organs would help establish the fact that these organs are in fact viable opportunities to benefit patients.
5. Consider eliminating the use of procurement biopsies, except in limited circumstances, as part of the allocation system. Instead, these biopsies should be made available to transplant centers AFTER the transplant to help in post-transplant management care.
6. Expand the circumstances where a patient can regain their allocation time in the event of a primary nonfunction to allow centers to become less risk averse (PMID 34562524)
7. Elimination of a relative percentile score for quality of the kidney such as the KDPI which provides a score of quality relative to the other kidneys procured. Instead, use of the KDRI would help at least return focus to the quality of the kidney to the intended recipient.

8. Creation of decision support tools that would help programs evaluate an organ offer with the perspective of what patients want and the probability of a better organ offer within a reasonable time frame which would justify declining the current organ offer.

8. The industry as a whole has acknowledged that changes cannot be made solely to one part of the transplantation system. Similar to the outcome requirements that OPOs must meet, should CMS again consider additional metrics of performance in relation to the organ transplantation rate, considering that the number of organs discarded remains high? What should these metrics be?

Process measures and outcomes measures that are patient centered. These measures need to be provided in a manner that can be understood by patients, are relatively stable over time, and remain under the influence of clinical practice of the transplant center. Examples of these measures can include:

- Time from referral to initiation of evaluation
 - Time from initiation of the evaluation to active waitlisting
 - Proportion of patients who complete an evaluation and discussed at selection conference who are waitlisted
 - Proportion of the waitlist that is inactive and thus not receiving offers
 - Staff to patient ratios for the waitlisted candidates
 - Organ offer acceptance ratios (expressed in a manner that is accessible to patients)
 - Probability of transplantation for patients like me
 - The extent to which bypass criteria shrink the available donor pool
 - Proportion of kidney transplants that are from living donor kidneys
- Are there additional quality measures that CMS should consider measuring a transplant program's performance? For a meaningful evaluation of transplant program outcomes from the recipient point of view, please comment on meaningful outcome measures that should be included in the transplant outcomes evaluations.

Patient-centered measures that are focused on patient preferences.

9. In the context of organ shortage and expanded use of marginal, suboptimal quality organs, and transplantation into standard and high-risk recipients, we are seeking public comments from the recipient perspective and expectations on meaningful measures including but not limited to graft survival benefit, shorter waiting list time, frailty improvement and quality of life after transplant, and other transplant benefits.

10. How can CMS meaningfully measure transplant outcomes without dis-incentivizing transplantation of marginal organs or dis-incentivizing performing transplants on higher risk patients?

One potential strategy would be to hold centers accountable for patient death or delisting events for those individuals who have received one or more real organ offers previously. This measure would increase accountability for transplant centers and require centers to consider the consequences of declining an organ offer for a patient. This strategy would encourage the use of a marginal organ when the alternative was that a patient was unlikely to receive another offer within a reasonable timeframe of similar or better quality. This would also eliminate the concern that transplant centers in parts of the country with longer wait times are going to have the challenge of greater waitlist mortality. A measure like this would require considerable effort to refine as it is imperative that a report like this not result in unintended consequences of fewer referred patients being listed for transplant.

Additionally, while there is increasing interest in long term allograft function, the goals for transplantation for a 25-year individual and a 75-year individual cannot be the same. In fact, a successful transplant that functions for many years will eventually end with the demise of a patient (from reasons unrelated to the transplant) with a functioning allograft. As a result, one potential strategy to encourage the listing and transplantation of higher risk patients is to eliminate patient death in the longer term from being seen as a post transplantation failure. For example, a death of a 70-year-old patient 5 years post-transplant from reasons that are not unrelated to the transplant should not count against a transplant center.

3. Transplant Recipient Patient Rights

1. How can transplant programs facilitate greater communication and transparency with patients on their waiting list regarding organ selection while limiting undue delays or undue anxiety to their patients?

1. Robust communications need to occur among patients, referring and treating nephrologists, dialysis facilities and transplant centers. However, as ASN mentioned earlier, it must be done responsibly to avoid overload and anxiety-inducing activities. ASN believes that there is value in providing organ offer decline information to patients with the following considerations:
2. Standardized communication that predefines the information included and the formatting of the communication while ensuring that a patient-centered presentation is used to help patients engage in communications and subsequent shared decision making.
3. Patients may have the option of either opting out of these communications or having these communications sent only to their current nephrologist who can help them participate in shared decision making.

4. Nephrologists should receive aggregated information for their patients (either at the level of the provider or the practice or both) to help them understand transplant center preferences and whether those align with their patients. If possible, the referring nephrologist should also request a patient specific breakdown of this data.
5. Improved decline offer codes have been recently implemented by the OPTN. Whether these codes are being used appropriately and can be used to create informative communications needs to be studied but represents a unique opportunity to improve patient communication.
6. Greater clarification from CMS and HRSA would help transplant centers understand the legal considerations around the decline of an organ offer on behalf of a patient.

The primary reason to make patients aware of when they are receiving offers – even if it is asynchronously – is the ability of notification to provide transparency and accountability into the system. This is of particular concern for the following reasons:

- More than a third of patients who have received an organ offer have either been delisted or subsequently died without a transplant. In addition, these individuals received on a median of 16 offers prior to being delisted or dying suggesting that these are not infrequent or rare events. By definition, these are organs that, if not discarded, are eventually used for a different patient lower down on the match run underscoring the fact that these organ offer declines were for organs that were used successfully.
- A common defense for organ offer declines is that there are many factors associated with organ quality that are not captured in the OPTN dataset and thus replication of clinical judgement is not always feasible. However, the fact that the number of times a deceased donor kidney is declined does not appear to be associated with longer term outcomes reinforces the notion that organ offer declines are not being driven primarily by organ quality. (Kidney360 November 2021, 2 (11) 1807-1818; DOI: <https://doi.org/10.34067/KID.0004052021>)
- Clear evidence of systematic factors unrelated to organ quality appear to interfere with the ability of patients to receive organ offers intended to them. In addition to a dramatic uptick in discards on weekends, organs that are accepted for transplant on the weekend are declined for more patients before they are eventually accepted for a patient. (PMID: 31015260) This finding suggests that patients are being overlooked for an organ offer because of the day of the week.

4. Equity in Organ Transplantation and Organ Donation

- 1. Are there revisions that can be made to the transplant program CoPs or the OPO CfCs to reduce disparities in organ transplantation?**

Equity needs to remain a cornerstone of the organ allocation system and transplant centers should be required to pay attention to the impact of their choice with respect to equity. This includes ensuring that there is careful capture and attention being paid to circumstances where unreasonable criteria disadvantage individuals with certain socioeconomic or racial or ethnic backgrounds. Capture of pretransplant referral and evaluation data is necessary to determine if centers are exacerbating disparities by which referred patients are able to move forward in the evaluation process and which patients are accepted for waitlisting at selection conferences. Social determinants of health within transplantation must also be assessed, for instance, patients from low socioeconomic zip codes appear to have significantly lower waitlisting for reasons that are unclear as well as worse outcomes.

Without a better understanding of these issues, a quality measure that looks at one-year graft failure would inadvertently penalize those centers with more disadvantaged individuals and thus encourage/exacerbate disparities. Like dialysis facilities, transplant programs need an adequately staffed team of social workers, financial coordinators, and other staff to be able to meet the needs of such individuals during the evaluation process and subsequently after being waitlisted.

Understanding the role of social determinants of health requires the capture of this information systematically so that it can be studied. While the OPTN has not been able to do so, they have now linked information to Lexis Nexis for a cohort of candidates but do not appear to have used that information to determine if there are biases in how centers select candidates for waitlisting and transplantation. Prior studies have demonstrated disparities in which candidates are passed over for organ offers suggesting that more scrutiny is needed. (PMID: 28751577) ASN notes that the disparities may also result from variations in referral patterns, education, and awareness on the part of patients of the benefit of transplantation, or by where transplant centers are located given that they are located in non-random parts of the country.

The use of social determinants of health as evaluation criteria for suitability for transplant needs to be studied but the absence of such data is a problem. The inherently slow process used by the current OPTN contractor to change, define, improve data elements in the OPTN registry suggests that this information is unlikely to be available anytime soon without a concerted effort on the part of CMS and HRSA to improve the data registry and the capture of data relevant to issues of equity.

- 2. Further, are there ways that transplant programs or OPOs could or should consider social determinants of health in their policies, such as those relating to requesting consent for donation, patient and living donor selection, or patient and living donor rights?**
- 3. How can those in the transplant ecosystem better educate and connect with these communities about organ donation, so as to address the role that institutional mistrust plays in consenting to organ donation?**

4. How can the CoPs/CfCs ensure that transplant programs, ESRD dialysis facilities, and OPOs distribute appropriate information and educate individuals in underserved communities on organ transplantation and organ donation?

Effective educational strategies need to be identified and studied. An upcoming report from the National Academies of Sciences, Engineering, and Medicine titled A Fairer and More Equitable, Cost-Effective, and Transparent System of Donor Organ Procurement, Allocation, and Distribution will highlight the economic (costs), ethical, policy, regulatory, and operational issues relevant to organ allocation policy decisions involving deceased donor organs and make recommendations to ensure open, transparent, fair, and equitable organ allocation. While the NIH has a long-standing program to fund studies to improve organ donation among minorities, this is a woefully underfunded program giving rise to concerns by some in the kidney community that this program is not a priority. This program at the NIDDK needs engagement from NIMHD and other federal agencies, including HRSA, to be able to develop an evidence-based repository of educational material and strategies to improve organ donation – both living and deceased – along with CFPB-like regulations on making sure that communication efforts from transplant centers and OPOs remain accessible to the public and easy to understand. It is equally important that dialysis facilities engage in similar efforts, particularly helping patients understand the relative benefits of transplantation especially living donor transplantation, and that research be funded to provide evidence on optimal engagement of and education for people with kidney failure.

Transplant candidates on the waitlist need to be provided clear, informative, and literacy-appropriate educational material about the benefit of less-than-ideal organs which would lower wait times for a transplant while providing good outcomes. CMS, HRSA, and the OPTN contractor, need to provide information and tools to help advocate for living donors.

5. What changes can be made to the current requirements to ensure that transplant programs ensure equal access to transplants for individuals with disabilities?

Critically, given the presence of organ failure requiring kidney replacement therapy and the associated comorbid and causal conditions, nearly all people with kidney failure possess a disability. In fact, the law establishing the ESRD benefit in 1972 provides Medicare coverage for any individual who is “*medically determined to have chronic renal disease and who requires hemodialysis or renal transplantation for such disease*” by deeming them “*to be disabled for purposes of coverage under parts A and B of Medicare*.” Notably, there is tremendous heterogeneity in the degree of disability among people with kidney failure. Given this heterogeneity, ASN interprets this question as how to ensure equitable access to transplant for all people with kidney failure, regardless of the extent of disability. This does not mean that everyone will be accepted for transplantation but rather that everyone will be viewed as an individual who may benefit

from transplantation. To promote equity, we believe that the paradigm used by transplant centers should shift from programs now seeking reasons to not transplant a patient to programs pressing forward based on reasons to transplant a patient.

Currently, to evaluate transplant centers, there are very little pretransplant referral, evaluation, or selection criteria data available to patients, referring nephrologists, or other members of the transplant community. This makes the evaluation of the quality of a transplant program essentially impossible. Not knowing how selective a center is makes it impossible to ascertain the real impact that the center is having for its patients. Centers may also be preferentially waitlisting patients with long wait times and low comorbidity burden, avoiding those on anticoagulants or antiplatelet agents and those with limited social support. All of this is behavior that would not be acceptable in other parts of medicine. Similarly, centers that have a disproportionately low rate of transplant on weekends and at other time periods, such as nights and holidays, need to be identified as creating significant disadvantages for their patients.

To ascertain whether centers are providing equitable access to care for all kidney failure patients, patients, referring clinicians and the other members of the transplant community need to know who is being declined at centers and for what reasons. The reasons for declining a patient should be detailed, discrete and nonoverlapping, with sufficient clarity to provide a further understanding of the challenges deemed sufficiently great to prevent transplant candidacy as well as a statement of how and whether these challenges are modifiable. Critically, listing alone is not sufficient, as listing a patient but subsequently declining numerous organ offers because of the patient's level of disability is actually more harmful to the entire community, including the patient. The only way to ensure equity for patients with disabilities is transparency in the process of waitlisting and organ offer acceptance in a manner that is patient accessible and friendly.

Programs should also be encouraged to employ prehabilitation, or the process of enhancing preoperative functional capacity to improve tolerance for the upcoming stressor, to prepare frail patients or those with disabilities for better function after transplant.

6. What changes can be made to the current requirements to address implicit or explicit discrimination, such as decisions made based on faulty assumptions about quality of life and the ability to perform post-operative care?

Transplant centers frequently decline to waitlist patients due to the absence of "adequate social support" using arbitrary thresholds that disproportionately affect individuals from lower socioeconomic groups and racial and ethnic minorities. The extent of this as a challenge to waitlisting and subsequent transplantation is not clear. Also notable is the lower transplantation rates among for-profit dialysis facilities suggesting that dialysis centers are also adversely impacting access to transplantation. The mechanisms by which these phenomena are occurring remains unclear and need more attention. (PMID 31503308).

Exclusion of patients without ‘adequate’ social support not only limits access to transplantation and exacerbates existing disparities, but it also ignores an opportunity to invest resources in supporting patients and expanding transplantation rates. Promoting greater transplantation rates among patients of perceived lower social support would decrease health care costs to the patient, their family, CMS (transplant is cheaper than HD) and society (transplant allows patients to work whereas dialysis does not). It is likely that many of these individuals will do better with a transplant than with continuing maintenance dialysis. CMS and HHS need to support research and innovation to better understand how this dynamic plays out, how impactful it is, and what are the steps along the way to avoid an over emphasis on “adequate social support.” ASN recommends CMS explore developing a transplant center metric focused on measuring access for underrepresented groups, including what additional data are needed to ensure that this is a robust measure.

B-1. Kidney Health and End-Stage Renal Disease Facilities

- 1. How can CMS increase the use of nutritional, lifestyle, and medical management interventions to improve health care and decrease the progression of CKD?**
- 2. What are the barriers to access for routine and preventive health care?**
- 3. How can we better educate patients about behaviors (such as diet and exercise) that may affect CKD progression?**
- 4. How can we increase awareness of known racial, ethnic, gender, sexual orientation, and economic disparities in care for CKD?**
- 5. How can primary care providers (PCPs) better support their patients in prevention and slowing progression of CKD? - What is working? - What is not working? - What can be done to increase screening of at-risk individuals and how can we ensure that PCPs provide timely referrals to nephrologists for individuals with poor or declining kidney function?**
- 6. How can we improve health literacy among the general population, and individuals at higher risk about the prevention of CKD?**
- 7. How can individuals facing complete kidney failure be informed and empowered to make choices about their care?**

The issues raised in these questions are multifactorial and require cross-cutting approaches to truly effectuate change. The good news is that many policies to address these issues currently exist, but CMS needs to focus many of the existing efforts, bolster them where necessary, and link them to other initiatives in healthcare and the

federal government. As ASN has commented before, there is a core set of steps that need to be taken to address kidney failure which include:

- i. Screening to identify at risk patients before they crash into dialysis, as well as screening those at risk at the point of entry to Medicare and annually afterwards.
- ii. Developing “explicit national content guidelines” to help “ensure that all treatment options and decision-points are clear and accessible to patients.”
- iii. Incentivizing the use of Angiotensin Converting Enzyme (ACE) Inhibitors and/or Angiotensin Receptor Blockers (ARB) through inclusion of relevant metric in CMS quality programs such as the Merit-based Incentive Payment System (MIPS): These agents have been established as a mainstay of therapy to slow progression of proteinuric CKD and are widely available as inexpensive generics.
- iv. Supporting the development of kidney health education and community engagement programming within communities hardest hit by racial disparities in kidney health, including recruiting and incentivizing community-based organizations to serve as education hubs and provide patient navigators.
- v. Ramping up Medicare’s Kidney Disease Education (KDE) program
 - a) Waiving the 20% copay for KDE
 - b) Providing access to these services to Medicare beneficiaries with CKD stage 3b and CKD stage 5 (non-dialysis) – currently the benefit is only available to those with CKD stage 4;
 - c) Including dietary consultations at all stages of CKD; and
 - d) Allowing dialysis facilities to provide kidney disease education services.
- vi. Providing important coverage support for patients approaching kidney failure or have already reached that stage.
 - a) Waiving the three-month waiting period for Medicare eligibility for people with kidney failure who elect to undergo in-center hemodialysis. Currently Medicare coverage only begins in the first month for patients who elect to undergo training for home dialysis. Patients undergoing in-center hemodialysis without other insurance experience delays in obtaining lifesaving arteriovenous fistulas or grafts before obtaining Medicare coverage, increasing cost and risk of death. Given that there are numerous social determinants of health such as unsustainable housing that prevent equitable access to home dialysis, this policy only further exacerbates disparities for individuals whose default option is in-center hemodialysis
 - b) Waiving the 20% copay for KDE
 - c) Ensuring each US state offers a Medigap plan. Dialysis patients in the 22 states without the option to buy a supplemental Medigap plan face steep co-pays, and often must spend down assets to become Medicaid-eligible, a nonsensical and financially devastating choice, further widening gaps in equitable care for vulnerable patients in these states.
- vii. Addressing costs of medications demonstrated to slow the progression of CKD, such as SGLT2 inhibitors, GLP1 agonists, and finerenone.

- viii. Funding care coordination for advanced CKD patients focused on slowing progression of CKD, reducing unnecessary inpatient utilization, and ensuring optimal dialysis starts where appropriate.
- ix. Urging CMS to maintain telehealth services reimbursement beyond the public health emergency and expand them to cover educational outreach efforts recommended in this letter while funding research on how equitable telehealth services are or are not to the general public and monitoring historically underserved communities for gaps in access to telehealth and tele-education.
- x. Adjusting the reimbursement for the KDE benefit that has remained unchanged for 30 years.

Screening

Systemic barriers to accessing basic health care can play a significant role in individuals developing kidney diseases and progressing to kidney failure. The leading causes of kidney diseases and kidney failure include hypertension, diabetes, and obesity. Black and Latinx individuals have the highest risk of being diagnosed with these conditions compared with other Americans. Black Americans also experience a three-fold higher incidence of kidney failure than White Americans. Accessibility to screening and preventive care must be improved in these at-risk groups. As indicated earlier, kidney diseases are an epidemic in America. However, in 2012, the US Preventive Services Task Force (USPSTF) rescinded its CKD screening recommendation, leaving primary care providers with no guidance on screening high-risk individuals.

Since then, novel treatments for kidney diseases have been discovered, including drugs like SGLT2 inhibitors and GLP-1 receptor agonists novel therapies for autoimmune and genetic kidney diseases, in addition to the generation of evidence quantifying the benefits of medical nutrition therapy for kidney diseases. These therapeutic options can slow the development and progression of CKD, thus highlighting the potential benefit of screening in asymptomatic, high-risk patients, such as those with diabetes and/or hypertension. As the nation reinvigorates the conversation about health disparities, ASN believes that screening for kidney diseases has never been more important.

ASN urges the Biden-Harris Administration to engage USPSTF to re-instate updated CKD screening guidelines and ensure the inclusion of appropriate screening for kidney diseases for patients with risk factors upon Medicare and Medicaid enrollment.

Educating

In a recent study published in the American Journal of Kidney Diseases, researchers reviewed education programs for people with kidney diseases. The researchers established the importance of such educational programs and the need to address gaps that can limit patients' ability to understand kidney failure treatment options and participate in shared decision-making (SDM). The study noted that:

Although education for patients with kidney failure is a critical component of patient-centered care and shared decision making (SDM), kidney failure treatment options were not presented neutrally and there was limited discussion of prognosis or conservative

management in this study of education programs. While quality of life and dialysis access was discussed in detail and educators were knowledgeable and experienced, key content gaps included mental health and cognition, advanced care planning (ACP), cost, and diet. Referral practices varied and did not seem to lead to timely or consistent attendance.

Educators reported experiencing patients' surprise upon learning the complexity and severity of their conditions, suggesting that even some patients with advanced CKD are not well informed. Explicit national content guidelines could help ensure that all treatment options and decision-points are clear and accessible to patients. Greater involvement by nephrologists to engage patients in SDM both before and after education sessions, track referrals and attendance, and oversee systematic process for reviewing and updating educational materials would also help ensure accuracy and improve SDM opportunities for patients with advanced CKD.

ASN urges the Biden-Harris Administration to shepherd “explicit national content guidelines” to help “ensure that all treatment options and decision-points are clear and accessible to patients.” The administration should also fund robust kidney health awareness efforts in the multiple platforms maintained and funded by HHS.

ASN also urges the administration to support the development of kidney health education and community engagement programing within communities hardest hit by racial disparities in kidney health, including recruiting and incentivizing community-based organizations to provide patient navigators. A localized, more representative and culturally competent health care workforce will help increase access to care for disadvantaged populations, advancing the goal of eliminating racial and ethnic health disparities.

Developing programs or incentives that foster a community-based approach to kidney health education and care access can help ensure that populations at-risk for kidney diseases who have not been historically well-served by the traditional healthcare system with respect to kidney health have access to education, resources, and care at the local level.

Kidney Disease Education Benefit

Medicare’s Kidney Disease Education (KDE) program is vastly underutilized and offers six educational sessions for Medicare beneficiaries. Medicare does not offer education benefits specific to earlier stages of kidney diseases to help patients manage and slow the progression of their disease.

The KDE benefit represents one approach to help patients facing kidney failure consider treatment options, but it is only available to patients with Stage 4 kidney disease. The program should be expanded to include persons with a GFR <45 ml/min (Stage 3b) to allow patients to access it for an expanded duration during their progression of CKD and to allow more providers to be able to offer their services. It is likely that earlier access to education and intervention would result in more effective delay in the progression

towards kidney failure. The Biden-Harris Administration should support key steps to expanding the program's reach:

1. Providing access to these services to Medicare beneficiaries with CKD stage 3b and CKD stage 5 (non-dialysis) – currently the benefit is only available CKD stage 4;
2. Including dietary consultations at all Stages of CKD; and
3. Allowing dialysis facilities to provide kidney disease education services.

The physician payment for home training is \$500 (which has been the rate for more than 30 years!). CMS should adjust that rate to current dollars which would be \$1750 today. The initial \$500 could be paid at the outset, while the additional \$1250 could be paid out after a patient has completed six months of successful home dialysis treatments.

Ultimately, the decision regarding modality choice should be the result of a shared decision-making process between the patient and the nephrologist. Improving and expanding the KDE program should be key to that process.

Other steps ASN encourages the administration to undertake for patients approaching kidney failure or have already reached that stage are:

1. Waiving the three-month waiting period for Medicare eligibility for people with kidney failure. Patients without other insurance experience delays in obtaining lifesaving arteriovenous fistulas or grafts before obtaining Medicare coverage, increasing cost and risk of death.
2. Waiving the 20% copay for KDE
3. Ensuring each US state offers a Medigap plan. Dialysis patients in the 22 states without the option to buy a supplemental Medigap plan face steep co-pays, and often must spend down assets to become Medicaid-eligible, a nonsensical and financially devastating choice.

ASN urges CMS to address costs of medications demonstrated to slow the progression of CKD, such as SGLT2 inhibitors, GLP1-receptor agonists, and finerenone. Fund care coordination for advanced CKD patients focused on slowing progression of CKD, reducing unnecessary inpatient utilization, and ensuring optimal starts.

ASN also urges CMS to maintain telehealth services reimbursement beyond the public health emergency and expand them to cover educational outreach efforts recommended in this letter. CMS should also fund research on how equitable telehealth services are or are not to the general public and monitor historically underserved communities for gaps in access to telehealth and tele-education.

As CMS engages other branches of the federal government, it should call for greater dialogue regarding low health literacy and cultural and attitudinal beliefs impact access to care. Ideally, that dialogue will include public health outreach throughout the K-12

education continuum and take into account culturally appropriate care, the legacy of discrimination within health care, social determinants of health, and the need for patient empowerment. CMS should also examine the value of including peer-mentoring. Several patient groups offer excellent advice on how to navigate the health system. Many times, patients know better than doctors – examples include when to be evaluated for a kidney transplant or learn more about home dialysis.

Also, CMS, NQF, and the primary care community should examine the creation of primary care quality metrics based on kidney screening and referrals to a nephrologist with appropriate guidance.

(Patient Perspective)

- 1. To improve long-term outcomes and quality of life, how can we support and promote transplantation prior to the need for dialysis (preemptive transplantation)?**
- 2. For people beginning dialysis, how can CMS support a safe transition?**
- 3. Are there concerns regarding the location or quality of care of the transitional care units?**
- 4. How can these care transitions be equitably provided?**

In the United States, 30 percent of all individuals diagnosed with kidney failure have never seen a nephrologist before their diagnosis. Until there is a commitment to screening and identifying individuals with kidney disease, there will be little progress on many of these fronts and, where there is progress, it is highly unlikely to be equitably accessible for all. Currently, pre-emptive listing for kidney transplantation has significant racial, ethnic and socioeconomic disparities that are likely related to many factors including the untimely referral of patients to nephrology care or even limited access to regular primary care. As stated above, the public health efforts aimed at the general public need to be far more forceful and comprehensive – especially in historically underserved communities.

In transitioning to dialysis, nephrologists recognize opportunities to improve care for patients during this vulnerable time, when hospitalization rates and mortality is high. CMS should partner with dialysis providers to develop a pilot project to enhance resources to patients, either via education prior to starting dialysis or via increased resources to avoid dialysis initiation in the hospital. This pilot should emphasize the needs for permanent dialysis access, the availability of options for dialysis modality, and the benefit of avoiding hospitalization during this challenging time.

As for transitional care units (TCUs), while generally supportive, ASN has some concerns that only some dialysis providers have the resources to establish TCUs and the growth of these units may contribute further to the rise of a smaller number of

companies with a greater market share of dialysis patients further restricting patient choice.

2. Home Dialysis (Patient Perspective)

1. What are patient barriers to dialysis modality choice?

There are multiple barriers to dialysis modality choice beginning with the high rate of “crashing into dialysis” and, therefore, being unprepared to make a dialysis modality choice which leads to in-center HD becoming the default choice. To name a few:

- Lack of widespread availability of home dialysis
- Restricted availability of training
- Lack of staff assistance
- Housing conditions and lack of care partner assistance
- Low confidence of some nephrologists to recommend home dialysis
- Lack of appropriate resources to maintain a home program
- Lower reimbursement rates
- Underutilization of the KDE benefit
- Patient insecurity of doing dialysis at home with or without a partner

On the downstream side is the lack of quality peritoneal dialysis in rehabilitation and acute care hospital settings. This results in modality change when people are temporarily (or permanently) unable to live independently. There is a de facto rule that if you cannot be discharged to home, you cannot do peritoneal dialysis. This needs to be addressed, preferably by creating centers of excellence such that acute, subacute, and chronic care facilities have reasons to invest in peritoneal dialysis proficiency. It is also important to remember that some in-center dialysis patients opt for this treatment modality because it gives them a place to go, meet others, or just get out of the home.

- **How can we overcome barriers to ensure patients understand their options and have the freedom to choose their treatment modality?**

ASN is developing initiatives to increase access to training in home dialysis during fellowship and to increase continuing educational opportunities for practicing clinicians. The KDE benefit recommendations above apply here as well including waiving the 20 percent copay. With such low rates of the use of the benefit, CMS must move swiftly to bolster its use as a front-line effort to increase home dialysis rates.

There are also financial policies that could help increase modality selection:

- Reimburse patients and caregivers for all home dialysis costs, including utilities and caregiver time. Include support for assisted PD at home.
- Support facilities in efforts to hire staff, who ultimately assist in educating and supporting patients.

- Provide home assistance for periods of transition or respite care. Staff assist could begin with full support that is weaned off as the patient becomes more independent with experience. Staff support could also be used temporarily when patients need back-up support such as when in a SNF or transitioning home after a hospitalization. Identify pathways for such support to be seamlessly included in discharge care planning.
- Waive the 20 percent copay for the KDE benefit.

CMS should consider a plan similar to Canadian and Australia/New Zealand programs where the government reimburses the patient for expected startup costs (plumbing/electrical work) and provides regular stipends or discounts for ongoing utilities, which may include plumbing, electrical, and waste disposal costs. In addition, while some states have paid family leave programs which may help, home dialysis training time needed may be prohibitive for patients who have work/childcare/elder-care or other responsibilities. While FMLA protects the job and there are patchwork programs that exist to help replace lost income, a more comprehensive family leave plan could remove barriers to training for home dialysis.

2. What are reasons for differing rates of home dialysis by race/ethnicity? How can we address any barriers in access to home dialysis to improve equity in access to home dialysis?

Data make clear that, in the United States, people of color have less access to home dialysis therapy. Nationally, Black patients are 30.1% less likely, and Hispanic patients are 7.6% less likely than white patients to start peritoneal dialysis (PD). Similarly, for home hemodialysis (HHD), Hispanic patients are on average 42.1% less likely, and Black patients are 9.8% less likely, to receive HHD.

A relative lack of health insurance partially causes this lack of access compared to White patients. 2018 data shows that Black patients are 1.5 times more likely to be uninsured than White patients, while the uninsured rate for Hispanic individuals was almost 2.5 times higher than the rate of White individuals. More broadly, a report by the Agency for Healthcare Research and Quality found that Black and Hispanic persons had worse access to care when compared with White persons and are less likely to be referred to nephrology care in a timely manner limiting the time for education about treatment modalities. Unsurprisingly, a recent survey of patients with ESRD showed that a more significant proportion of Black patients (57%) than White patients (44%) had an emergent or "crash" dialysis start.

As mentioned above, there are multiple financial policy steps that could be undertaken to address preparing individuals to go home and supporting them with these costs. CMS should convene an intergovernmental dialogue to develop proposals to address housing, transportation, and other issues to ensure equitable access to home dialysis. At the same time, CMS should provide additional new dollars to nephrologists and dialysis facilities reporting Z codes to quantify the impact of environmental and housing issues and using the increased data to support evidence-based solutions.

3. With regard to home dialysis, how can CMS ensure adequate safety standards such as appropriate infection control behaviors and techniques are enforced?

Infection control success at home is largely a matter of appropriate education of patients and their care partners on prevention techniques. Initiatives like the CDC Making Dialysis Safer coalition has developed many useful resources for hemodialysis catheter infection prevention measures such as core interventions for reducing catheter related bloodstream infections, but little has been developed to date on peritoneal dialysis (PD) infection prevention protocols. In addition, measures in the Quality Incentive Program (QIP) also only measure infection reporting and events in hemodialysis patients. CMS should consider similar measures for PD.

In addition, performance standards for PD catheter placement should be ensured.

4. What can CMS do to increase availability and use of home support resources with regard to home dialysis as described in 42 CFR 494.100(a)((3)(iv))? Given the increase in home dialysis patients, is there a need to revise the current standards § 494.100, including but not limited to updating and revising training and care delivery requirements?

Bold action from the agency is required to increase the availability and use of home dialysis. Ambiguity in the available guidance leads to policies that adopt the most stringent interpretation to avoid risk resulting in practices that inadvertently rob patients of the largest benefits of self-care at home - patient autonomy and increased independence. ASN's specific recommendations are provided below.

Revise applicable regulations to allow for specific facilities that may only provide Home Dialysis therapies in order to provide clarity for facilities, providers, and regulatory agencies. In these facilities, some in-center regulations may not be relevant. CMS should work with dialysis providers to specify what regulations would be unnecessary for dialysis facilities that are certified to care only for home dialysis patients. Such changes may increase the number of patients that are able to receive high-value care in the comfort and convenience of their home.

Creating this differentiation would allow greater flexibility for the agency to regulate dialysis care by setting, crafting requirements that match the site of care more appropriately and foster innovation. Enabling this differentiation in the regulatory framework will ultimately encourage greater development of these sites of care offerings because requirements for home programs can be tailored as appropriate to ensure patient safety.

Surveyors and facilities need regulations and guidance specific to home dialysis that allows providers the flexibility needed to support, improve, and innovate care in the wide variety of home environments that exist. Current regulations apply in-center regulations

to home through exceptions set forth in various guidance documents creating confusion among potential new home providers and surveyors, resulting in discouragement to providers and delays in certification.

Ambiguity in the guidance leads to policies that adopt the most stringent interpretation to avoid risk resulting in practices that inadvertently rob patients of the largest benefits of self-care at home - patient autonomy and increased independence.

In addition, CMS should reduce the administrative burden associated with medical justification requirements for increased frequency of treatments, more than 3-4 per week, and for any change in modality to allow for respite care and maximal flexibility.

With these changes, safety concerns may arise. CMS should consider convening a workgroup with patient, nephrologist, and dialysis provider stakeholders to avoid unintended consequences around provision of safe and effective care before CMS implements changes.

These guidance changes will create clarity for home dialysis and support facilities, giving stakeholders the confidence to invest in these types of care settings and giving providers the confidence to deploy these new options for their patients.

5. If more patients choose home dialysis, would there be systems and infrastructure in place to support this? Were more patients to choose home dialysis, what other supports, systems or infrastructure might be necessary?

Yes, if more patients choose home dialysis, stakeholders can rapidly deploy the systems and infrastructure to support this choice, provided that the regulatory and sub regulatory landscape keeps pace with innovation. There are steps CMS should take to further ensure that systems and the workforce are prepared to meet expanded demand. Undoubtedly, well trained nurses and nephrologists are critical to initiate and maintain patients on home modalities.

When nephrologists are surveyed, 94 percent would prefer either PD or HHD for themselves. Nephrology nurses show similar preferences. This discordance between nephrologists' personal preferences for home therapies and the in-center hemodialysis modality most commonly used by patients can, in part, be explained by the training experience. In one study, 87 percent of nephrology fellowship program directors reported training in PD to be inadequate in our country and a major factor limiting PD utilization. A 2016 ASN survey found HHD and PD to be the top two topics in which graduating fellows most desired additional instruction. These results point to a window of opportunity to increase utilization of home therapies.

Leverage the skills of members of the multidisciplinary care team for home dialysis training. Current regulations require that home dialysis patient training be conducted by a Registered Nurse (RN) who meets the applicable regulatory requirements. We

appreciate and share the agency's commitment to ensuring that patients dialyzing at home are properly trained by qualified professionals. We think this goal can be achieved with having RN supervision over training rather than requiring that the RN conduct all aspects of the training.

Specifically, to expand capacity for home training and support, CMS should remove the words "be conducted" by an RN from the home training CfCs and, instead, insert language requiring that the training "have oversight and participation" by an onsite, home therapies RN. Additionally, CMS should clarify that the RN does not need to be physically present for all aspects of the training, provided that the patient is in the line of site of a home therapies RN if they are actively treating the patient during the training sessions. In both cases, the home RN and nephrologist should be responsible for signing off that the trained patients are competent in self-dialysis and able to dialyze at home. The home RN should provide the patient training related to medication preparation and administration and responding to medical complications.

This approach will ensure safety and quality for patients and support RNs involved in ESRD treatment and training – helping to combat some of the burnout these professionals face. This minor clarification will help to reinforce that sentiment while promoting CMS' goal of improving both the patient and practitioner experience.

Empower independence for dialysis patients. Self-dialysis in-center can be a meaningful pathway to independence for patients who seek to eventually dialyze at home but are not yet ready to do so. It can also provide an alternative for patients who have trained for self-dialysis, but ultimately decide not to dialyze at home. In some countries self-dialysis models have developed that allow for patients to conduct their own hemodialysis treatments in a common house on their own schedule. Today, rigid definitions and interpretations of requirements are serving as barriers to self-dialysis in the U.S. We recommend that CMS modernize the requirements related to patients engaged in in-center self-care.

Specifically, CMS should add to the definition of "self-dialysis" to empower patients to be engaged in activities related to their dialysis care such that they can become more independent over time. ASN proposes to update the definition of "self-dialysis" by adding the specific functions a person who performs self-dialysis should be able to complete. The new language is shown below in italics.

42 CFR § 494.100 Definitions

Self-dialysis means dialysis performed with little or no professional assistance by an ESRD patient or caregiver who has completed an appropriate course of training as specified in § 494.100(a) of this part. At a minimum, a person who performs self-dialysis should:

- i. Have the machine set up for favorable orientation toward the patient;*
- ii. Be able to set up the equipment required for treatment;*

- iii. Be allowed to touch the machine during treatment and respond to alarms;*
- iv. Be able to manage the access site pre- and post-treatment, with or without self-cannulation; and*
- v. Be able to take and record their own weight and vital signs, as relevant.*

Once the patient can perform self-dialysis pursuant to this new definition, CMS should clarify that self-dialysis patients do not need to be “in the view of staff” during treatment. CMS standards do not distinguish between trained in-center self-care patients and patients that are largely dependent on the clinical staff to deliver their treatment and currently require ESRD patients who are conducting in-center, self-care to be in the line of sight of an RN, even when the patient is fully trained in self-dialysis. This creates an unnecessary burden for patients, who must schedule times for availability when they can be within the line of sight of an RN. This dynamic can make it difficult for patients to manage care on top of other important, competing demands, including professional and personal responsibilities.

Modify the requirements for home training RNs. Today, CMS requires that the nurse responsible for overseeing self-care and/or home care training must be an RN and have at least 12 months experience providing nursing care and an additional three months of experience in the specific modality for which the nurse will provide self-care training. Given the strains on the nursing workforce and the increased demand for home dialysis and self-care, we recommend that CMS consider replacing the time based requirement with a competency based requirement such as completion of a home RN training program deemed appropriate by the Medical Director of the facility as is required for patient care technician competency or allow for modality experience to be developed concurrently with the 12 months of nursing experience, i.e., the 12 months of nursing experience inclusive of the three months of modality experience.

Modify one-on-one training requirements. Some of the training on the machine and basics of dialysis can be done in a classroom style learning setting with up to six home candidates. Most training is done while the patient is dialyzing, which can be burdensome. Then, training for actual dialysis should be done in the home so that the patient is trained in the setting where they will be dialyzing. This change would increase capacity, decrease RN and patient fatigue experienced during current training sessions.

Create incentives for alternative programs. Alternative programs should receive financial incentives beyond the training bonus for adequate support. Additional staffing time, education, equipment, and space required for self-dialysis, TCU, home programs should not be a financial disincentive for the dialysis clinic. Similarly, nephrologists need incentives beyond those offered in the past.

Increase patient protections. In anticipation of more patients choosing home dialysis, CMS should ensure that certain supports, systems, and standards are in place to promote patients’ autonomy and increase care and financial protections. Specifically, CMS should work to ensure that:

- Patients receiving dialysis at home have the right to discuss their treatment with the multidisciplinary care team in person or via teleconference according to their preference;
- Patients should not be charged a fee for accessing a copy of their medical record;
- Patients receiving dialysis at home should have the ability to choose whether to participate in initial and annual care planning via teleconference (via audio or audio and video communication) with the multidisciplinary care team at home or face-to-face in the clinic. If the patient chooses and if permitted according to the FDA's labeling of the medications, self-administration of medications at home should be permitted (including by a care partner); and
- Clinic policies should not prohibit home patients from dialyzing on specific days of the week (e.g., Sundays) and clinics should be prohibited from unduly restricting hours.

These measures will help to support and empower patients who choose home dialysis, as well as convey the benefits and feasibility of home care.

6. To what degree does telehealth and remote monitoring technology impact decisions of home dialysis use? - Would allowing physicians to leverage evolving telehealth and remote monitoring technology for their patients increase the selection of and uptake of home dialysis as a modality?

It is unclear exactly to what degree the use of telehealth and remote patient monitoring impact uses of home dialysis uses; however, it would be valuable for CMS to support research into this question. Increased use of digital tools and online applications often empower patients to take a more active role in their healthcare decisions alongside their care providers. RPM tools enable providers to track the progress of disease and empower dialysis patients with the option to have their physiologic and therapeutic information monitored remotely, reducing the need for in-person visits.

Some nephrologists have expressed their opinion that having remote monitoring technology (real-time or just store-and-forward) is helpful in getting patients home since most patients understand the theoretical benefits of home treatments but are nervous about being alone at home. The nephrologist's or nurse's ability to remotely monitor treatments, provide either real-time or next-day feedback, and provide around the clock support has helped convince patients that even though they are physically alone at home, they have a safety net of "virtual" partners as well. In addition, patients are greatly in favor of telehealth visits as it decreases the need to take time off work and travel to the dialysis facility, which are real burdens.

ASN has long supported the designation of a patient's home and dialysis facility as originating sites for home dialysis services, without geographic restrictions and were pleased to see Congress grant this request in the 2018 Balanced Budget Act, which included the CHRONIC Care Act and its provisions to waive these requirements for home dialysis patients. ASN urges CMS to consider the following:

- CKD patients need regular care to properly manage their disease, including education on their modality options if and when they enter kidney failure. Allowing some of this care to be remotely delivered can ameliorate some of the challenges patients face in accessing this care.
- Kidney transplant patients require extensive evaluation and education before and after their transplant surgery and continued monitoring post-surgery to evaluate organ function, medication adherence, and other vital transplant outcomes. Accessing this care requires regular visits with medical staff at kidney transplant centers, which are often urban institutions requiring patients to travel a long way to seek care. Many of these visits can be conducted by telehealth, saving patients time and expense.
- Clinicians who may be called upon to serve in an acute care setting can use telehealth or RPM capabilities to provide dialysis care to patients in a dialysis center or at home.

ASN supports the continued use of telehealth and remote patient monitoring post-PHE with consultation of the broader kidney community.

3. Dialysis in Alternative Settings

a. Nursing Homes

Home dialysis patients may require short- or long-term care in nursing homes and other subacute facilities. For those patients treated with peritoneal dialysis, there are limited facilities that will care for peritoneal dialysis patients and even fewer that do it well. This ultimately may require transition to hemodialysis, placement in facilities that are geographically distant from family and other patient support, limited choice in facilities, and poor outcomes. We encourage CMS to streamline the process for peritoneal dialysis in nursing homes in similar facilities and pay more for PD Centers of Excellence in rehabilitation and other care facilities. In many ways, this could be a net cost neutral intervention as the cost of transportation from facilities to hemodialysis units is not trivial and would not be a consideration with continued PD

1. Should dialysis facilities have geographical limitations for distance between the certified dialysis facility and nursing homes where they provide home dialysis services?

The relationship between the patient and their maintenance dialysis care team is extremely important and valuable. ASN envisions that a nursing home could become ‘home dialysis centers of excellence,’ particularly in PD. This realization could be supported by additional reimbursement and could reduce the need for “just in time visits” for every patient each time they are admitted to a home. Health equity could be partially addressed by making sure that these centers of excellence are geographically distributed and could create access issues where there are no dialysis facilities near the nursing home, since many rural communities do not have dialysis centers.

There also appears no outward justification to limit the number of agreements that a given dialysis facility can have to provide home dialysis services in nursing homes, since larger, centralized home dialysis programs typically perform better.

2. Should CMS enhance protections for dialysis in institutional settings in the CfCs, such as including a written agreement to outline the roles and responsibilities of the dialysis facility and nursing home when home dialysis services are provided to residents, have protections for residents incapable of self-care, including clarifying staff roles, responsibilities, safety, and supervision when the home dialysis services are not administered by the dialysis facility staff?

ASN believes this step would help nursing homes and dialysis providers have some clarity around how to set up and manage a program. A lack of protections could leave nursing home administrators trying to interpret guidance without the historical experience and perspective that is needed to ensure patient safety.

b. Alternative Types of Dialysis Treatment Facilities including Mobile Dialysis

1. Should the use of mobile dialysis be limited to emergency circumstances and enrollment as a Special Purpose Renal Dialysis Facility?
2. How can mobile dialysis be used? Should these units be independently certified or used as an extension to an existing facility if approved outside of emergency circumstances?
3. What are the oversight considerations of these mobile dialysis units if units do not have a brick-and-mortar location and are moving among various locations?
 - If used outside of an emergency circumstance, should there be geographical limitations?
7. Should mobile units have separate/different physical environment requirements compared to a brick-and-mortar building?
8. What health and safety standards are necessary to ensure a safe physical environment in mobile units?
9. What are the concerns related to equipment handling and maintenance related to mobile units that are different from brick-and-mortar facilities?
10. How can CMS ensure appropriate staffing roles, responsibilities and oversight of patient's dialysis care and needs by interdisciplinary team members for mobile units?
 - Would these units require different staffing mix or requirements than a stationary dialysis unit?

- 11. What other alternative types of dialysis treatment facilities should we consider?**
- 12. What should be the appropriate use of alternative types of facilities, such as only for emergency situations?**
- 13. How should CMS certify these alternative types of facilities?**
- 14. Are these facilities able to meet current patient safety and equipment standards?**
- 15. Given the importance of water quality for dialysis, how do we ensure safe water standards with facilities that do not have water treatment centers?**
- 16. Do patients in Medicare Advantage plans have a choice whether or not to dialyze at one of these alternative facilities?**
- 17. What kind of emergency plans would be appropriate for mobile units or other alternative settings?**

This set of questions is very thorough and critical to making decisions about mobile units. ASN believes the questions of relevance to brick-and-mortar dialysis centers apply to mobile units as well such as water supply, infection prevention and control, staffing ratios, facility safety, etc. ASN recommends CMS first explore these questions through the lens of emergency dialysis services and/or service to areas of limited access to dialysis centers. It seems to make sense for there to be CfCs generalized for all dialysis services with differentiated requirements for home dialysis, TCUs, mobile units, and alternate models of care, however, without making every class of dialysis units subject to identical requirements.

c. Alternate Models of Care

- 1. Should there be two sets of guidelines for staff-assisted home dialysis in residential homes and staff-assisted home dialysis in alternative settings; and if so, how should they differ?**
- 2. What factors should be taken into consideration for establishing different guidelines?**

By the unique nature of alternative settings, there will need to be some adjustment for staff-assisted home dialysis in alternative settings distinct from staff-assisted home dialysis in residential homes. However, the guidance could be covered by one set of home dialysis CfCs with different subsections. In the case of alternative settings, there

needs to be clear lines of responsibility in the delivery of staff-assisted dialysis services and direction on what qualifications/training are required to provide those services.

Innovation and the Artificial Kidney

Two questions from the background section of the RFI would benefit from the society's perspectives on the role of artificial kidneys in the future of kidney care. First, the agency asked for information on how to "Increase the number of organs available for transplant for all solid organ types". ASN sees three strategies related to artificial kidneys that CMS could pursue to meet that need.

Elevate the development of artificial kidneys as alternatives to dialysis to a national priority.

A renewed commitment from the federal government to increase the number of available organs by promoting the development of artificial kidneys is necessary to catalyze the development of alternatives to dialysis for people with kidney diseases. This messaging is necessary because of the federal government's significant role as the single payor for kidney replacement therapy and the largest funder of kidney research. Positioning the federal government in support of transformative innovation will incentivize new innovators to develop solutions, provide reassurance to investors to enter the kidney space, and offer hope to people with kidney failure that those who pay for their therapies want them to have better treatment options. This would not be a new commitment from the federal government, but an echo to Executive Order 13879 which states that "It is the policy of the United States to: increase patient choice through affordable alternative treatments for ESRD by... encouraging the development of artificial kidneys." As the most significant stakeholder in the kidney space, signaling the federal governments dissatisfaction with the status quo by prioritizing artificial kidneys would have a significant catalyzing impact on the amount of organs available for people with kidney failure.

Support KidneyX, a public-private partnership between ASN and the US Department of Health and Human Services, in its role identifying and promoting innovators developing new treatment options for people with kidney diseases through prize competitions.

KidneyX is a one-of-a-kind player in the kidney community with bipartisan support in Congress and from successive administrations. For KidneyX to meet its full potential and continue to foster the development of technologies such as a wearable or implantable artificial kidneys and xenotransplantation, the federal government must increase its support for KidneyX by including \$25 million for KidneyX in the FY 2023 President's Budget. Congress has demonstrated its commitment to KidneyX by appropriating \$10 million for the program since FY 2020, with an additional \$5 million proposed in House and Senate FY 2022 appropriations bills, meeting the Biden Administration's FY 22 budget request. To date, KidneyX has provided more than 60 awards to innovators across 5 prize competitions for solutions ranging from patient-developed solutions to improve quality of life such as dialysis accessible clothing, to cutting-edge innovations such as the artificial kidney and xenotransplantation which hold promise to provide better quality of life and improve access to care. Further,

KidneyX is delivering on its pledge to catalyze private markets to invest in the advancement of kidney care.

Recognize that innovation is imminent for people with kidney failure but still in an early enough stage to be shaped by public policy.

While artificial kidneys have been under development for decades, treatment options are maturing more quickly today. The Kidney Health Initiative (KHI) a public-private partnership between ASN and the US Food and Drug Administration (FDA) developed definitions for artificial kidney solution concepts. Artificial kidneys can generally be categorized as enhanced dialysis, portable dialysis, wearable, and implantable concepts. Options for home dialysis (portable dialysis) are growing, with two new entrants (Quanta and Outset) entering the US market in the past year. KidneyX has highlighted several wearable artificial kidney concepts in preclinical development, two of which have completed proof of concept clinical trials. Biomechanical implantable solutions are also advancing with one developer successfully completing component testing in animal models. Xenotransplants have recently been in the news with three first of their kind human studies conducted to date.

These and other artificial kidney solutions to the organ shortage are advancing through the pipeline to address the organ shortage. The federal government has an opportunity to get ahead of innovation and prepare the regulatory and reimbursement landscape for new treatment options.

The next question from the background section of the RFI relevant to the artificial kidney asks how to: "Ensure that the Centers for Medicare & Medicaid Services (CMS) and the Department of Health and Human Services (HHS) policies appropriately incentivize the creation and use of future new treatments and technologies". There are three strategies CMS could pursue to address this issue.

Establish a reimbursement pathway for artificial kidney concepts.

A significant disincentive to new entrants into the kidney space is how kidney care is paid for. In the context of artificial kidneys, innovators do not have clarity on how their innovation will be reimbursed. The federal government is "all-in" on dialysis, but that commitment has not been extended to other alternatives to dialysis such as artificial kidneys. This lack of clarity makes it risky for investors to support artificial kidney concepts, which has a stifling impact on innovation. This would also not be a new strategy for the federal government. Coordinating payment policies to support artificial kidneys was a commitment made in the Advancing American Kidney Health initiative. Addressing reimbursement for innovative treatment options like artificial kidneys in advance of commercialization of those products is critical from an equity and access perspective. Without the "all-in" coverage the federal government employs for dialysis, artificial kidneys will not be available to those who need them most. CMS can provide monetary incentives at every level of the product life cycle to ensure that novel technologies break through a concentrated and stagnant field. For example, financial

incentives could be provided to providers to incentivize prescribing artificial kidney solutions rather than conventional in-center dialysis.

Coordinate with the FDA to create guidance documents for alternatives to dialysis such as artificial kidneys that will assist with adoption and product development.

Specific guidance developed by regulators and payers would significantly reduce risks, costs, and uncertainties surrounding for product developers. For example, guidance on verification and validation studies and clinical trials that regulators and payors are looking for would assist innovators in planning their product development. Additionally, innovators would benefit from clarity from regulators and payors on what safety and efficacy data are necessary for the FDA and what data CMS would like to see to demonstrate value for Medicare patients. The public process of creating guidance documents would benefit the kidney community at large by identifying and addressing regulatory and payment barriers, pre-competitive issues, and ensuring the inclusion of the patient perspective. The impartial and scientific review of artificial kidney solution pathways that would be included in the guidance development process would benefit decision makers across government. FDA guidance has been provided the artificial pancreas community. The four FDA guidance documents related to home hemodialysis helped spur innovation in that field, supporting more than a dozen companies developing home dialysis therapies today. FDA guidance documents would incentivize the creation and use of novel technologies like the artificial kidney.

Anticipate and incentivize the total product system needed to support future innovations such as artificial kidneys.

As the most significant payer in the kidney space with an “all-in” commitment to care for kidney failure, CMS has significant power to shape the market for kidney care in the long term. Artificial kidneys, whether implantable bioartificial kidneys or portable dialysis, will be developed by new players and may require different care delivery. This can be demonstrated by examining the total product system. For example, if a person with kidney failure in a rural setting is prescribed a wearable artificial kidney solution: 1) who will maintain this device? 2) where will the patient go if maintenance is required? 3) how is health data monitored and by whom? 4) who is providing the supplies to maintain the device? 5) how are these services being paid for and by whom? Artificial kidney solutions are radically different from conventional in-center dialysis and will require different health infrastructure and healthcare professionals to support. After examining the landscape, CMS has an opportunity to consider the ecosystem needed to support innovations when they are approved and reimbursed, so that new innovations do not fail because of an inhospitable environment.

C. Organ Procurement Organizations (OPOs)

ASN re-affirms its support for the Organ Procurement Organizations (OPOs) Conditions for Coverage Final Rule issued on November 20, 2020. On February 2, 2021, ASN requested the Biden-Harris administration to implement this final policy as expediently as possible to bring objective and verifiable standards to assess the performance of

OPOs, increase the number of organs available for transplant, and dismantle the racial inequity in the U.S. transplant system. This was implemented on March 30, 2021.

ASN thanks the administration for moving forward on this critical effort. Evaluating the performance of OPOs utilizing objective and verifiable metrics as outlined in the final rule will increase transparency and accountability in the US transplant system and increase equity in organ donation. The improvements outlined in the final rule are widely supported by a bipartisan group of stakeholders in Congress and across the federal government. ASN is committed to building a more equitable future of kidney health and increasing accountability and transparency in our organ transplant system.

1. OPO Assessment and Recertification and Competition

a. Independent of CMS' specific outcome measures, what other metrics or attributes reflect a model or highest performing OPO?

The hallmarks of an OPO that is high performing include engagement in the process of continuous improvement. Organ donation is a multi-step process spanning identification of potential donors at the donor hospital, referral to the OPO, organ quality assessment, procurement, and finally allocation and organ acceptance. High-performing OPOs attend to each of these steps, developing collaborative relationships with donor hospitals and the community to maximize opportunities for donation consent, and with transplant centers to streamline placement of “hard to place” organs. High-performing OPOs attend to optimal donor management to maximize organ yield. OPOs that are forward thinking have engaged in the use of data analytics to understand their own performance as well as areas of improvement and may leverage technology to facilitate organ assessment and information sharing with transplant centers such as telepathology.

b. What are quantitative or qualitative indicators of excellent performance and how can CMS incorporate these with outcome measures when assessing OPOs for recertification purposes?

The Scientific Registry of Transplant Recipients (SRTR) is working on an updated framework for arriving at transplant metrics, engaging diverse stakeholders including patient, families, donor families, professionals, OPOs, professional societies, payers, regulators, advocacy organizations and the public. Donor organ recovery and organ yield will be among the evaluated metrics, along with discussion of data sources, data quality, and risk adjustment, at the consensus conference in July 2022 (<https://www.srtr.org/about-srtr/the-task-5-initiative/>). However, we would also urge the inclusion of process measures and recognition that measures such as organ utilization require engagement from transplant centers and an alignment of metrics across the various components of the system.

c. Should CMS consider additional metrics, such as those that measure equity in organ donation or an OPO's success in reducing disparities in donation and transplantation, and how should this be measured?

The NIDDK has a small but important program for improving organ donation among racial and ethnic minorities. However, this effort has not created the type of programmatic changes in OPO practices that one would expect. In addition to needing to expand the NIDDK program to become a more robust and meaningful program, OPOs should be required to take up evidence-based approaches to organ donation, to have internal quality measures that help them recognize opportunities for improvement, and to invest in the effort to expand the evidence based for effective means of improving organ donation.

Designated research authorization requestors (i.e., donor coordinators) generally work for the local OPO in remote hospitals, or the requestors may be trained by the OPO but not be employed by the OPO. Requestors may utilize different styles and formats during discussions with next of kin, depending on the specific circumstances surrounding an individual donor, which may lead to provision of heterogeneous information. Processes for obtaining consent for donation should be customized to overcome the differences in religious, cultural, and knowledge-based beliefs but should incorporate best practices. A national forum on best practices to reduce disparities may be beneficial.

OPOs should be encouraged to become more data driven and adopt the use of application programming interfaces (APIs) for sharing information with UNOS, transplant centers, and donor hospitals. OPOs need to meet staffing thresholds to ensure that they have the resources to both procure and allocate the organs as necessary. OPOs need to partner with the SRTR and UNOS to develop more actionable data reports, share best practices and participate in the ETCLC actively. In addition, OPOs should be required to have an active outreach program in the community to continue education about organ donor registration and not just in donor hospitals.

d. Are there ways to scale, or rate, performance of other (new) factors that CMS may consider in assessing OPO performance?

To truly assess OPO performance HHS needs to make all OPO process data publicly available, which will enable transparency and research into differential OPO communications with donor hospitals, donor families and donor management strategies. This will inform ongoing solutions through operational improvement and professionalization of the OPO workforce to a high level of clinical competency and evidence-based procurement practice, as well as iterative policymaking. We also want to draw attention that statistical measures create different thresholds for small and large OPOs because of the associated confidence intervals used. This needs to be a

consideration while looking at metrics to ensure that large OPOs are not disadvantaged inadvertently.

- e. Have OPOs included additional board positions or structures beyond what is required by CMS to improve operations?**
 - **What structure best serves accountability, and efficient and effective organ procurement?**

The extent to which OPOs are overseen by the MPSC and to the extent that this committee is adequately staffed to provide the necessary oversight or the operational expertise to help with challenges is unclear.

- f. What would be the anticipated impact from consolidation or expansion of the OPO community?**
 - **Would consolidation or expansion of OPOs facilitate increased competition and improved performance or have a negative impact?**

Regarding contiguity of an open DSA, contiguity could potentially provide some advantages such as economies of scale and familiarity with the local transplant centers, ASN does not believe that this should be an overriding concern. Similarly, to how various QIOs are currently responsible for more than one ESRD network, we envision the possibility that multiple DSAs could be managed effectively by a single OPO with different teams in different locations. This would perhaps allow for cross pollination of ideas between teams and allow for improvements in management structure and efficiencies. ASN notes that given the differences in the size and density of OPOs across the country, this needs to be an individualized decision.

The disincentive for OPOs to take over an open DSA is that there is likely to be a period during which relationships with hospitals and transplant centers need to be re-established, identification of the challenges and overcoming those challenges will require time – during which unified metrics are likely to suffer and risk making the combined DSA more of a liability than not.

A competing OPO bidding for an open DSA is also going to want to conduct its own due diligence in the bidding process. CMS needs to establish a minimum data sets that bidders may request for at least the preceding 24 months to inform their proposal. ASN recommends that CMS require all OPOs to begin preserving this data now, as a condition of an OPO being eligible for recertification in 2026 and recommend that these data preservation requirements be incorporated into future DSA contracts.

It remains unclear how the governing body and the advisory board function at various OPOs. There are potential conflicts of interest given that many of these board members are senior staff at the local transplant centers. Additionally, given that these are often volunteer positions, it is unclear to what extent the members of these boards are able to

devote their time to providing true oversight of the OPO or for that matter how willing or able they are to criticize the OPO when necessary. These challenges in those DSAs with a single transplant center are even greater – and given the misalignment of interest that will now occur between the OPO and centers in the original DSA under the new 250nm allocation system, this needs greater attention and study.

OPOs ought to have medical boards with clear and open processes to identify its members, have adequate expertise on the boards with clear and shared responsibility for the performance of the OPO and the need to institute processes that would encourage continuous improvement cycles.

- g. Any other helpful information that could inform potential changes to the current recertification and competition processes.**

2. Organ Transport and Tracking

- 1. Are there best practices regarding the arrangement of organ transportation between an OPO and a transplant program?**

Increasing the complexity of organ transport add costs and cold ischemia time, which can degrade organ quality and increase the chance of discards. Improved courier contacts and/or consideration of “life flights” are needed to assist OPO’s in less populated metropolitan centers to more expeditiously ship organs. There have been proposals for drone organ delivery in major metropolitan centers with traffic issues where couriers, traffic, and organ loading add unnecessary cold ischemia time (PMID 30203436).

Attempts to identify the center that an organ is going to prior to cross clamp of the organ should be encouraged and ought to be considered standard practice. Additionally, centers should be more accountable when they back out of an organ offer which adversely impacts the ability of the OPO to place an organ successfully.

- 2. How can the tracking of organs during transport be improved?**

The current system is an inadequate system and does not meet the needs of allocation in the 21st century. This is particularly true as the system complexity continues to grow in the move towards continuous distribution. The ongoing UNOS pilot study employs a large GPS tracking device that apparently needs to be managed, stored, and returned - steps that would appear to make this a challenging approach when scaled up to the entire system. If the entire allocation system uses a single type of tracker, centers should either be able to return them to the local OPO – or alternatively, use something small and inexpensive enough that it can be discarded after use.

The inability of OPOs to ship organs on perfusion pumps because the costs and inconvenience associated with trying to retrieve a pump from a center outside the original DSA is another barrier. This also underscores another failure on the part of the

OPTN to revise the DDR forms or DonorNet enough to be able to capture the information on perfusion pumps. This lack of data has essentially left unanswered many questions about the utility of perfusion pumping of organs.

- **Should specific requirements be implemented to facilitate real-time tracking of organs?**

Real time tracking of organs needs to be accompanied by the investment of understanding of the logistics of transportation. For example, organs from smaller cities where outbound flights end earlier in the evening may be better off being allocated to a center that is driving distance away in an effort to minimize cold ischemia and improve organ utilization. However, once again, this requires the engagement of the OPTN contractor and their organ center to be able to invest in the technologies (or more accurately contracting with established vendors) to provide this information. Increased transparency of logistical consideration in organ allocation is necessary to ensure that certain groups of individuals such as rural patients or patients at centers in smaller cities are not inadvertently disadvantaged. This would be particularly important for the UNOS Organ center to invest in given its role for national allocation.

- **What additional factors should be considered to ensure organs undergoing real-time tracking arrive at their intended destination timely?**

Weather, traffic conditions, available donor operating time at the local hospital – some of these factors are motivation for onsite donor recovery centers. These considerations have already been incorporated in many IT vendor systems engaged in logistics and transportation as well as companies that provide mapping and other transportation solutions. Rather than re-invent the wheel, we would encourage creating partnerships with those that already have these capabilities.

3. Can the OPO CfCs address the issue of organs that are lost during transport to a transplant program?

Improved organ tracking technology, improved logistics, and greater investment in donor staff at OPOs should make this a rare or “never” event.

4. Are there other ways HHS can incentivize creation or use of additional mechanisms to reduce the likelihood organs will be lost or damaged after procurement but before transplantation?

This requires the establishment of a quality process that tracks the instances of organ loss or damage during procurement at the OPO with public data on its occurrence is necessary to see what is happening and how often. It would also be important to track how often this leads to discard of the organ since injury appear to be leading to greater discard primarily at higher KDPI.

3. Donor Referral Process

1. What specific patient events, clinical triggers, or subsets of clinical information are used to send notifications to OPOs?

Clinical triggers for potential donor referral include patients on a ventilator with any of the following:

- Any consideration of withdrawal of life sustaining therapies, or deceleration of care (example: palliative care consults with DNR for purposes to not escalate care) OR
- Brain death testing discussed, planned or initiated OR
- GCS < 5, not due to sedation or paralytics OR
- Family initiates conversation about donation

Referral may occur by phone with OPO coordinator extracting information into the OPO EMR, although in some cases OPOs also have direct access to hospital OPOs.

Investment in integration of electronic records should improve efficiency in the potential donor referral process.

2. Should a patient being placed on invasive mechanical ventilation, except for a planned medical or surgical procedure, be one of the triggers for a referral to the OPO?

The vast majority of individuals who are intubated are subsequently successfully extubated. Informing OPOs of all of these events is likely to result in a deluge of referrals that are likely going to make it harder – not easier – to identify potential donors.

3. Could the referral to the OPO be made by someone other than a doctor or nurse, such as a respiratory therapist?

Respiratory therapists should not be making referrals to the OPO without consultation with the medical team given that they are often unaware of the full medical condition of the patient. An alternative strategy may be to require therapists to include questions about referrals in their checklists for terminal extubation and other similar circumstances.

4. What is the minimum information necessary to facilitate notification to the OPO and what additional clinical information, if any, may also be beneficial?

5. Do donor hospitals that are making electronic referrals leverage the existing admission, discharge, and transfer elements in electronic medical record systems to transfer information to OPOs, and if so, how is this information utilized? We are interested to learn if there is any standardization in the industry for transmitting and receiving this information as well as any common data sets that are currently collected.

Clinical transfer of information to OPOs and DonorNet needs to be facilitated by APIs and other electronic means. There are already large opportunities to do so with the use of FHIR standards or the adoption of common data models such those like PCORNet or the OMOP Model that is being used by OHDSI (supported by the FDA). This model now potentially includes transplant specific variables and needs to be leveraged by UNOS for TEIDI and DonorNet, OPOs and transplant programs proactively. (PMID: 33027834 and PMID: 33027834)

6. Are there aspects to donor referral processes or how referrals are made that help to engender trust or potentially worsen mistrust among underserved populations, including racial, ethnic, and religious minorities?

There are programs that do this well and those that perform poorly do not do this well. Recent data suggests this is a part of the phenotype of a low performing OPO (PMID: 34510735).

7. Are there clinical decision support protocols or algorithms that can reduce the cognitive burden and thereby assist clinicians in identifying potential donor candidates?

- **If so, are there concerns regarding potential bias in clinical decision support protocols or algorithms that can introduce or exacerbate inequities, and how can those biases be addressed?**

There are currently no widely accepted clinical decision support tools to help identify potential donors. The work to do this needs to be incentivized and encouraged but will require large datasets and the adoption of common data models is needed to be able to leverage clinical data (rather than administrative claims data) to build these tools. We should note that these models, even if they do not explicitly include race or socioeconomic factors may end up perpetuating biases because of the underlying dataset composition used to develop the models. While caution is required here, this is a more complex problem that is beyond the scope of this RFI.

8. Are there opportunities for OPOs to use electronic health record (EHR) application program interfaces (APIs) to facilitate key information transfer between the hospital and OPO?

In short, the use of APIs, common data models, and advanced data analytics are necessary to facilitate sharing of information, provide data insights and actionable information that can result in improved system performance.

4. Organ Recovery Facilities

Effectiveness:

1. What benefits and risks may OPOs experience in regard to cost-effectiveness, organ yield, and organ quality from operating an organ recovery facility?

The onsite donor recovery centers (such as Mid-America Transplant in St. Louis and Legacy of Hope in Alabama) have reported significant improvements in efficiency, organ yield, organ placement, and donor recovery costs (PMID 26947113, 17467474, 2462713, 33274521). This is a functioning model, has precedent and might be an opportunity to consider expanding. This may be most effective in those mid major cities where performance is suboptimal.

Organ recovery centers are able to facilitate donor interventions that may improve organ quality, research into efforts to study techniques for evaluating organ quality or establish organ reconditioning efforts when appropriate. There is growing evidence that a broader use of organ recovery centers could result in more organs procured per donor, at lower cost to public and private payors, and organ procurement can transpire in a manner that is more convenient, and safer for surgical recovery teams.

However, more study is required to understand how the role of these centers are optimized and how these organ centers are perceived by donor families and their willingness to donate the organs of their loved ones.

2. Are there particular benefits to securing organs from marginal or extended criteria donors while at an organ recovery facility?

Donor recovery centers may implement advanced management protocols that improve organ yield from high-risk donors. These centers may also facilitate the development and study of additional interventions that might improve organ performance, utilization and subsequent outcomes. Reconditioning of organs to improve performance is another approach that has not been adequately studied and these centers may support the development of these techniques.

3. Are OPOs able to achieve better placement of these organs relative to organs recovered at donor hospitals?

The published experience supports some benefits: PMID 26947113, 17467474, 2462713, 33274521). However, we think more research is needed in this space to understand if there are any unintended consequences, but this requires greater transparency in OPO data. It is potentially feasible that improved control of timing of the organs (i.e., not waiting for a donor hospital OR) would help in logistics, lower cold ischemia and thus improve utilization. However, this currently remains to be studied.

Impacts on other stakeholders:

1. Are there any negative impacts or disincentives to donor hospitals or transplant centers?

Revenue collected from Medicare Cost Report billings is dependent on the transplant hospital's Medicare Organ Ratio. This relationship creates an explicit and significant financial disincentive for transplant hospitals to allow authorized donation after brain death (DBD) donors to be transported to off-site organ recovery facilities. Allowing hospitals to continue to receive credit for the donors that are transported to recovery facilities would eliminate this inadvertent financial disincentive. Given the current dependence of transplant centers on this revenue to support the pretransplant activities of a program, inadvertent reductions such as this need to be eliminated till such time that there is a complete overhaul of the financial model being used currently to support pretransplant clinical activities.

Also, it is not clear how donor families perceive organ recovery centers and if the use of these centers is seen as a disincentive for families – especially for those that have a distrust of the medical system already. Differential impacts and perceptions may inadvertently exacerbate existing disparities in organ donation.

5. “Zero Organ Donors” and Discarded Organs

- 1. How has the sharing of information on organ offer and acceptance data impacted practice, including information on root causes for failure to place organs as well as organs that were declined but later successfully transplanted at another center?**

This information is currently shared in a passive manner on the UNet site and does not include provider level information. In the absence of an active decision of a transplant program to actively review this report and their decisions by seeking out this information and reviewing it, this information will not have an impact. At present, the data portal from the OPTN is not user friendly and does not provide access to pertinent information in any easily accessible manner, does not provide notification when new information is posted, and does not provide navigation that is either customizable by role or preference.

Additionally, for information about an organ that was utilized elsewhere to have a meaningful impact on clinical decision making requires the ability to be able to link it back to the original offer that was declined in a timely manner. This requires information that includes early outcomes such as a DGF and creatinine to be available in a relatively short time frame which it is not currently.

- 2. What is the impact to these types of information sharing in practice, and if they have been productive, how can CMS build requirements around OPO – transplant center collaboration to support best practices in reducing the number of organ discards?**

Given the nature by which the information is currently shared with transplant centers, the somewhat unintuitive manner in which the data portal is configured, and the low

level of advertising of information that is available, ASN is concerned about how much of a clear and perceptible impact it will have on the transplant system.

Currently, transplant centers set their own bypass criteria – and the majority of centers have very open criteria. Perhaps resetting bypass criteria to reflect the past 6 or 12 months of center level practices should occur by default. Centers would retain the option to change these settings, but it is likely that the default settings would improve the utility of these settings.

However, ASN also suggests caution with the use of defaults. A conservative center would continue to have increasingly restrictive settings if there were no intervention on their own. If this idea is implemented, this should be accompanied by transparency of the setting to the public along with a measure of the extent to which the available donor pool is excluded by these settings. This would help patients make informed choices about where to be listed. In addition, with this level of transparency and active decision making with the bypasses, these organ offers should no longer be excluded from the denominator of the organ offer acceptance criteria reported by SRTR – or at the very least, the SRTR should report the organ offer acceptance rate (OAR) with and without these bypasses included in the denominator.

3. Should this type of collaboration between OPOs and transplant programs be incorporated into quality assurance performance improvement (QAPI) requirements for OPOs and transplant centers?

OPO and transplant center collaboration should be strongly encouraged. Currently there are some OPOS that hold monthly calls to discuss organ discards, particularly unilateral organ discards as well as organ offers that were declined by several centers within the region that went on to be used and performed well. These quality efforts are essential to the effort to reduce the level of risk aversion in the system at present but represent yet another example of a quality related activity that does not generate revenue but requires significant time commitment from clinicians. We should also note that with the rising trend of centers outsourcing their organ offer screening practices to private vendors and the elimination of DSA boundaries in the allocation system, maintaining OPO-transplant center relationships is of paramount importance. (PMID 33314637). Clinical practices related to procurement biopsies that have been shown to be associated with an increased risk of discard are highly variable at present. (PMID 34196034) Changes in these practices at present as we attempt to gain uniformity will depend on strong OPO-Transplant center relationships.

The ETC Learning Collaborative (ETCLC) has quality improvement (QI) teams that partner with multiple OPOs and transplant centers in recognition of the need for strong collaborative relationships for a successful allocation and transplantation system. These efforts should be encouraged and allowed to persist long term given that it is not possible for clinical staff at individual programs to participate individually with multiple OPOs for QAPI simultaneously. If this was required, it would create a significant

administrative burden and time commitment that would not be possible without specific requirements and efforts to protect time to be able to engage in these activities.

In addition:

- 1. We are interested in ways information on organ discard rates and organ acceptance practices can become more available and whether CMS should track and evaluate this information more closely and consider it for recertification purposes.**

ASN notes that the direct attribution of a discard to a transplant center is not possible since a discard is the result of repeated declines for multiple patients at multiple centers. Instead of being accountable for a discard, transplant centers should be held accountable for their choices in the allocation process. In light of this, centers should be measured based on the extent to which they are willing to accept the organs that are offered to their patients (with and without bypass offers) and, perhaps most importantly, the impact that their choices have for the probability of transplantation for their waitlisted patients.

While ASN recognizes the value of the organ offer acceptance rates and the statistical considerations with respect to whether to include or exclude bypassed offers, ASN believes this is not a patient friendly representation of the data.

ASN suggests the use of measures that are more approachable and patient friendly such as adjusted probability of transplantation – and patients should have the ability to view differences in these measures between centers to help them pick the center at which that they would want to be listed. Similarly, the centers' selectivity and reasons for turning down organs should also be disclosed in an aggregated but understandable manner for patients – in addition to greater transparency about which patients are being turned away by transplant centers and why they are not being considered candidates for transplantation.

ASN would also like to note that organ discard codes have recently been revised by the OPTN contractor and were implemented in Dec 2021. The extent to which the new codes are going to help understand the reasons for discard remains to be seen, but ASN is concerned that in attempting to make a one size fit all set of codes for all organs, significant tradeoffs were made. For example, there is no simple and direct manner in which acute kidney injury in the donor kidney can be selected as a criterion. While procurement biopsies are associated with a third of all discards, there are no additional granular information options that would help determine what aspect of the procurement biopsy results are of concern and contributing to the declined organ offer. It remains unclear to what extent the OPTN contractor is currently monitoring the changes in the organ offer decline codes and their utilization by transplant centers to identify early problems or to what extent they are committed to make rapid iterative changes to these codes in the event that a problem is identified.

This problem of procurement biopsies is further compounded by the development of a kidney biopsy form by the OPTN contractor without reference to the extensive peer reviewed literature on the subject and the engagement of a single kidney pathologist who does not participate in the evaluation of procurement biopsies. Without any effort to evaluate the proposed standardized biopsy form proposed and failing to try to use an evidence base to determine criteria for which donor kidneys ought to qualify for a procurement biopsy, the contractor has chosen to move forward on this front.

While organ discards have received extensive attention from researchers and regulators alike, an even greater challenge pertains to the large number of kidneys that are not obtained from deceased donors from whom other organs are procured and transplanted (PMID 34897982 and 32342627). There is now ample evidence to suggest that kidneys are frequently not procured. These non-procurements are at least in part at least in part an effort to lower discard rates, underscoring the danger of providing excess focus on this step in the multistep process of transplantation, which starts with the identification of a potential donor to the successful outcome post transplantation.

2. We are also interested in ways in which it may be possible to determine an “acceptable” baseline rate of organ discards based on medically disqualifying factors and how this should be assessed.

As a first step, organ discard rates should be benchmarked against discard rates seen in other large, deceased donor allocation systems. In doing so, it would be important to recognize that the majority of the discards in those systems are of organs that are much more marginal and from much older donors than those in the US allocation system.

This is partially due to the labeling effect of a percentile system that results in a ranking of kidneys relative to each other rather than relative to the value that they would provide a patient. We would like to re-emphasize that the KDPI is a quality score that compares and provides the value of an organ relative to other organs rather than the value of the organ to a patient. The raw score KDRI at least provides value of organs to patients despite its many other limitations. As a first step, we would encourage elimination of the KDPI in favor of the KDRI

Very few clinical characteristics have been shown to be associated with significantly worse graft survival outcomes. There is a dire need for much more robust and thorough analysis to better predict which organs should be justifiably discarded. With a few (extreme) exceptions, even the few factors currently associated with worse kidney graft outcomes are insufficiently studied and qualified. As a result, ASN recommends that the only restriction be placed on donor age potentially consistent with practice patterns in other parts of the world.

6. Donation after Cardiac Death (DCD)

1. What has contributed to the recent rapid increase in DCD organ donation?

Utilization of donated kidneys procured from donors after cardiac death has been recognized as a potential option to help address the organ shortage. Barriers to DCD utilization include: (1) increased costs for OPOs to procure DCD organs due to high “dry runs” (team dispatch without organ procurement) and high discards of procured organs; (2) increased risks of adverse outcomes associated with DCD transplant (Tx); and (3) center concern for regulatory performance and center cost implications of increased complications after DCD transplantation. Attention on DCD utilization to increase organ supply has been able to overcome some of the barriers to achieve good outcomes with increased DCD utilization, but attention to mitigating such barriers should continue.

7. OPO Tissue Banking Activity and Relationships with other Tissue Banking Organizations

8. Organs for Research

- 1. We are interested to know if there are currently sufficient incentives to provide organs for research absent a metric or process measure for this purpose. If an incentive is needed in this area, how should OPOs be assessed on this aspect of its operations?**

Three broad types of deceased donor research may be conducted. Donor management research takes place on a donor’s organs before those organs are transplanted. The goal of donor management research is to maximize the number and function of transplantable organs. Research may also be conducted on organs that are not transplantable or other tissues such as lymph nodes or spleen, seeking to improve understanding of the human body, including novel treatments outside of transplantation. Organs for research are essential if we are going to improve our understanding of both organ preservation and the pathophysiology of kidney disease, especially reperfusion injury. While OPOs are not primarily meant to support research efforts, they have made invaluable efforts to support the NIH funded APOLLO study (a study involving collecting blood and urine from donors of transplanted organs). It should be noted that without the voluntary contributions of the OPOs, this study would not have been possible to conduct – underscoring the fact that it is in fact possible to be able to support research without this process interfering with their primary role of organ procurement for transplantation.

Research efforts from the OPOs are needed if we are going to improve the science/understanding of organ preservation which is likely to support improved allograft survival and influence allocation. Similarly, studies related to acute kidney injury, ischemic reperfusion injury, donor pretreatment strategies, hypothermic machine perfusion are all examples of potential areas of research that need to be supported if we are going to improve deceased donor transplantation and its outcomes.

OPO’s should develop a common model to review research requests, share those protocols and studies nationally, to develop a research “warehouse”. This will be increasingly important as more investigators participate in donor management and organ management strategies using state of the art technologies including metabolic

reprogramming, ex vivo organ support systems, and clinical strategies to manage donors. An Institute of Medicine report provides some insight into this area.

OPO's should develop common tools for consenting potential donor families to include research as an option with or without clinical use of the donor organ. Currently these practices vary by individual consents for studies separate from the donor authorization, to combined consent. Separate special consents reduce the likelihood of enrollment as it places pressure on donor coordinators to obtain multiple consents.

Given the large number of organs being discarded, OPOs should be incentivized to partner with academic centers who would be interested in obtaining human tissue for research without the imposition of exorbitant fees that are sought at times for these organs. The failure to achieve some utility for an organ by failing to utilize the organ for research does a disservice to the donor families.

Similarly, OPOs should be encouraged to share data repositories that they have such as datasets on pump perfusion, biopsy data, digital imaging and others. Engagement with studies funded by NIH, NSF, PCORI being conducted at transplant centers, especially those that are focused on improving organ donation among minorities and other subpopulations should be of interest to the OPOs.

OPOs should be encouraged to engage in quality improvement efforts that could be reportable. Similarly, participation in clinical and health services research efforts should be actively encouraged and should be a consideration at the time of contract renewal.

2. Data on organs submitted for research is self-reported by OPOs and there is currently no method to independently verify this information on a regular basis limiting utility in annual performance measures. Are there other methods CMS should consider that would be effective?

The overwhelming majority of OPOs use a common data capture system from a single vendor. This creates the opportunity to simplify data capture from the OPOs for the creation of process measures including the engagement into research activities and the number of organs placed with research groups. There is an urgent need to separate the OPTN data/informatics infrastructure creation and maintenance tasks from the task of administering the OPTN itself. Creation of robust electronic data capture systems that meet prespecified interoperability standards would be one means of streamlining as well as expediting data capture. These standards could also be applied to transplant specific modules that are available from all of the dominant electronic medical record companies would further improve the exchange of clinical and other process measure related information between OPOs, transplant programs and the OPTN.

Barriers to systematic analysis include lack of documentation of research authorization as a defined field in DonorNet®. Authorization is collected by OPOs on a variety of local documents using specific language that is inconsistent across OPOs. Although scanned authorization forms are uploaded to DonorNet®, attachment labeling conventions vary,

and documents must be individually downloaded and reviewed to determine authorization status. Reprogramming of DonorNet® to include field-defined capture donor research authorization would support systematic assessment of research authorization at national level, and also support efficient access to authorization status information during the conduct of approved studies (PMID: 34514194)

Currently, the exception of pancreata for research has created the potential opportunity for OPOs to completely avoid zero organ donors. While we recognize the value of this exception, it is important to have clear guardrails in place to avoid abuse. Clear rules about what constitutes adequate utilization of these organs for research and the kinds of research programs that would qualify for this exception should be clearly defined. Clear reporting of research organs and the programs that benefitted from these programs need to be reported publicly.

D. Nephrology Joint Ventures

- 1. Would it be helpful for CMS to collect information on joint venture arrangements as part of Medicare enrollment in order to support analysis of the impact of these arrangements on the quality of care furnished to Medicare beneficiaries?**

Yes. Information on the profit/not-for-profit status of dialysis facilities, vascular access centers, and transplant centers and their financial arrangements are necessary to create transparency for patients. This information should be clearly and easily available to patients. In particular, financial arrangements that include payments to healthcare providers, healthcare systems, academic universities, hospitals and long-term care facilities should be available to patients.

Given that much of the responsibility for helping patients navigate dialysis services and the transplant referral system depends upon advice from social workers, financial counselors, insurance navigators and others in similar role, ASN suggests that there be greater transparency over the adequacy of staffing in these roles. Patients should be made aware of any financial incentives and quality benchmarks that may exist for these individuals to receive additional financial renumeration.

- 2. Should a dialysis facility or nephrologist be required to disclose information on joint venture arrangements to patients for improved transparency?**

Yes. Academic Universities, healthcare systems, hospitals, and other organizations should also be required to disclose information on joint ventures.

- 3. Do joint ventures between nephrologists and dialysis facilities have an impact on resource use, patient care, and/or choice of modality? If so,**

please describe how joint venture arrangements affect resource use, patient care, or choice of modality

This question is hard to answer without more information about joint ventures. This is a black box. We need to collect information about existing joint ventures first, then those relationships can be studied and compared to non-joint ventures to help answer these questions. Disclosure of joint ventures between dialysis organizations and University systems, healthcare organizations, hospitals, physician groups and individual physicians should be disclosed to patients and publicly available.

What we do know is that there is extensive evidence that referral rates for transplantation are different between profit and non-profit dialysis facilities. Even educational efforts for staff and patients about transplantation have also been shown to be less effective in for-profit facilities. That raises questions about the need for greater transparency or increased transparency of information that may represent potential conflicts of interest. (PMID 34310358, 34039566, 31503308, 24891272, 34729834)

Patients should have easy access to the information about potential conflicts of interest and financial disclosures should be collected and made available in order to be able to determine the impact that these financial relationships have, if any. It remains unclear to what extent joint ventures in nephrology have either benefited or harmed patient access to care at the facility or subsequent referral. Of particular interest would be the extent to which dialysis facilities have attempted to “cherry pick” which patients they are willing to accept when referred to them, or “lemon drop” less financially lucrative patients, particularly those individuals who have only Medicaid. Also of particular interest would be the extent that these relationships are associated with variations in the socioeconomic and racial and ethnic composition of patients accepted for care as well as which patients are being referred for care at affiliated vascular access centers, programs for transplantation or other patterns of resource utilization such as referral to emergency rooms and modality choice. Financial transparency may be of particular importance with the advent of potential access to xenotransplantation in the coming years.

Conclusion:

ASN is committed to working with CMS, HRSA, HHS, dialysis providers, OPOs, and transplant centers – the transplant ecosystem – to ensure that every individual facing kidney failure has equal access to life-saving kidney transplantation should they so desire and are medically able. Nothing less for everyone is equitable nor acceptable.

Again, thank you for the opportunity to provide comments on CMS' request for information on improving the transplant ecosystem – a challenge that ASN stands ready to provide assistance with – in any way possible. To discuss this letter further, please contact David White, ASN Regulatory and Quality Officer, at dwhite@asn-online.org or (202) 640-4635.

Sincerely,

A handwritten signature in black ink, appearing to read "Susan Quaggin".

Susan E. Quaggin, MD, FASN

President