

July 6, 2021

The Honorable Shalanda Young
Acting Director
White House Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Dear Acting Director Young:

On behalf of the more than 37,000,000 Americans living with kidney diseases and the nearly 22,000 nephrologists, scientists, and other kidney health care professionals who comprise the American Society of Nephrology (ASN), thank you for the opportunity to comment on the White House Office of Management and Budget's (OMB) Request for Information (RFI) regarding the *Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government*. ASN applauds the Biden-Harris Administration for this extremely important executive order directing OMB to identify effective methods for assessing whether agency policies and actions (e.g., programs, services, processes, and operations) equitably serve all eligible individuals and communities, particularly those that are currently and historically underserved.

This letter provides an overview of the current state of inequities and disparities in kidney diseases and proposes four areas that OMB should consider when evaluating agency policies and actions, namely:

- 1) Does this policy reduce inequities in the early diagnosis and treatment of kidney diseases for all patients with, or at risk of, kidney disease?
- 2) Does this policy help transform transplantation such that all eligible patients have increased access to donor kidneys?
- 3) Does this policy accelerate research and innovation to expand patient choice, including the choice to do home dialysis?
- 4) Does this policy focus on achieving equity and eliminating disparities in kidney diseases?

Inequities and Disparities in Kidney Diseases

While health inequities and disparities challenge the US health care system in several ways, ASN's comments focus on the epidemic of chronic kidney disease (CKD). This epidemic impacts more than 37,000,000 Americans, 90% of whom are unaware that they have kidney diseases.

Kidney diseases are the ninth leading cause of death in the United States, causing more deaths than breast cancer. These deaths are in part due to an extremely high risk of cardiovascular disease (CVD) associated with CKD as well as a high risk of

progression to kidney failure—a permanent form of kidney disease that impacts more than 800,000 people in the United States.ⁱ Unfortunately, kidney diseases and kidney failure are more common among Black people, Hispanic or Latinx people, Native or Indigenous Americans, people in lower income brackets, and among the elderly—communities that have been disproportionately affected by the COVID-19 pandemic.

Preliminary Medicare claims and observational data show that the COVID-19 pandemic has worsened existing disparities among CKD populations and that acute kidney injury from COVID-19 can cause or exacerbate kidney diseases. For those individuals who progress to kidney failure, Black Americans are 3.7 times more likely to develop kidney failure than white Americans, and Latinx Americans are 1.5 times more likely to develop kidney failure than non-Hispanic or Latinx Americans. Further, Black, Indigenous American, and Latinx Americans are less likely to receive a kidney transplant or initiate home dialysis as discussed in greater detail later in this letter.

Additionally, Black, Asian, Native Hawaiian or Pacific Islander (NHPI), and multiracial populations were more likely to be diagnosed later in the CKD disease process. For example, compared to 58% of white patients, 74% of Black Americans were not diagnosed with kidney failure (also called End-Stage Renal Disease [ESRD]) until their kidney dysfunction was so advanced that their estimated glomerular filtration rate (eGFR) was less than 10 mL/min/1.73 m². (Attached to this comment letter is ASN's May 4, 2021, comment letter to the Agency for Healthcare Research and Quality's [AHRQ] "Request for Information (RFI) on the Use of Clinical Algorithms That Have the Potential to Introduce Racial/Ethnic Bias into Healthcare Delivery.")

Often poorer and sicker than other Medicare beneficiaries, dialysis patients rely on federal and state subsidies and welfare programs, such as Medicaid. In 2018, ESRD beneficiaries made up about 1% of total Medicare enrollment and 2.5% of dual-eligible enrollment. The dual-eligible population may also have different social risks, with associated implications for health outcomes and service use. Dually eligible beneficiaries with kidney failure are more often Black Americans, Latinx Americans, Indigenous Americans, or NHPIs and have higher costs compared to non-dual eligible beneficiaries, despite similar utilization patterns to their non-dual-eligible counterparts.

The systemic barriers to accessing basic healthcare likely play a substantial role among individuals of lower socioeconomic status, including those who will rely on Medicaid, developing kidney disease and progressing to kidney failure. For example, Medicare-Medicaid dual eligibility status has been found to correlate with a lower likelihood of care for patients with kidney diseases who are ultimately progress to kidney failure.

The intersection between COVID-19 and kidney diseases also caused untold devastation. Americans on dialysis are more likely to be hospitalized for COVID-19 than other Medicare beneficiaries, and those hospitalized due to COVID-19 are nearly three times more likely to dieⁱⁱ. Therefore, Black and Latinx Americans are more likely to have kidney disease, are more likely to be on dialysis, are more susceptible to COVID-19 infection, and are more susceptible to death from this virus. Further, COVID-19 can

cause kidney dysfunction. A recent national study of US veterans with no prior history of kidney disease who became hospitalized with COVID-19 showed that approximately 30% of the patients experienced acute kidney injuryⁱⁱⁱ.

To truly change these dynamics, ASN recommends that OMB evaluate Department of Health and Human Services (HHS) budget requests with four overarching questions:

1. Does this request lead to interventions that reduce inequities for disadvantaged patients who have kidney disease or patients who are at risk of kidney disease such that these patients have equitable access to practices that:
 - a. prevent the development of kidney disease?
 - b. diagnose kidney disease early?
 - c. provide coordinated care to improve patient awareness of treatment options for CKD and kidney failure?
 - d. educate patients with kidney disease?
2. Does this request help transform transplant and increase access to donor kidneys?
3. Does this request accelerate innovation and expand patient choice, including the choice to do home dialysis?
4. Does this request achieve equity and eliminate disparities in kidney disease?

The roots of disparities among those with or at risk for kidney diseases are deep and multifactorial, spanning from inequities in disease detection and prevention to access to optimal therapies for kidney failure such as transplantation and home dialysis, and these disparities are closely linked to social determinants of health and systemic racism on a national level. These disparities will not be adequately addressed in the absence of dismantling these inequitable structures in and outside of health care, however, the kidney health disparities discussed below can and must begin to be addressed through federal health care policy.

- **Earlier intervention to prevent, diagnose, coordinate care, and educate individuals patients with kidney diseases or who are at risk for developing kidney diseases.**

In addition to the gross inequities in the burden of kidney diseases, kidney diseases are costly to the American taxpayer. Annually, Medicare spends more than \$130 billion managing the care of all kidney patients and nearly \$50 billion alone on care for those with kidney failure. These expenditures do not include spending on kidney health by the Veterans Health Administration, the Department of Defense, the Indian Health Service, or private payers. In many cases, kidney diseases and kidney failure can be prevented or delayed. Therefore, an increased focus on prevention, research, and innovation can help improve patients' lives, mitigate disparities, and reduce these staggering expenditures.

Early Stages of Kidney Diseases

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 carry these diagnosed with these diseases more than other Americans. 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.

Over the last decade, novel treatments for kidney diseases have been discovered, including drugs like SGLT2 inhibitors and GLP-1 receptor agonists, in addition to the generation of evidence quantifying the benefits of medical nutrition therapy for kidney diseases. These therapeutic options can slow the risk of development and progression of CKD, thus highlighting the potential benefit of screening in asymptomatic, high-risk patients, such as those with diabetes and hypertension. Furthermore, 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).^{iv}

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.^v

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 programming within communities hardest hit by racial disparities in kidney health, including recruiting and incentivizing community-based organizations to serve as patient navigators. A 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.

Late-Stage CKD and Kidney Failure

Kidney Disease Education Benefit

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

The KDE education benefit represents one approach to help patients facing potential kidney failure consider kidney failure treatment options, but it is only available to Stage 4 patients with 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. The Biden-Harris Administration should support key steps to expanding the program’s reach:

1. Permitting advanced practitioners (i.e., physician associates, nurse practitioners, and clinical nurse specialists), in addition to physicians, to serve as referral sources for the benefit.
2. 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 – stage 5 is the most advanced stage before kidney failure;
3. Including dietary consultations at all Stages; and

4. 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. 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.

- **Transform Transplant and Expand Access to Donor Kidneys**

Transplantation is the best available therapy for many individuals with kidney failure. However, Black Americans, Latinx Americans, Native Americans, and NHPs face disparities in nearly every step of transplant care. Black Americans are less likely than white Americans to be identified as transplant candidates,^{vi} referred for evaluation,^{vii} placed on the kidney transplant waitlist,^{viii} receive kidney transplants especially pre-emptive transplants,^{ix} and/or receive living donor kidney transplants,^x while also being more likely to receive lower quality kidneys^{xi}, have organ offers declined for them and have poorer transplant graft survival.^{xii}

Many factors contribute to these inequities that are within the control of federal policy makers. These include duplicative and confusing federal oversight structures of organ procurement, allocation, and transplantation that engender risk aversion, transplant center evaluation measures that are misaligned with patient interests, and the use of patient evaluation criteria to gatekeep transplant access that have a limited association with patient outcomes (especially compared to patient outcomes on other kidney replacement therapies), such as income, race, requirement of dual insurance, substance use, and obesity.

The failure of the Organ Procurement and Transplantation Network (OPTN) to innovate, having failed to create a robust national living donor swap program, create modern

robust data capture systems, or develop clinical decision support tools to facilitate organ transplantation are highlights of this inertia.

ASN recommends that the Biden-Harris Administration establish an Office of Organ and Transplant Policy to coordinate currently siloed organ policy efforts particularly within the Centers for Medicare & Medicaid Services (CMS) and the Health Resources & Services Administration (HRSA), with an emphasis on increasing equity in transplantation. The disconnected oversight of the entire transplantation system demands an HHS department-wide approach to address the inequities of the system that are growing while the national waitlist is steadily shrinking and is currently has the lowest proportion of prevalent ESKD patients in the past two decades.

The office should align quality metrics within the transplant system that currently work at cross-purposes with the objective of increasing equitable access to kidney transplants and work with stakeholders, including ASN, to develop alternate proposals. While there may be sound clinical reasons for some variances in transplant center criteria for potential recipients, the Office of Organ and Transplant Policy needs to ensure transparency across the system so patients, and their nephrologists, have a clear understanding of which centers would be willing to consider them as candidates and where they are in the transplant process.

The Office should also be directed to identify barriers to access such as the requirement of dual insurance. Dual insurance requirements were designed to ensure coverage of immunosuppressive medications after Medicare coverage expired after three years but this policy discriminated against lower wealth individuals. Now that Medicare coverage of immunosuppressives has been extended for the life of the allograft, this policy should be completely expunged from federal policy.

Eliminating or disallowing transplant centers to deny patients acceptance into a program based on their financial status will increase access for socioeconomically disadvantaged patients—particularly patients who are Black, Latinx, Native American, and NHPs—who may otherwise be good candidates for transplantation.

ASN thanks the administration for finalizing 42 CFR 486, the “Organ Procurement Organization Conditions for Coverage.” This final rule will aid in the implementation of objective organ procurement metrics and accountability reform to increase organ supply.

- **Accelerate Innovation and Patient Choice, Including the Choice to do Home Dialysis**

The goals of increasing patient choice and accelerating innovation work best for patients when they are thought of as equal parts of the same equation. Kidney failure treatments, in particular, are preference sensitive, mandating that patients and their care partners have access to sufficient knowledge, technology, and expertise to engage

in the care they feel will best allow them to achieve their life goals. ASN recommends that the Biden Harris Administration pursue both of the following:

1. Increasing patient choice in kidney care options and environments, including telehealth, home dialysis, self-care dialysis, in-center dialysis, conservative care, and transplant.
2. Supporting policies and programs to accelerate development of – and patient access to – new kidney diagnostics, therapeutics, and devices, ending decades of relative stagnation of innovation in kidney care.

Patient Choice

Telehealth

Early in the COVID-19 public health emergency (PHE), public health officials realized that health care delivery needed to pivot rapidly towards delivering health care via telehealth and away from in-person encounters—a strategy designed to minimize exposure to the virus for vulnerable patients and the health-care professionals providing care. At the start of the PHE, with stay-at-home orders in place and warnings on the risk for severe illness from COVID-19, fee-for-service (FFS) in-person visits for primary care fell precipitously in March 2020. According to a report issued by HHS in April 2020, nearly one-half (43.5%) of Medicare primary care visits were provided through telehealth compared with less than one percent (0.1%) in February before the PHE began.^{xiii}

In nephrology, significant adjustments to telehealth in the PHE included waivers for care of patients undergoing dialysis. Adjustments specific to dialysis included the suspension of the required one quarterly in-person visit for home dialysis, the suspension of the one monthly in-person exam for in-center dialysis as long as the patient was deemed stable, and the ability to conduct telehealth visits while patients are receiving in-center dialysis treatments.

Looking to the future of telehealth, ASN believes the principles that should govern the approach to telehealth for people with kidney diseases include the following:

- Ensuring equitable access to patient-centered care whether it is delivered in-person or via telehealth, and that care delivered in-person and via telehealth be of equally high quality.
- Guaranteeing that care, both via in-person and telehealth, be available to every patient with kidney disease, regardless of race, ethnicity, sex, gender identity, sexual orientation, age, income, class, disability, immigration status, nationality, religious belief, language proficiency or geographic location.
- Protecting both patients' choice to receive or not receive care via telehealth as well as nephrologists' choice to provide care via telehealth or in-person: both patient and physician must mutually consent to the use of telehealth post-PHE.
- Protecting confidentiality and privacy.

- Gathering and analyzing data on telehealth performance from the PHE and continuing to gather data following the PHE to inform future telehealth policies.
- Crafting long-term telehealth policies that are flexible, patient-centered, patient-informed, and supported by said data.

Guided by these principles, ASN believes the federal government should take the following 10 steps moving forward to preserve patient choice and stability in the delivery of kidney care after the PHE:

1. Remove geographic and originating site restrictions for all telehealth services (note, these have been partially removed for the delivery of home dialysis by pre-PHE Congressional action).
2. Maintain, without change, the status of telehealth for home dialysis patients that existed pre-PHE.
3. Allow the choice of telehealth visits for those in-center patients deemed stable (patient can be in-center or home) but requiring one face-to-face visit at least every third month.
4. Require the nephrologist to provide monthly in-person visits if medically necessary or requested by the patient.
5. Allow telehealth visits for new patients as well as existing ones.
6. Allow telehealth services for acute kidney injury (AKI) patients on outpatient dialysis three times in one month and requiring the fourth visit be in-person.
7. Include people with kidney diseases who are not on dialysis to use telehealth for scheduled visits.
8. Maintain parity between telehealth and in-person rates.
9. Allow audio only telehealth visits when visual and audio equipment is not available or there are broadband constraints.
10. Maintain current waiver flexibilities for at least 6 months after the PHE is lifted or until December 31 of the year in which it is lifted—whichever is longest—if waivers have not already been extended or made permanent to allow for smooth transitions in care.

ASN believes the United States is at an inflection point regarding telehealth. Telehealth along with remote patient monitoring have great potential to transform care delivery. However, it is necessary for the nation to make a commitment to preventing the “digital divide” from becoming yet another long-lasting disparity in health care. Some patients experience poor access to necessary technologies and are not able to fully benefit from new digital tools or expanded access to telehealth. This “digital divide” has only been accentuated during the pandemic. Low-income patients and the elderly may encounter connectivity and broadband issues more frequently, or not have appropriate access to communication devices.^{xiv}

For all the reasons above, ASN recommends that the Biden-Harris Administration support these policies—especially allowing audio only telehealth when visual and audio is not present for those without broadband access, the elderly, and lower-income households.

Home Dialysis

Patients with kidney failure undergoing dialysis can do so at an in-center facility or at home. There are two types of home dialysis: peritoneal dialysis (PD) and home hemodialysis (HHD). PD treatment uses a special solution infused into and then drained from the individual's abdominal cavity to filter blood and remove waste. Hemodialysis (HD) is a treatment in which an artificial membrane, known as a hemodialyzer, is used to filter the blood. HD is the most common type of treatment used in dialysis facilities, but it can also be done at home.

At the end of 2018, there were only 69,000 patients performing dialysis in the home, or approximately 12.5% of all dialysis patients, the rest were receiving in-center hemodialysis. Nearly 85% of patients utilizing home dialysis performed peritoneal dialysis.^{xv} While the portion of patients performing home dialysis in the United States is slowly increasing, the country lags behind many other industrialized countries. As a result, the Center for Medicare & Medicaid Innovation (CMMI) created two nephrology models: the mandatory ESRD Treatment Choices (ETC) model and the voluntary Kidney Care Choices (KCC) model. The ETC model is designed to increase rates of both home dialysis and kidney transplant to improve patient outcomes and reduce costs in the Medicare ESRD Program.

Home dialysis offers significant clinical, socioeconomic, and quality of life advantages. Home patients are associated with better survival rates, better preservation of residual kidney function, and fewer low blood pressure episodes.^{xvi} Home dialysis also provides many patients with greater autonomy and flexibility over their care. These patients can choose when they dialyze, reduce their dependence on transportation, and improve their financial stability if it allows the patient to continue to work. One study found that home dialysis patients are five times more likely to hold employment than patients who dialyze in-center.^{xvii}

Despite the benefits of home dialysis, data show much lower rates of home dialysis for Americans of color. From 2005 to 2013, Black patients were 30% less likely and Latinx patients 19% less likely than white patients to start on peritoneal dialysis (PD), an effect that was attenuated when adjusting for socioeconomic factors, while minority groups were between 7% and 35% less likely to receive HHD.^{xviii} The finding that socioeconomic status attenuates this relationship highlights modifiable inequities in home dialysis.

Patients with kidney disease identify a several reasons that prevent them from pursuing home dialysis. A common one is a lack of awareness about home dialysis being an option. This is especially the case among individuals who begin dialysis in an unplanned, urgent, or emergent ("crash") manner, often with little or no pre-dialysis nephrology care, with a dialysis catheter during an unplanned hospitalization.^{xix}

Other commonly identified barriers to home dialysis:

- Lack of home or stable home environment.
- Limited space in the home due to size and/or number of residents.
- Expense of adapting plumbing and electrical systems.
- Increased expense of water and electricity.
- Patient living alone without the support of a care partner.
- Lack of home assistance paid by Medicare and private payers.
- Lack of training especially for those who “crash” into dialysis.
- Lack of confidence and/or patient’s physical limitations.

ASN recommends that the Biden-Harris Administration work with Congress to overcome these barriers by:

1. Creating a short-term staff assistance benefit as a process to transition a patient to home dialysis. Staff assist could begin with full support that is tapered 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 skilled nursing facility (SNF) or at home recovering from an acute illness.
2. Providing additional home support assistance through rulemaking in the ETC Model.
3. Discounting or reimbursing incremental utility usage increases.
4. Providing co-pay assistance.
5. Incentivizing PD before initiating fistula placement access.
6. Ensuring that quality metrics in the Medicare ESRD program do not indirectly penalize dialysis facilities that have high home dialysis rates.
7. Eliminating requirements to regularly document plans of care justifying more than thrice weekly treatments for HHD.
8. Establishing parity in reimbursement between home dialysis and in-center dialysis.
9. Increasing reimbursement for surgeons performing PD access placement.
10. Gathering patient input for the creation of home dialysis quality metrics.

Steps taken to advance the use of home dialysis are greatly supported by the preceding recommendations on telehealth as well. The discussion on data later in this letter will also address the use of “Z” codes covering social determinants of health (SDoH) related to housing and economic circumstances for patients.

Innovation

Kidney X

As discussed in this letter, the status quo for treating and managing kidney diseases—especially kidney failure—is too costly to taxpayers and burdensome to people with kidney diseases to continue without intervention. That is why ASN committed itself, and \$25 million of its own money, to create KidneyX.

KidneyX is a public-private partnership between HHS and ASN to accelerate innovation in the prevention, diagnosis, and treatment of kidney diseases. KidneyX is incentivizing innovators to fill unmet patient needs through a series of prize competitions, de-risking the commercialization process by fostering coordination among federal agencies and creating a sense of urgency on behalf of patients and families.

To date, KidneyX has awarded 61 prizes to patients, care providers, clinicians, community health workers, academic researchers, small and large businesses, spanning over 22 states. Solutions have ranged from patient-developed innovations, safer and more convenient methods for in-home dialysis, tools to sustain kidney care during COVID-19 and future pandemics, and early steps toward a wearable or implantable artificial kidney.

A bipartisan effort, KidneyX was first unveiled as a concept at the 2016 the Obama-Biden Administration's White House Organ Summit and was a central pillar of former President Donald J. Trump's July 2019 Executive Order on Advancing American Kidney Health. KidneyX is a true public-private partnership: ASN has already committed \$25 million to KidneyX and is securing additional private funding and is committed to matching federal funding to achieve a total \$250 million in the first five years. Since its inception, KidneyX has demonstrated the success of its public-private prize funding model, delivering on its mission of accelerating innovation in kidney care, attracting new innovators and investors to the kidney space, and broadening the availability of novel ideas and capital to improve the lives of the 37,000,000 Americans with kidney diseases.

Building on this success, KidneyX launched the Artificial Kidney Prize in 2020, the first of a multiphase prize to accelerate the development of the first wearable or implantable artificial kidney. Winners of Phase 1 of the Artificial Kidney Prize will be announced in September 2021, and ASN is requesting a \$25 million appropriation from Congress in fiscal year (FY 22) to support continued development of an artificial kidney through Phases 2 and 3 of the Artificial Kidney Prize and other innovations to catalyze further private investment in meeting the long unmet needs of this underserved population.

ASN encourages OMB to prioritize innovation for people with kidney diseases by continuing to support KidneyX as a federal priority. KidneyX must continue to direct the innovator and investment communities towards unmet needs of people with kidney diseases, steward these innovations so they can also be accessed by the people and families who needed them the most, and work across the kidney community to identify solutions and engage a broad spectrum of innovators to pursue their development.

Biomedical Research Workforce and Research to Eliminate/Lessen Health Disparities and Inequities

ASN supports the National Institutes of Health (NIH) in its efforts to "advance racial equity, diversity, and inclusion within all facets of the biomedical research workforce and expand research to eliminate or lessen health disparities and inequities." ASN is pleased to see NIH address systemic challenges and barriers affecting the NIH

workforce and NIH-supported biomedical community as these efforts will have a significant impact on improving the nation's kidney health. Kidney diseases disproportionately affect those that are disenfranchised, and ASN advocates tirelessly for efforts to reduce health disparities and to develop a medical research and physician workforce that reflects the patient population it serves.

ASN encourages NIH and OMB to determine its support for initiatives by ensuring that each initiative adheres to the following basic principles:

- Advancing the issues that people with kidney disease confront now.
- Addressing the lack of innovation that has been, and still is present in kidney care.
- Improving conditions around disparities for children and adults with kidney disease.
- Creating new solutions for people with kidney disease that can be embraced by the community (e.g., easily translated into policy and practice).
- Achieving a diverse workforce representative of the kidney patient population.

ASN applauds the commitment from NIH to support workforce diversity and encourages NIH to highlight the work of underrepresented minority faculty in basic science and translational research funded through the NIH in materials (e.g. print brochures, short videos, social media posts, etc.) that can be easily distributed to aspiring biomedical scientists and allied health professionals at undergraduate institutions (i.e. Historically Black Colleges and Universities, Hispanic-Serving Institutions, Tribal Colleges and Universities, and other institutions) and post-baccalaureate programs. This effort should not just be focused on health disparities and equity-focused research.

ASN recommends that the Biden-Harris Administration support NIH efforts:

1. Sustaining existing, and promoting new, mentorship programs for underrepresented minorities in research.
2. Expanding loan forgiveness programs, promoting those by other government agencies, and consider partnering with other agencies to increase the amount of loan forgiveness provided.
3. Increasing access to application submission resources, changes to application submission instructions/guidance, interactions with and support from NIH staff during application process as these will help transcend the gap in resources of the parent institutions.
4. Ensuring a robust pipeline of the research workforce by developing new and expanding current initiatives that promote careers in biomedical research among undergraduate and high school programs, particularly targeting those from backgrounds with disproportionately high rates of kidney disease.
5. Maintaining support of the Network of Minority Health Research Investigators (NMRI) and the NMRI Annual Workshop, which has helped to nurture the career of many minority investigators in our field, including those whose focus is the elimination of kidney health disparities. Since 2015, ASN has provided travel

stipends to 97 nephrologists and kidney scientists to participate in this important program.

6. Moving further upstream and partner with innovative high school programs. NIH should consider developing radical and hands on biomedical science curricula focused particularly on disparity diseases.
7. Encouraging U2C/TL1 applicants to incorporate health equity and diversity and inclusion within their mission.
8. Targeting funding for underrepresented minority faculty in the basic science and translational research funding spaces to encourage greater involvement and scientific contribution from these historically disadvantaged groups.
9. Providing full transparency on the current diversity of funded investigators as well as the portfolio dedicated to health equity and health disparity research.

ASN supports NIH efforts to develop, maintain and renew scientific research capacity by cultivating the biomedical research workforce. ASN further recommends that NIH prioritize funding community engagement research in order to identify priority issues for improving outcomes for patients, this is particularly significant for reducing existing disparities.

- **Achieve Equity and Eliminate Disparities**

What does “achieving equity and eliminating disparities” ultimately look like? Even if the answer to that question may not be able to be fully expressed in this comment letter, ASN hopes the steps described will advance our society further along this path. While the recommendations herein may seem incremental, that makes them no less essential. The first essential step in kidney care is already underway.

Medical Algorithms

Examination of the use of race in clinical decision-making algorithms, such as the Kidney Donor Profile Index (KDPI) and estimated glomerular filtration rate (eGFR), is currently underway by the kidney community. ASN and the National Kidney Foundation (NKF) created a task force in 2020 to specifically address this issue with its final report expected later this summer.

ASN unequivocally reaffirms that race is a social, not a biological, construct, and the society remains committed to ensuring that racial and ethnic biases do not affect the diagnosis and treatment of kidney diseases. As stated in a letter to ASN membership in March 2021, “ASN asserts that 1) race modifiers should not be included in equations to estimate kidney function and 2) current race-based equations should be replaced by a suitable approach that is accurate, inclusive, and standardized in every laboratory in the United States.” Any such approach must not differentially introduce bias, inaccuracy, or inequalities.

Data Collection

Existing data already convey a disturbing landscape of disparity in kidney care from SDoH to diagnosis to kidney transplantation. Data collection now needs to focus on what “moves the needle” on these issues. ASN encourages the Biden-Harris Administration to direct HHS to focus on collecting data that does just that by collecting more data on the “why” of low rates of home dialysis and home dialysis retention. This can be aided by more research and assessment of patient experience and patient-reported outcomes that are impactful on individuals’ wellbeing.

ASN also urges more systematic ascertainment of social determinants of health data, including the most common non-clinical barriers to home dialysis, such as housing or financial insecurity, minimal caregiver support, other mental and certain physical illnesses, or advanced age. This information will help identify barriers to equitable care and develop policies to overcome these barriers.

Providing real time data on the progress of the CMMI kidney models could also increase kidney innovation—as would more real-time data from the United States Renal Data System (USRDS).

Conclusion

The more than 37,000,000 Americans living with kidney diseases and the nearly 22,000 nephrologists, scientists, and other kidney health care professionals who comprise ASN thank the Biden-Harris Administration for its commitment to addressing inequities and barriers to government programs for many individuals. The administration’s *Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government* is an important step down that path. ASN is committed to ensuring that racial and ethnic biases do not affect the prevention, diagnosis, and treatment of kidney diseases, including access to transplantation, home dialysis, new therapies, and innovation.

Thank you for the opportunity to provide comments on OMB’s RFI to identify effective methods for assessing whether agency policies and actions (e.g., programs, services, processes, and operations) equitably serve all eligible individuals and communities, particularly those that are currently and historically underserved. 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

<https://www.usrds.org/esrd-quarterly-update/>

ⁱⁱ https://www.washingtonpost.com/national/health-science/medical-databases-show-1-in-10-hospitalized-middle-aged-coronavirus-patients-in-us-do-not-survive/2020/04/11/284485a2-7bfe-11ea-b6ff-597f170df8f8_story.html?utm_campaign=wp_to_your_health&utm_medium=email&utm_source=newsletter&wpisrc=nl_tyh&wpmk=1

ⁱⁱⁱ <https://cjasn.asnjournals.org/content/16/1/14>

^{iv} [https://www.ajkd.org/article/S0272-6386\(21\)00561-8/fulltext](https://www.ajkd.org/article/S0272-6386(21)00561-8/fulltext)

^v Ibid

^{vi} Patzer, R. E., et al. The Role of Race and Poverty on Steps to Kidney Transplantation in the Southeastern United States. *Am J Transplant*. 2012. doi: 10.1111/j.1600-6143.2011.03927.x

^{vii} Epstein, A. M., et al. Racial Disparities in Access to Renal Transplantation — Clinically Appropriate or Due to Underuse or Overuse? *N Engl J Med*. 2000. doi: 10.1056/NEJM200011233432106

^{viii} Kasiske B. L., Ellison, M. D. Race and socioeconomic factors influencing early placement on the kidney transplant waiting list. *JASN*. November 1998, 9 (11) 2142-2147.

^{ix} <https://pubmed.ncbi.nlm.nih.gov/31413065/>

^x Ibid

^{xi} Mohandas, R. et al. Racial and Socioeconomic Disparities in the Allocation of Expanded Criteria Donor Kidneys. *Clin J Am Soc Nephrol*. 2013. doi: 10.2215/CJN.01430213

^{xii} Purnell, S.T., et al. Reduced Racial Disparity in Kidney Transplant Outcomes in the United States from 1990 to 2012. *J Am Soc Nephrol*. 2016. doi: 10.1681/ASN.2015030293

^{xiii} <https://www.hhs.gov/about/news/2020/07/28/hhs-issues-new-report-highlighting-dramatic-trends-in-medicare-beneficiary-telehealth-utilization-amid-covid-19.html>

^{xiv} <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7648180/>

^{xv} <https://adr.usrds.org/2020/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities>

^{xvi} <https://www.nxstage.com/patients/benefits-of-home-hemodialysis/>

^{xvii} <https://onlinelibrary.wiley.com/doi/10.1111/nep.12482>

^{xviii} Shen JI, Chen L, Vangala S, Leng L, Shah A, Saxena AB, Perl J, Norris KC. Socioeconomic Factors and Racial and Ethnic Differences in the Initiation of Home Dialysis. *Kidney Med*. 2020 Feb 11;2(2):105-115. doi: 10.1016/j.xkme.2019.11.006. PMID: 32734231; PMCID: PMC7380374.

^{xix} <https://systematicreviewjournal.biomedcentral.com/articles/10.1186/s13643-016-0297-2>