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The Honorable Seema Verma  
Hubert H. Humphrey Building  
Room 314G-01  
200 Independence Avenue SW  
Washington, DC 20201

July 7, 2020

Re: File Code CMS-5531 – Medicare and Medicaid Programs, Basic Health Program, and Exchanges: Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program

Dear Administrator Verma:

The National Kidney Foundation (NKF) appreciates the opportunity to offer comments on the second interim final rule (IFR) promulgated by the Centers for Medicare and Medicaid Services (CMS). We thank CMS for responding quickly to the COVID-19 pandemic and for the historic regulatory flexibilities that continue to enable the healthcare system to protect vulnerable kidney patients during the public health emergency (PHE).

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 NKF has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD), including transplantation since 1997 through the NKF Kidney Disease Outcomes Quality Initiative (KDOQI).

In our comments on the first IFR, we noted the importance of recognizing that the flexibilities provided by CMS that are tied in duration to the PHE will need to be extended in order to protect patients affected by chronic kidney disease (CKD), end-stage renal disease (ESKD), kidney transplant recipients, and living donors, all of whom are at high risk for COVID-19 infection and severe consequences should they contract it. We thank the Department of Health and Human Services (HHS) for the recent notice from the Press Office that the PHE will be extended. **We continue to believe that the most straightforward way to ensure that patients and professionals have the regulatory resources needed to weather the COVID-19 pandemic is simply to extend the PHE for as long as is necessary to protect the most at-risk Americans.** CMS' own preliminary analyses indicate that ESKD beneficiaries are the highest risk population for COVID-19 infection. The vulnerabilities of these patients, alongside CKD patients, kidney transplant recipients, and living donors –millions of Americans in total – will not cease until COVID-19 countermeasures are widely available.

ESKD beneficiaries are especially susceptible to COVID-19 due to the combination of the underlying physiological vulnerabilities of ESKD patients and the settings in which they receive care, namely in-center dialysis facilities where patients are in close contact with one another for 4 hours at a time 3 days a week. Preliminary data suggest that COVID-19 rates are significantly lower for home dialysis patients. Throughout the PHE, NKF has advocated for flexibilities and incentives to transition dialysis patients to home where they are better able to social distance. As more data emerge that home is the safest setting for dialysis patients, it is essential that CMS continue to incentivize dialysis providers to start & transition patients to home dialysis. In addition, dialysis facilities should have every possible flexibility necessary to care for their in-center population. CMS should make these flexibilities and incentives available to dialysis facilities until COVID-19 countermeasures are available and have been administered to dialysis patients.

#### Covid-19 Testing

NKF appreciates the numerous provisions outlined in the interim final rule intended to accelerate Covid-19 testing. Data from the Preliminary Medicare COVID-19 Data Snapshot highlight the importance of regular COVID-19 testing for ESKD patients, who contract COVID-19 at rates dramatically higher than aged, disabled, and dual eligible beneficiaries. Pre-symptomatic and asymptomatic COVID-19 is prevalent in in-center dialysis facilities, but little testing is taking place until a patient is hospitalized. ESKD patients and the professionals who care for them should be prioritized for testing. We support CMS' efforts to develop testing protocols for dialysis facilities, prioritizing in-center hemodialysis clinics relative to home dialysis clinics. We encourage CMS to design these protocols to account for two seemingly opposing concepts. First, that COVID-19 testing extremely important for dialysis patients and staff to make them aware of their risks so they can take steps to manage them; and second, that universal testing in dialysis facilities may have unintended consequences that must be acknowledged and appropriately managed.

Early in the PHE NKF offered our support for weekly testing of all in-center dialysis patients. We continue to believe that weekly testing may be warranted for dialysis clinics in areas of significant disease activity and at the discretion of the dialysis facility staff who may feel that for their specific population, weekly testing is in best interest of their patients and staff. We note that many patients would prefer that their dialysis clinic tests them weekly, as this empowers them to be aware of and manage their risks to themselves and others. We recommend that CMS provide the resources for dialysis facilities to test their patient populations up to weekly for the duration of the COVID-19 pandemic. We note that some regions may have a robust infrastructure for mobile testing, which may be an option for dialysis facilities that wish to provide tests to patients in that manner. We encourage CMS to provide the resources to test patients up to weekly while allowing flexibilities for dialysis facilities to test patients on the schedule and via the avenue that best meets the needs of patients and staff.

Not only are in-center dialysis patients at high risk for severe COVID-19 infection, but in frequently traveling to and from in-center dialysis facilities, nursing homes, and Skilled Nursing Facilities (SNFs), in-center dialysis patients may inadvertently transmit COVID-19 to others. NKF supports the following risk stratification recommendations for COVID-19 testing beginning with in-center ESKD patients. We continue to urge the leadership of the Department of Health and Human Services (HHS) to work with states to ensure that patients affected by kidney disease, kidney transplant recipients, and living donors have priority access to testing.

1. In-center dialysis patients. CMS should ensure that dialysis facilities have the resources needed to test patients up to weekly.
2. All CKD and ESKD patients, living donors, and transplant recipients who exhibit COVID-19 symptoms
3. All CKD and ESKD 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 ESKD 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 G3 through G5.

More nuance is required in considering how this testing should be deployed. The dialysis facility is the primary site of care for the in-center dialysis population. The dialysis facility may thus be the most convenient location to be tested, especially for patients living in rural areas where remote testing sites can be inaccessible. Allowing dialysis facilities to bill separately for nasopharyngeal testing provided on the same day as the dialysis treatment using the AY claims modifier would incentivize greater viral testing of the in-center dialysis population. Separate billing is important because viral testing is time, labor, and resource intensive, none of which are covered by the dialysis bundle. However, broad viral testing in dialysis facilities does raise concerns. Data suggest that nasal swabs may continue to detect viral RNA for weeks after the active infection has resolved, even though no viable virus is present. The implications of these data are that dialysis facilities may appear to be sites of outbreaks when they are not, causing anxiety for patients and staff to remain at home. In addition, COVID-19 tests are not perfect, producing both false positives and false negatives. A high prevalence of cases in a dialysis facility in a community with low prevalence is likely an inaccurate portrayal of the reality and can affect the day-to-day workflows of providing dialysis.

NKF supports COVID-19 testing for the dialysis population in the most efficient manner possible. While initially this may mean allowing for separate billing of nasopharyngeal swabs, our hope is that best practices for COVID-19 testing in high-risk settings will emerge. Pooled testing in a dialysis shift followed by individualized testing when necessary would ensure that dialysis patients are not being swabbed, which is painful, unnecessarily. Similarly, as noted, some communities can arrange for mobile testing sites to visit dialysis facilities, which would lower the burden on facility staff while

ensuring patients are receiving the highest quality testing. We encourage CMS to take all of these considerations into account as it develops its testing protocols.

## Section II. B. Scope of Practice

NKF strongly supports the scope of practice flexibilities for nonphysician healthcare professionals. CKD and ESKD are highly complex conditions and patients benefit from the support of a multidisciplinary team of qualified and highly trained professionals able to address their different clinical and social needs. The COVID-19 pandemic continues to exacerbate the complex needs of these vulnerable patients. As such, scope of practice flexibilities will continue to be critically important, both during the PHE and as COVID-19 poses as ongoing threat after the PHE has concluded. We support CMS' allowing the testing to be ordered by any healthcare professional who is authorized to do so under applicable state law. We agree that such flexibilities will accelerate Covid-19 testing for our most fragile patients.

NKF thanks CMS for recognizing pharmacists as healthcare providers with a scope of practice waiver for ordering and furnish Covid-19 testing under the PREP Act (April 8.2020). This will expand the availability of Covid-19 testing for our patients with CKD, receiving dialysis or having a kidney transplant.

In regard to Section 27557--Pharmacists Providing Services Incident to a Physician Service, the statement "[t]his clarification does not alter current payment policy for pharmacist medication management services furnished incident to the professional services of a physician or NPP" implies that there is a consistent payment policy across regions of the country. However, the current payment policy for pharmacist services "incident to" the services of the billing physician is not consistent across the Medicare Administrative Contractors (MACs) and requires further clarification. A common misconception by physicians and pharmacists in some CMS regions is that CPT 99211 (Level 1) code should be used to bill for pharmacist-provided 'incident-to' physician medication management services, no matter the complexity of the visit. This misconception limits the enthusiasm for physicians or NPPs in certain CMS regions to enter into collaborative practice agreements with pharmacists to provide medication management services. Other CMS regions do not disallow level 2-5 E/M codes to be billed, based on documented visit complexity

NKF recommends clarifying that when a pharmacist performs pharmacy services (e.g. medication management) "incident to" a physician that physicians or healthcare practices should bill the E/M code that is most appropriate for the level of service provided. This clarification will be beneficial for expanding patient access to healthcare during Covid-19 pandemic. In addition, it will encourage nephrologists and nephrology NPPs to collaborate with pharmacists to develop new care models incorporating medication management services for our patients under the new CMMI Comprehensive Kidney Care Contracting Models initiated by the Advancing American Kidney Health initiative.

#### N. Payment for Audio-Only Telephone Evaluation and Management Services

NKF greatly appreciates CMS' attention to making audio-only visits more accessible to patients. As CMS is aware, audio-only visits can be extremely productive and for many patients constitute their only access to healthcare. It is imperative that CMS understand that patients affected by kidney disease and kidney transplant recipients will continue to be vulnerable to the threat of COVID-19 after the PHE has concluded and until there are COVID-19 countermeasures. Our understanding is that when the PHE concludes, codes 99441-99443 will return to non-covered status by the Physician Fee Schedule (PFS). This would be inappropriate, as would returning to the Relative Value Units (RVUs) first established by CMS. Audio-only visits will not be continued if CMS returns to initial level of reimbursement, which substantially undervalued the service compared to the time and effort involved.

#### AA. Updating the Medicare Telehealth List

NKF welcomes the willingness of CMS to continue to evaluate whether additions to the Medicare telehealth list may be warranted. We would reiterate the need for telehealth to continue to be an option for patients and professionals in the interim between the conclusion of the PHE and the availability of COVID-19 countermeasures during which kidney patients, transplant recipients, and living donors will continue to feel reticent to visit their providers in person. For the purposes of the pandemic and in general, patients appreciate the conveniences of telehealth and audio-only visits. Continuing to offer flexibility in care options will be paramount. While telehealth and audio-only visits can be preferable for stable patients, face-to-face visits can be a better option for others. We encourage CMS to provide the option for vulnerable patients to receive the care in the manner that best aligns with their comfort level for the entirety of the COVID-19 pandemic.

#### **BB. Payment for COVID-19 Specimen Collection to Physicians, Nonphysician Practitioners and Hospitals**

##### Covid-19 Specimen Collection Policy

As noted above, NKF would support incentives for dialysis facilities to dramatically increase testing of asymptomatic and pre-symptomatic in-center dialysis patients. CMS does not separately reimburse ESKD facilities for specimen collection when the specimen collection occurs on the day of treatment. For practical purposes, this means that COVID-19 specimen collection is part of the ESKD bundled payment and there is no additional incentive to perform it on the day the patient receives their dialysis treatment. It would be our preference that in-center dialysis patients are not required to come to their facility any more than is absolutely necessary. We recommend that, at least preliminarily until more efficient and accurate testing is available, CMS allow for reimbursement for specimen collection through the AY modifier on the 72x claim until COVID-19 countermeasures have been developed. We do note that guardrails for this policy would be warranted to prevent patients from being

swabbed unnecessarily and to ensure that it is not a barrier to the adoption of other testing methods and protocols.

Expanding the Specimen Collection Policy

Though NKF supports CMS' policy of paying a nominal specimen collection fee and travel allowance to independent laboratories for collection of specimens for COVID-19 testing from homebound beneficiaries, we believe the policy should be extended to beneficiaries who are at increased risk of severe COVID-19 infection, require routine lab work, and would otherwise have to leave their homes to receive it.

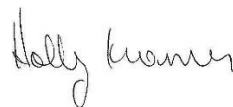
We strongly recommend that CMS allow more patients to benefit from the flexibilities provided for specimen collection for the purposes of COVID-19 testing. We request that CMS clarify that "homebound" for the purposes of specimen collection includes patients who are certified by a physician as requiring 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.

NKF extends our gratitude to the leadership and staff of CMS for their efforts to protect patients affected by kidney disease during the PHE. We hope to continue to be a partner to the Department of Health and Human Services and particularly CMS as we continue to move forward during these unprecedented times. We would welcome the opportunity to further discuss or collaborate on any of the issues or recommendations contained herein. Please contact Miriam Godwin, Health Policy Director, at [miriam.godwin@kidney.org](mailto:miriam.godwin@kidney.org).

Sincerely,



Kevin Longino  
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