American Society of Nephrology

March 1, 2022

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Dear Dr. Baron and Dr. Nasca:

On behalf of the American Society of Nephrology (ASN), thank you for seeking ASN's advice concerning the future of training, certification, and practice in nephrology. ASN values its strong working relationship with the American Board of Internal Medicine (ABIM), the Accreditation Council for Graduate Medical Education (ACGME), and other organizations focused on improving the quality of patient care and medical education.

In a letter dated Monday, January 10, 2022, ABIM invited ASN to share its "views on the future of the procedural requirements for ABIM Initial Certification in Nephrology." ACGME announced in an email sent to program directors on Tuesday, January 18, 2022, that the Review Committee for Internal Medicine (RC-IM) is preparing "to begin a major revision of the current program requirements" for many internal medicine subspecialties, including nephrology, and invited "comments related to specific topics that should be addressed as the revised requirements are developed."

ASN considers these invitations from ABIM and ACGME as exciting opportunities to reconsider every aspect of the future of nephrology. However, these opportunities highlight ongoing factors in the field of nephrology that will preclude a comprehensive response to ABIM's and ACGME's invitations at this time. The future of training, certification, and practice in nephrology are interconnected, and ASN believes a joint response to both the invitations from ABIM and ACGME is appropriate. This joint response explains ASN's concerns about the timing of these invitations, describes ASN's unique place in the kidney community, recommends reconsidering every aspect of the future of nephrology at this time, and—most important—commits ASN to facilitating this effort in 2022.

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ASN appreciates the opportunity to comment on these issues, which are of great significance to the more than 37 million Americans with kidney diseases in the United States, the nearly 11,000 nephrologists who care for them, and the 940 nephrology fellows who are currently training in the 152 nephrology fellowship training programs accredited by ACGME. **While appreciating this opportunity, ASN has several concerns about the timing of these invitations from ABIM and ACGME:**

1. The COVID-19 pandemic has affected the kidney community—particularly people with kidney diseases—more than almost any other medical specialty. People with kidney diseases have been significantly affected by COVID-19 because of their high risk for infection and serious illness due to SARS-CoV-2, which, given a high burden of comorbid conditions, results in a much higher risk of death from the virus. For example, deaths among dialysis patients were 18% higher in 2020 than in 2019, and, alarmingly, the number of people currently receiving dialysis in the United States has dropped for the first time in the 50-year history of the Medicare End-Stage Renal Disease Program.

   People who are Black or African American, Hispanic or Latinx, Indigenous or Native American, Asian American, and Native Hawaiian or other Pacific Islander are significantly more likely than White Americans to experience kidney diseases and kidney failure. Therefore, the pandemic has compounded the health risks for the millions of Americans who identify as members of these communities.

   During the latest surge in cases caused by the Omicron Variant, shortages in health professionals and staff, supplies, dialysis capacity, and dialysis shifts or dialysis settings where COVID-19 positive patients can safely be isolated have caused severe stress in many parts of the United States. This untenable situation has resulted in facility closures, shortened treatment times, and backlogs in moving patients among dialysis facilities, hospitals, and skilled nursing facilities. Since the Omicron Variant is starting to recede throughout the country, ASN's members, leadership, and staff can now begin to focus more attention on other important priorities, such as responding to the invitations from ABIM and ACGME.

2. The internal medicine residents and nephrology fellows currently in training have, for the most part, only trained during the pandemic. Before ASN, ABIM, and ACGME can consider major changes to nephrology training, certification, and practice, it is important to begin to better understand how the pandemic has overwhelmed health care systems and disrupted medical education, training, and clinical rotations.

3. The COVID-19 pandemic is exacerbating concerns about the health care workforce in the United States. These concerns extend from burnout to the currently unknown effects of post-COVID conditions (or long COVID) to shortages of health care professionals in many parts of the country. Before ASN, ABIM, and ACGME can consider major changes to training and certification, it is important to consider how these workforce challenges will alter nephrology practice in the future. For example, how will the roles and responsibilities of nephrologists, nephrology nurses, and other health professionals evolve to meet the future needs of patients throughout the country?

4. ASN responded last month to a request from the US Centers for Medicare & Medicaid Services (CMS) "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 its response, which is included, ASN provided specific suggestions to the federal government and emphasized: "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" (**Attachment 1**).

   When implemented, these recommendations will have a dramatic effect on the future of training, certification, and practice in nephrology. CMS's request for information was intended to help the federal government accomplish the July 2019 US Executive Order on Advancing American Kidney Health (**Attachment 2**). Based on the executive order, the federal government is committed to working with the kidney community to:

   - Reduce the number of Americans developing kidney failure by 25% by 2030.
   - Increase substantially the number of kidney failure patients in the United States who receive dialysis in the home or receive a kidney transplant by 2025.
   - Double the number of kidneys available for transplantation by 2030.

5. The private sector is already moving quickly to adopt many of these changes. For-profit and not-for-profit companies are partnering with nephrologists to manage the care of people with kidney diseases. These value-based care (VBC) initiatives financially reward health professionals who (and companies that) successfully slow the progression of kidney diseases, increase the rates of home dialysis and kidney transplantation, and improve the outcomes for dialysis patients and transplant recipients. As explained in the enclosed article from ASN *Kidney News*, "Start-up companies, larger for-profit health care providers, and venture capital firms have formed a marketplace of new products aimed at helping nephrologists improve their management of [chronic kidney disease] at a population level" (**Attachment 3**).

   It is important to determine how companies like Cricket Health, CVS Kidney Care, EverGreen Nephrology, Global Nephrology Solutions, InterWell Health, REACH Kidney Care, Somatus, and Strive Health are currently altering practice and will continue to alter nephrology practice in the future. When combined with the previous point about CMS's efforts to help accomplish the Executive Order on Advancing American Kidney Health, this understanding of the future of nephrology practice will help influence potential changes to training and certification.

6. Since formally approaching ACGME about participating in the Advancing Innovation in Residency Education (AIRE) program in 2019, ASN has continued to develop proposals for subspecializing in nephrology. While consensus is lacking in the kidney community to encourage subspecialization, ASN believes the time has come to determine whether the kidney community should evaluate its historical belief that a) all nephrology fellows should have the same experience and expectations during training, b) the initial certification examination in nephrology should be the same for everyone who completes fellowship training (regardless of their clinical interests), and c) nephrologists should not have a way to differentiate themselves professionally through a stand-alone subspecialist certification by ABIM (regardless of their clinical experience).

ASN believes the kidney community must reach an agreement on this issue before ABIM and ACGME consider changes to procedures and program requirements, respectively.

7. As outlined in the included letter from ASN and ABIM to ACGME in 2019, a longstanding lack of consensus exists in the kidney community about requiring procedures (**Attachment 4**). Recently, *Kidney360*—ASN's online-only, open access peer-reviewed journal—published a pro-con debate on this topic, which is included (**Attachments 5 and 6**).

   Several ASN task forces will soon make recommendations for providing practical solutions to critical issues, such as increasing the use of home dialysis therapies, improving dialysis access (and decreasing reliance on central venous catheters), and integrating augmented intelligence and digital health into the specialty. For example, the ASN Home Dialysis Task Force is currently surveying nephrology fellowship training program directors and division chiefs to better understand barriers to improving home dialysis training.

   Given the current lack of consensus about procedures and the forthcoming recommendations from the society's task forces, ASN urges ABIM to pause any decision concerning the future of the procedural requirements for ABIM Initial Certification in Nephrology and urges ACGME to pause a major revision of the current program requirements in nephrology. As will be outlined later in this letter, ASN pledges to lead an effort in 2022 to reconsider every aspect of the future of nephrology.

ASN believes the best way forward is to redefine the future of nephrology as a specialty based on what we have learned from:

1. Responding to COVID-19.
2. Understanding how the pandemic has affected graduate medical education, particularly nephrology training.
3. Determining how we plan to address the future workforce challenges.
4. Implementing forthcoming recommendations from CMS and continuing to accomplish the Executive Order on Advancing American Kidney Health.
5. Leveraging VBC and understanding the models from new for-profit entities caring for people with kidney diseases.
6. Determining whether nephrology should subspecialize and how.
7. Reaching consensus on procedures.

Once the future of nephrology is defined through the plan and timeline outlined below, the kidney community can make concrete recommendations to ABIM and ACGME about procedures and program requirements, respectively. ASN is uniquely positioned to facilitate this important effort because of the society's historical emphasis on improving training, certification, and practice in nephrology; focus on the entirety of nephrology; and proven track record.

To create a world without kidney diseases, ASN "elevates care by educating and informing, driving breakthroughs and innovation, and advocating for policies that create transformative changes in kidney medicine throughout the world." With 20,000 members in 132 countries, ASN accomplishes this ambitious mission by always focusing on doing what is best for the more than 850 million people worldwide with kidney diseases and their families and doing what is best for strengthening the relationship between these patients and their health professionals.

Moreover, ASN represents every member of the interprofessional kidney health care team, including physicians, scientists, doctors of pharmacy, pharmacists, advanced practice providers, nurses, dieticians, and social workers. ASN is jointly accredited to provide continuing education credits to these health professionals who focus on every aspect of nephrology, including (but not limited to) general nephrology, acute kidney injury, critical care nephrology, interventional nephrology, kidney transplantation, nephro-cardiology, and onco-nephrology.

ASN has a long history of working with ABIM, ACGME, other members of the kidney community, and key stakeholders on issues related to training, certification, and practice in nephrology. To emphasize this point with key examples, ASN:

- Supports the Nephrology Fellowship Training Program Directors as a vital constituency within the society.
- Sponsors the National Resident Matching Program's Medical Specialties Matching Program for nephrology.
- Supports the ASN Data Resource Center, which provides reports regularly on the nephrology match, issues related to nephrology fellows and training, and the experiences of early-career nephrologists.
- Administers the In-Training Examination for Nephrology Fellows jointly with the National Board of Medical Examiners (NBME).
- Includes as members (for free) all the nephrology fellows in the world.
- Provides free to members (including fellows) both the Nephrology Self-Assessment Program (NephSAP) and the Kidney Self-Assessment Program (KSAP).
- Holds the most highly rated board review course in nephrology.
- Works with the National Kidney Foundation (NKF) to implement the recommendations from the NKF-ASN Task Force on Reassessing the Inclusion of Race in Diagnosing Kidney Diseases, which has resulted in nephrology being the first specialty to remove race from a major clinical algorithm.
- Partners with the Council of Medical Specialty Societies and ACGME on "Equity Matters: A Diversity, Equity, Inclusion, and Antiracism Initiative for Physicians and Medical Leadership."
- Drives excellence in patient care through several initiatives, including:
    - Nephrologists Transforming Dialysis Safety, a partnership with the Centers for Disease Control and Prevention to "enhance the quality of life for people with kidney failure by engaging nephrologists as team leaders in transformational change that continuously improves the safety of life sustaining dialysis."
    - The Diabetic Kidney Disease Collaborative, which focuses on addressing "urgent and unmet needs in the diagnosis and treatment of people with diabetic kidney disease."
    - AKI!Now, which "promotes excellence in the prevention and treatment of AKI by building a foundational program that transforms the delivery of AKI care, reduces morbidity and mortality, and improves long-term outcomes."

To supplement these efforts, ASN provides the most continuing education in nephrology, is the largest kidney-specific publisher, and is the largest private funder of kidney-related research and travel support (through its separate foundation, KidneyCure) in the world. As outlined in the included editorials from ASN *Kidney News*, ASN has also dedicated more resources to promoting diversity, equity, and inclusion and to pursuing health care justice than any other member of the kidney community (**Attachments 7 and 8**).

ASN considers ABIM's invitation concerning the future of procedural requirements for ABIM Initial Certification in Nephrology and ACGME's request for specific topics to address during RC-IM's major revisions to the program requirements for nephrology as an exciting opportunity to reconsider every aspect of the future of nephrology. To accomplish this goal, **ASN will convene the kidney community, representatives from ABIM and ACGME, and other stakeholders during the next eight months to**:

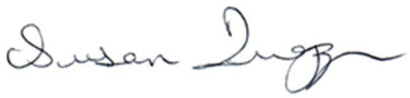
1. Decide the core skills, knowledge, and experiences in kidney medicine that every nephrology fellow must learn during fellowship training as well as ensure competency-based medical education in nephrology.
2. Evaluate the historical belief (within the kidney community) that all nephrology fellows should have the same experience and expectations during training, that the initial certification examination in nephrology should be the same for everyone who completes fellowship training (regardless of their clinical interests), and that nephrologists should not have a way to differentiate themselves professionally through a stand-alone subspecialist certification by ABIM (regardless of their clinical experience).
3. Assess which subspecialties of nephrology have evolved to the point of requiring formal training and certification to ensure the highest-quality care possible for the more than 37 million Americans with kidney diseases.
4. Identify potential gaps in training for those nephrology fellows who have started their training on or after Wednesday, July 1, 2020.
5. Determine how best to ensure that the future of nephrology training, certification, and practice:
    a. Promotes diversity, equity, and inclusion.
    b. Pursues health care justice.
6. Begin to articulate how best to align the future of nephrology training, certification, and practice with other members of the interprofessional kidney health care team, particularly doctors of pharmacy, pharmacists, advanced practice providers, nurses, dieticians, and social workers.
7. Articulate the expectations for nephrology fellowship training programs in the future (based on the above goals).

ASN commits to issuing final recommendations by October 2022. Based on this timeline, ASN can share the final recommendations with ABIM and ACGME this fall as well as with the entire kidney community during ASN Kidney Week, which is scheduled to take place November 3-6 in Orlando, FL.

ASN respectfully requests that ABIM and ACGME pause all discussions about the future of procedural requirements for ABIM Initial Certification in Nephrology and specific topics to address during major revisions to the program requirements for nephrology, respectively, until the kidney community can reconsider every aspect of the future of nephrology. This eight-month process will also incorporate what we have learned from responding to COVID-19; understanding how the pandemic has affected graduate medical education, particularly nephrology training; determining how we plan to address the future workforce challenges; implementing forthcoming recommendations from CMS and continuing to accomplish the Executive Order on Advancing American Kidney Health; leveraging VBC and understanding the models from new for-profit entities caring for people with kidney diseases; determining whether nephrology should subspecialize and how; and reaching consensus on procedures.

Again, thank you. The ASN membership, leaders, staff, and I look forward to working with ABIM, ACGME, other members of the kidney community, and key stakeholders to determine the future of training, certification, and practice in nephrology. To discuss this letter, ASN's commitment to this important effort, or the society, please contact ASN Leadership Development Coordinator Molly Jacob at mjacob@asn-online.org or (202) 640-6579.

Sincerely,



Susan E. Quaggin, MD, FASN
President

February 1, 2022

Chiquita Brooks-LaSure
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:

<u>Screening</u>

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.

<u>Education</u>

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:

<u>Assisted home dialysis and remote monitoring.</u>

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.

<u>Address shortages in home dialysis staff.</u> 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.

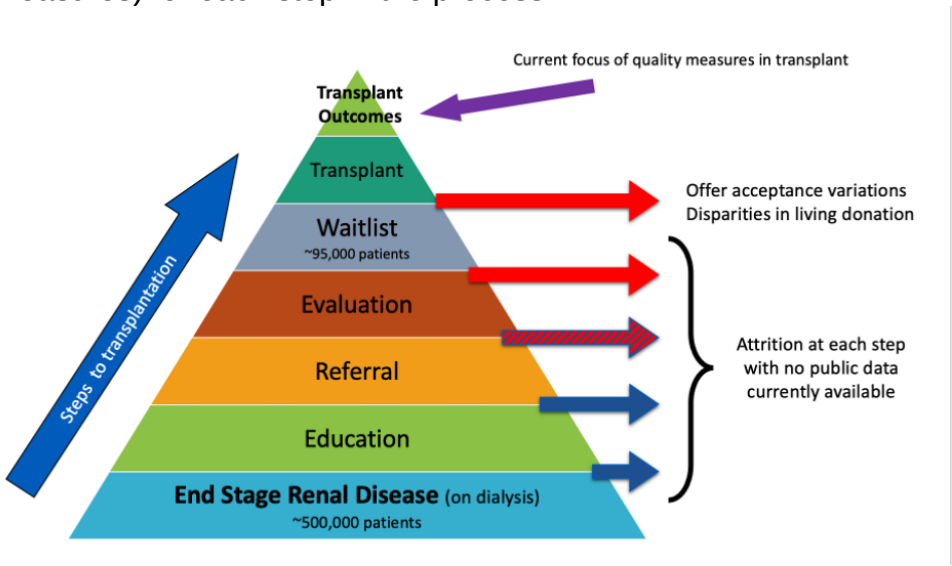
CoP accountability should extend to referring dialysis centers and nephrologists, especially if referrals prior to dialysis initiation are to be encouraged. Transplant programs do not currently have the ability to evaluate all patients who would potentially benefit from transplant in a timely manner, 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.



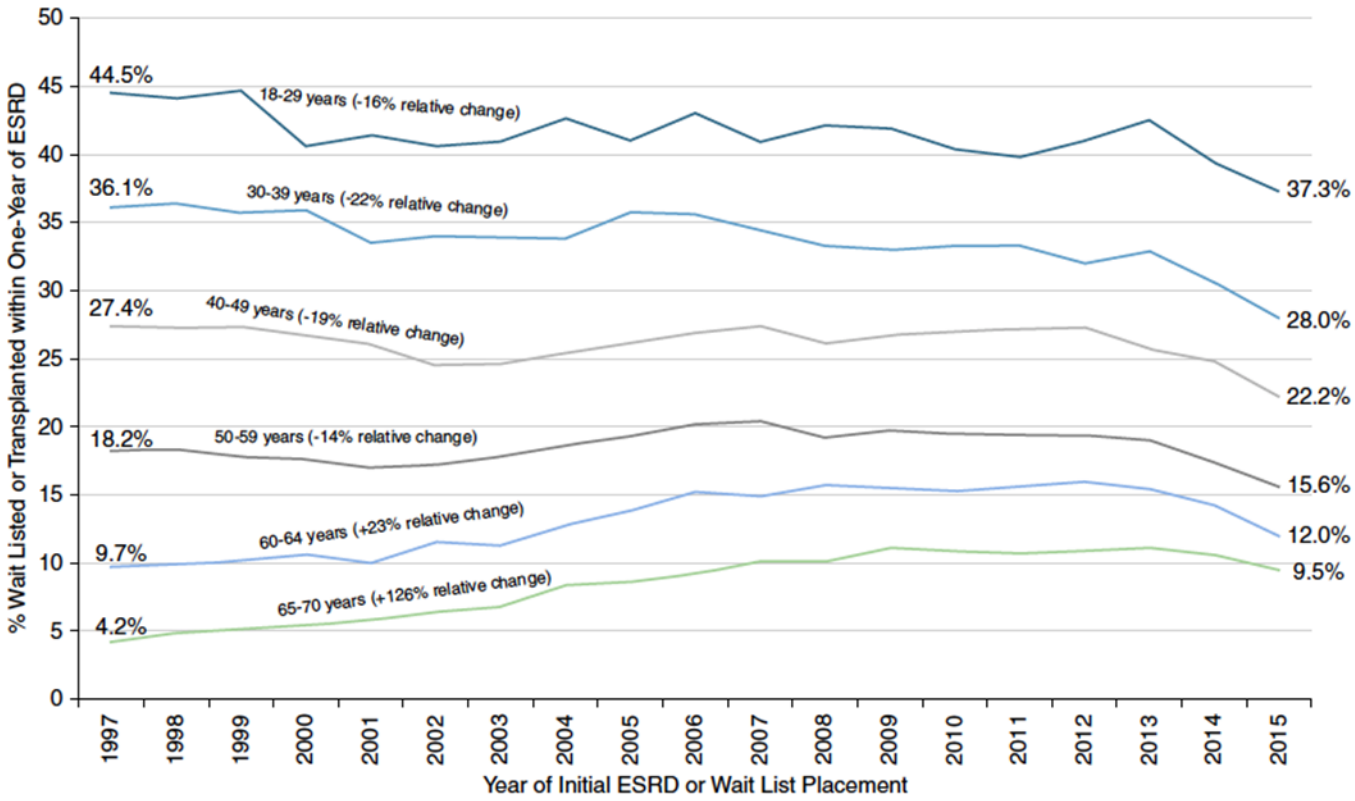
One method to potentially avoid unintended consequences is to calculate quality measures in such a way that considers the spectrum of the process from dialysis to transplant at any given time, so as to leverage the multistep nature of the process of education, referral, evaluation, waitlisting, transplantation, 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.

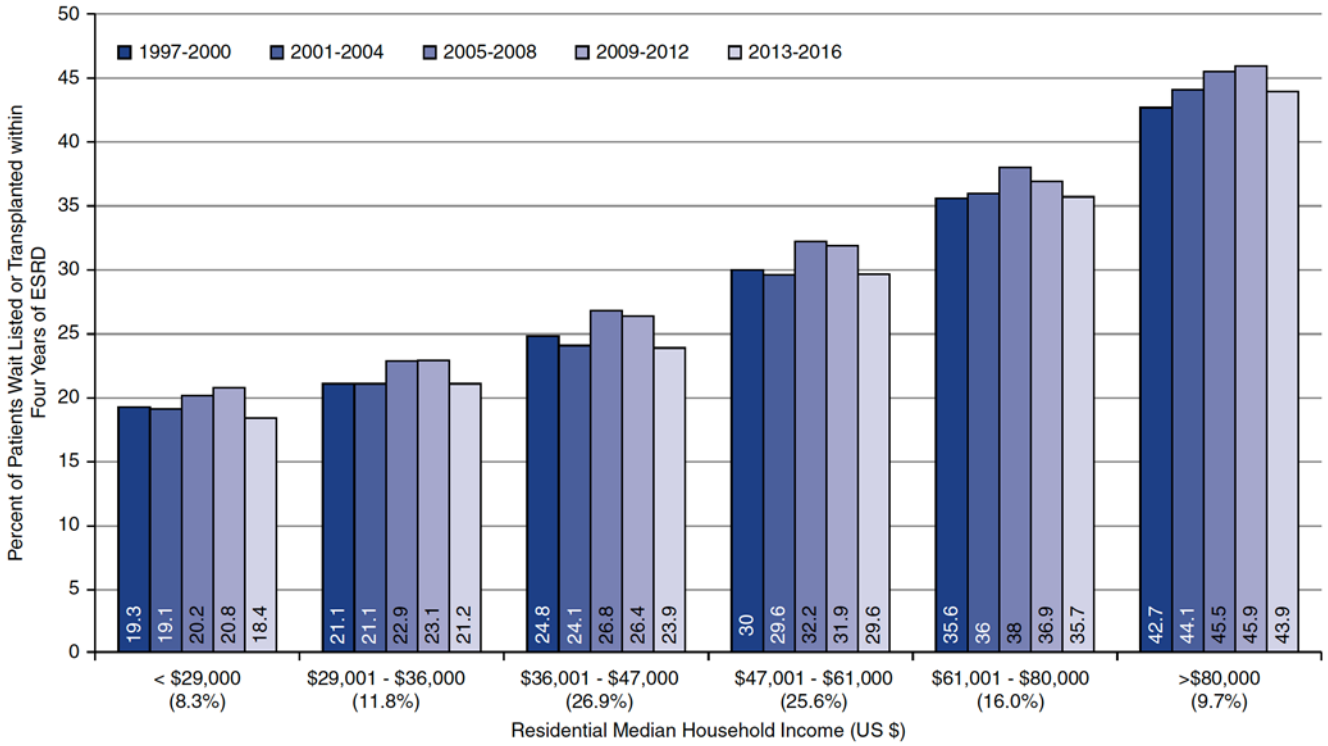
For example, the proportion of patients referred should be based on the number of patients who completed the education step, while the proportion of patients evaluated should be reported as a fraction of those patients who were referred for transplantation. This multistep process, however, spans different 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.

<u>Communication among Patients, Transplant Centers, Referring Providers and Dialysis Facilities</u>

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 <u>disabled</u> 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 programing 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.

<u>Kidney Disease Education Benefit</u>

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 this 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 heterogenous 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 is 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 quality 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,

Susan E. Quaggin, MD, FASN

President

ADVANCING AMERICAN Kidney Health

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

CONTENTS

INTRODUCTION

One of the top healthcare priorities of the Trump Administration—and many other stakeholders in American healthcare—has been the shift from paying for sickness and procedures to paying for health and outcomes.

There is no better example of an area that needs this transformation than the way we prevent and treat kidney disease. Approximately 37 million Americans have kidney disease, and, in 2017 kidney disease was the ninth-leading cause of death in the United States. The primary form of treatment for kidney failure is dialysis, which is one of the most burdensome, draining long-term treatments modern medicine has to offer. I know this personally—as so many Americans do—because my father was on dialysis for years.

Dialysis is also far from sustainable: One hundred thousand Americans begin this treatment each year, and approximately one in five of them are likely to die within a year. Further, the best option we currently have to offer those with kidney failure is a kidney transplant, but there are almost 100,000 Americans currently on a waiting list for new kidneys. A kidney transplant saved my father's life; we want to make that same outcome possible for many more Americans, while also looking to the future to develop new, better options.

Today's status quo in kidney care also carries a tremendous financial cost. In 2016, Medicare fee-for-service spent approximately $114 billion to cover people with kidney disease, representing more than one in five dollars spent by the traditional Medicare program.

But there is hope. A system that pays for kidney health, rather than kidney sickness, would produce much better outcomes, often at a lower cost, for millions of Americans. The Trump Administration plans to effect this transformation through a new vision for treating kidney disease—*Advancing American Kidney Health*—laid out in this document.

We have set three particular goals for delivering on this vision, with tangible metrics to measure our success:

1. We need more efforts to prevent, detect, and slow the progression of kidney disease, in part by addressing upstream risk factors like diabetes and hypertension. **We aim to reduce the number of Americans developing end-stage renal disease by 25 percent by 2030.**

1. We need to provide patients who have kidney failure with more options for treatment, from both today's technologies and future technologies such as artificial kidneys, and make it easier for patients to receive care at home or in other flexible ways. **We aim to have 80 percent of new American ESRD patients in 2025 receiving dialysis in the home or receiving a transplant.**

2. We need to deliver more organs for transplants, so we can help more Americans escape the burdens of dialysis altogether. **We aim to double the number of kidneys available for transplant by 2030.**

With the help of many stakeholders, inside and outside of government, HHS has diagnosed the problems with our system, detailed what success looks like, and laid out how to get there. Over the next several years, we will execute on the strategies laid out in the following pages: pioneering new payment models, updating regulations, educating and empowering patients, and supporting new paths for research and development.

This effort will build on the work underway throughout many HHS agencies including ASPR, CDC, CMS, FDA, HRSA, IHS, and NIH, and will engage outside kidney-care stakeholders and innovators in other fields.

By executing on this bold, comprehensive vision, we can achieve our goals, bring kidney care for all Americans into the 21st century, and show that some of the most stubborn, costly problems in American healthcare can be solved.

Alex M. Azar II
Secretary of Health and Human Services

I. EXECUTIVE SUMMARY

Goals for Advancing Kidney Health in America

As part of the Administration's focus on improving person-centered care, the U.S. Department of Health and Human Services (HHS) is announcing its vision for advancing kidney health to revolutionize the way patients with chronic kidney disease and kidney failure are diagnosed, treated, and most importantly, live. The initiatives discussed in this paper are designed to tackle the challenges people living with kidney disease face throughout the stages of kidney disease, while also improving the lives of patients, their caregivers, and family members. The overall goals of these efforts are to:

- **GOAL 1:** Reduce the Risk of Kidney Failure
- **GOAL 2:** Improve Access to and Quality of Person-Centered Treatment Options
- **GOAL 3:** Increase Access to Kidney Transplants

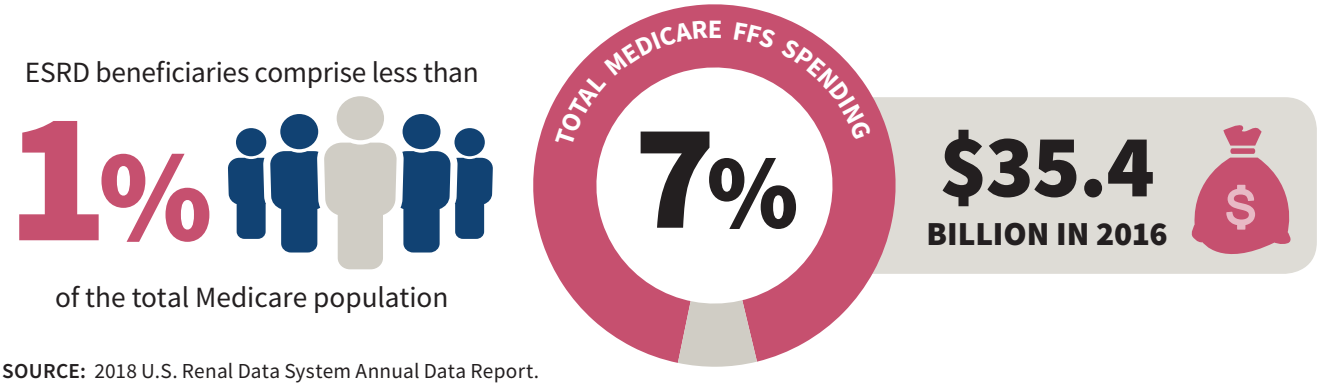
Brief Context on Kidney Disease

Approximately 37 million Americans, or 15 percent of the nation's adults, have kidney disease.[1] Kidney disease reduces the ability of a person's kidneys to filter blood, causing wastes to build up in the body. In 2017, the ninth leading cause of death in the United States was kidney disease.[2]

Major risk factors for kidney disease include uncontrolled diabetes, high blood pressure, and a family history of kidney failure. In some individuals, kidney disease progresses to kidney failure, often referred to as end-stage renal disease (ESRD), which requires dialysis or transplantation to survive.[3] ESRD is a life-threatening illness with a death rate (50 percent mortality in 5 years) worse than most cancers that significantly affects quality of life. Even ESRD that is well managed with dialysis can result in premature death or severe disability, heart disease, bone disease, arthritis, nerve damage, infertility, and malnutrition.[4] Infections, including those related to the dialysis procedure, are frequent causes of hospitalization and death among persons with ESRD. Dialysis treatments also pose a risk of non-infectious complications. Currently, the only treatment alternative that can restore some or most of normal kidney function is transplantation, which requires immunosuppressive therapy (to prevent rejection of the kidney by the recipient's body) and therefore places recipients at risk for infection and malignancy due to immunosuppression.

FIGURE 1

Medicare spending for ESRD beneficiaries



SOURCE: 2018 U.S. Renal Data System Annual Data Report.

Another indicator of the burden of kidney disease is the financial cost of treatment. Most individuals with kidney failure are eligible for Medicare coverage, regardless of age.[5] Many Medicare beneficiaries with kidney failure suffer from poor health status, often resulting from disease complications and multiple co-morbidities that can lead to high rates of hospital admissions and readmissions.[6] Total Medicare spending for beneficiaries with chronic kidney disease (CKD) and ESRD, including spending on comorbidities and other health care services that may be unrelated to ESRD, was over $114 billion in 2016, representing 23 percent of total Medicare fee-for-service (FFS) spending, of which $35.4 billion was spent on beneficiaries living with ESRD.[7] While less than 1 percent of the total Medicare population has ESRD, spending on ESRD beneficiaries accounts for approximately 7 percent of total Medicare FFS spending.[8] **Figure 1** (previous page) shows the proportion of Medicare FFS spending attributable to Medicare beneficiaries living with ESRD.

Over the past 70 years, there has not been the same level of innovation in treatments for people living with kidney failure compared to treatments for other health conditions.[9] To improve quality of life among people living with kidney failure, it is clear that new technological advances and alternatives to dialysis for renal replacement therapy are urgently needed.

Additional information about kidney disease and its risk factors can be found in the Appendix.

Examples of Key Initiatives to Achieve Goals of the Kidney Care Vision

Efforts across HHS to advance kidney disease prevention and care in the United States include scaling programs nationwide to optimize screening for kidney diseases, educating patients on care options with coordinated care networks and other tools, supporting ground-breaking research to inform the next generation of targeted therapies, creating new payment models and financial incentives to encourage utilization of home dialysis and increase access to kidney transplants, encouraging accelerated development of innovative products such as an artificial kidney, and undertaking a variety of efforts to increase the number of kidneys available for transplant from both living and deceased donors.

Goal 1: Reduce the Risk of Kidney Failure

Examples of how HHS is addressing **Goal 1** include the Indian Health Service's (IHS') efforts to adopt a person-centered approach to care to improve outcomes for American Indians and Alaska Natives (AI/ANs) at risk for diabetes complications such as kidney failure. The incidence of diabetes-related ESRD (ESRD-D) among AI/AN populations decreased by over 40 percent between 2000 and 2015, resulting in lower levels of disease burden for patients and lower spending on ESRD care.[10] The Centers for Disease Control and Prevention (CDC) is updating its Hypertension Control Change Package for Clinicians to improve CKD detection and care quality among persons at high risk for CKD progression. CDC is also investing in state and local efforts to develop a public health response to CKD risk factors such as diabetes and heart disease.[11]

Goal 2: Improve Access to and Quality of Person-Centered Treatment Options

HHS' efforts to address **Goal 2** include the National Institutes of Health (NIH) Kidney Precision Medicine Project, which will use kidney biopsies to help redefine kidney disease into new molecular subgroups, paving the way for personalized treatments. The Office of the Assistant Secretary for Preparedness and Response's (ASPR's) programs are working to ensure individuals who need dialysis treatment have ready access to treatment in the aftermath of disaster situations, through the availability of portable dialysis technologies. The U.S. Food and Drug Administration (FDA) has cleared devices for home hemodialysis, and FDA actively supports innovative efforts to improve the quality of current dialysis treatment and to develop new alternatives to dialysis for renal replacement therapy through its Breakthrough programs and participation in KidneyX, the Kidney Innovation Accelerator. The Centers for Medicare & Medicaid Services (CMS) has reviewed potential refinements to the ESRD-Prospective Payment System to facilitate Medicare beneficiaries' access to certain innovative treatment options and, through the Center for Medicare and Medicaid Innovation (Innovation Center), is providing

financial incentives to help clinicians better manage care aligned with beneficiaries' preferences regarding home dialysis and kidney transplantation. CDC is working to translate evidence-based recommendations into practical strategies to improve the quality and safety of care for patients undergoing dialysis. CDC formed the Making Dialysis Safer for Patients Coalition, through which it collaborates with partner organizations and patient representatives to implement core interventions proven to reduce dialysis bloodstream infections.[12]

Goal 3: Increase Access to Kidney Transplants

To advance **Goal 3**, The Office of the Assistant Secretary for Health (OASH) is considering recommendations from the Advisory Committee on Blood and Tissue Safety and Availability regarding updating the U.S. Public Health Service Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation, which may increase available options for individuals who need kidney transplants. The Health Resources and Services Administration (HRSA) is working to provide additional support for individuals who are considering living donation by reducing financial barriers. In addition, new Innovation Center models include financial incentives for health care providers to help Medicare beneficiaries move through the kidney transplantation process.

Given the substantial burden kidney disease places on patients and their caregivers, it is imperative that HHS continues to advance improvements and innovations in kidney disease prevention and care. This paper outlines HHS' goals for improving kidney care, finding alternatives to current dialysis treatment, and increasing access to kidney transplants, and it describes agency initiatives designed to address these goals.

II. GOALS AND OBJECTIVES

Goal 1: Reduce the Risk of Kidney Failure

The number of people with kidney failure has been growing in recent years, afflicting more than 726,000 Americans in 2016.[13] Yet, 90 percent of adults with kidney disease and nearly half in advanced stages of CKD are unaware they have the condition.[14] Associations have been found between diabetes, hypertension, and CKD. For example, roughly 1 out of 5 adults with hypertension, and 1 out of 3 adults with diabetes, may have kidney disease.[15] Moreover, among U.S. adults aged 18 years or older, diabetes and high blood pressure are the primary reported causes of ESRD. Kidney disease usually progresses slowly in most individuals, and blood and urine tests can be used to monitor the progression of the disease. Depending on the person and the stage of the disease, interventions can sometimes slow this progression. Lifestyle and medication treatment for risk factors including diabetes and hypertension are also important factors to address the progression of CKD. Two objectives for HHS' efforts to reduce the risk of kidney failure are:

OBJECTIVE 1. Advance public health surveillance capabilities and research to improve identification of populations at risk and those in early stages of kidney disease

OBJECTIVE 2. Encourage adoption of evidence-based interventions to delay or stop progression to kidney failure

Goal 2: Improve Access to and Quality of Person-Centered Treatment Options

More than 100,000 Americans begin dialysis each year.[16] Approximately one in five will die within one year, and half within five years.[17] Those with kidney failure typically must undergo dialysis (often at a dialysis center) at least three times per week for three to four hours per session, or through daily home peritoneal dialysis or home hemodialysis, and maintain an extremely restrictive diet. Infections are a serious adverse outcome related to dialysis. Each year, approximately 29,500 bloodstream infections occur in hemodialysis outpatients, and as many as one in two peritoneal dialysis patients develops peritonitis.[18] These types of infections can lead to sepsis and can compromise the patient's treatment options, including ability to receive a kidney transplant. Eighty-seven percent of Americans with kidney failure start treatment with hemodialysis. Of those on hemodialysis, the majority (98 percent) receive in-center hemodialysis and only 2 percent use home dialysis.[19] Up to 85 percent of patients are eligible for home dialysis,[20] and in one study, 25 to 40 percent of patients reported that they would select home dialysis if given the opportunity.[21] Higher survival has been reported among individuals in the U.S. receiving home dialysis when compared to individuals receiving in-center hemodialysis treatment.[22,23,24,25] Supporting person-centered treatment options means increasing the number of treatment modalities available for individuals living with kidney failure, including home modalities, transplantation, and other alternatives to in-center hemodialysis still under development.

Rapidly emerging technologies offer hope that new treatment options can improve patient outcomes and lower the cost of care. HHS therefore supports efforts to develop and bring to market novel treatments such as wearable, implantable, and/or biohybrid artificial kidneys as well as other biological and drug-based alternatives to current dialysis treatments.

HHS aims to reduce morbidity and mortality among people living with advanced kidney disease and increase the proportion of those with kidney failure receiving optimal treatment aligned with their individual needs and preferences, based on informed patient choice.

OBJECTIVE 1. Improve care coordination and patient education for people living with kidney disease

and their caregivers, enabling more person-centric transitions to safe and effective treatments for kidney failure

OBJECTIVE 2. Introduce new value-based kidney disease payment models that align health care provider incentives with patient preferences and improve quality of life

OBJECTIVE 3. Catalyze the development of innovative therapies including wearable or implantable artificial kidneys with funding from government, philanthropic and private entities through KidneyX, and coordinating regulatory and payment policies to incentivize innovative product development

Goal 3: Increase Access to Kidney Transplants

Nearly 95,000 patients are on the waiting list to receive a kidney transplant.[26] Kidney transplantation is generally associated with better outcomes compared to dialysis,[27] but only 30 percent of individuals who have experienced kidney failure are living with a functioning kidney transplant.[28] Many Americans never have the chance to receive a kidney transplant due to shortages of available kidneys. Objectives to improve access to kidney transplants are:

OBJECTIVE 1. Increase the utilization of available organs from deceased donors by increasing organ recovery and reducing the organ discard rate

OBJECTIVE 2. Increase the number of living donors by removing disincentives to donation and ensuring appropriate financial support

III. HHS INITIATIVES

By coordinating across HHS and partnering with people living with kidney disease, their caregivers, organ donors, health care providers, and other stakeholders, HHS will enhance the ability of people with kidney disease to improve their day-to-day well-being and quality of life. The specific activities and initiatives HHS is undertaking to address the goals of this vision are described below.

Goal 1: Reduce the Risk of Kidney Failure

OBJECTIVE 1. Advance public health surveillance capabilities and research to improve identification of populations at risk and those in early stages of kidney disease

In recent years, HHS has increasingly focused on developing better capabilities to identify kidney disease early among high-risk patient populations and to support new research to uncover clinically-useful biomarkers that allow better prediction of the course of CKD and identify patients who could be helped by particular therapies, or who should not be given specific drugs.

- CDC created and manages the national CKD Surveillance System, the only interactive and most comprehensive collection of CKD-related data in the United States, helpful for monitoring progress toward achieving national Healthy People[29] objectives. Through its investments in the CKD Surveillance System and innovative epidemiological research, CDC continues to strengthen understanding of kidney disease prevalence, risk factors, and health consequences.

  Find more information on the CKD Surveillance System at: https://nccd.cdc.gov/ckd/default.aspx

- The NIH-funded Chronic Renal Insufficiency Cohort (CRIC) Study is examining risk factors for progression of CKD and cardiovascular disease among patients with established CKD. Additionally, the study is developing predictive models to identify high-risk subgroups, informing future treatment trials, and examining the effect of ongoing clinical management on outcomes. For example, CRIC researchers defined mortality risk subgroups in patients with CKD based on whether levels of the hormone FGF23 in the blood change over time. FGF23 levels in the blood were stable over time in most patients with CKD, but distinct subpopulations with rising FGF23 levels over time were linked to higher risk of death.

  Find more information about CRIC at: https://www.niddk.nih.gov/about-niddk/research-areas/kidney-disease/effects-chronic-kidney-disease-adults-study-cric

- Hypertension is a leading cause of kidney disease and is the second leading cause of ESRD, accounting for 26 percent of ESRD cases.[30] Heart disease can lead to and exacerbate CKD. Hypertension can lead to kidney disease, which in turn can lead to worsened hypertension. It is a dangerous cycle that, if not stopped, can lead to a heart attack, stroke, heart failure, or kidney failure. The landmark NIH-funded Systolic Blood Pressure Intervention Trial (SPRINT) study showed that lower blood pressure targets decrease the risk of death in high-risk patients with cardiovascular disease (CVD) and CKD.[31]

  Find more information on the SPRINT trial at: https://www.nhlbi.nih.gov/science/systolic-blood-pressure-intervention-trial-sprint-study

- Diabetes is another major risk factor for kidney disease. Although testing for kidney disease is recommended for people with diabetes, almost 60 percent of Medicare beneficiaries with a diabetes diagnosis are not screened for kidney-damage (albuminuria), and approximately 93

percent of those with hypertension only (a risk factor for kidney disease) are not being tested for this disease.[32] CDC is collaborating with NIH on the Longitudinal Study of Markers of Kidney Disease, and with the National Centers for Health Statistics to investigate and validate new markers for early kidney disease and identify new treatment options for diabetes-related kidney disease.

Find more information on the Longitudinal Study of Markers of Kidney Disease at: https://www.cdc.gov/kidneydisease/about-the-ckd-initiative.html

- The NIH-funded Kidney Precision Medicine Project seeks to uncover the biological root causes of kidney disease through high throughput molecular, genetic, and cellular techniques from research kidney biopsies. This will lead to new biomarkers, disease subgroups, molecular targets, and most importantly the development of new drugs to treat and possibly forestall kidney disease. Recruitment of patients for renal biopsy will start in Summer 2019.

  Find more information on the NIH-funded Kidney Precision Medicine Project at: https://www.niddk.nih.gov/research-funding/research-programs/kidney-precision-medicine-project-kpmp

- The NIH-funded Preventing Early Renal Loss in Diabetes (PERL) Study is a randomized, double-blind trial to test whether the medication allopurinol can slow the progression of kidney disease in people with type 1 diabetes and early diabetic kidney disease. Results from this study are expected to be available at the end of 2019.

  Find more information about PERL at: http://www.perl-study.org/

- Identification of patients with CKD for population health management, research and surveillance using data available in electronic health records (EHRs) is challenged by poor recognition and resulting under-diagnosis of the disease, particularly in its early stages. As a result, diagnosis codes cannot be used to accurately identify patients with CKD from the EHR. The NIH convened researchers, clinicians, and informaticists to develop and validate an electronic phenotype for CKD. An electronic phenotype is a defined set of data elements and rules that help identify groups of patients using a computerized query. The resulting NIH CKD phenotype uses laboratory measures commonly available in the EHR to identify patients likely to have CKD.

  Find more information on the electronic phenotype at: https://www.niddk.nih.gov/health-information/communication-programs/nkdep/working-groups/health-information-technology

Looking forward, HHS will further intensify its efforts to make kidney disease detection more accessible, including:

- As part of its CKD Initiative, CDC will continue to collaborate with other government agencies, universities, and national organizations to support a robust portfolio of epidemiological studies, including cost-effectiveness studies of the long-term efficacy of public health interventions for CKD, and the Systematic Review on Barriers to CKD Screening Project, which identifies and synthesizes current evidence on kidney disease screening and screening rates in the United States. These activities support efforts to raise awareness of CKD and its complications, promote prevention and control of risk factors for CKD, and improve early diagnosis and treatment among people living with kidney disease.

- The CKD Epidemiology in the Military Health System (MHS), a collaborative effort between the CDC and the Uniformed Services University of the Health Sciences, aims to describe the epidemiology of kidney disease among the active duty and non-active duty populations and assess their risk factors for developing kidney disease. Specifically, this project examines 1)

the effects of maintaining good physical and psychological health on risk of CKD, and 2) the long-term effects of non-sedentary lifestyle on risk of chronic conditions, including CKD. Because the project includes non-active duty persons, i.e., family members of active duty individuals and retirees from active duty, the findings will have implications beyond military personnel.

Find more information on CKD Epidemiology in the MHS at: https://www.cdc.gov/kidneydisease/about-the-ckd-initiative.html

OBJECTIVE 2. Encourage adoption of evidence-based interventions to delay or stop progression to kidney failure

In the United States, 30 million individuals have diabetes, 84 million adults have prediabetes (are at high risk for type 2 diabetes), and 75 million adults have high blood pressure.[33,34] HHS has supported the development of several evidence-based national models for better managing kidney disease and risk factors for its progression. These models aim to reduce the national rate of kidney failure.

- American Indian/Alaska Native (AI/AN) populations have the highest prevalence of diabetes of any U.S. racial/ethnic group.[35] The Special Diabetes Program for Indians (SDPI) represents an important part of this broader approach to providing team-based care and care management. The program has included a number of different components over time such as community directed grants that focus on locally developed solutions to improve diabetes prevention and care, demonstrations and initiatives such as the SDPI Diabetes Prevention Initiative, which built on the findings of an earlier clinical trial at NIH, the diabetes audit which collects data on diabetic care provided by grantees to track outcomes, dissemination of diabetes treatment algorithms and standards of care, and ongoing educational programs such as webinars, periodic meetings and conferences, and consultations with health professionals that have expertise in diabetes. Since its implementation, the incidence of diabetes-related kidney failure among AI/AN populations decreased by over 40 percent between 2000 and 2015, resulting in lower spending for programs that cover the costs of AI/AN ESRD care.[36] The SDPI and related efforts have also contributed to improvements in other diabetes-related outcomes, including childhood obesity trends,[37] hospitalizations for uncontrolled diabetes,[38] and diabetic retinopathy.[39]

  Find more information on the SDPI at: https://www.ihs.gov/sdpi

- The CDC's National Diabetes Prevention Program (National DPP) is a partnership of public and private organizations working together to build a nationwide delivery system for a 12-month lifestyle change program proven to prevent or delay onset of diabetes.[40] Congress specifically authorized the National DPP in 2010 because of previous research—including the NIH-funded Diabetes Prevention Program (DPP) and the DPP Outcomes Study—that demonstrated the potential of the CDC-recognized lifestyle change program to prevent or delay the onset of type 2 diabetes. The National DPP is founded on four key pillars: 1) a trained workforce of lifestyle coaches; 2) national quality standards supported by the CDC Diabetes Prevention Recognition Program; 3) a network of program delivery organizations sustained through health benefit coverage; and 4) participant engagement and referral. CDC also supports states' efforts to make the NDPP and other diabetes management interventions available to high-burden populations and communities. These efforts include strengthening community-clinical linkages to screen, test, and refer people with prediabetes to CDC-recognized organizations offering the National DPP lifestyle change program; providing support to enroll and retain participants in the program; and supporting pharmacist-patient care processes that help people with diabetes better manage their medications.

  Find more information on the CDC's National DPP at: http://www.cdc.gov/diabetes/prevention

- The NIH National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) promotes an integrated health system model of team-based clinical care based on the pragmatic experience of the IHS' Kidney Disease Program. NIDDK has developed new clinical tools and educational programs that improve the care of people with kidney disease in primary care settings. NIDDK works in collaboration with government, nonprofit, and health care organizations to raise awareness about screening for individuals at risk for kidney disease; educate individuals about how to manage their disease; provide information, training, and tools that help health care providers; and support important health systems changes.

  Find more information on the NIH NIDDK at: http://www.niddk.nih.gov

- The Innovation Center's Medicare Diabetes Prevention Program (MDPP) expanded model is a structured behavior change intervention that aims to prevent the onset of type 2 diabetes among Medicare beneficiaries with an indication of prediabetes. This model is an expansion of the Diabetes Prevention Program model test under the authority of section 1115A of the Social Security Act.

  Find more information on the MDPP at: https://innovation.cms.gov/initiatives/medicare-diabetes-prevention-program/

Looking forward, HHS will continue to support these programs and look for known and innovative ways to scale their adoption, in partnership with communities.

- In late 2017, CDC announced a new five-year cooperative agreement to scale up the National DPP in underserved areas and populations including Medicare beneficiaries, men, African Americans, Asian Americans, Hispanics, American Indians, Alaska Natives, Pacific Islanders, and noninstitutionalized people with visual impairments or physical disabilities.

- In late 2019, CDC will update its Hypertension Control Change Package for Clinicians (HCCP) to include tools and resources to support CKD screening and early diagnosis among persons with hypertension. This effort, part of CDC's broader Million Hearts® initiative,[41] will better support clinician efforts to end the pernicious cycle between CKD and hypertension.

  Find more information on the Hypertension Control Change Package for Clinicians at: https://millionhearts.hhs.gov/files/HTN_Change_Package.pdf

  Find more information on the Million Hearts initiative at: https://millionhearts.hhs.gov

- CDC has begun a collaboration with local health departments to develop innovative approaches to increase the reach and effectiveness of public health strategies for diabetes, heart disease, and stroke, including the use of clinical decision support tools within EHRs to promote early detection of kidney disease.

- HHS supports continued funding for the SDPI, as reflected in the President's Fiscal Year (FY) 2020 budget that proposes reauthorizing the SDPI at $150 million per year through FY 2021.

- NIH has recently funded the Improving Chronic Disease Management with Pieces (ICD-Pieces) study, testing whether computer-generated reminders working in tandem with clinicians can reduce hospitalizations in patients with coexisting CKD, diabetes, and hypertension, and improve use of innovative and proven interventions.

  Find more information on the ICD-Pieces study at: http://icd-pieces.com/

- ASPR is launching a new initiative called ExaHealth, to develop collaborative tools to accelerate discovery of new therapies. The ExaHealth initiative will be one of many partnerships with the Department of Energy to develop artificial intelligence tools and new methods for studying

complex biological functions in a concerted way, in order to develop new and more effective medical interventions. These interventions will focus on acute onset of disease during pandemics and man-made disasters, as well as and chronic diseases, whose onset can occur throughout a person's lifetime, including patients at risk for progression towards CKD and ESRD.

Goal 2: Improve Access to and Quality of Person-Centered Treatment Options

OBJECTIVE 1. Improve care coordination and patient education for people living with kidney disease and their caregivers, enabling more person-centric transitions to safe and effective treatments for kidney failure

HHS supports the data and knowledge infrastructure necessary to inform more person-centric transitions to safe and effective care for kidney failure.

- For example, the NIH supports production of the annual U.S. Renal Data System (USRDS) Atlas, which provides up-to-date statistics on incidence, morbidity, and mortality for patients transitioning through kidney failure. These data have been used to inform clinical practice for kidney disease patients and development of targeted interventions for specific populations. In 2018, USRDS published a special transitions section that describes the transition from CKD to ESRD in greater detail using linked data from the Veterans Health system. Key summary findings include the finding that heart failure and acute kidney injury (AKI) are the most common cause of hospitalizations in the six months before the start of hemodialysis, and infectious complications (vascular access infection, septicemia) are the most common causes of hospitalizations after the start of hemodialysis.[42] Future efforts of the USRDS include a detailed investigation of causes of early mortality among patients who start hemodialysis, as well as expanded exploration of data sets other than Medicare data to support additional analyses related to kidney disease and kidney care.

  Find more information on the USRDS at: https://www.usrds.org/

- Through its Making Dialysis Safer for Patients Coalition, CDC coordinates a wide array of organizations and individuals to promote implementation of evidence-based interventions to prevent dialysis bloodstream infections. Best practices and strategies for implementation of these interventions include provider training and feedback, patient engagement and empowerment, and use of audit tools, checklists, and other resources. These interventions have been shown to significantly reduce dialysis-related bloodstream infections (by 30 to 50 percent) and associated outcomes.[43]

  Find more information on the Making Dialysis Safer for Patients Coalition at: https://www.cdc.gov/dialysis/coalition/index.html

- Through the National Healthcare Safety Network (NHSN), CDC tracks bloodstream infections – including those caused by antibiotic resistant organisms, vascular access infections, and other outcomes among hemodialysis patients treated in clinics, and gives clinics immediate access to the data reported. CDC produces standardized infection ratios that are posted publicly on Medicare's Dialysis Facility Compare website. National aggregate rates of infection are used for benchmarking and in quality improvement initiatives.

  Find more information on NHSN at: https://www.cdc.gov/nhsn/dialysis/index.html

- ASPR and CMS have formed a collaboration to improve access to dialysis care during every disaster and have launched the emPOWER program. emPOWER provides data and mapping tools

to help communities protect the health of more than 4.1 million Medicare beneficiaries who rely on electricity-dependent medical equipment and healthcare services, including nearly 400,000 dialysis patients. In the wakes of Hurricanes Irma and Maria, the emPOWER Program helped ASPR, CMS, and territorial public health officials identify healthcare and resource gaps for dialysis patients and immediately engage with End-Stage Renal Networks[44] and dialysis providers to ensure continuity of their life-maintaining healthcare services.

Find more information on the emPOWER Program at: https://empowermap.hhs.gov/Fact Sheet_ emPOWER_FINALv5_508.pdf

Looking forward, HHS will continue to strengthen patient voices in policy development, address the needs of vulnerable populations with portable dialysis technologies, and use payment incentives to support patients making choices about their kidney care modalities.

- The Innovation Center has announced four new optional kidney care models: Kidney Care First (KCF) for nephrology practices and Comprehensive Kidney Care Contracting (CKCC) which offers three distinct payment options. These models will build on the existing Comprehensive ESRD Care (CEC) Model, which began in 2015 and will end in 2020, and incorporate design elements from the recently announced Direct Contracting and Primary Care First models. One of the key lessons learned from the CEC Model was the need to increase coordinated care for beneficiaries with late-stage chronic kidney disease and beneficiaries transitioning onto dialysis. These models will provide strong incentives to better manage and coordinate care for beneficiaries with kidney disease. Model participants will be incentivized through utilization measures and cost incentives to avoid unplanned dialysis starts in the hospital, in an effort to avoid the cost and high mortality that occurs when beneficiaries abruptly start dialysis. Additionally, CMS will also establish measures to demonstrate whether kidney disease is being delayed by the Model's interventions and develop a quality measure to incentivize better managing beneficiaries with late-stage CKD to avoid the more expensive and burdensome dialysis process.

  Find more information on the CKC Model at: https://innovation.cms.gov/initiatives/voluntary-kidney-models/

- The FDA is developing a new survey to gain insight into patient preferences for new kidney failure treatments. Information collected will be used by FDA and its partners including device developers, patients, providers, payers, and other researchers to inform the development of new treatments, including alternatives to dialysis. The patient preferences survey will be an important example of how patient engagement can contribute to building infrastructure for expanded patient-centered outcomes research and how patient input can be used in FDA's review processes. Results and methods will also be shared with those involved in data collection efforts for other disease conditions to similarly inform the development of new treatments.

- NIH is developing and testing an interoperable open-source electronic care plan tool for people with multiple chronic conditions, including diabetes and kidney disease, to better coordinate their care. In the context of kidney care, this tool will enable patients, physicians, nurses, pharmacists, dieticians, and other health professionals, as well as community health workers, to transfer critical, person-centered kidney care information across multiple settings of care with diverse electronic health record systems using uniform data standards, supporting better coordination of kidney care and research.

- Dialysis facilities are currently required to inform patients of their care options. To strengthen patient education and support for patients' selection of treatment modalities, CMS is considering options for new ways to improve quality of life for dialysis patients while also reducing Medicare costs and minimizing regulatory burden.

- ASPR is working to ensure people living with kidney failure have access to readily available portable dialysis technologies and access to treatments in any situation. Currently, treatment options are limited following disaster events, and individuals on dialysis must be evacuated and provided temporary housing to continue treatments. Beginning in 2019, ASPR will procure and test portable dialysis units that can provide support to people living with kidney failure in low-resource settings or within their homes, so that they can have access to dialysis with minimal power and from publicly-available water sources, allowing them to return home sooner when a disaster occurs.

- CMS supports person-centered optimal starts for individuals living with ESRD. An "optimal start" reflects adequate patient preparation resulting in pre-emptive transplant, initiation of renal replacement with peritoneal dialysis or initiation of hemodialysis with a functioning permanent vascular access. The Innovation Center is announcing the ESRD Treatment Choices (ETC) Model, which will include financial incentives for ESRD facilities and Managing Clinicians selected to participate in the model to better align with beneficiary choice on modalities such as home dialysis or kidney transplants.

  Find more information on the ETC Model at: https://innovation.cms.gov/initiatives/esrd-treatment-choices-model/

OBJECTIVE 2. Introduce new value-based kidney disease payment models that align health care provider incentives with patient preferences and improve quality of life

As part of HHS' commitment to transition to payment and delivery models that focus on patient outcomes, preferences, and lowering costs, CMS is introducing a new payment model and has proposed another payment model to encourage more coordinated care to delay kidney failure and ensure that people living with kidney failure have access to the best available care options. Additionally, Medicare will continue to support payment rule changes for the ESRD PPS that focus on patient care, support innovation, reduce burdens, and lower costs.

- The Innovation Center's ETC Model includes financial incentives for ESRD facilities and Managing Clinicians selected to participate in the model to better align with patient choice regarding home dialysis and kidney transplantation. The ETC Model will test the effectiveness of outcomes-based payment adjustments to health care providers to increase utilization of home dialysis and kidney/kidney-pancreas transplants. The Home Dialysis Payment Adjustment (HDPA) would be in effect for the first three years of the Model, and would increase payment for home dialysis and home dialysis-related services. The Performance Payment Adjustment (PPA) would decrease or increase payment for dialysis and dialysis-related services based on a participating ESRD facility or Managing Clinician's rate of home dialysis and transplants. The goal of the Model is to increase the transplant and home dialysis rate across the country.

- The Innovation Center's optional kidney care models (KCF and CKCC) include incentives for health care providers to better manage the care for beneficiaries with kidney disease including incentives for pre-emptive transplants, improving beneficiaries' transition to dialysis, and ensuring dialysis initiation is appropriately timed. The Model also includes incentives to manage the total cost and quality of care for beneficiaries with kidney disease and kidney failure, and strong financial incentives to move beneficiaries through the transplant process. Together with the new ETC Model, the optional kidney care models demonstrate CMS' commitment to supporting high quality, coordinated care for people living with ESRD.

- CMS is considering ways to encourage ESRD facilities to furnish new and innovative drugs and biological products for the treatment of ESRD. The Transitional Drug Add-on Payment Adjustment (TDAPA) is an add-on payment adjustment under the ESRD PPS intended to facilitate this goal for

Medicare beneficiaries. This is done by encouraging ESRD facilities to furnish certain qualifying new renal dialysis drugs and biological products by allowing additional payment for them while utilization data is collected.

- CMS recognizes that continual refinement of the ESRD PPS is necessary to benefit people living with ESRD, and is therefore working with an analytical contractor to perform payment analysis and develop potential refinements to the ESRD PPS. CMS plans to ask for stakeholder input on data collection.

- Based on comments received during and after the CY 2019 ESRD PPS rulemaking, CMS is considering issues related to payment for new and innovative supplies and equipment that are renal dialysis services furnished by ESRD facilities for ESRD beneficiaries.

OBJECTIVE 3. Catalyze the development of innovative therapies including wearable or implantable artificial kidneys with funding from government, philanthropic and private entities through KidneyX, and coordinating regulatory and payment policies to incentivize innovative product development

Ultimately, the best way to improve care for people living with kidney failure is to support the development of novel therapies extending beyond the choices available today. Investing in foundational research at the NIH, catalyzing rapid product development through public-private partnerships, and creating clear and forward-looking guidelines for marketing approval for emerging technologies like organ preservation may unleash innovation for years to come.

- KidneyX was officially launched in 2018 as a public-private partnership with the American Society of Nephrology to support the development of innovative therapies and diagnostics. KidneyX is designed to leverage rapidly emerging technologies in areas such as regenerative medicine, nanotechnology, and advanced materials to support early-stage development and lower the risk of commercialization. KidneyX's first prize, Redesign Dialysis, offers $2.6M for kidney failure treatments beyond currently available options of dialysis and transplantation. Included among the 15 winning teams announced in April 2019, were companies developing advanced nanofiltration for toxin removal, miniaturized wearable dialyzers, real-time infection and clotting sensors, cell-based implantable dialyzers, and regenerative kidneys. The second phase currently underway will seek testable prototypes and announce winners in April 2020.

  Find more information on KidneyX at: https://www.kidneyx.org

- In June 2019, the HHS Chief Technology Officer signed an agreement with the heads of CMS, NIH, FDA, and CDC to work closely together on KidneyX to ensure that unnecessary barriers to patient access for innovative technologies are addressed. In July 2019, KidneyX is also launching a patient innovator prize focused on identifying and scaling new products and practices that patients and caregivers have developed for their own care, recognizing that innovation often happens at the frontlines of health. In 2020, KidneyX plans to launch Redesign Dialysis Phase III to advance new products into human clinical trials, another prize focused on helping dialysis patients manage fluids, a leading cause of ESRD hospitalizations, and a prize focused on spurring development of therapies to slow progression of kidney disease.

- HHS and the Department of Veterans Affairs (VA) are exploring a partnership to streamline and expedite clinical trials for kidney care-related treatments using the VA health system, similar to the National Cancer Institute (NCI) and VA Interagency Group to Accelerate Trials Enrollment (NAVIGATE), a partnership between the VA and the NCI to facilitate enrollment of veterans with cancer into NCI-funded clinical trials.

- In May 2019, FDA issued final guidance that industry should consider when utilizing animal studies to evaluate organ preservation devices. This guidance will help support the development of next-generation organ preservation devices and systems, potentially capable of increasing the supply of transplantable kidneys by salvaging and maintaining more kidneys. In addition to recommendations that could be considered relevant for most animal studies such as developing animal study protocols with consideration of the applicability of anatomical, physiological, and immunological factors for humans, studies should include a control group as a comparator. Specifically, for kidney preservation devices, animal studies should consider three phases of the organ for transplantation: procurement, preservation, and reperfusion. Following these recommendations will speed the review of kidney preservation devices, as well as potentially improving the quality and functionality of these devices.

  Find the FDA's final guidance at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/utilizing-animal-studies-evaluate-organ-preservation-devices

Goal 3: Increase Access to Kidney Transplants

OBJECTIVE 1. Increase the utilization of available organs from deceased donors by increasing organ recovery and reducing the organ discard rate

From 2007 through 2017, the annual rate of kidneys procured but not transplanted has ranged between 18-20 percent. In 2017, the discard rate of 18.9 percent reflected 3,534 kidneys that were procured but not transplanted into waiting patients.[45] Some donor kidneys are not transplanted due to medically justifiable reasons; however, it is estimated that thousands of discarded kidneys could provide benefit to people on dialysis.[46] Education about the appropriate clinical use of kidneys would help maximize the limited supply of donated organs used.[47,48] Addressing the availability and utilization of kidneys is one of the ways HHS can help people living with ESRD through transplantation.

- HRSA supported a Collaborative Innovation and Improvement Network (COIIN) pilot project through the Organ Procurement and Transplantation Network (OPTN) with a limited number of participating kidney transplant programs. The goal was to increase transplantation and reduce the number of discarded kidneys, with a particular focus on increasing utilization of kidneys deemed to be moderate-to higher-risk due to their clinical characteristics. In addition to supporting education of transplant program staff, patients, and referring physicians on the effective use of these organs, the COIIN pilot also modified OPTN performance monitoring criteria to reduce the risk-avoidance behaviors associated with the current monitoring system. Initial results suggest that the COIIN pilot has resulted in increased utilization of kidneys among the first cohort of participating transplant programs. It is possible that a recent decline in the discard rate of moderate-risk kidneys may in part be related to the COIIN pilot.

  Find more information on the HRSA COIIN at: https://optn.transplant.hrsa.gov/resources/coiin/

- The OPTN implemented a policy change in June 2018 to expedite the process of allocating organs and improve the efficiency of organ placement. This change reduces the amount of time a transplant program has to accept or refuse an organ offer, as well as reduces bottlenecks in the system by limiting the number of organ offers a program can accept for any candidate at the same time.

- CMS added a transplant waitlist measure to the ESRD Quality Incentive Program (QIP) for dialysis facilities via rulemaking in 2018 as a measure of dialysis center performance. The goal of the ESRD QIP is to promote high-quality services in ESRD facilities treating patients with ESRD. Under this value-based purchasing program, CMS pays for ESRD treatment by linking a portion of payment directly to dialysis facilities' performance on quality of care measures. A list of CMS quality measures for ESRD care is included in the Appendix.

Looking forward, HHS plans to take a number of actions directly aimed at increasing the utilization and availability of organs.

- HHS is updating the PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation. The goal of the existing 2013 Guideline was to reduce risk of unintended HIV, HBV, and HCV transmission, while preserving availability of high quality organs: Since 2013, however, shifts in the composition of the donor pool, as well as advances in testing and treatment technologies, have created opportunities to revise the Guideline. The current initiative will re-evaluate and, where warranted, revise elements of the Guideline based on current risks to patients and improvements in technology. HHS is also considering the April 2019 recommendations of the Advisory Committee on Blood and Tissue Safety and Availability concerning revising the Guideline. The revised Guideline is intended to strengthen the overall process for assessing, communicating, and managing donor risk for HIV, HBV, and HCV.

  Find the current PHS Guideline at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3675207/pdf/phr128000247.pdf

- HRSA has funded the OPTN to expand the COIIN pilot project in 2020, allowing more kidney transplant programs to participate in this OPTN quality improvement activity focused on changing program waitlist management and organ acceptance practices.[49]

- The Innovation Center's ETC Model includes a learning collaborative operated by the Center for Clinical Standards and Quality (CCSQ), designed in collaboration with HRSA and informed by the HRSA OPTN COIIN, to reduce the disparity in performance among Organ Procurement Organizations (OPOs) and transplant centers with the goal of increasing recovery of kidneys by OPOs and utilization of kidneys by transplant centers. This quality improvement learning component will bring HRSA, CMS, transplant centers, OPOs, and the nation's largest donor hospitals together to generate increased quality and cost-savings to Medicare through the use of systematic quality and process improvement. Additionally, this activity will directly engage patients and families to motivate, activate and empower them to drive the requirement/demand for utilization of viable kidneys.

- HHS is organizing a federal workshop to discuss considerations related to the use of Hepatitis C virus positive (HCV+) donor organs in recipients who do not have HCV. Due to the recent increase in the number of deaths from the opioid epidemic, more HCV+ potential organs are available. HCV is now considered to be largely curable with the advent of direct acting anti-viral (DAA) therapy. Ten clinical trials are in process or have been completed to study whether intentional use of HCV+ donor organs in HCV uninfected recipients is safe and effective when recipients are proactively treated with DAA agents. The planned federal workshop is intended to help facilitate a proactive and coordinated approach to developments in this area of study, specifically with regards to potential changes in the standard of clinical care in transplantation.

- NIH research led to the seminal discovery of the APOL1 gene, which explains why kidney disease progresses faster among African Americans compared to Caucasians. Building on the discovery of the APOL1 gene in African Americans, NIH founded the APOLLO initiative, which will produce information about the best use of donor kidneys with APOL1 gene variants and also improve donor-recipient matching to decrease the rate of organ discard. OPOs nationwide are participating in this study. Recruitment began in 2019 and will continue at least through 2021. More precise quantification of risks of poor outcomes related to donor/recipient genetic architecture will enhance the efficacy of the allocation of precious donor kidneys. Study results are anticipated in 2023.

  Find out more information on the APOLLO initiative at: https://theapollonetwork.org/info.cfm

- HRSA, through the OPTN, is developing a new model to test accelerated placement of certain kidneys that are at high risk for discard. Following recommendations from the National Kidney Foundation Consensus Conference,[50] the OPTN Organ Center will develop and test a proof of concept for expediting allocation of these organs with safety monitoring. The OPTN will evaluate the concept for safety and improvements in allocation efficiency.

- HHS is analyzing and improving transplantation metrics with a focus on increasing organ utilization while maintaining good outcomes.

- HRSA, through the OPTN, convened an Ad Hoc System Performance Committee, which among other issues, has discussed new potential performance metrics that monitor patient safety while encouraging innovative practice.

- Per the 2019 OMB regulatory agenda, CMS is reviewing the OPO conditions for coverage and will be proposing changes to the standards used to evaluate OPOs to ensure proper data collection on the availability of transplantable organs and transplants.

- CMS has begun to develop and test new dialysis facility transplant referral measures, which, if approved, could be added to Quality Incentive Program (QIP) through rulemaking in the future and then via the Consolidated Renal Operations in a Web-enabled Network (CROWNWeb) system and ultimately, Dialysis Facility Compare.[51]

OBJECTIVE 2. Increase the number of living donors by removing disincentives to donation and ensuring appropriate financial support

Living donors account for 30 percent of all kidney transplants in the U.S. However, many financial and risk-based disincentives to donation persist, which may serve as barriers for individuals who would otherwise be willing to donate a kidney.

- To further support living donors, HRSA is planning to expand the Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation program by increasing the eligibility income threshold. HRSA is implementing a pilot to expand the qualifying expenses to include coverage for lost wages and family expenses. The expansion of the current reimbursement program will reduce financial barriers to organ donation and support the goal of increasing living donor transplants.

  Find more information on the Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation program at: https://grants.hrsa.gov/2010/Web2External/Interface/Common/EHBDisplayAttachment.aspx?dm_rtc=16&dm_attid=49472bf1-7438-42ff-b406-d597fcf3b498

- In FY 2019, HRSA awarded a demonstration cooperative agreement to provide for reimbursement of up to $5,000 in lost wages related to donor evaluation and surgical procedures regardless of the donor's income. Findings from this three-year demonstration project will inform whether expansion of the Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation program has a positive effect on kidney donation.

TECHNICAL APPENDIX

Background Information on Kidney Disease

Prevalence of Chronic Kidney Disease (CKD) and End-Stage Renal Disease (ESRD)

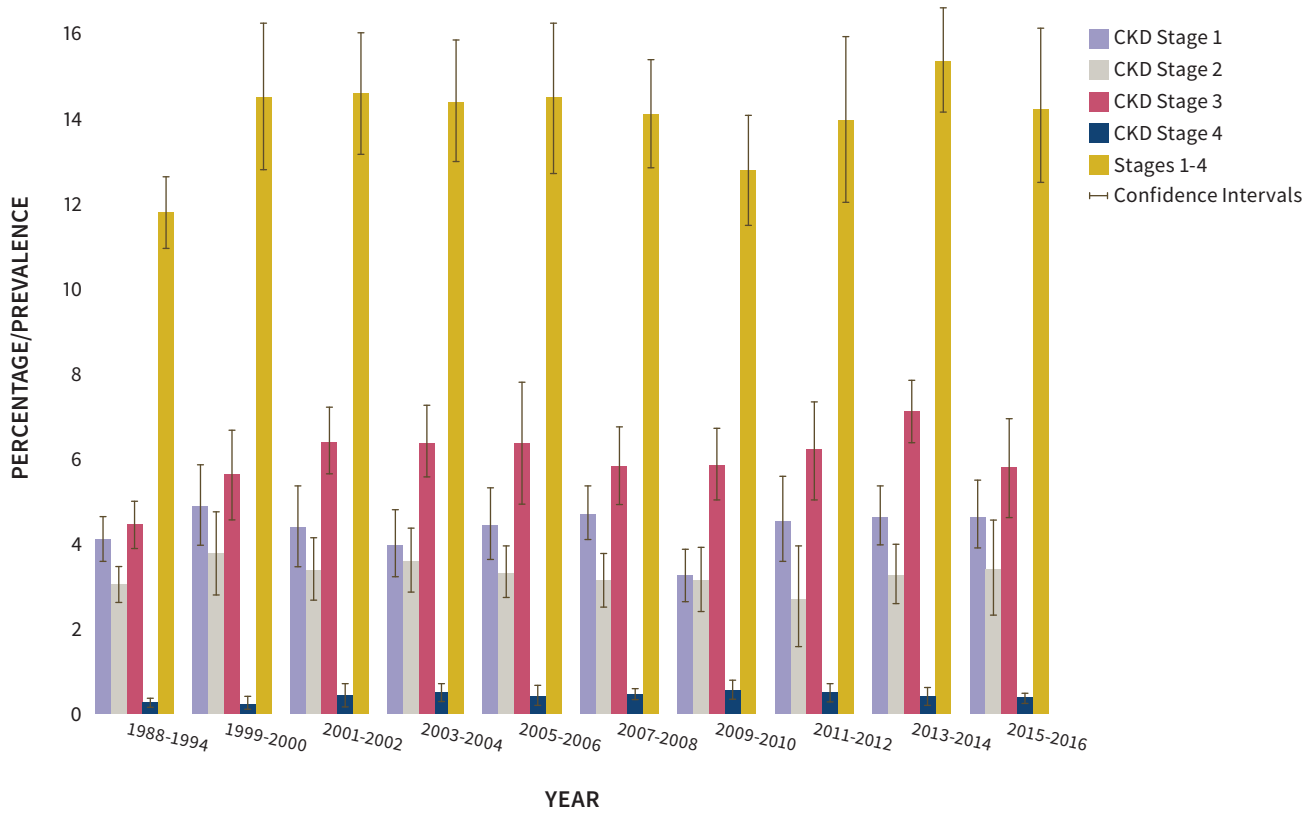
Kidney disease occurs when kidneys are damaged and become unable to filter blood optimally, causing wastes to build up in the body. The condition is clinically categorized into five stages as the disease progresses. The last stage of the disease occurs when the kidneys stop working altogether, which is often referred to as ESRD. Individuals in this stage of the disease require ongoing dialysis, if a transplant is not available, in order to filter wastes out of the body.

Figure 2 shows the prevalence of CKD in the U.S. population for stages 1 through 4 of the disease.[52]

Figure 3 shows the disproportionate prevalence of the disease among older and minority individuals.

FIGURE 2

Prevalence of CKD by Stage, 1988-2016



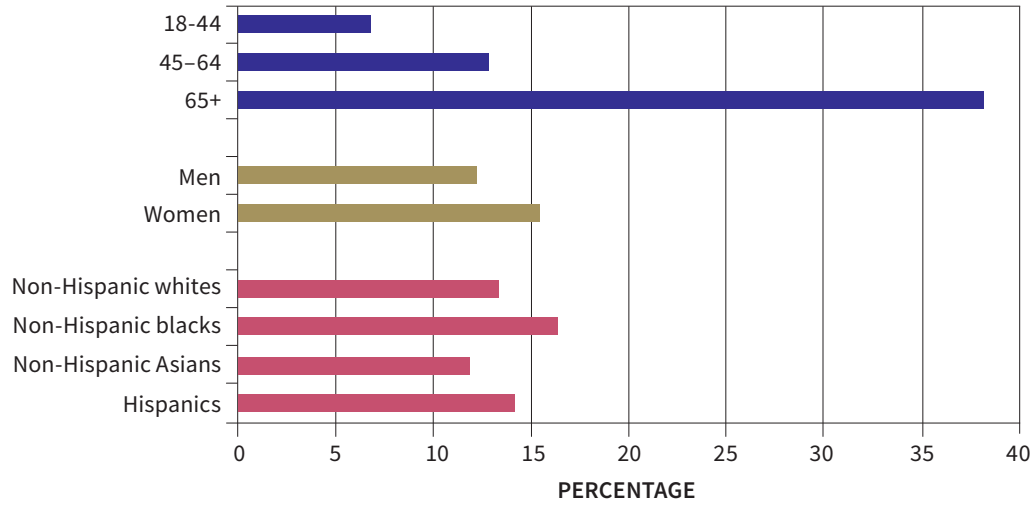
SOURCE: Centers for Disease Control and Prevention. Chronic Kidney Disease Surveillance System—United States. Website. https://nccd.cdc.gov/CKD.

NIH research led to the seminal discovery of the APOL1 gene, which explains why CKD progresses faster among African Americans compared to Caucasians.[53]

As of December 31, 2015, the prevalence of dialysis treatment was 1,470 per million U.S. population. **Figure 4** shows that the prevalence of ESRD has been increasing over time. The prevalence of ESRD more than doubled between 1990 and 2015, and the number of prevalent ESRD cases has continued to rise by approximately 20,000 cases per year, reaching 726,331 prevalent cases by 2016.[54,55]

FIGURE 3

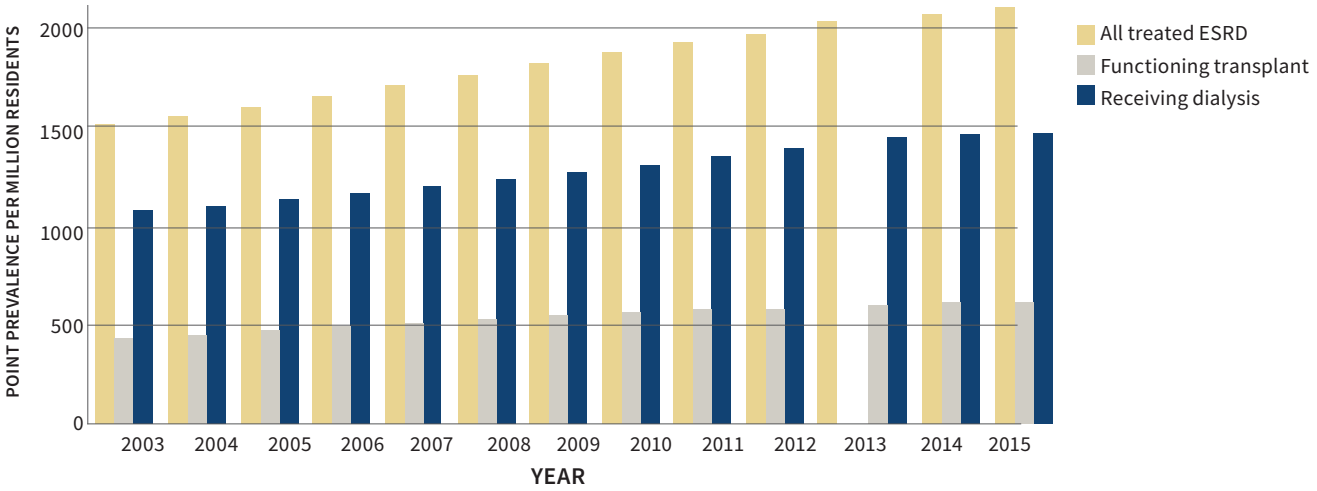
Percentage of CKD Among U.S. Adults Aged 18 Years and Older, by Sex and Race/Ethnicity



SOURCE: Centers for Disease Control and Prevention. Percentage of CKD stages 1–4 among US adults aged 18 years or older using data from the 2013–2016 National Health and Nutrition Examination Survey and the CKD Epidemiology Collaboration (CKD-EPI) equation.

FIGURE 4

Prevalence of Treated ESRD, 2003-2015



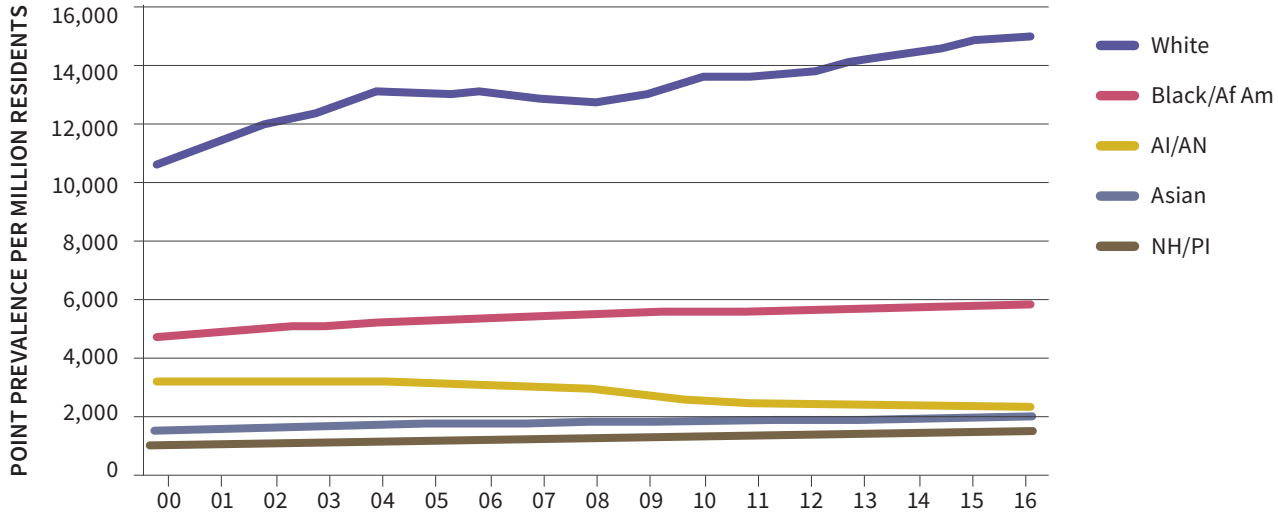
SOURCE: Centers for Disease Control and Prevention. Chronic Kidney Disease Surveillance System—United States. Website.https://nccd.cdc.gov/CKD.

Similar to trends for CKD, **Figure 5** shows that the prevalence of ESRD is higher among racial minorities.[56] Compared to Whites, ESRD prevalence in 2016 was approximately 9.5 times greater in Native Hawaiians and Pacific Islanders (NH PI), 3.7 times greater in African Americans (Black Af/Am), 1.5 times greater in American Indians and Alaska Natives (AI/AN), and 1.3 times greater in Asians.[57]

Figure 6 shows that the burden of ESRD varied significantly by state in 2015, ranging from highs of 2,428.8 per million residents in the District of Columbia, 2,212.6 in Illinois, and 2,203.6 in South Dakota to lows of 1,185.8 per million residents in Vermont, 1,175.6 in Maine, and 1,155.7 in New Hampshire.[58]

FIGURE 5

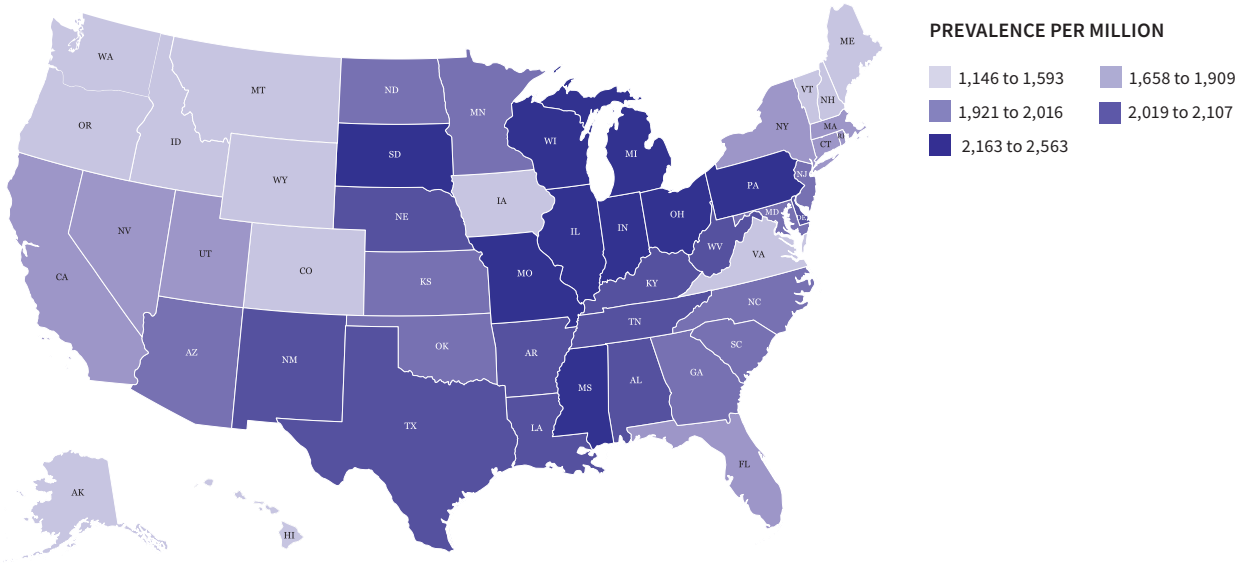
Trends in the Standardized Prevalence of ESRD, by Race, 2000-2016



SOURCE: USRDS Annual Data Report. Special analyses, USRDS ESRD Database. Point prevalence on December 31 of each year. Standardized to the age-sex distribution of the 2011 U.S. population. Special analyses exclude unknown age, sex, and unknown/other race. Abbreviations NH/PI: Native Hawaiian/Pacific Islander; AI/AN: American Indian/Alaska Native.

FIGURE 6

Prevalence of ESRD by U.S. State for 2016



Risk Factors

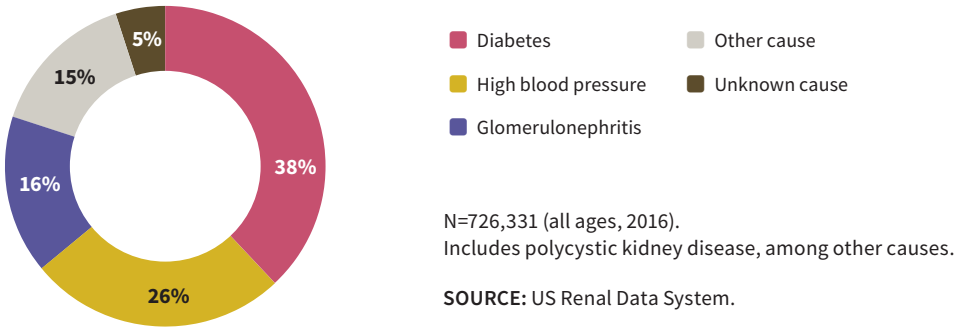
Major risk factors for ESRD include diabetes and high blood pressure (see **Figure 7**), in addition to having a family history of kidney failure. Approximately 48 percent of individuals with severely reduced kidney function who are not on dialysis, are not even aware they have CKD.[59]

One positive trend is the decreasing rate of ESRD among American Indians and Alaska Natives (AI/ANs). The incidence of diabetes-related ESRD (ESRD-D) among AI/AN populations decreased by over 40 percent between 2000 and 2015, resulting in lower levels of disease burden for patients and reduced spending for programs that cover the costs of AI/AN health care.[60] Measures related to the assessment and treatment of ESRD-D risk factors showed more improvement during this period in AI/ANs than in the general U.S. population.[61] This reduction in ESRD rates occurred after the Indian Health Service (IHS) began implementing public health and population management approaches to diabetes and improvements in clinical care in the mid-1980s. The approach taken by IHS to reduce diabetes may be a model for reducing ESRD risk factors in other health care systems.

Figure 8 shows the significant decline in ESRD-D incidence in AI/ANs compared to Whites between 2001 and 2015.

FIGURE 7

Reported Causes of ESRD in the United States

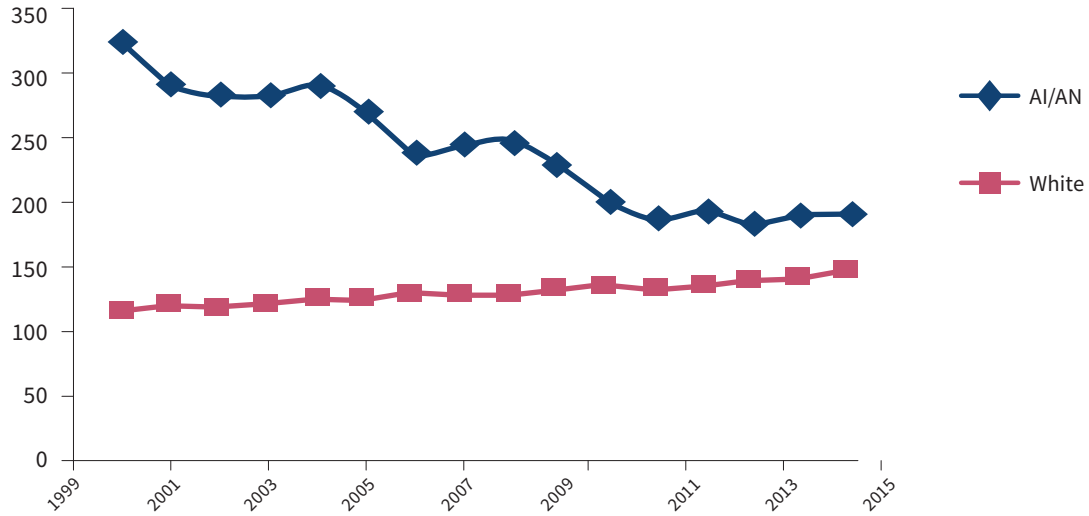


N=726,331 (all ages, 2016).
Includes polycystic kidney disease, among other causes.

SOURCE: US Renal Data System.

FIGURE 8

Incidence per Million of Diabetes-Related ESRD in AI/AN and White Populations



SOURCE: ASPE Analysis of USRDS 2017 Annual Data Report Reference Tables.

Treatment Options for ESRD

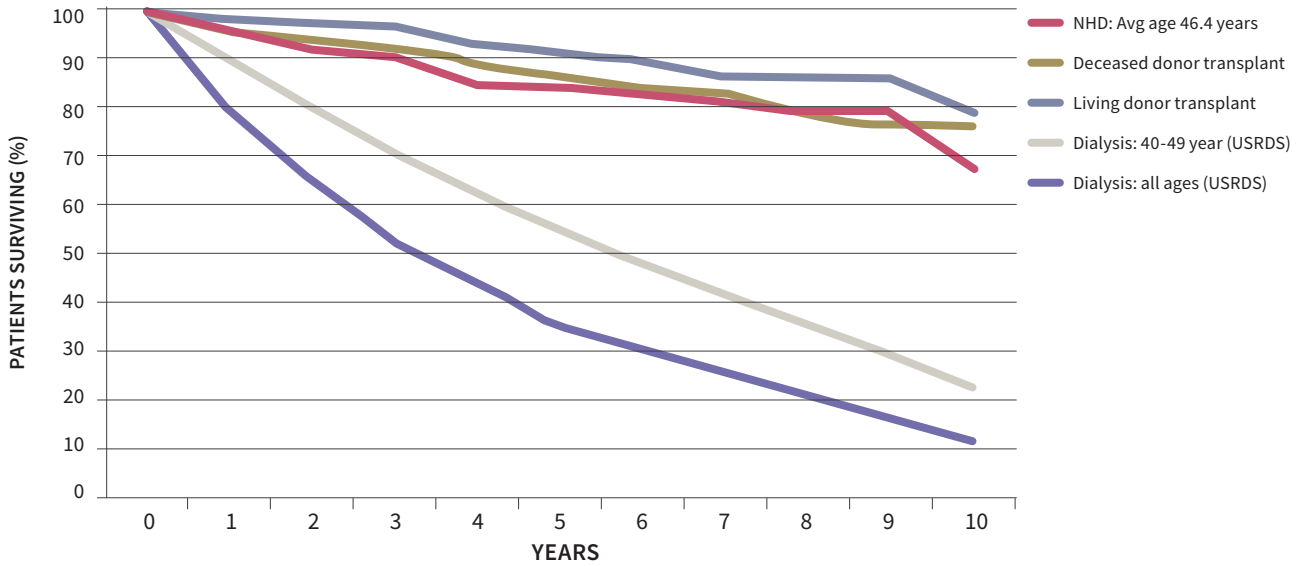
USRDS data indicate that at the end of 2016, approximately 63.1 percent of all prevalent ESRD patients were receiving hemodialysis (HD) therapy, 7.0 percent were treated with peritoneal dialysis, and 29.6 percent had a functioning kidney transplant. Among HD cases, 98.0 percent used in-center HD, and 2.0 percent used home HD.[62] While home-based dialysis may not meet the needs of every patient, home dialysis has clear benefits for those who are suitable candidates. In addition to being more convenient for many people living with ESRD, **Figures 9** (below) **and 10** (following page) show that survivability rates for home dialysis are comparable to those of transplant recipients and hemodialysis.[63,64]

A 2015 Government Accountability Office (GAO) report found that facilities have financial incentives in the short term to increase provision of hemodialysis in facilities rather than increasing home dialysis.[65] For example, hemodialysis facilities may be able to increase the number of in-center patients without adding a dialysis machine because each machine can be used by six to eight in-center patients. However, for each new home patient, facilities may need to pay for the cost of an additional dialysis machine. GAO also reported that facilities might be less inclined to provide home dialysis depending on the adequacy of Medicare's payments for home dialysis training and because Medicare's monthly payments to physicians for managing the care of home dialysis patients are often lower than for managing in-center patients.[66]

The CMS Innovation Center is announcing five new payment models, which include incentives to optimize care for Medicare beneficiaries with kidney disease. These models represent important efforts by HHS to improve care for patients with chronic kidney disease in the near future. Looking further into the future, investments in research and new technology may be able to increase access to even better treatment options. Innovations in kidney disease treatments include technology such as wearable, implantable, and biohybrid dialysis units, which could substantially improve quality of life for people living with ESRD. NIH funding for biomedical research related to kidney disease totaled approximately $600 million in fiscal year 2018.[67] The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

FIGURE 9

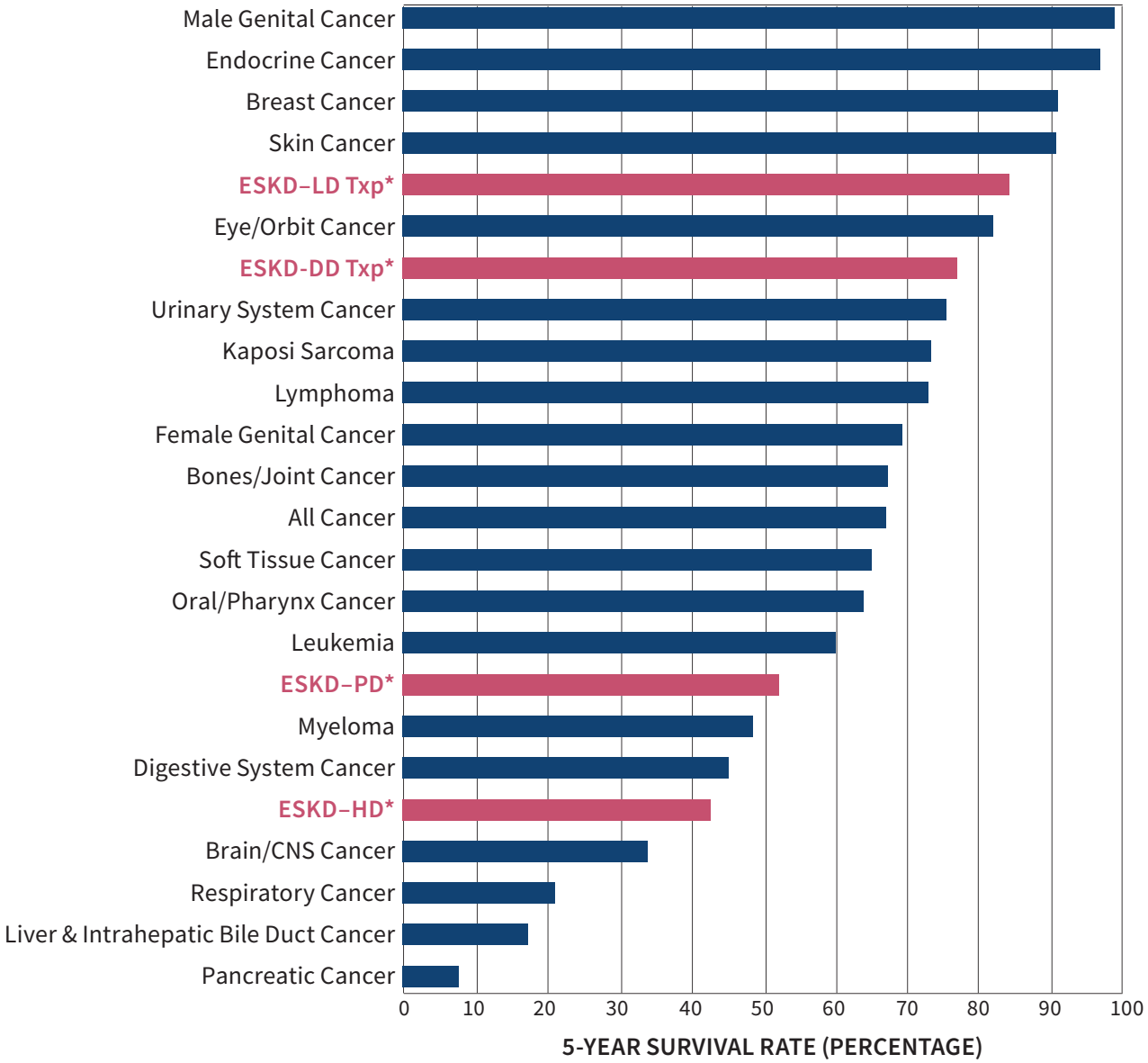
Survivability Rates for Nocturnal Home Hemodialysis (NHD) vs. Other Treatment Modalities



SOURCE: USRDS 2018 Annual Data Report.

FIGURE 10

5-Year Survival of Cancers and ESRD by Treatment Type



*Reference population: incident ESKD patients, 2011. Adjusted for age, sex, race, Hispanic ethnicity, and primary diagnosis

LEGEND

ESKD-LD Txp: end-stage kidney disease, received living donor transplant
ESKD-DD Txp: end-stage kidney disease, received deceased donor transplant
ESKD-PD: end-stage kidney disease, receiving peritoneal dialysis
ESKD-HD: end-stage kidney disease, receiving hemodialysis

SOURCES: United States Renal Data System, 2018 USRDS annual data report; SEER Cancer Statistics Review, 1975-2015.

provides the majority of NIH's funding for biomedical research on kidney disease, ESRD treatment, and kidney donation.[68] HHS, in partnership with the American Society of Nephrology, also supports KidneyX, which is designed to improve kidney care by investing in the development of new products and technologies like wearable and implantable dialyzers and regenerative kidneys.

Health Care Spending on CKD and ESRD

When Medicare entitlement was first extended to individuals with ESRD in 1972, approximately 10,000 individuals were receiving dialysis. By 2016, excluding transplant patients, there were 511,270 beneficiaries being treated for ESRD. While ESRD patients comprise less than 1 percent of the total Medicare population, they accounted for approximately 7 percent of Medicare FFS spending, totaling over $35.4 billion in 2016.[69] Medicare spending on CKD and ESRD was over $114 billion in 2018, representing 23 percent of total Medicare FFS spending.[70] Growth in total CKD spending has primarily been driven by an increase in the number of identified cases, particularly those in the earlier disease stages (CKD Stages 1-3).[71] In 2016, Medicare patient obligations – which may be paid by the patient, by a secondary insurer, or may be uncollected – represented 9.6 percent, or approximately $4 billion, of total FFS Medicare Allowable Payments.[72]

Between 2015 and 2016, average per person per year spending for hemodialysis (HD) care increased from $88,782 to $90,971, or 2.5 percent, while total spending on HD care rose from $26.8 billion to $28.0 billion, or 4.5 percent (similar to the total growth in ESRD spending of 4.6 percent).[73] Total spending for patients who have received kidney transplants increased from $3.3 billion to $3.4 billion, or 3 percent, and per capita spending increased from $34,080 to $34,780, or 2.1 percent.[74]

Kidney Transplantation

For some people living with ESRD, a transplant using a healthy kidney from a donor may be an option. The Innovation Center's ETC Model will support the goal of increasing access to kidney transplants through financial incentives for ESRD facilities and Managing Clinicians. A functioning transplanted kidney does a better job of filtering wastes than dialysis,[75] and transplant recipients have improved life expectancy compared to individuals on dialysis.[76] Of the 36,529 organ transplants performed in the U.S. in 2018, approximately 21,000 were kidney transplants.[77] Of these, approximately 30.4 percent were from living donors and 69.6 percent from deceased donors.[78] One-year patient survival rates are similar for individuals who received transplants from living kidney donors and from deceased donors: 98.8 percent and 96.3 percent, respectively. Five years after transplantation, the patient survival rate among those who received a kidney transplant from a living donor is 92.1 percent, compared to 83.2 percent for those who received a kidney transplant from a deceased donor.[79]

The OPTN reports there are nearly 95,000 candidates on the waiting list to receive a kidney transplant. On average, twenty candidates die each day while waiting for an organ transplant.[80] One important factor contributing to the size of the waiting list is the number of discarded kidneys from deceased donors.

Figure 11 (see following page) is a chart displaying the demand for kidney transplants and the policy options that can optimize the availability of donor kidneys for transplantation.

Organ Donation and Procurement

More than 145 million Americans are registered to become organ donors.[81] However, signing up to be a donor does not guarantee that the donor's organs or tissues will be suitable for transplantation, and registering as a donor usually takes place many years before donation becomes possible. In the case of living donation, transplant centers evaluate potential living donors to determine whether they are suitable to be a donor and to avoid the occurrence of any adverse physical, psychological, or emotional outcome before, during, or after the donation.

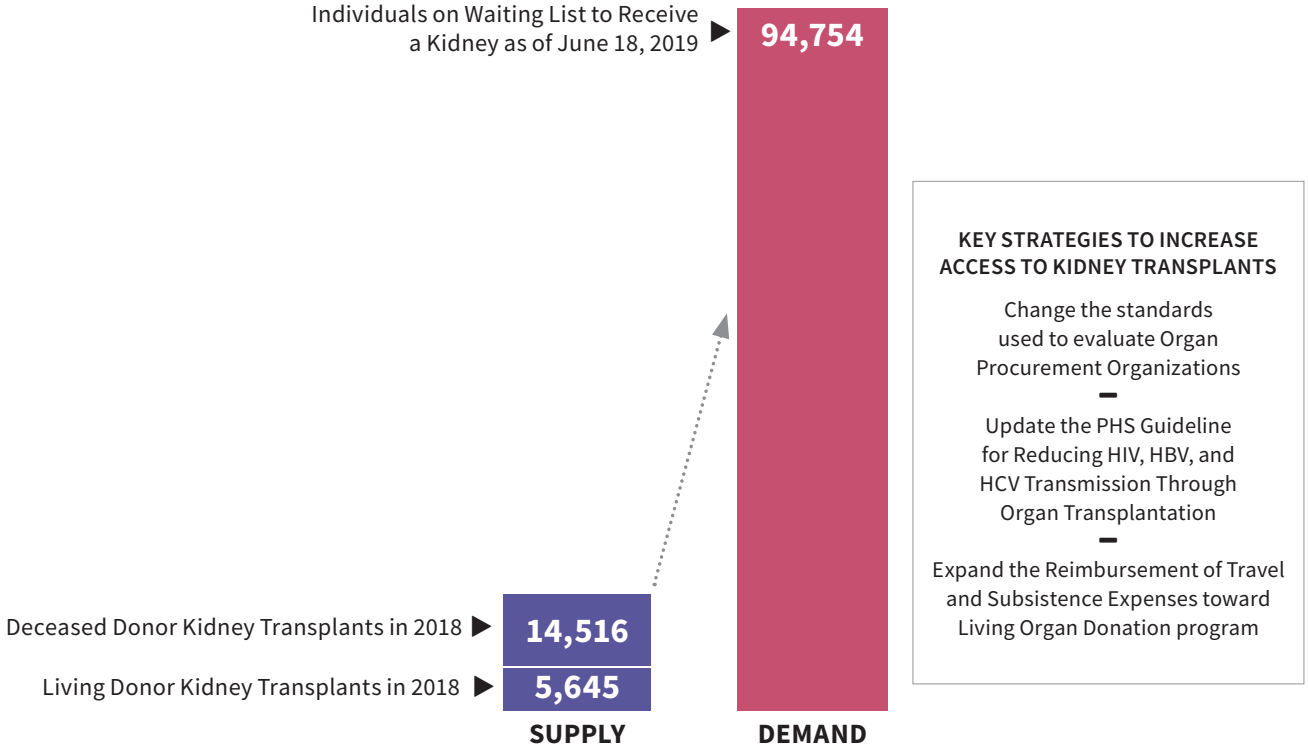
To become a deceased donor, an individual has to die under specific circumstances, such as after an accident involving severe head trauma, or a brain aneurysm or stroke. In such cases where an individual is severely injured and unresponsive, physicians attempt to save the individual's life and then perform tests to determine whether the individual is brain dead and cannot breathe on his or her own. Organ donation occurs only after the donor is legally declared dead. In accordance with federal regulations, hospitals notify the local Organ Procurement Organization (OPO) of every patient who has died or is nearing death and provide information to the OPO to determine whether deceased patients have the potential to be an organ donor.[82]

The OPO transplant coordinator searches the organ donor registries to see if the deceased person is registered as a donor. If so, that registration serves as legal consent for organ donation. If the deceased person has not registered as a donor and there was no other legal consent for donation such as a notation on the driver's license, the OPO asks the deceased individual's spouse or next of kin for authorization. After authorization, a medical evaluation takes place, including obtaining information about the deceased person's medical history from his or her family. If the deceased person is determined to be an eligible donor based on the medical evaluation, the OPO contacts the Organ Procurement and Transplantation Network (OPTN).[83,84]

The OPTN operates the national database of all patients in the U.S. waiting for a transplant. OPTN's computer system matches the donor's organs to potential recipients. The network has policies that define how donor organs are matched and allocated to patients on the waiting list. The OPTN policies take into consideration the unique medical needs of children and provide priority to children for some organs. OPTN policy also addresses the needs of patients with a highly sensitized immune system and therefore at higher risk of rejecting a donor organ.

FIGURE 11

Gap between Supply and Demand for Kidney Transplantation



SOURCE: Organ Procurement and Transplantation Network data

When matching organs from deceased donors to patients on the waiting list, many of the factors taken into consideration are the same for all organs. These usually include:

- Blood type
- Body size
- Severity of patient's medical condition
- Distance between the donor's hospital and the patient's hospital
- The patient's waiting time
- Whether the patient is available (for example, whether the patient can be contacted and has no current infection or other temporary reason that transplant cannot take place)

However, depending on the organ, some factors become more important, so there is a different policy for each organ. For example, some organs can survive outside the body longer than others, so the distance between the donor's hospital and the potential recipient's hospital may be given greater weight than other factors in certain situations.

After the OPO enters information about a deceased donor into the database, the computer system generates a list of patients who match the donor, by organ. Each available organ is then offered to the best-matched patient for evaluation by the patient's transplant team.

After a match is identified, the transplant team determines whether the available organ is medically suitable for the matched patient. Even if an organ is suitable, the transplant team may decline the organ offer for example, if the patient is too sick to undergo a transplant, has an untreated infection, or is unavailable for transplant. In these situations, the organ is then offered to the next patient on the waiting list. During the organ matching process, organs are maintained on artificial support, and the hospital medical staff and the OPO procurement coordinator closely monitor the condition of the donated organs. After removal from the donor, organs remain viable for transplantation for only a limited period of time, which varies by organ type, so the OPO must arrange timely transportation of the organs to the hospitals of the intended recipients. **Figure 12** is a list of the reasons recovered kidneys are not used.

FIGURE 12

Reported reasons why recovered kidneys are not used for transplantation:

- infection
- organ trauma
- too old on pump
- too old on ice
- ureteral damage
- deceased organ
- vascular damage
- biopsy findings
- positive hepatitis
- donor social history
- poor organ function
- donor medical history
- organ not as described
- anatomical abnormalities
- warm ischemic time too long
- no recipient located – list exhausted
- recipient determined to be unsuitable for transplant in the operating room

SOURCE: OPTN/SRTR 2016 Annual Data Report: Deceased Organ Donation

Current Quality Measures Relevant to Kidney Care

Calendar Year 2019 Quality Payment Program (QPP) Measures for Clinicians by Reporting Method

QPP #	Measure Name	Claims	Registry	QCDR	Web Interface	EHR
1	Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)	✓	✓		✓	✓
46	Medication Reconciliation Post-Discharge	✓	✓			
47	Advance Care Plan	✓	✓			
119	Diabetes: Medical Attention for Nephropathy		✓			✓
167	Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure		✓			
325	Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions		✓			
327	Pediatric Kidney Disease: Adequacy of Volume Management		✓			
328	Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/dL		✓			
329	Adult Kidney Disease: Catheter Use at Initiation of Hemodialysis		✓			
330	Adult Kidney Disease: Catheter Use for Greater Than or Equal to 90 Days		✓			
403	Adult Kidney Disease: Referral to Hospice		✓			
405	Appropriate Follow-up Imaging for Incidental Abdominal Lesions	✓	✓			

Qualified Clinical Data Registry (QCDR) Measures

QCDR Measure ID	Measure Name
MUSIC15	Kidney Stones: SWL in patients with total renal stone burden > 2 cm or > 1 cm lower pole stones
ACRad26	Appropriate venous access for hemodialysis
RPAQIR9	Advance Care Planning (Pediatric Kidney Disease)
RPAQIR4	Arteriovenous Fistula Rate
RCOIR7	Improved Access Site Bleeding
RCOIR5	End Stage Renal Disease (ESRD) Initiation of Home Dialysis or Self-Care
RPAQIR13	Rate of Timely Documentation Transmission to Dialysis Unit/Referring Physician
RPAQIR5	Transplant Referral
RPAQIR16	Peritoneal Dialysis Catheter Success Rate
RPAQIR17	Peritoneal Dialysis Catheter Exit Site Infection Rate
RPAQIR18	Advance Directives Completed
RCOIR10	Upper Extremity Edema Improvement
RCOIR1	CKD 3-5 Patients Seen at the Recommended Frequency Levels
CLLC5	Monitoring for albuminuria in patients with CKD
RCOIR3	CKD 3-5 Patients with a Urine ACR or Urine PCR Lab Test
PPRNET13	Chronic Kidney Disease (CKD): eGFR Monitoring
PPRNET14	Chronic Kidney Disease (CKD): Hemoglobin Monitoring
RPAQIR1	Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy
RCOIR4	CKD 4-5 Patients with Transplant Referral
CLLC7	Renal Dysfunction: New Oral Anticoagulants (NOACs) Management
AQUA15	Stones: Urinalysis documented 30 days before surgical stone procedures
AQUA14	Stones: Repeat Shock Wave Lithotripsy (SWL) within 6 months of treatment

Quality Incentive Program (QIP) Measures for Dialysis Facilities by Data Source

SHORT NAME	MEASURE NAME	PY 2021	PY 2022	PY 2023	DATA COLLECTION PERIOD CY 2021 /CY 2022 /CY 2023
CLAIMS-BASED MEASURES					
SRR	Standardized Readmission Ratio	✓	✓	✓	January 1, 2019 – December 31, 2019 January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
STrR	Standardized Transfusion Ratio	✓	✓	✓	January 1, 2019 – December 31, 2019 January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
SHR	Standardized Hospitalization Ratio	✓	✓	✓	January 1, 2019 – December 31, 2019 January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
VAT-Fistula	Standardized Fistula Rate	✓	✓	✓	January 1, 2019 – December 31, 2019 January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
VAT-Catheter	Long-Term Catheter Rate	✓	✓	✓	January 1, 2019 – December 31, 2019 January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
CROWNWEB BASED MEASURES					
Depression	Clinical Depression Screening and Follow-up	✓	✓	✓	January 1, 2019 – December 31, 2019 January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
VAT-Fistula	Standardized Fistula Rate	✓	✓	✓	January 1, 2019 – December 31, 2019 January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
VAT-Catheter	Long-Term Catheter Rate	✓	✓	✓	January 1, 2019 – December 31, 2019 January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
UFR	Ultrafiltration Rate	✓	✓	✓	January 1, 2019 – December 31, 2019 January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
Kt/V	Comprehensive Dialysis Adequacy	✓	✓	✓	January 1, 2019 – December 31, 2019 January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
Hyp	Hypercalcemia	✓	✓	✓	January 1, 2019 – December 31, 2019 January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
PPPW	Percentage of Prevalent Patients Waitlisted	x	✓	✓	January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
MedRec	Medication Reconciliation	x	✓	✓	January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
NHSN BASED MEASURES					
NHSN BSI Reporting	NHSN Dialysis Event Reporting	✓	✓	✓	January 1, 2019 – December 31, 2019 January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
NHSN BSI Clinical	NHSN Bloodstream Infection in Hemodialysis Patients	✓	✓	✓	January 1, 2019 – December 31, 2019 January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021
ICH_CAHPS BASED MEASURES					
ICH_CAHPS	In-center Hemodialysis Consumer Assessment of Healthcare Provider and Systems	✓	✓	✓	January 1, 2019 – December 31, 2019 January 1, 2020 – December 31, 2020 January 1, 2021 – December 31, 2021

List of Acronyms

AI/AN	American Indian/Alaska Native
APOL1	Apolipoprotein L1
ASPE	Assistant Secretary for Planning and Evaluation
ASPR	Assistant Secretary for Preparedness and Response
CDC	Centers for Disease Control and Prevention
CEC	Comprehensive ESRD Care
KCF	Kidney Care First
CKCC	Comprehensive Kidney Care Contracting
CKD	Chronic Kidney Disease
CMS	Centers for Medicare and Medicaid Services
COIIN	Collaborative Improvement and Innovation Networks
CROWNWeb	Consolidated Renal Operations in a Web-enabled Network
CTO	Chief Technology Officer
DAA	Direct-acting Anti-viral
DPP	Diabetes Prevention Program
EMP	ESA Monitoring Policy
ESA	Erythropoietin Stimulating Agent
ESRD	End Stage Renal Disease
ESRD-D	Diabetes-related ESRD
ETC	ESRD Treatment Choices
FDA	Food and Drug Administration
FFS	Fee-for-Service
FY	Fiscal Year
GAO	Government Accountability Office
HD	Hemodialysis
HHS	Health and Human Services
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
MHS	Military Health System
NIH	National Institutes of Health
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NKF	National Kidney Foundation
OASH	Office of the Assistant Secretary for Health
ONC	Office of the National Coordinator for Health Information Technology
OPO	Organ Procurement Organization
OPTN	Organ Procurement and Transplantation Network
PHS	Public Health Service
PPS	Prospective Payment System
QCDR	Qualified Clinical Data Registry
QIP	Quality Incentive Program
QPP	Quality Payment Program
SDPI	Special Diabetes Program for Indians
USRDS	U.S. Renal Data System

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83. An eligible death is defined as per OPTN Policy 1.2 as death of a person aged 70 years or younger who is legally declared brain dead according to hospital policy and does not exhibit any of the following indications: tuberculosis, human immunodeficiency virus (HIV) infection with specified conditions, Creutzfeldt-Jacob Disease, herpetic septicemia, rabies, reactive hepatitis B surface antigen, any retrovirus infection, active malignant neoplasms (except primary central nervous system tumors and skin cancers), Hodgkin disease, multiple myeloma, leukemia, miscellaneous carcinomas, aplastic anemia, agranulocytosis, fungal and viral encephalitis, gangrene of bowel, extreme immaturity, or positive serological or viral culture findings for HIV.

84. The purpose of the OPTN is to improve the effectiveness of the nation's organ procurement, donation, and transplantation system by increasing the availability of and access to donor organs for patients with end-stage organ failure. The OPTN is administered by United Network for Organ Sharing (UNOS) under contract to the U.S. Department of Health and Human Services.


DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

Shifting Practice Landscape For-Profit Companies Move into CKD Care

By Katie Westin Kwon and Eugene Lin

The past few years have seen a number of for-profit companies seeking to partner with nephrologists to manage their patients with later stage chronic kidney disease (CKD). Kidney disease is an expensive medical condition to treat: Medicare's total cost of care for patients with kidney disease in 2018 was $81.8 billion (1). Both Medicare and private payers have advanced care models that reduce that cost. New value-based care (VBC) initiatives focus on the patient population that is at risk for developing end stage kidney disease (ESKD). These programs will financially reward providers who successfully slow kidney disease progression and increase home dialysis and transplantation rates. Companies that succeed will profit by capturing some of the resulting savings to payers.

Previously, the reimbursement structure for nephrology has primarily focused on dialysis. This, in turn, has created a landscape where an outsized portion of the nephrologist's income derives from dialysis at the expense of other aspects of kidney care. This has been cited as a contributing factor to the nephrology workforce crisis; residents perceive nephrology to be overly focused on the complicated care of patients with ESKD (2). Additionally, misaligned financial incentives prioritize keeping in-center hemodialysis chairs filled rather than guiding patients toward alternative therapies, like home dialysis or kidney transplant (3).

The new VBC models have introduced incentives to focus on patients with advanced CKD not yet on dialysis (4). For-profit companies have noticed. Start-up companies, larger for-profit healthcare providers, and venture capital firms have formed a marketplace of new products aimed at helping nephrologists improve their management of CKD at a population level (Table 1).

Population-based care requires a different set of tools compared to traditional fee for service. Enhanced data analytics allows providers to risk stratify patients so they can target care-coordination efforts to patients most at risk for poor outcomes. A practice may evaluate its entire cohort of patients to make sure they are all appropriately prescribed medications to slow progression of their CKD or may hire a care manager to see every patient post-hospitalization for care coordination. However, the indiscriminate application of intensive disease management can be expensive, especially among patients without albuminuria (5). Traditionally, such care-management tools are beyond the reach of a small- or mid-sized nephrology practice. The for-profit companies seek to meet this need. Some companies are even aggregating the patient panels of multiple practices to help smaller practices spread risk and meet the required numbers to participate in the various VBC models.

The benefit to the practicing nephrologist is a clinical rebalancing, such that the CKD clinic is no longer a "loss leader" but instead, a significant source of income. For the for-profit companies investing in nephrology, VBC represents a big growth opportunity. The challenge, as our patients' advocates, is to ensure that VBC incentives remain aligned with patients' best interests. We have been given substantial flexibility to achieve the desired outcome of fewer people needing in-center dialysis care. Our role as nephrologists will be to direct the dollars being invested in an efficient and focused manner to create CKD care that best supports our patients. ■

Katie Westin Kwon, MD, is a partner at Lake Michigan Nephrology, which has joined Global Nephrology Solutions (GNS) and will participate in value-based care with GNS in 2023. Eugene Lin, MD, MS, is an Assistant Professor of Medicine at the Keck School of Medicine of the University of Southern California, Los Angeles.

Dr. Kwon reports no conflicts of interest. Dr. Lin receives consulting income from Acumen, LLC, a federal contractor.

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Table 1. Notable for-profit companies innovating in nephrology

Companies	Investors	Notable characteristics
Cricket	Valtruis	Virtual multidisciplinary team to support enrolled CKD patients at no cost to practice; payer contract negotiations
InterWell	Fresenius	VBC contracts; aggregates smaller practices to participate
Global Nephrology Solutions	Audax	Participating physicians own equity in GNS; services include practice management and VBC
Somatus	Longitude Capital; Anthem Healthcare	Partners with payers and nephrology practices; also with health systems to provide inpatient/outpatient dialysis
Strive	Capital Group (Division of Alphabet)	Partners with health systems, nephrologists, and primary care
CVS Kidney Care	Partnership with Satellite Healthcare	Developing a home hemodialysis machine
Evergreen Nephrology	Rubicon Founders	Partners with nephrologists for the management of full-risk Medicare patients; focuses on dialysis preparation, home dialysis, and transplantation

CKD, chronic kidney disease; VBC, value-based care; GNS, Global Nephrology Solutions.

May 16, 2019

Thomas J. Nasca, MD, MACP
President and Chief Executive Officer
Accreditation Council for Graduate Medical Education
401 North Michigan Avenue
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Chicago, IL 60611

Dear Dr. Nasca:

On behalf of the American Society of Nephrology (ASN) and the American Board of Internal Medicine (ABIM), thank you for your leadership in medical education and accreditation.

The Accreditation Council for Graduate Medical Education (ACGME) Program Requirements for Graduate Medical Education in Nephrology specify that fellows in training are required to develop competence in performing kidney biopsies [IV.B.1.b).(2).(b).(iii)]; placing temporary vascular access for hemodialysis [IV.B.1.b).(2).(b).(v)]; and continuous renal replacement therapy (CRRT) [IV.B.1.b).(2).(b).(ii)]. It is also an ACGME Program Requirement [I.D.4.a).(1).a] that "the program should be of sufficient size to ensure fellows' adequate exposure to patients with…both hemodialysis and peritoneal dialysis including patients who utilize home dialysis treatment modalities, and that fellows demonstrate competence in peritoneal dialysis [IV.B.1.b).(2).(b).(iv)].

Despite the debate in recent years about the need to retain requirements for competency in biopsies and temporary hemodialysis catheter placement, they are current requirements. Recently, the ASN Council (the society's governing body) reaffirmed a commitment to the requirement of competence in these procedures as being essential for nephrology fellowship training. Eligibility to take the ABIM initial certification exam requires attestation of demonstrated competence with these procedures and therapies by the fellowship program director. ABIM certification eligibility is predicated on these ACGME requirements being met.

Both published literature during the last decade as well as substantial anecdotal evidence have made it abundantly clear that some nephrology fellowship programs accredited by the ACGME provide little or no experience with kidney biopsies, care of patients treated with home HD or PD, and, to a lesser extent, placement of dialysis catheters and CRRT. This concern has been extensively discussed at the ASN Nephrology Fellowship Training Program Director meetings and is widely acknowledged within the nephrology training community.

Surveys and ACGME milestones reports show that nationwide approximately 25% of graduating fellows have not achieved competence to perform dialysis catheter placement and/or kidney biopsies independently without supervision as is required. Some programs provide no hands-on training in one or both of these procedures or little to no experience with taking care of patients utilizing home dialysis (either home HD or PD).

This situation is concerning as there is increasing emphasis from the Centers for Medicare and Medicaid Services (CMS) and the kidney community to increase utilization of home therapies. While there are no new systematic analyses of peritoneal dialysis training and competence, older published information indicates that many programs had insufficient numbers of PD patients and were not providing any meaningful longitudinal experience with such patients. In one survey study, more than 40% of recently graduated nephrologists did not feel competent in the care of such patients.

Two major concerns stem from these circumstances. First, nephrology fellows are graduating from training programs without the core competencies expected by health systems, hospitals, employers, and other stakeholders, including people with kidney diseases. Second, there are serious professionalism concerns stemming from false attestation of program directors to competencies that are not achieved, tacit acceptance of this inaccuracy by fellows knowing that their program directors are reporting dishonestly, and fellowship programs that continue to accept new fellows for training knowing that these fellows will not receive required training as well as procedural experiences and competencies.

On behalf of ABIM and ASN, we urge ACGME, as the organization responsible for accreditation of nephrology fellowship training programs, through its Internal Medicine Review Committee, to address this serious situation. ASN and ABIM believe that a variety of likely mechanisms could be implemented, including but not limited to the following:

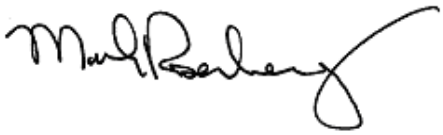
- Requiring documentation of a minimum number of patients on home dialysis (HD and PD) available for supervised care by fellows (similar to current kidney transplant experience requirements) or a mandatory longitudinal home dialysis clinical experience.
- Requiring a minimum number of hands-on native and transplant kidney biopsies, supervised by nephrology program faculty, with documentation of role of the fellow in the biopsy, such as logs of biopsies reported by fellows to ACGME and reviewed by program directors.
- Requiring a minimum number of hands-on temporary HD catheter placements with documentation of role of the fellow in the placement of the catheter:
    - Allow “credit” for procedures performed during residency.
    - Use logs of catheter placements reported by fellows to ACGME and reviewed by program directors.
- Communicating with Chiefs of Nephrology, Chairs of Medicine, and Designated Institutional Officials about these training requirements and the need for institutional oversight of compliance.
- Asking ACGME field staff who perform the Nephrology Program site visits to pay careful attention to determining if programs are training fellows in the required procedures. This mechanism is particularly important given that site visits have not occurred frequently in NAS, but with the maturity of NAS, more regularly scheduled site visits are occurring. However, if attention is not given to this issue at the site visit, then it may be missed for another 10 years or more without accreditation systems that otherwise would detect the issues of concern.

ASN and ABIM are eager to work with ACGME to address this issue. It is abundantly clear that a greater degree of oversight of nephrology fellowship training programs in the United States is needed to ensure that all programs provide the training opportunities necessary to achieve all expected competencies, and that all graduating trainees in fact have the competencies being attested to by their program directors to allow them to sit for the ABIM initial certification exam for Nephrology Board Certification.

Thank you for considering this issue. To discuss this letter, please contact ABIM Nephrology Board Chair Jeffery S. Berns, MD, FASN, at Jeffrey.Berns@uphs.upenn.edu or ASN Councilor David H. Ellison, MD, FASN (who serves as liaison to the ASN Workforce and Training Committee), at ellisond@ohsu.edu.

Sincerely,

Jeffrey S. Berns, MD, FASN
ABIM Nephrology Board Chair



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Kidney biopsy should remain a required procedure for nephrology training programs: PRO

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Introduction:

Kidney biopsy has become an integral part of diagnosing and treating kidney disease in the field of nephrology. In the 1990s, 91% of kidney biopsies were performed by nephrologists.(1) However, there has been a decline in numbers of kidney biopsies performed by nephrologists over the past decade.(2–4) Some of the implicated factors include: logistics, time constraints, fellow and faculty comfort, litigation, ease of accessibility to radiologists, and concern for post-biopsy complications.(4–6)

The Accreditation Council for Graduate Medical Education (ACGME) and the American Board of Internal Medicine (ABIM) currently require performing kidney biopsy as a competency for graduation and initial board certification, respectively.(7,8) This suggests programs need to continue to provide opportunities to train nephrology fellows in kidney biopsies and assess their training for competency. However, there are no defined competency-based criteria or minimum number of biopsies to define adequate training. A survey of program directors in 2017 noted that only 51% believed that kidney biopsy competency training should continue to be required during fellowship training.(4) In 2018, a spirited debate ensued with Berns discussing the pros and Shankland discussing the cons of continuing to require kidney biopsies for fellowship programs.(5,9) Berns concluded, “In the absence of an overwhelming consensus to the contrary among the broad nephrology community, training nephrology fellows in these procedural skills should not be abandoned.”(5) This brings up the question, is this landscape still relevant? Should our fellowship programs still require biopsies as part of training? Our argument is yes.

Advantages to Kidney Biopsy

With uncertain requirement for competency, and only a slight majority of program directors suggesting biopsies should be a continued competency, why should biopsies be a core part of fellowship? We see several advantages for this competency. Continuing with kidney biopsies would allow us to align with fellow interest, nurture patient-provider communication, improve diagnosis, and build the next generation of nephrologists.

From a nephrology fellow perspective, 58% enjoyed performing kidney biopsies and encouraged further training based on a 2016-2017 survey study at Walter Reed that assessed kidney biopsy trends following graduation.(4) The study also noted that 83% of fellows felt they were adequately trained to perform kidney biopsies during training. With good communication and clinical skills being paramount for the nephrology practitioner, having kidney biopsies be part of continued practice would ensure delivering patient-centered and quality care. Additionally, involving nephrologists in kidney biopsies would allow continuity of care and follow the natural progression of disease that would impact diagnosis and management.

Shanklan et al argued that kidney biopsies should be performed by experienced radiologists to minimize patient complications such as bleeding risks.(9) However, several studies noted no difference in complication risk when performed by fellows under supervision versus radiologists.(2,6,10,11) Nephrologists have also been shown to have a better glomerular yield than radiologists in several studies.(2,3) This could be attributed to better understanding of the anatomy and use of 14- or 16-gauge needles. Radiologists often use the 18-gauge needle which has been shown to have a smaller glomerular yield with no change in rate of post-biopsy bleeding.(12)

Another advantage to performing kidney biopsies by nephrologists is to increase interest in the field. One of the factors implicated in the decline in interest in the field of nephrology is the lack of procedural training when compared to other specialties.(13) Integrating procedures such as kidney biopsy training can increase exposure to procedural training. For those programs that can accommodate this interest, individualizing a fellow's experience with even more procedural training may give a new avenue to increase recruitment. This recruitment may also lead to increase in nephrology interventional practitioners, diversifying our nephrology workforce options even more. See table below for advantages of kidney biopsy training and suggestions for implementation (Table 1)

Future directions:

We propose increasing initiatives for simulation-based training to increase faculty and fellows' confidence in performing kidney biopsies. The ACGME includes simulation training as part of one of the assessment tools to ensure competency in procedural training. Dawoud et al developed a turkey breast/pork kidney phantom-based simulation training of real-time ultrasound guided renal biopsy.(14) The curriculum improved fellows' confidence by an average of 46.9 points on a 100-point scale. More importantly, it resulted in improvement in retrieval of kidney biopsy tissue by 94% when compared to 73% in fellows who did not participate in the training. Finally, the rate of hematocrit drop was also significantly lower post training (1.18 vs 2.68; p=0.049). Sharma et al developed an educational workshop targeting nephrology fellows that utilized a mannequin and cadaveric based simulation layout to increase confidence, interest and knowledge when performing kidney biopsies. The study found an increase in the

level of procedural confidence from 14% to 41% after the workshop. Sixty seven percent of participants also noted they would “extremely likely” recommend the workshop.(3) Finally, providing intermittent training and/or workshops every 6 months has been shown to restore confidence and knowledge in procedural based training.(15)

We also note that our governing body’s guidance on procedural requirements may need adjustment. The current nephrology ACGME guidance on procedural training is imprecise and may explain the decline in kidney biopsy training during fellowship training. There needs to be a priority to develop an evidence-based competency assessment tool to define procedural excellence at the end of training. A committee of different stakeholders including the ACGME, ABIM, program directors, fellows, nephrology educators skilled in kidney biopsy and other procedural training is likely needed to develop a consensus to define competency-based training metrics that can be incorporated into the ACGME milestones and disseminated to all nephrology fellowships in the US.

With increasing case complexities, we also should embrace collaborative care of our patients with other specialties. The use of ultrasound has allowed this with our radiology colleagues; let us continue to build the relationships with rheumatologists, cardiologists, pulmonologists, and other providers that may benefit from the information gleaned from a kidney biopsy. Continuing our central role in kidney biopsy performance would avoid fragmentation of care and allow us to be at the forefront of our patients’ decision-making.

Conclusion:

With procedural training during fellowship, we should consider the advantages of kidney biopsies moving forward. Performance of kidney biopsies is a skill that needs to be nurtured during fellowship training to prepare future nephrologists on managing complex patients and delivering individualized care. Procedural training has been shown to be safe and effective with higher glomerular yield when performed by nephrology fellows. Some strategies to improve the current decline in procedural training would include integration of simulation-based training, redefining competency-based assessment and providing structured, collaborative procedural rotations with protected time to increase confidence and interest in performing kidney biopsies. The question then becomes not, "Should we continue kidney biopsies during fellowship?" but instead, "How should we advocate for this as a priority?"

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Tables:

Table 1: The advantages of kidney biopsy training and recommendations for implementation

Advantages	**Implementation Recommendations (PROS)**
Fellow factors: Skillful kidney biopsy procedural training	**P**rovide simulation-based training every 6 months as part of nephrology fellowship training requirements
Fellowship factors: Re-engage nephrology fellowship educators	**R**e-define evidence-based competency recommendations by involving stakeholders and disseminate to all fellowships
Specialty factors: Interest and diversification of the nephrology workforce	**O**rganize individualized procedural training for interested fellows and expose medical students and residents to this possibility
Patient factors: Patient-centered care	**S**upport communication between fellows and patients in biopsy care

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"Tradition, Tradition, Tradition". This declaration is the main theme of *Fiddler on The Roof,* the iconic musical that questions traditions; traditions that become integral parts of our daily lives and behaviors; traditions so ingrained that we don't even question their value, practicality, or usefulness. Traditions give us comfort but do not promote inquiry and as Tevye from the musical learns, some traditions do not fit into the modern world. Shortly after the percutaneous renal biopsy (PRB) was adopted as a critical diagnostic tool for nephrologists, it became tradition to train nephrology fellows in this procedure. Competence in this procedure eventually became a requirement (for both native and transplanted kidneys) by both the Accreditation Council for Graduate Medical Education (ACGME) and the American Board of Internal Medicine (ABIM) (1,2). Nephrology fellowship program Training Program Directors (TPD) are required to "sign-off" on this procedure to certify that graduating nephrology fellows are "board eligible", allowing them to take the nephrology subspecialty board exam. Given the changing landscape of nephrology, should renal biopsy training remain a requirement, or has tradition clashed with the modern world's changing views on its value, practicality, and usefulness? I have been charged with arguing that the kidney biopsy should NOT remain a required procedure for training programs (the CON argument).

The procedure of obtaining tissue for diagnosis through percutaneous sampling of the kidney was developed in the early 1950s by Iverson, Brun, Kark and Muehrcke, all nephrologists (3). As a result, the PRB has been a procedure "traditionally" performed by nephrologists. In 1990 a survey of 516 nephrologists that were trained from 1964-74 reported that 95% of practicing nephrologists performed PRB. By 1995 35% of PRB were performed by radiologists. By 2011 only 55% of nephrologists were preforming PRB. And a report in 2012 found that over the 22-

year time span of 1988 to 2010, only 35% of PRB were performed by nephrologists, with the majority of the others being done by the evolving subspecialty of interventional radiology (IR) (3). These findings were similar to a 2018 report that reported the practice habits of 55 nephrologists who had trained at Walter Reed Military Medical Center in which 83% considered themselves adequately trained to do the procedure, yet only 35% of them were performing PRB (4). At Rush University Medical Center (RUMC) where I am the TPD, we have always made a point to train our fellows in PRB. In 2018 we surveyed 78 fellows who trained at RUMC between 1984 to 2017. We found that 100% considered themselves adequately trained in the procedure yet only 58% performed a PRB after graduation and entering practice. To further emphasize these changing practices over time, we broke down the group into 4 time periods based on when fellowship training was completed: 1984-1990, 1991-2000, 2001-2010, and 2011-2017. As shown in Figure 1, the percentage of graduating fellows that did a single PRB post-fellowship dropped from 100% in the early 1984-1990 training years to only 20% in the most recent period of 2011-2017. Of the 71 former RUMC trainees still in practice at the time of the survey, only 12 (17%) continued to perform their own renal biopsies! Of those fellows not performing PRBs, they all sent their patients to IR. The main reason they reported for this practice was that performing the biopsy themselves was too time consuming and that the IR alternative was so readily available. Procedure liability was also a moderate factor in this decision for 52% of our past trainees not doing biopsies, but reimbursement was a consideration in only 30% (5). In fact, in the Walter Reed report, they found that orders for a kidney biopsy increased as the PRB transitioned from nephrologists to IRs, suggesting that these considerations became barriers to the nephrologist doing the procedure him/herself (6).

What are the pros and cons of this transition from nephrologist to IR? Some potential concerns of IR doing the "lion's share" of the PRBs are sample adequacy and complication rate. Regarding the later, prospective comparisons are not available, however in a retrospective analysis there was no difference on the complication rate (hematoma or need for transfusion, gross hematuria or pain) between PRBs done by nephrologists or radiologists using real time ultrasound (7). The issue of tissue adequacy is a bit more complicated. While Sousanieh el al were not able to find a difference in the complication rates of PRB when using the smaller 18-gauge needle, they did find that that using it led to clinically significantly fewer glomeruli compared to 14 and 16-gauge PRB needles. A sample size of 20 glomeruli is generally considered an "adequate" sample to minimize the risk of missing a focal glomerular lesion. This magic number of 20 was obtained in 85% of PRB using 14-gauge (average 2.3 cores obtained), 82% using a 16-gauge (average 2.3 cores) but only 46% using an 18-gauge biopsy needle (average 2.2 cores) (8). Of course, the glomerular yield using an 18-gauge needle can be increased by obtaining more cores. As interventional radiologists often use 18-gauge needles as a default for tissue sampling, communication by the nephrologist to the interventional radiologist on the number of desired cores or needle gauge size may be prudent.

An obvious advantage of IR doing the PRB is that they are likely able to do the procedure using either real time ultrasound (the means by which the majority of nephrologists are trained), in addition to computed tomography which may be preferred for obese patients, cystic kidneys or for those in whom kidney visualization by renal ultrasound is inadequate (7). Additionally, many IR programs are able to obtain tissue through the transvenous approach (TVRB), a major advantage in patients with bleeding disorders. Despite the transvenous approach being typically

limited to higher risk patients, one study found no difference in diagnostic yield or complication rate for PRB (n 400) and TVRB (n 400 of which 303 had a bleeding disorder) (7). And finally, an obvious advantage to IR performed PRBs is that if a bleeding complication were to occur, it would be diagnosed and treated by the team that did the procedure.

I shall now address the elephant in the room; what even determines PRB competence? How many percutaneous renal biopsies should be performed before a nephrology fellow is considered competent? Do they all need to be supervised? Should a determination be based on numbers alone (objective) or should there be some observer subjectivity to this determination? Neither the ABIM nor ACGME provides any specific guidance to this critical issue. In a 2008 poll in which 93 of 136 nephrology fellowship training programs responded, 28% of reporting programs had no minimum required number of biopsies, and of those programs that did have a minimum number, 25% of required that only 0-2 procedures be done, and 20% required 3-6 (9). These numbers were consistent whether considering a biopsy of the native or transplanted kidney. Granted, competence probably is a function of both procedure number and innate skill, but can you really expect someone to be at a safe and proficient level when they have performed but a handful of procedures?

Additionally, it is not obvious if competence (however that is defined) in PRB is even an absolute requirement for graduation (ACGME) or board eligibility (ABIM). ACGME data suggests that 25% of fellows completing training in 2017 were not considered ready to perform temporary dialysis catheter placement or kidney biopsy without supervision (specific numbers for each procedure are not available) (10). Yet I doubt any of these were not allowed to take the

subspecialty boards. TPDs have admitted to “vouching” for PRB competence in their graduating trainees despite lacking confidence in their ability (11).

Given the abysmal rate of nephrology graduates doing a single PRB after graduation, and the alternative of the procedure being done by interventional radiologists, where do we go from here? I would hardly recommend any program that feels they have the numbers and skills to adequately train a fellow in be competent in PRB, to stop training altogether. Still, they should have the option to not attempt to “certify” every one of their fellows. Additionally, the many programs that struggle with this requirement for all their fellows and yet feel compelled to sign off on these trainees despite not being convinced of their competence, should not be required to do so. The ACGME and ABIM should make competence in PRB an elective designation and not a mandated requirement (12).

All nephrology training programs should have the indications, contraindications, risks, and benefits of the PRB in their curriculum. Fellows not planning on PRB certification should observe several of the procedures, whether performed by a nephrologist or an interventional radiologist. Programs that decide to certify a fellow for PRB should establish a minimum number of procedures (I will go out on a limb and suggest a minimum of 6 for each for native and transplant PRB) as well as one of these being a successfully performed PRB observed by a nephrology or IR faculty member that regularly does the procedure. This should result in a program specific standardized document that states competence in a given fellow performing a PRB and should specify if this certification includes PRB of both native and transplanted

kidneys. This document should go into the fellow's academic file and serve as a guide to hospital privileges upon graduation.

In conclusion, the time has come for sensibility and practicality to supersede tradition. The days of PRB as a procedure in which training and competence certification should be mandated have passed. It is time for the ACGME and the ABIM to accept this new paradigm and adjust their training and certification requirements accordingly.

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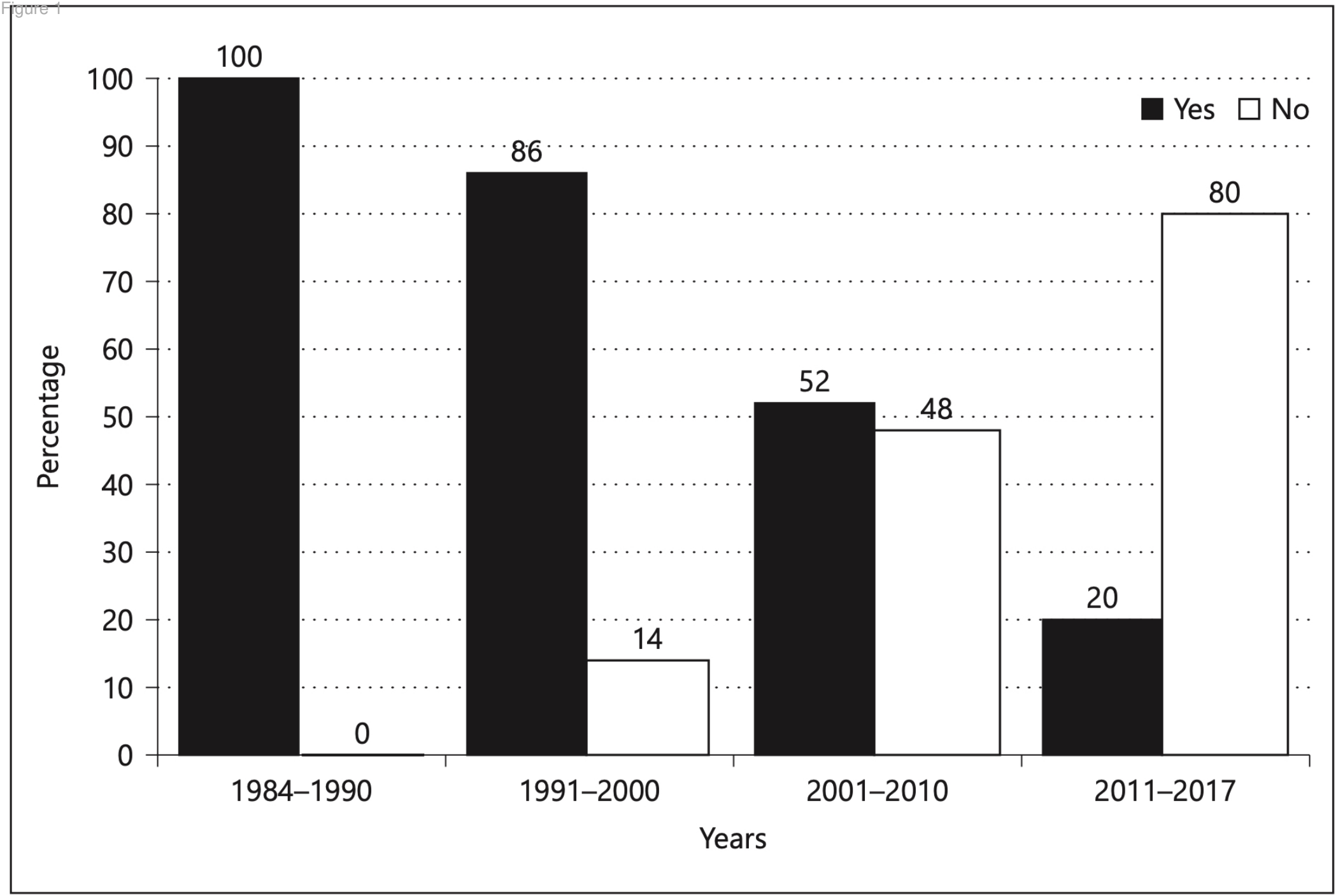
Fig. 1. Performance of PRB post-fellowship based on the year of fellowship completion. Used with permission from reference (5).

Figure 1


100
86
52
48
20
80
0
14
Yes
No
Percentage
100
90
80
70
60
50
40
30
20
10
0
1984–1990
1991–2000
2001–2010
2011–2017
Years

Diversity, Equity, Inclusion, and Justice
Yesterday, Today, and Tomorrow

ASN Executive Vice President's Update

By Tod Ibrahim

In 1960, my father immigrated to the United States to avoid religious persecution, experienced racism in Ohio, overstayed his student visa, and was considered "illegal." My mother—whose family has deep, often racist, roots in the United States—eloped with my father, helped him become a US citizen, experienced sexism (especially in the workplace), worked for two female members of Congress, and volunteered as a counselor during the AIDS crisis.

Their individual and shared experiences shape my commitment to diversity, equity, inclusion, and justice. The American Society of Nephrology (ASN) was a pacesetter—and is now an advocate—in this arena because its members, leaders, and staff share the same commitment.

Valuing people from different races, ethnicities, cultures, and gender identities and expressions makes an organization diverse. An equitable organization treats everyone fairly, impartially, and justly. By involving, accommodating, and embracing people who have historically been excluded, an organization is inclusive. Starting (essentially) at "square one" a decade ago, ASN has increasingly promoted diversity, equity, and inclusiveness "to enhance the nephrology profession and the lives of people with kidney diseases through improved health care, research, and education" (1).

Of the more than 37 million people with kidney diseases in the United States, a disproportionate number are Black or African American, Hispanic or Latinx, Indigenous or Native American, Asian American, and Native Hawaiian or other Pacific Islanders. Disproportionately, people with kidney diseases also have lower socioeconomic status. As is well documented, the kidney health of these Americans is unacceptable (2). Achieving health care justice for them requires the following:

- Identifying opportunities to promote fairness in health care and society
- Influencing social determinants of health, particularly in populations at risk for and overburdened with kidney diseases
- Acknowledging that all kidney health policy should be rooted in the principle of justice
- Making it incumbent on all kidney health professionals to seek just, equitable social conditions for their patients, their colleagues, and their communities (3)

Teams, medical specialties, and associations that embrace diversity, equity, inclusion, and justice make better decisions, are more innovative, perform at a higher level, experience less turnover, are considered more satisfying workplaces, and are financially more profitable (4). Compelling data underscore this reality. Such a culture also reveres empathy. As the poet Lucille Clifton observed, "Every pair of eyes facing you has probably experienced something you could not endure" (5).

Promoting diversity, equity, and inclusion among kidney health professionals depends on "some of the same solutions" as health care justice but often necessitates "different sets of strategies—at the levels of federal and local policies, multisector and community-academic partnerships, institutional policies and practices, individual and social group attitudinal and behavioral change—and targeted interventions to address not only organizational but also broader social and environmental influences on health," according to ASN Secretary Deidra C. Crews, MD, ScM, FASN, and colleagues (6).

By making a public commitment, examining the society, establishing a presence, funding the next generation, continuing to learn, and addressing policy issues, ASN has created a strong foundation in diversity, equity, inclusion, and justice (Table 1). The society's leadership, staff, and I are committed to building on this bedrock in 2022 and beyond.

In addition to continuing many of the 26 activities listed in Table 1, ASN has identified five priorities centered on diversity, equity, inclusion, and justice for 2022. First, ASN must continue working with the National Kidney Foundation (NKF) to implement recommendations from the NKF-ASN Task Force on Reassessing the Inclusion of Race in Diagnosing Kidney Diseases. ASN is responsible for addressing the legislative and regulatory issues related to the task force's recommendations, including the need to encourage and fund "research on [glomerular filtration rate] GFR estimation with new endogenous filtration markers and on interventions to eliminate racial and ethnic disparities" (7). This recommendation compels KidneyCure (established in 2012 as the ASN Foundation for Kidney Research) to enhance its grant portfolio as well.

Last month, ASN participated in a workshop, "Designing Interventions That Address Structural Racism to Reduce Kidney Health Disparities." The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) held the workshop to review how structural racism contributes to health and health disparities for people with kidney diseases, as well as to "identify feasible areas for intervention," including "study designs needed to evaluate potential interventions" (8). NIDDK will summarize the results of the workshop in the near future.

Second, the society launched the ASN Health Care Justice Committee in March 2021. Recently, the ASN Council discussed the committee's first set of recommendations. In the coming months, ASN will announce specific plans to pursue justice in medical education, scholarship, clinical care, innovation, and advocacy. Following the committee's advice, for example, Kidney Week 2022 will include a "Health Equity" abstract category.

In 2020, I served as president of the Council of Medical Specialty Societies (CMSS), a coalition of 47 medical specialty societies (including ASN) that represents more than 800,000 US physicians. Last year, CMSS partnered with the Accreditation Council for Graduate Medical Education to launch "Equity Matters: A Diversity, Equity, Inclusion, and Antiracism Initiative for Physicians and Medical Leadership."

ASN's third priority is to initiate a "capstone project" with other specialty societies as part of "Equity Matters." This project will result in concrete recommendations for increasing the pool of US medical school applicants who identify as underrepresented in medicine, improving the likelihood of their acceptance and enrollment, and reducing barriers to their successful graduation to residency training and beyond.

CMSS also plays a key role in ASN's fourth priority. Earlier this year, CMSS worked with the American Medical Women's Association, Executive Leadership in Academic Medicine, and other leading groups to establish a new alliance: the Gender Equity in Academic Medicine and Science Alliance (GEMS Alliance). The GEMS Alliance will work collectively to ensure that "all women achieve their full potential in advancing medicine and science" (9).

As its fifth priority, ASN responded last month to a request from the US Centers for Medicare & Medicaid Services "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" (10). In its 71-page response, ASN provided specific suggestions to the federal government and emphasized: "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."

To strengthen, target, and increase the likely success of its current and future initiatives to promote diversity, equity, inclusion, and justice, ASN is enhancing the collection of member demographic information and under-

ASN has increasingly promoted diversity, equity, and inclusiveness "to enhance the nephrology profession and the lives of people with kidney diseases through improved health care, research, and education."

standing of its members. In the future, ASN plans to:

1. Publish an anti-racism toolkit on its website.
2. Continue to refine the ASN Loan Mitigation Pilot Program. All six of the program's first participants will start nephrology fellowships on July 1, 2022.
3. Seek options for assessing workplace culture.
4. Facilitate conversations among the US Food and Drug Administration, commercial entities, the society's members, and other stakeholders on setting guidelines and developing tools to promote increased diversity of participants in clinical trials.
5. Engage with Historically Black Colleges and Universities, Hispanic-Serving Institutions, and others to reach potential health professionals, researchers, and scientists from groups underrepresented in medicine.

A pacesetter yesterday. An advocate today. An innovator tomorrow. ASN is fully committed to promoting diversity, equity, inclusion, and justice in nephrology, health care and science, and broader society. ■

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Table 1. ASN's activities for promoting diversity, equity, inclusion, and justice

Make a public commitment
1. Dedicating goals in ASN's Strategic Plans (2016–2020 and 2021–2025) to increasing diversity, achieving equity, embracing inclusion, and pursuing justice
2. Producing "ASN Values Statement on Diversity and Inclusion"
3. Issuing an ASN statement against racism and signing the AAMC and CMSS statements against racism
4. Facilitating a webinar on "Going Beyond the Statement: Dismantling Systemic Racism in Nephrology"
5. Testifying during the House of Representatives Ways and Means Committee Hearing on the "Disproportionate Impact of COVID-19 on Communities of Color"
Examine the society
6. Improving demographic data collection from members by increasing participation and expanding and advancing inclusiveness
7. Requesting that all ASN committees examine their demographic data
8. Requiring implicit/unconscious bias training for ASN leaders, including committee members
9. Launching midcareer awards to recognize clinicians, researchers, educators, mentors, and leaders
10. Establishing the ASN Diversity, Equity, and Inclusion Committee and the ASN Health Care Justice Committee
11. Reevaluating every aspect of the annual process for identifying, nominating, and selecting candidates to run for the ASN Council to ensure diversity, equity, and inclusion
Establish a presence
12. Providing administrative support to Women In Nephrology
13. Featuring regular sessions at ASN Kidney Week related to diversity, equity, inclusion, and justice, including the annual in-person Wesson-Himmelfarb Diversity and Inclusion Lunch (and virtual gatherings throughout the year)
14. Holding an annual LGBTQ+ and Allies Members Reception at Kidney Week (and virtual gatherings throughout the year)
15. Convening a KHI "Member Town Hall: Diversity in Clinical Trials"
16. Exhibiting at the AMSA, APSA, LMSA, and SNMA Annual Meetings
Fund the next generation
17. Partnering with the RWJ Foundation to fund ASN-Harold Amos Medical Faculty Development Program Scholars
18. Providing travel support for members to attend the NIDDK Network of Minority Health Research Investigators Annual Workshop
19. Launching the ASN Loan Mitigation Pilot Program to attract people who are underrepresented in medicine to careers in nephrology
Continue to learn
20. Proposing sessions at Kidney Week on caring for underserved populations (such as patients who are LGBTQ+ and people with physical disabilities)
21. Publishing perspectives on caring for diverse patient populations (such as appropriately identifying and supporting individuals who are of NHPI background and highlighting the need to support individuals who live in rural parts of Hawaii)
22. Examining perceptions of visa issues for nephrology fellows who are IMGs
23. Launching a multi-pronged approach to position nephrology as attractive to and inclusive of osteopathic students and physicians, as well as mitigating potential biases
Address policy issues
24. Partnering with NKF to form the NKF-ASN Task Force on Reassessing the Inclusion of Race in Diagnosing Kidney Diseases, which resulted in nephrology being the first specialty to recommend removing race from a major clinical algorithm
25. Advocating for Congress to pass the Health Equity and Accountability Act of 2020—legislation to address disparities in health care
26. Joining "Equity Matters: A Diversity, Equity, Inclusion, and Antiracism Initiative for Physicians and Medical Leadership," a collaboration between ACGME and CMSS
Organizations and Acronyms
Accreditation Council for Graduate Medical Education (ACGME)
American Medical Student Association (AMSA)
American Physician Scientists Association (APSA)
Association of American Medical Colleges (AAMC)
Council of Medical Specialty Societies (CMSS)
International Medical Graduates (IMGs)
Kidney Health Initiative (KHI)
Latino Medical Student Association (LMSA)
Lesbian Gay Bisexual Transgender and Queer or Questioning and Others (LGBTQ+)
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
National Kidney Foundation (NKF)
Native Hawaiian and Other Pacific Islander (NHPI)
Robert Wood Johnson (RWJ) Foundation
Student National Medical Association (SNMA)

Identifying, Confronting, and Addressing Systemic Racism in US Nephrology

By Crystal A. Gadegbeku, Tod Ibrahim, Anupam Agarwal, and Susan E. Quaggin

In the United States, people who are Black or African American, Hispanic or Latinx, Indigenous or Native American, Asian American, and Native Hawaiian or other Pacific Islanders (NHPIs) are underpaid, financially disadvantaged, and underrepresented in corporate leadership and government. When compared to White Americans, minoritized people have higher rates of unemployment, have been denied opportunities to build wealth, are more likely to have mortgage applications rejected, face higher debt for student loans, and are less likely to have the same educational opportunities.

Besides experiencing discrimination and being poorer with fewer professional opportunities than White Americans, Black and Latinx Americans are less likely to have health insurance, have less access to health care, and experience lower-quality care when they do have access. They also have higher rates of kidney diseases, asthma, cancer, cardiovascular diseases, diabetes, HIV/AIDS, hypertension, and obesity, to name a few chronic diseases. The COVID-19 pandemic has accentuated and exacerbated these health disparities and inequities: Black, Latinx, and Indigenous people are more likely to be infected by and die from the virus, whereas White Americans disproportionately received more vaccinations in the early stages of the rollout (1).

Addressing these disparities and inequities requires identifying and confronting racism on a systemic level. Health status closely correlates with racism and socioeconomic status (as does allostatic load), which is further stagnated by a lack of upward mobility through multiple generations. In addition to health and health care, these social determinants of health include economic stability, social and community context, neighborhood and built environment, and education.

Unfortunately, the educational system in the United States (including undergraduate and graduate medical education) disadvantages people who are Black, Latinx, Native American, and NHPIs. Black Americans are currently 13.4% of the US population, but racism undermines their opportunity to pursue professions like medicine where few apply (8.4%), matriculate (6.2%), match into residency programs (5.1%), work in academic medicine (3.6%), or reach the rank of full professor (1.9%) (Table 1). From 1970 to 2020, the percentage of Black Americans graduating from US medical schools has not changed, whereas, by comparison, the percentage of women has increased from 8.4% to 49.6% (2).

The Association of American Medical Colleges defines "underrepresented in medicine" (UIM) as "those racial and ethnic populations that are underrepresented in the medical profession relative to their numbers in the general population" (3). Nephrology has a higher percentage of UIM fellows than most other internal medicine specialties, particularly cardiology, gastroenterology, hematology/oncology, pulmonary and critical care medicine, and rheumatology (4). "With the exception of rheumatology, the subspecialties with the lowest percentages of UIM fellows were also the largest fellowships and the more procedural specialties."

As illustrated in Table 2, US medical schools need to quadruple the number of Latinx and double the number of Black medical students to begin to make medicine more representative. Until this important goal is accomplished, every medical specialty is competing to attract a limited number of underrepresented students into their residency and fellowship positions. How limited? Of the 19,938 graduates of US medical schools in 2019, only 1,238 and 1,063 identified as Black or Latinx, respectively (5).

The situation is equally troubling for PhDs. Less than 2% of the PhDs who receive funding from the National Institutes of Health (NIH) are Black, Latinx, Native American, or NHPI researchers. As was asserted in a recent editorial, "The NIH director and leadership must recognize that its previous approaches, most of which have focused on filling the 'pipeline' without simultaneously addressing our profession's systemic racism, have failed" (6). It is impossible to have a leaky pipe when no pipeline exists, so it is not surprising that fewer underrepresented individuals receive funding for their research, hold key leadership positions, or become endowed professors.

Taken together, these sobering facts contribute to the current disparities and inequities we face in nephrology: Of the more than 37 million adults with kidney diseases in the United States, a disproportionate number are Black, Latinx, Native American, Asian American, and NHPIs. The kidney health consequences these Americans face are particularly horrifying (Table 3). To advance kidney health, the American Society of Nephrology (ASN) must address systemic racism that results in health-related disparities and inequities in social determinants of health.

For the past decade, ASN has focused on promoting diversity and inclusiveness within the society to enhance the nephrology profession and the lives of people with kidney diseases through improved health care, research, and education. ASN supports two Harold Amos Medical Faculty Development Program Scholars from historically disadvantaged backgrounds, provides travel support for 25 ASN members each year to attend the National Institute of Diabetes and Digestive and Kidney Diseases' Network of Minority Health Research Investigators Annual Workshop, and requires implicit/unconscious bias training for the society's leaders and staff. Later this year, ASN will initiate a loan mitigation pilot program, funding six nephrology fellows annually from minority populations.

ASN fully recognizes the need to do more to address inequities that negatively impact the kidney community. Therefore, building on these initiatives, ASN in 2021 is prioritizing opportunities to address health disparities and influence social determinants of health in the United States and throughout the world, particularly in populations at risk for and overburdened with kidney diseases; highlighting specific health-equity issues that should be addressed on a policy level; working to achieve optimal care for all people at risk for and overburdened with kidney diseases; and helping to dismantle racist structures that impact social determinants of health and lead to health disparities and inequities.

This summer, the National Kidney Foundation (NKF)-ASN Task Force on Reassessing the Inclusion of Race in Diagnosing Kidney Diseases will inform the kidney community and other stakeholders on how to move forward with an inclusive, equitable measurement of kidney function that recognizes race as a social, not a biological, construct (7). Through this process, NKF and ASN have ensured that any change in eGFR reporting carefully considers the multiple social and clinical implications, be based on rigorous science, and be part of a national conversation about uniform reporting of eGFR within, between, and among health care delivery systems. ASN is proud that the kidney community is taking the lead in critically evaluating the use of race in this clinical algorithm, likely forging a path for other specialties to follow in addressing this issue.

Identifying, confronting, and addressing racism in health care, in general, and kidney medicine, in particular, will require a wide-ranging approach and partnerships with myriad stakeholders beyond the kidney community. For example, ASN agrees with "The Moral Determinants of Health," which include having the United States (and many other democracies) ratify "the basic human rights treaties and conventions of the international community," stating in statute "health care as a human right" (and a wise investment of resources to promote wellness that fosters opportunity for people to contribute meaningfully to society), "restoring US leadership to reverse climate change," "achieving radical reform of the US criminal justice system," "ending policies of exclusion and achieving compassionate immigration reform," "ending hunger and homelessness," and promoting "order, dignity, and equity to US democratic institutions and ensuring the right of every single person's vote to count equally" (8).

As a first step toward achieving these goals, the American College of Physicians (ACP) in January 2021 unveiled "A Comprehensive Policy Framework to Understand and Address Disparities and Discrimination in Health and Health Care" (9). This approach includes recommendations to "create safe, inclusive, and supportive educational and workplace environments"; "address disparities in coverage, access, and quality of care for racial and ethnic minorities"; and change "criminal justice and law enforcement policies and practices that result in racial and ethnic disparities in interactions, sentencing, and incarceration and disproportionate harm to these communities."

As a member of the ACP Council of Specialty Societies, ASN looks forward to working closely with ACP to help implement this framework. ASN and ACP are also members of the Council of Medical Specialty Societies (CMSS), a coalition that includes 45 medical societies representing more than 800,000 US physicians. CMSS has partnered with the Accreditation Council for Graduate Medical Education to launch "Equity Matters: A Diversity, Equity, Inclusion, and Antiracism Initiative for Physicians and Medical Leadership."

The United States offers tremendous opportunities, hope, and audacity difficult to match elsewhere. A promising future for this country, however, depends on overcoming systemic racism today for all Americans to enjoy healthy and happy lives. ■

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Table 1. Black and African Americans in academic medicine

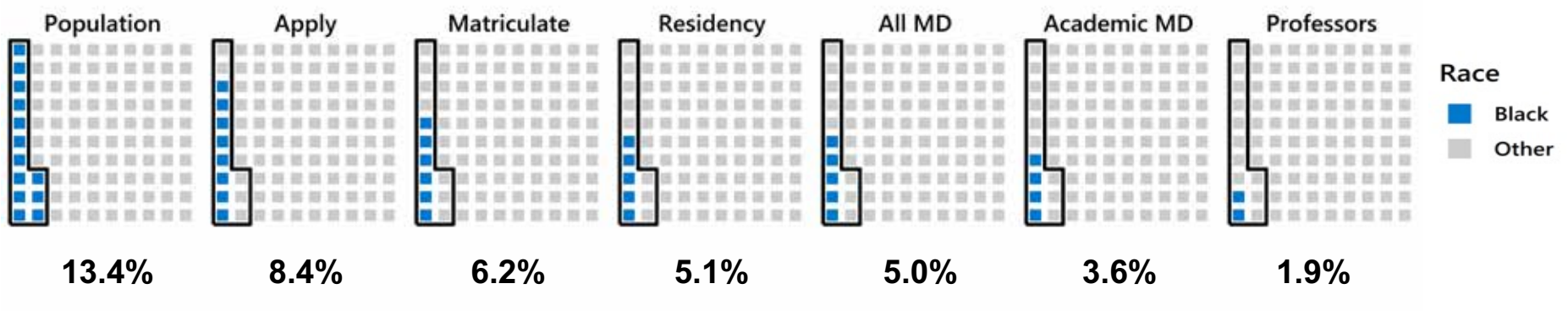

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Table 2. The US population and US medical school graduates by race and ethnicity*

	US population		US medical school graduates in 2019
	2020	2030	
White	60.1%	55.8%	54.6%
Hispanic or Latinx	18.5%	21.0%	5.3%
Black or African American	13.4%	12.8%	6.2%
Asian American	5.9%	6.7%	21.6%
Multiracial	2.8%	2.8%	8.0%
Indigenous or Native American	1.3%	0.7%	0.2%
Native Hawaiian or other Pacific Islanders	0.2%	0.2%	0.1%

*Does not equal 100% due to rounding and other counting issues.

Association of American Medical Colleges. Diversity in Medicine: Facts and Figures 2019. Figure 13. Percentage of U.S. medical school graduates by race/ethnicity (alone), academic year 2018–2019. Accessed May 24, 2021. https://www.aamc.org/data-reports/workforce/interactive-data/figure-13-percentage-us-medical-school-graduates-race/ethnicity-alone-academic-year-2018-2019

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Table 3. Kidney health disparities and inequities in the United States: A partial list

1	Black people comprise 13.4% of the US population but 33% of the nation's population on dialysis for kidney failure.
2	Kidney failure prevalence is about 3.5 times greater in Black people, 2.7 times greater in Native Hawaiians and Pacific Islanders (NHPIs), 1.5 times greater in Latinx people, and 1.4 times greater in Native Americans than in White Americans.
3	Kidney failure is increasing among Native Americans at an alarming rate (nearly 10% between 2017 and 2018 alone), while decreasing among White Americans during the past decade.
4	People who are Black, Latinx, Native American, and NHPI are significantly less likely than their White counterparts to receive any kidney care before kidney failure, missing key opportunities for intervention.
5	The median age of initiating dialysis is younger for NHPIs (57 years old) than for Whites (65 years old).
6	Black, Latinx, Native American, and NHPI people on dialysis are significantly less likely than their White counterparts to receive a kidney transplant and are also less likely to receive a living donor kidney transplant (the optimal type of transplant) than Whites.
7	Even though NHPIs experience better survival for kidney transplants, they have substantially lower transplant rates compared with Whites.
8	Black Americans have disproportionately high rates of kidney transplant (allograft) failure compared to White Americans, with up to a 60% higher risk of allograft failure.
9	When compared to White Americans, Black Americans are less likely to be placed on the transplant waiting list and, once on it, experience disparities in the time it takes to receive a kidney.
10	Every racial/ethnic minority group in the United States is significantly less likely to be treated with home dialysis than White Americans, and demographic and clinical characteristics are insufficient to explain this differential use: Home dialysis is 40% to 50% lower among Black and Latinx people compared to Whites.