National Kidney Foundation®

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The Honorable Seema Verma
200 Independence Ave SW
Room 314G-01
Washington, DC 20201

June 1, 2020

Re: Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

Dear Administrator Verma,

The National Kidney Foundation appreciates the opportunity to offer comments on the interim final rule, Medicare and Medicaid Programs: Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency. NKF thanks the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) specifically for the attention paid to the needs of kidney patients during the Covid-19 public health emergency (PHE). Early action by the Administration that enabled patients to social distance and avoid areas where the risk of transmission is high is likely responsible for staunching a Covid-19 crisis in the kidney community.

We do, however, believe that there is more that can be done and hope to be a partner to CMS in continuing to meet the needs of patients affected by kidney disease, living donors, and transplant recipients. A theme that runs through the following comments is the need for many of the existing waivers and flexibilities to extend beyond the conclusion of the national public health emergency. Patients will still continue to be threatened by Covid-19 once the national emergency has ended, particularly as states begin to reopen. We respectfully request that CMS work with patient and professional communities to identify an appropriate timeline for the extension of the flexibilities and waivers that have so successfully preserved the safety of our most vulnerable patients during this unprecedented time.

The National Kidney Foundation (NKF) is the largest, most comprehensive and longstanding, patient centric organization dedicated to the awareness, prevention, and treatment of kidney disease in the U.S. In addition, the National Kidney Foundation has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD), including transplantation since 1997 through the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI).

<u>B. Frequency Limitations on Subsequent Care Services in Inpatient and Nursing Facility Settings, and Critical Care Consultations and Required "Hands-on" Visits for ESRD Monthly Capitation Payments</u>

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NKF appreciates the rapidity with which CMS and Congress have made telehealth services available to patients affected by kidney disease. Patients have found that telehealth visits generally work well and have little to no impact on the quality of care they receive. On May 21, 2020, NKF and the American Society of Nephrology (ASN) sent a letter to Secretary Azar outlining a set of recommendations for prioritizing the needs of patients with kidney disease, living kidney donors, and kidney transplant recipients as states begin to end their stay at home orders. A key recommendation from that letter is that the waivers provided for the purposes of the public health emergency (PHE) should be extended for as long as is needed to protect patients who will continue to be vulnerable to COVID-19 infection after the declared national emergency has concluded. **We request that this additional flexibility is provided for the ESRD-related CPT codes identified in the IFR. We also request that CMS consult with the patient and professional communities to discuss the nephrology and transplant related telehealth waivers that could be made permanent.**

We also thank CMS for providing clarification that HHS is exercising enforcement discretion with regards to the quarterly in-person visit required for home dialysis patients using telehealth under section 1881(b)(3)(B) of the Act. We note that the enforcement discretion is provided on an "interim basis" and would request that CMS consult with the patient and professional community to determine how long enforcement discretion may be warranted.

C. Telehealth Modalities and Cost-sharing

NKF appreciates the numerous flexibilities that CMS has provided in the provision of telehealth, particularly measures that allow use of any device that could otherwise meet the interactive requirements for Medicare telehealth, meaning that multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner may be utilized. Our understanding from the patients and professionals we serve is that one of the greatest barriers to adoption of telehealth is the availability of the technology to facilitate the interactions. Many of our patients are socioeconomically disadvantaged, elderly, and/or live in rural areas. It is imperative that patients are able to access their care teams using the technologies and devices that are available to them.

F. Clarification of Homebound Status under the Medicare Home Health Benefit

NKF greatly appreciates CMS' thoughtful and comprehensive explanation of eligibility for the Medicare Home Health Benefit for the purposes of the PHE. In previous communications to HHS, **NKF has established our position that home dialysis patients, transplant recipients, and living donors must be afforded every opportunity to receive care in the home.**

The Covid-19 PHE highlights the vulnerabilities in the in-center model of care for dialysis in which patients must be in close proximity to others for four hours at a time three times per week. NKF is engaged in identifying every possible opportunity to transition in-center patients to home dialysis where they are

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better able to social distance. Providing nursing or technician support in the home to patients who select home dialysis has been identified as one solution to driving greater adoption of and retention on home dialysis. Even current regulations, however, require home dialysis patients to leave their homes for monthly lab work. Transplant recipients also require lab work to monitor allograft function, immunosuppression levels and other parameters. While the interval between labs may be extended in some stable patients late posttransplant during the Covid-19 pandemic, regular monitoring is essential for managing care early after transplant. Finally, living donors require routine labs to monitor health after donation.

Our belief, based on CMS' clarification that patients can qualify as "homebound" for the purposes of the Medicare Home Health (HH) Benefit if a physician has certified that it is medically contraindicated for the patient to leave the home due to increased susceptibility to Covid-19, was that home dialysis patients, transplant recipients, and living donors could be eligible to receive at minimum blood draws in the home if CMS clarified that home health services could be provided solely for the purposes of venipuncture. We understand CMS' position that venipuncture does not typically require skilled services, however, would reiterate that it is not reasonable to expect home dialysis patients, living donors, and transplant recipients to leave their homes and put themselves at risk simply for the purposes of having their blood drawn.

It is essential that CMS identify regulatory mechanisms to assist these patients with self-isolation. For home dialysis patients, we simply request that CMS eliminate the monthly laboratory billing requirement. Patients who, in the judgment of their physician, are medically stable need not risk violating social distancing orders nor expose themselves to unnecessary infection risks in order to satisfy a billing requirement to include monthly laboratory work. We recommend that CMS not only eliminate the monthly laboratory billing requirement for the purposes of the PHE, but in perpetuity. This requirement has little clinical value to home dialysis patients, many of whom are stable, and only incentivizes overutilization of medical services. For home dialysis patients who do require remote labs, our understanding is that specimen collection is covered by the ESRD PPS and that dialysis facilities are theoretically able to send staff to the home of a PD patient to draw their blood. We are concerned, however, that without an additional incentive, dialysis facilities will not make this service available to home dialysis patients. Thus, we ask for the duration of the PHE that these labs and specimen collection fees are paid as separately billable from the ESRD bundle with an AY modifier.

NKF is agnostic to the mechanism by which CMS makes remote labs available to transplant recipients and living donors. As stated above, NKF has in the past recommended that CMS clarify that home health services could be provided to these patients solely for the purposes of venipuncture, however we would alternatively welcome clarification that transplant recipients and living donors are homebound and therefore eligible for remote specimen collection by independent labs under section 60.1.2 of the Medicare Claims Processing Manual.[1] Similarly to the changes to the changes for specimen collection for Covid-19 testing, we ask CMS to provide a specimen collection fee and associated travel allowance to

[1] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c16.pdf

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facilitate remote blood draws for homebound patients. The specimen collection fee will provide a necessary incentive for independent laboratories to provide these services.

M. Medicare Clinical Laboratory Fee Schedule: Payment for Specimen Collection for Purposes of COVID-19 Testing

We strongly recommend that CMS allow more patients to benefit from the flexibilities provided for specimen collection for the purposes of Covid-19 testing. As noted above, we request that CMS clarify that "homebound" for the purposes of specimen collection includes patients who are certified by a physician as requiring self-isolation due to susceptibility to Covid-19. We believe that clarification of "homebound" has only thus far been provided as it pertains to the Home Health Benefit. Such clarification would not only allow transplant recipients and living donors to benefit from remote specimen collections, but would also enable physicians to continue to screen hypertensive and diabetic patients and patients with other cardiovascular conditions for chronic kidney disease (CKD) in their homes. Ensuring that chronic condition screenings can continue during and after the public health emergency is vital, as many primary care and family medicine practices are actively discouraging patients from office visits.

Q. Innovation Center Models

NKF reaffirms its support for the ESRD Treatment Choices (ETC) and Kidney Care Choices (KCC) models. We understand the extraordinary duress the nephrology community is under, however we are concerned that the opportunity to dramatically improve patient access to transplantation, home dialysis, and better transitions of care between advanced CKD and ESRD will be lost if the models are not implemented expeditiously once the PHE has concluded. While a delay in the implementation of the models is warranted, we hope to see the ETC rule finalized shortly and both the ETC and KCC models implemented as soon as possible.

AA. Origin and Destination Requirements Under the Ambulance Fee Schedule

NKF is extremely concerned by reports that physicians and other providers are unable to secure transportation for Covid-19 positive dialysis patients and patients under investigation for Covid-19. While many state Medicaid programs have directed their non-emergency medical transport (NEMT) providers to transport these patients, patients who are dually eligible for both Medicare and Medicaid only account for approximately 40 percent of the dialysis population. This leaves a significant portion of the dialysis patient population reliant on the Medicare program to provide transportation options as last resorts during the PHE. Among these dialysis patients, those with confirmed or suspected Covid-19 should be provided the opportunity to be transported to and from dialysis, SNFs, and the hospital by ambulance. We ask CMS to direct the Medicare Administrative Contractors (MACs) to clarify that such transports are covered by Medicare and that medical isolation because of COVID-19 status, either positive or suspected, will meet medical necessity to justify payment.

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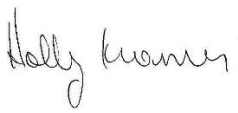
Waive the Prohibition on Home Dialysis for Acute Kidney Injury (AKI) Patients

NKF notes that existing CMS policy does not allow for dialysis facilities to bill Medicare for AKI patients using home dialysis. We appreciate CMS' rationale that under normal circumstances, AKI patients require close supervision by the dialysis facility staff or by the staff in the SNF. Covid-19 is creating significant numbers of new AKI patients. Typically, patients with acute kidney injury (AKI) are treated using a special type of dialysis in the hospital through a Continuous Renal Replacement Therapy (CRRT) machine, followed by outpatient in-center hemodialysis after discharge. However, because so many COVID-19 patients have AKI, hospitals are running out of CRRT capacity, and must instead begin peritoneal dialysis (PD) to replace these patients' renal function. In order to discharge these patients, the hospital must perform a second procedure to place a catheter for hemodialysis. This is both an unnecessary use of hospital resources and unnecessarily traumatic for the patient. We urge CMS to waive the prohibition on home dialysis for AKI patients during the public health emergency to give hospitals and dialysis facilities the flexibility to manage potential influxes of AKI cases. This is especially critical in rural areas and other parts of the country that may not be able to rapidly scale up their capacity to provider CRRT. In addition, we request that CMS add CPT codes 90935, 90937, 90945, and 90947, the codes assigned for inpatient or outpatient dialysis for AKI patients, to the approved telehealth list during the crisis in order to remove the face-to-face requirement for these services. This will allow nephrologists to more easily and safely prescribe PD for ICU patients with COVID-19 and AKI.

We would like to express our gratitude to CMS for its ongoing efforts to respond to the Covid-19 crisis. On behalf of the patients who have been afforded opportunities to receive care by telehealth, isolate in their homes using home dialysis, or to move forward with a vascular access procedure or a transplant: thank you. NKF hopes to continue to be a resource to HHS and CMS as we work together for patients during and after the PHE. We would welcome the opportunity to discuss any of the comments herein. Please contact Miriam Godwin (miriam.godwin@kidney.org)

Sincerely,



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