



The Honorable Mitch McConnell
Majority Leader
United States Senate
S-226, United States Capitol
Washington, DC 20510

The Honorable Nancy Pelosi
Speaker
United States House of Representatives
H-232, United States Capitol
Washington, DC 20515

The Honorable Charles Schumer
Minority Leader
United States Senate
S-255, United States Capitol
Washington, DC 20510

The Honorable Kevin McCarthy
Minority Leader
United States House of Representatives
H-204, United States Capitol
Washington, DC 20515

Wednesday, March 25, 2020

Dear Speaker Pelosi, Minority Leader McCarthy, Majority Leader McConnell, and Minority Leader Schumer,

On behalf of the American Society of Nephrology (ASN), thank you for your leadership advancing the care of the 37 million Americans with kidney diseases, and for your efforts to address the health concerns and economic hardships experienced by all Americans as a result of the COVID-19 pandemic. People with kidney diseases—particularly the approximately 500,000 on dialysis and 222,000 with kidney transplants—are among the most vulnerable to COVID-19, and ASN is focused on ensuring they receive the highest quality care in the context of the coronavirus outbreak.

ASN is grateful for the policies and appropriations Congress has already enacted to mitigate the COVID-19 pandemic. We acknowledge that both the outbreak and the response are dynamic and fast-moving, and that action to mitigate the crisis is being taken across the federal government – including a number of actions recommended by ASN in a Thursday, March 19 letter to Department of Health and Human Services Secretary Alex M. Azar, II, a copy of which is attached.

In order to provide optimal care for Americans with kidney diseases during this pandemic, and to promote the safety and well-being of the health care professionals who provide this care, ASN has identified a number of initial actions Congress can take to address the care of kidney patients during the COVID-19 outbreak. As the scope and effect of the pandemic becomes more visible, need for additional Congressional action may be similarly revealed. The ASN leadership, staff, and more than 22,000 members stand ready to assist Congress in any way possible with this effort.

In summary, ASN recommends that Congress:

- Protect kidney patients and kidney health practitioners
 - Prioritize the vulnerable patients who are slated to receive a kidney transplant or are receiving dialysis for COVID-19 testing and prioritize their care teams' access to PPE, and

- Increase the supply of and funding for development of personal protective equipment (PPE) and COVID-19 tests in general
- Help more patients with kidney failure receive the care they need at home
 - Expand access to care for kidney patients via telehealth by waiving statutory limitations
 - Create flexibility in survey and certification requirements to expedite home dialysis training
 - Provide emergency funding for care partners (family members or health professionals) to help in-center dialysis patients transition to home care; new patients begin dialysis at home; and people already dialyzing at home to continue to do so
 - Provide the Assistant Secretary of Preparedness and Response (ASPR) authority to award grants to hospitals and health systems for peritoneal dialysis (PD) access surgeries
 - Facilitate adoption of technology to support home dialysis
 - Provide funding (such as Small Business Administration grants) to companies that are developing, manufacturing, and disseminating products and technologies that support expanded use of home dialysis
- Maintain the nation's health workforce by retaining physicians and scientists currently in the U.S. and by expediting entrance of physicians into the country
- Minimize the health and economic risks of COVID-19 and future natural disasters by supporting basic and clinical research and the innovation economy
 - Increase funding for pandemic preparedness research at the National Institutes of Health for vulnerable populations, particularly those with kidney diseases
 - Provide financial assistance for small businesses developing, manufacturing, or disseminating PPE or products that enable home modalities of kidney care (such as Small Business Assistance Grants)
 - Provide additional financial support for teaching hospitals and academic medical centers who shoulder the responsibility of COVID-19 care and research and absorb many of the associated costs
 - Increase funding for the development of an artificial kidney and other technologies to increase the resilience of our kidney health infrastructure through [KidneyX](#)

Protect kidney patients and kidney health practitioners

Prioritizing people with kidney transplants or receiving dialysis for testing. People on dialysis are particularly at-risk for contracting COVID-19. Dialysis patients depend on receiving dialysis therapy (the majority of patients receive it thrice-weekly in an outpatient dialysis center), have an associated risk of being exposed to COVID-19 or exposing patients and healthcare professionals if they have contracted the virus, and have compromised immune systems. Transplant candidates and donors also have unique and important COVID-19 testing needs. Ideally, *all candidates* should be tested pre-transplant surgery to ensure they are not positive for COVID-19 as they prepare to initiate an immunosuppressive drug regimen. Additionally, *all*



deceased donors should be tested to ensure no COVID-19 positive organs are transplanted into immunosuppressed patients (tests specifically designed for deceased donors are available), and every living donor should be screened before donation.

Until the testing kit shortage is reduced, ASN recommends that dialysis patients who have COVID-19 symptoms, as well as transplant patients and donors, be given priority status for existing tests. ASN formally urged the administration to issue guidance or recommendations along these lines on March 19 (see attached 3/19/20 letter to Secretary Azar). Should the administration be unable to issue such guidance, we ask that Congress remove any statutory barriers inhibiting such actions or mandate the issuance of the above guidance if no barriers exist.

Increasing the supply of and funding for personal protective equipment (PPE) and COVID-19 tests in general. While ASN recognizes that PPE and testing shortages are the focus of a number of initiatives and funding from Congress, the Trump Administration, and stakeholders in the private sector, PPE and testing shortages remain the foremost concern for our members on the frontlines of addressing this crisis.

Similar to the challenges presented by the present shortage of testing kits, the lack of sufficient PPE is a challenge for all healthcare professionals, but particularly for those caring for patients on dialysis. PPE production should be accelerated if at all possible and health professionals as well as care partners serving dialysis patients be given priority status—ideally conveyed through guidance from the administration—to access the PPE supplies that do exist.

Congress must do everything in its power to encourage the production of and marshal existing supplies of PPE for all health professionals and particularly those caring for vulnerable kidney patients, as well as care partners serving dialysis. Additional funding beyond that provided in the Coronavirus Preparedness and Response Supplemental Appropriations Act and proposed in the Families First Coronavirus Response Act is essential to meet these needs.

Ensure patients with kidney failure can receive the care they need at home

Expand access to care for kidney patients via telehealth by waiving statutory limitations.

While the Centers for Medicare and Medicaid Services (CMS) have rapidly expanded the emergency use of telehealth by providing 1135 waivers, additional statutory flexibility is needed to provide the full protection of people with kidney diseases. In particular, Congress should allow individuals receiving home dialysis to conduct all of their interactions with a nephrologist through telehealth at home by issuing a temporary relief from Social Security Act Sec.1881(b), mandating the third MCP visit in a quarter from a nephrologist must be in person. ASN also supports temporary relief from 1834(m) limitations that may further allow for telehealth interactions, beyond the 1135 waivers that CMS has already issued.

ASN requests that Congress require CMS to provide a 3% per-treatment add-on payment to dialysis facilities for every new patient who receives home dialysis through December 31, 2020. This payment is the equivalent to the Home Dialysis Patient Adjuster that was proposed in the CMS ESRD Treatment Choices Model, for which a final rule is pending at the Office of Management and Budget. ASN also requests that Congress instruct CMS to waive the 20%



coinsurance for patients under Medicare Fee-for-Service for home training and home dialysis treatments.

Create flexibility in survey and certification requirements. ASN requests that Congress instruct CMS to temporarily relax survey and certification requirements to establish a new home dialysis training and support facility for existing dialysis facilities to allow them to immediately begin training patients to transition to home dialysis, if the agency does not make this change of its own accord in an expedited fashion. Under current regulation facilities have to allocate a separate space in the facility dedicated to home dialysis training and be certified separately as a home dialysis facility. Allowing existing facilities to train patients to perform dialysis at home during this time of emergency—including via telehealth, as described above—will help expedite the number of patients who can be safely trained and transitioned to conduct dialysis at home.

Provide emergency funding for care partners to help in-center dialysis patients transition to home care. Care partners serve a critical role in the home dialysis infrastructure. Either family of an individual receiving home dialysis or a professional, care partners must see their charges through an often-daunting daily procedure where even small mistakes can produce grave consequences. As the risk of infection for transmissible disease is much lower in a home care setting, anything that can be done to increase the use of home dialysis and remove barriers to home care will reduce the spread of COVID-19. ASN requests that Congress provide emergency funding for care partners – both family members and health professionals (which could be achieved through the home health benefit) - to accelerate the transition of in-center dialysis patients to home modalities; enable new patients to begin dialysis at home; and better support people already dialyzing at home. ASN also requests that CMS clarify that provision of home visits are not considered an inducement under Stark or Anti-Kickback Statutes.

Provide the Assistant Secretary of Preparedness and Response (ASPR) authority to award grants to health centers for peritoneal dialysis (PD) access surgeries. PD is the most common dialysis modality that permits patients to dialyze at home, in which the process allows a patient's peritoneal membrane to filter out harmful products normally removed by their kidneys. While a fairly straightforward therapy to administer, PD initiation requires the surgical insertion of a PD catheter in a patient's abdomen. Importantly, implantation of PD catheters requires less time in a hospital setting, and done properly, reduces the rate of post-acute follow-up care. Many patients with kidney failure are first diagnosed in the hospital, so giving hospitals the resources to place a PD catheter sets these patients on a path to home dialysis instead of the more common default path of in-center dialysis. Dialysis organizations and nephrologists are currently working as diligently as possible to maintain safety in dialysis units, but this is an increasingly difficult task as COVID-19 affects more in-center patients, making options for people to go home early in their course of kidney failure all the more essential at this time.

Congress should consider giving ASPR the statutory authority to award grants to hospitals to perform PD access surgeries and requisite nursing and patient education. This would enable health systems to triage newly presenting patients with kidney failure directly to home modalities of care, reducing exposure to and spread of COVID-19.

Facilitate adoption of technology to support home dialysis. Technology to support the increased use of home dialysis should be utilized to the fullest extent. ASN recommends that Congress require CMS to include capital-related assets, such as home dialysis machines, in the ESRD Transitional Add-on Payment Adjustment for New Innovative Equipment and Supplies for 2021 (as finalized at 84 FR 60648). For supplies and equipment (including capital-related assets) that were purchased or leased during March 2020 and December 31, 2020 and used to treat home dialysis patients and then approved for TPNIES in the 2020 ESRD PPS final rule, CMS would make retroactive TPNIES payments for those treatments as a way to help treat dialysis patients safely during the COVID-19 response.

Maintain the nation's kidney health workforce by retaining physicians and scientists currently in the U.S. and by expediting entrance of physicians into the country.

The U.S. health care workforce heavily relies on health professionals and scientists, including physicians and medical residents, who are practicing or otherwise lawfully present in the U.S. on a visa or other protected status. These providers and researchers, who are often at academic medical centers and safety-net facilities on the front line of the COVID-19 pandemic, represent crucial components of our health care workforce. Additionally, most new medical residents match to their residency programs in March and start training and treating patients on or around July 1, necessitating a predictable and timely visa application process. ASN recommends that Congress encourage the Department of State and the U.S. Citizenship and Immigration Services to enact several policies that ensure a robust kidney health workforce by:

- Extending visas and other protected status for physicians and medical residents through the COVID-19 national emergency
- Expediting approvals of extensions and changes of status for physicians and medical residents practicing or otherwise lawfully present in the U.S.
- Continuing and expanding the H-1B premium processing option to such applications to facilitate an expedited process
- Opening visa processing at embassies and consulates worldwide for physicians and medical residents as emergency and mission critical visa services
- Allowing physicians and medical residents (including those on J-1 and H-1b visas, such as participants in the Conrad 30 program) to be redeployed as needed to respond the COVID-19 pandemic

Minimize the health and economic risks of COVID-19 and future natural disasters by supporting basic and clinical research and the innovation economy

Increase funding for pandemic preparedness research at the NIH for vulnerable populations living with chronic illness. According to the CDC, 6 of 10 Americans have a chronic illness and 4 of 10 have two or more chronic illness. Chronic illness not only increases vulnerability to diseases such as COVID-19, but people with chronic illness may have unique care needs that must addressed during epidemics or national disasters, such as people with kidney failure.



While Congress provided an initial \$836 million to the National Institute of Allergy and Infectious Diseases (NIAID) to prevent, prepare for, and respond to coronavirus, more research in pandemic preparedness to address chronic illness is needed—particularly to meet the needs of kidney patients. Such research would fall under the purview of the National Institute of Diabetes, Digestive, and Kidney Diseases (NIDDK), the National Institute of Biomedical Imaging and Bioengineering (NIBIB), the National Center for Advancing Translational Sciences (NCATS), the National Heart Lung and Blood Institute (NHLBI), and the National Institute on Minority Health and Health Disparities (NIMHD).

Provide financial assistance for small businesses developing, manufacturing, or disseminating PPE or products that enable home modalities of kidney care. Small businesses across the country are facing unprecedented challenges during the COVID-19 pandemic that threaten their survival. Small businesses involved in the supply chain of critical products to address the COVID-19 pandemic such as PPE and home modalities of kidney care are no exception. Congress should provide or prioritize financial assistance to small businesses who are providing these products, aiding the physical health of the nation and the lifeblood of American innovation.

Provide additional financial support for teaching hospitals and academic medical centers who shoulder the responsibility of COVID-19 care and research and absorb many of the associated costs. America's teaching hospitals and academic medical centers are the vanguard of care and research, including for COVID-19. As noted by the American Association of Medical Colleges, teaching hospitals provide 25% of the nation's medical and surgical intensive care beds, 36% of cardiac intensive care beds, 61% of pediatric intensive care beds, and are home to 69% of all Level 1 trauma centers.

Teaching hospitals and academic medical centers are playing an important role in the research and diagnosis of COVID-19 and development of technological solutions to help mitigate this crisis, especially in areas where funding for public health laboratories and other critical infrastructure is stretched thin.

Teaching hospitals and academic medical centers are proud to serve their communities and country during this time of need. However, they are also incurring large and unsustainable costs as they research, diagnose, and provide care for COVID-19, putting their ability to provide this service - both now and in the future - in jeopardy. More precise estimates of the funds spent by these institutes to mitigate COVID-19 will be produced after the initial response, but early indications show that spending on this crisis would have serious implications for the future of many institutions if not quickly addressed: New York institutions alone have likely spent billions addressing COVID-19 to-date.

It is critical that congress expediently support teaching hospitals and academic medical centers who provide this national service at time when no one else can.

Increase funding for the development of an artificial kidney and other technologies to increase the resilience of our kidney health infrastructure through KidneyX. ASN has identified a suite of unmet technology and product development gaps, the society believes



would greatly enhance health professionals' ability to address the spread of COVID-19 and future epidemics, listed below. The KidneyX Steering Committee is actively discussing how KidneyX (a public-private partnership between HHS and ASN) can assist or partner to bring forward the necessary technology. ASN is also engaging with other stakeholders in the private sector to explore avenues to advance possible solutions.

ASN believes that both rapid-cycle, short-term opportunities exist for innovation to support patients and health professionals during the COVID-19 pandemic, as well as longer-term opportunities to enhance our nation's capacity to meet the unique needs of kidney patients in future emergency situations. Preventing the need for dialysis altogether and helping more patients with kidney failure obtain a kidney transplant, dialyze at home, or access a novel technology, such as an artificial kidney, will make America more resilient in the future.

ASN continues to advocate for a \$25 million appropriation for KidneyX for the first artificial kidney prize competitions. In addition, ASN believes that increased funding from congress beyond the \$25 million would enable work to immediately commence on the following areas:

- **Novel "molecular point-of-care" testing kits** that reveal test results immediately (similar to flu) and can be easily administered and developed quickly for broad distribution; as discussed, the testing kit shortage is particularly problematic for the vulnerable dialysis patient population. The need for novel testing kits is particularly relevant for patients on in-center hemodialysis. Many dialysis unit staff do not have the training/skills to properly administer the deep respiratory culture necessary for traditional reverse-transcriptase polymerase chain reaction (RT-PCR) COVID-19 testing, which may result in inadequate samples that lead to false negative results, significant delays in patients getting access to proper testing, and the unnecessarily exposure of additional patients and staff to possible COVID-19.

However, we also seek to avoid having to send all dialysis patients with flu-like symptoms to the emergency room, which itself carries exposure risks and creates additional burden on the patient and the healthcare system. The development of a molecular point of care test, for example, would enable testing in the dialysis units that is significantly faster and safer than the current test.

- **Infection prevention** capabilities (that need to be continually evaluated and updated based on the changing landscape from COVID-19). For instance:
 - **New masks** designed to replace the N95 to offer health professionals protection without the need to fit test.
 - **Portable isolation pods** for use in dialysis facilities to reduce the spread of COVID-19 from infected patients to non-infected patients (and staff) in the dialysis unit, which is a major concern at present.
 - **Anti-fog face shield** to address the fact that the masks that health professionals currently use fog rapidly, making performance of basic patient care tasks cumbersome and inefficient.



- **A data collection system** that captures pertinent data from electronic medical records (EMR) [protocol or standard operating procedure] of kidney patients with COVID-19. ASN is partnering with dialysis companies to collect and ultimately analyze COVID-19-related data for dialysis patients. The American Medical Association's creation of a CPT code for COVID-19 reporting, as well as the CMS Interoperability and Patient Access Proposed Rule, may also help facilitate this goal.

Again, thank you. ASN appreciates your leadership on behalf of kidney patients and in addressing the COVID-19 outbreak, and the society hopes that the recommendations included in this letter are helpful. If you have any questions, or if ASN can offer any further information or assistance, please contact ASN Director of Policy and Government Affairs Rachel N. Meyer at rmeyer@asn-online.org or 202-640-4659.

Sincerely,

A handwritten signature in black ink, appearing to read "Anupam Agarwal", with a long horizontal line extending from the end of the signature.

Anupam Agarwal, MD, FASN
President

cc: Senate Appropriations Committee, Subcommittee on Labor, Health and Human Services, Education and Related Agencies
Senate Finance Committee, Subcommittee on Health Care
Senate Health, Education, Labor, and Pensions Committee, Subcommittee on Primary Health and Retirement Security
House Appropriations Committee, Subcommittee on Labor, Health and Human Services, Education and Related Agencies
House Energy and Commerce Committee, Subcommittee on Health
House Ways and Means Committee, Subcommittee on Health