May 21, 2020

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Guidelines for Opening Up America Again

Dear Mr. Secretary,

The National Kidney Foundation (NKF) and the American Society of Nephrology (ASN) appreciate the Administration's efforts to address kidney patients' needs as the nation navigates the COVID-19 epidemic. Our organizations urge the Administration to continue to take the unique needs of kidney patients into account as the nation takes steps to reopen. Kidney patients, including patients with chronic kidney disease (CKD), end-stage renal disease (ESRD) and kidney transplant recipients are especially vulnerable to severe COVID-19 infection due to compromised immune systems, multiple comorbid conditions that increase their risk for COVID-19 complications, and because patients with kidney failure require in-center dialysis care that requires frequent and close contact with others.

Additionally, early data from New York City indicate that 20 to 40 percent of COVID-19 ICU patients develop kidney failure and need emergency dialysis. Perhaps most disheartening, new data suggests that the mortality rate for patients on chronic dialysis who develop COVID-19 is in the range of 10-20% and that for kidney transplant patients mortality associated with COVID-19 may be as high as a staggering 30%.

NKF and ASN thank the Administration for recognizing that reopening the country must account for the needs of special populations that will continue to be vulnerable to the ongoing threat of COVID-19 infection. As a preliminary matter, we note, per the above statistics, that kidney patients are one of these special populations. To reinforce that point, we request that the Administration update its definition of "vulnerable individuals" to include patients affected by kidney disease.[1]

We also agree that patients affected by kidney disease, like all vulnerable individuals, should continue to shelter in place. For kidney patients and transplant recipients who rely on routine contact with the healthcare system, this requires that the Department of Health and Human Services (HHS), the Centers for Medicare and Medicaid Services (CMS) and the other federal agencies working to facilitate patients' ability to isolate and social distance. As such, we ask that the Administration adopt policies and procedures that:

- Ensure that kidney patients, their families and clinicians have adequate access to personal protective equipment, priority access to COVID-19 testing, and early access to a vaccine once it is developed.

[1] "Individuals with serious underlying health conditions, including high blood pressure, chronic lung disease, diabetes, obesity, asthma, and those whose immune system is compromised such as by chemotherapy for cancer and other conditions requiring such therapy"

- Support end-stage renal disease (ESRD) patients' ability to safely access dialysis services and other related care.
- Prioritize the safe resumption of organ transplantation, which has significantly declined as a result of COVID-19.
- Extend and build upon temporary policy changes that may be required to meet the ongoing needs of kidney patients.
- Address the needs of patients who develop acute kidney injury (AKI) as a result of COVID-19 infection.
- Ensure that every hospital has adequate supply of dialysis equipment and dialysis solutions to provide appropriate care for hospitalized patients with kidney failure.

Testing, Supplies, and Vaccination

Despite the Administration's laudable efforts, many parts of the country cannot access adequate viral or serological testing. In the absence of universal testing availability, we encourage the Administration to work with state and territorial health departments responsible for testing decisions to stratify patient access to COVID-19 testing based on susceptibility to severe infection, including weekly SARS-Cov-2 testing for in-center dialysis patients until adequate measures of immunity can be developed

The following risk stratification recommendations are closely aligned with the CDC's Priorities for COVID-19 Testing.[2] Per those recommendations, we note that kidney patients are high risk and should fall under the category of "[p]ersons identified by public health officials or clinicians as high priority." We would welcome the assistance of the Administration in communicating the special vulnerability of these patients to state and territorial Departments of Health as they allocate scarce testing resources.[3]

1. All In-center dialysis patients, who should be tested weekly until adequate measures of immunity can be developed.
2. All CKD and ESRD patients, living donors, and transplant recipients who exhibit COVID-19 symptoms
3. All CKD and ESRD patients, living donors, and transplant recipients who reside in nursing homes, assisted living facilities, congregate living arrangements, multi-generational families, and multi-family communities
4. All ESRD patients living in communities that are experiencing or expected to experience surges in COVID-19 cases per the White House Task Force
5. Transplant patients (including recipient, living donor and deceased donor screenings)
6. Patients with CKD stages 3 through 5.

NKF and ASN thank CDC for recognizing that patients with chronic kidney disease (CKD) are at higher risk for severe illness.[4] Accordingly, CKD patients must be prioritized for testing. Unfortunately, awareness of CKD is low among both clinicians and patients and so it often goes undiagnosed until its latest stages. We are concerned that patients with undiagnosed CKD who are at high risk from COVID-19 infection may not be appropriately triaged for testing and subsequent care. CKD is closely related to other non-

[2] https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html
[3] *Ibid.*
[4] https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-at-higher-risk.html

communicable diseases like hypertension, diabetes mellitus and obesity, as well as older age. While CDC's guidance on people who are at higher risk for severe illness includes people with CKD, people 65 years and older, people with severe obesity, people with diabetes, and people with severe heart conditions, it excludes people with hypertension. Hypertensive patients are independently at risk for more severe disease and may also have already or will develop CKD, which may compound their risk. NKF and ASN recommend that CDC add patients with hypertension to the list of people who are at higher risk of severe illness.

Further, many of the populations identified as high risk for more severe cases of COVID-19 are also at high risk for undiagnosed CKD. The CDC should urge state and territorial health departments to facilitate the testing of high-risk patients for both COVID-19 and CKD. Doing so will enhance our national response to COVID-19 and improve population health and our resiliency to future public health threats. NKF and ASN would be pleased to work with CDC and partners at the state and territorial level to facilitate the identification of all high-risk patients and ensure they are managed appropriately, both for the purposes of the COVID-19 pandemic and for improving the health of the nation.

NKF and ASN urge the Administration to work with FEMA to ensure that supplies of personal protective equipment (PPE) provided by the federal government are distributed as quickly as possible to areas with reported shortages. In line with the Administration's recent action to distribute PPE to nursing homes across the country, we ask that, to the extent PPE is released from the stockpile, it be distributed to patients who are most at risk, especially dialysis and transplant patients, their families, and their health care practitioners, including dialysis facilities.

Finally, NKF and ASN applaud the Administration's efforts to accelerate the discovery, production, and distribution of a coronavirus vaccine. We are encouraged by estimates that suggest a vaccine could arrive in 12 to 18 months. We ask that the Administration communicate to its vaccine development partners that validation of the vaccine will require specific testing in patients with advanced CKD and ESRD, and transplant recipients, who may have an impaired immune response to vaccination. In addition, understanding that supplies of a vaccine may initially be limited, we encourage you to work with state and territorial health departments to develop a triage system that protects our most vulnerable populations, including CKD and ESRD patients, potential living donors, and kidney transplant recipients, by allowing them to be "first-in-line" for a vaccine.

Dialysis

Dialysis patients are at special risk of contracting COVID-19 due to both underlying physiological vulnerabilities and the in-center model of dialysis, which requires patients travel to dialysis. This model of care puts patients in close contact with drivers, clinicians, dialysis facility staff, and other patients several hours per visit, three to four times a week while they undergo their necessary dialysis treatments. We thank the Administration for its swift response to the potential for transmission in dialysis facilities, which is likely responsible for limiting the scope at which COVID-19 was spread between dialysis patients relative to other countries.

As states implement the Guidelines for Opening Up America Again, we strongly encourage the Administration to communicate that prioritizing the protection of dialysis patients will help mitigate the

risk of resurgence and protect the most vulnerable patients, thereby assisting states with achieving a balance between reopening their economies and ensuring the health of the public.

The Administration should take the following actions at the federal level that will, at baseline, protect dialysis patients across the country. This includes, but is not limited to, extending the timelines for the regulatory flexibilities that have already been provided beyond the end of the public health emergency (PHE). This is especially important because surges in COVID-19 cases may overwhelm state resources and put vulnerable patients at risk even once the national PHE has concluded.

Improve ESRD Patient Access to Home Dialysis

- **Implement through CMMI the ESRD Treatment Choice (ETC) and the Kidney Care Choices models**, which will improve patient access to home dialysis. The COVID-19 public health emergency (PHE) highlights the vulnerabilities of the in-center model of dialysis delivery and so emphasizes the need for payment incentives to transition more patients to home dialysis and improve quality of care for patients with advanced CKD and ESRD.
- Continue to provide regulatory flexibilities that enhance patient access to home dialysis, including:
    - Allowances for a Special Purpose Renal Dialysis Facilities (SPRDF) to serve as a home dialysis training facility.[5]
    - Extension of the waiver at 494.100(c)(1)(i) which requires the periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel.[6]
    - Extension of the waiver at § 494.180(d) to allow dialysis facilities to provide services directly on the main premises of a nursing home or skilled nursing facility and the associated flexibilities in billing procedures.[7]
- The majority of patients on home dialysis are sufficiently stable that the benefit of monthly labs does not outweigh the risk to the patient of coming into the facility. We recommend waiving the requirement to include monthly labs on claims during the PHE for home dialysis patients. For home dialysis patients who require lab work, NKF and ASN recommend that Medicare reimburse for a technician to come into the patient's home, which can be paid separately from the ESRD bundle.
- Add CPT code 90989 for home dialysis training to the approved telehealth list.
- Create a temporary safe harbor through OIG for the provision by the dialysis facility of support services in the home for home dialysis patients.

Improve ESRD Patient Safety in Dialysis Facilities

- Waive the requirements to include monthly labs on claims if, during the billing month, a patient has been transferred to a facility dedicated to treating COVID-19 patients that is aggregating patients from different dialysis organizations.

[5] https://www.cms.gov/files/document/covid-19-esrd-facilities.pdf
[6] *Ibid.*
[7] *Ibid.*

- Suspend in-person infection control surveys/inspections, including those referred to as "desktop" surveys until the national PHE has ended.

Improve ESRD Patient Access to Transportation

- For the purposes of the PHE, ensure that dialysis patients who are Covid-19 positive or under investigation for Covid-19 can access non-emergency ground ambulance transport without burdensome documentation or prior authorization. This will require that CMS revise its medical necessity standard to include patients who require medical isolation due to confirmed or suspected COVID-19 infection.

Prepare to Manage Growing Cases of Acute Kidney Injury (AKI)

- Between 14 and 30 percent of COVID-19 patients develop Acute Kidney Injury (AKI) a condition associated with very high short-term mortality that can lead to chronic kidney disease or even permanent kidney failure requiring dialysis. Hospitals are struggling to respond to the unanticipated number of AKI cases overwhelming ICU and dialysis resources. We recommend the Administration implement the following policy changes that will enable states to efficiently manage their hospital resources during the PHE. We note that these policy changes may need to be extended beyond the end of the national PHE should some states continue to experience surges in COVID-19 cases that threaten their hospital capacity:
    - Allow physicians to bill the provision of AKI services via telehealth using CPT code 90935 during the PHE
    - Allow dialysis facilities to be reimbursed for providing peritoneal dialysis (PD) to COVID-19 patients who are placed on peritoneal dialysis (PD) when hospitalized and are able to continue it in the outpatient setting.
    - Patients with AKI who are using home dialysis can derived special benefit from assistance with dialysis that is provided in the patient's home. Support services provided by a caregiver or a dialysis facility staff member may increase the likelihood that AKI patients discharged from the hospital can successfully recover in their homes rather than in Skilled Nursing Facilities (SNFs).

Elective Surgeries

NKF and ASN appreciate the Administration's guidance that elective surgeries can resume, as clinically appropriate, on an outpatient basis. Despite this guidance, we are concerned that CKD patients approaching dialysis, as well as ESRD patients, are struggling to access procedures that are necessary for planned starts to dialysis, namely creations of arteriovenous fistulas and grafts and placements of venous and peritoneal dialysis catheters. As states resume elective procedures in outpatient and ultimately the acute setting, **we ask the Administration to offer "reentry" guidance to hospitals to assist them in prioritizing medically necessary procedures that have been postponed due to the COVID-19 PHE.**

Organ Donation and Transplantation

Transplantation is widely considered the preferred course of kidney replacement therapy for most patients. Securing transplants for patients whose kidneys have failed or who are approaching kidney

failure could insulate them from the risk of contracting COVID-19 in the dialysis setting, now or during future prospective outbreaks.

Unfortunately, both deceased and living kidney donation have experienced precipitous declines during the COVID-19 crisis. Deceased donation has fallen from a high of 527 transplants per week to 323 during

the week of April 26. Living donation has experienced an even more dramatic decline, falling to just 22 transplants during the most recent week for which data are available.[8] Living donation has been virtually non-existent during the PHE. We are concerned that without a proactive effort on behalf of the Administration, living donation in particular may struggle to meaningfully recover.

Living Donation

The reasons for the suspension of living donor surgeries are multifactorial, including the limited availability of testing and PPE, the reticence to expose otherwise healthy living donors to COVID-19 in transplant centers, concerns about transmission of COVID-19 through donation, and the lack of operating room (OR), staff, and ventilator capacity for surgeries. Each of these barriers must be addressed before living donation will once again reach its pre-COVID-19 peak.

- We reiterate our recommendation that transplant centers and transplant patients receive priority access to PPE. If PPE is released from the stockpile, we ask FEMA to work with states, regions, and territories to ensure that transplant centers in need of supplies get preference.
- We request the assistance of the Department of Health and Human Services in ensuring that living donors and transplant recipients are included as high priority in the CDC's guidance on Priorities for COVID-19 Testing. Though these patients may be asymptomatic, transplant centers may be hesitant to proceed with the transplant until the status of donor and recipient are confirmed.
- As states reopen, we request that HHS work with stakeholders to determine appropriate pre-transplant quarantine procedures for living donors to minimize their risk for COVID-19 infection.
- NKF and ASN greatly appreciate the clarification provided early in the PHE that transplants are essential surgeries. This was invaluable at a time where hospitals were engaged in discussions about how to allocate their limited resources. We ask again that the Department of Health and Human Services provide similar "reentry" guidance to hospitals that assists them with prioritizing medically necessary procedures such as transplants.
- NKF and ASN are concerned that any potential economic downturn will have a disproportionate impact on living donation. We encourage the Department of Health and Human Services to deploy all levers at their disposal to provide financial assistance to willing living organ donors, including rapidly finalizing the proposed rules, Removing Financial Disincentives to Living Organ Donation (HRSA-2019-0001) and Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation Program Eligibility Guidelines.
- We note that the potential for COVID-19 transmission through donation exists. The Administration must be prepared for this possibility and not allow it to act as a national deterrent for transplantation, as the benefits of transplantation to the nation continue to outweigh the risks of COVID-19 transmission.
    - We appreciate that the Health Resources and Services Administration (HRSA) has noted that it will allow for flexibility in its post-transplant survival measure. NKF and ASN

[8] https://unos.org/covid/

request that CMS similarly provide a formal waiver of its one-year post graft and patient survival measure for the purposes of the PHE.

Deceased Donation

While the above recommendations apply also to deceased donation and are similarly critical to its safe resumption, we ask the Administration to specifically facilitate a return to normal operations for the nation's 58 Organ Procurement Organizations (OPOs).

- "Reentry" guidance from the Administration to hospitals on prioritization of procedures and supplies should also note that OPO staff must be able to access trauma centers in hospitals in order to evaluate potential deceased donors and ORs in order to facilitate the organ recovery.
- Donor hospitals must also have priority access to PPE, ventilators, and Covid-19 testing. We ask the Administration to note this in the requested guidance to hospitals.
- NKF and ASN recommend that CMS convene the leadership of the ETC Transplant Learning Collaborative to discuss directly with CMS policymakers other policy solutions that may assist OPOs and transplant centers in overcoming COVID-19 related barriers to transplantation.

Drug Supply

Section 3714 of the 'Coronavirus Aid, Relief, and Economic Security Act'' or the ''CARES Act" mandated that Medicare Part D and Medicare Advantage plans allow for up to a 3-month supply of prescription drugs through the COVID-19 "emergency period." CMS has offered similar flexibilities to the Medicare Administrative Contractors (MACs) regarding greater-than-30-day supplies of Part B drugs including the immunosuppressive therapies on which transplant recipients rely. We are concerned that patients affected by kidney disease may continue to need these extended supplies after the national emergency has ended and ask the Administration and Congress to take steps to ensure Medicare plans continue to exercise this flexibility as long as it is required to assure patient safety.

NKF and ASN appreciate the Administration's leadership in responding to the PHE. We hope to continue to be a resource to federal and state policymakers as we collectively work through this national public health crisis. Please contact Miriam Godwin (Miriam.Godwin@kidney.org) or Rachel Meyer (rmeyer@asn-online.org) if you have questions or need additional information on the issues raised herein.

Sincerely,

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