May 19, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Verma:

I am writing on behalf of Kidney Care Partners (KCP) to support the Administration’s efforts to provide flexibilities to respond to the public health emergency created by the spread of the 2019 Novel Coronavirus (COVID-19). KCP is an alliance of more than 30 members of the kidney care community, including patient advocates, health care professionals, providers, and manufacturers, to advance policies that support the provision of high quality care for individuals with chronic kidney disease (CKD), including those living with End-Stage Renal Disease (ESRD).

KCP supports the proposals in the “Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency” Interim Final Rule with Comment (IFC) related to the services provided to Medicare beneficiaries living with kidney disease, including kidney failure or ESRD. We also offer additional suggestions to remove barriers that have become apparent during the last few weeks since the Centers for Medicare & Medicaid Services (CMS) promulgated the IFC. They include:

- Providing additional flexibilities related to telehealth services;
- Recognizing medical isolation due to positive or suspected COVID-19 as constituting medical necessary to justify a non-emergency ground ambulance transport;
- Allowing providers to provide financial assistance to patients who need help with transportation, food, medications, and similar expenses; and
- Providing flexibility for treating patients with acute kidney injury (AKI).

In addition, we have attached our most recent letter that includes these requests, as well as other suggestions for relief that do not require rulemaking and could be accomplished through guidance.
I. KCP supports the expansion of authority to provide telehealth services and encourages CMS to address some outstanding issues related to providing telehealth services to patients with CKD.

KCP supports the IFC’s addition of the ESRD codes to the telehealth services for the duration of the PHE, as well as permitting the required clinical examination to be furnished as a Medicare telehealth service during the PHE for the COVID-19 pandemic. We are also pleased that CMS will not conduct reviews to consider whether those visits were conducted face-to-face, without the use of telehealth. We agree that allowing telehealth services for CKD patients will help reduce the risk of exposure to these patients, whom the Centers for Disease Control and Prevention (CDC) have identified at high-risk and needing to self-quarantine.

KCP is also pleased that CMS has eliminated the status indicator of “N” (Noncovered) for CPT codes 98966-98968 and CPT codes 99441-99443 on an interim basis for the duration of the PHE for the COVID-19 pandemic and providing separate payment for them.

We also agree that devices, such as iPhones, iPads, and other multimedia communication equipment that includes audio and visual and permit two-way, real-time interactive communications between patients and their physician/practitioner should be permitted to be used during this time. KCP appreciates that the Office for Civil Rights (OCR) is also loosening enforcement of the HIPAA regulations to allow the good faith use of software such as FaceTime or Skype.

Finally, we also welcome the decision not to subject practitioners to administrative sanctions for reducing or waiving any cost-sharing obligations federal health care program beneficiaries may owe for telehealth services furnished consistent with the applicable coverage and payment rules.

However, we ask that CMS also provide additional flexibility to fill gaps in the policies outlined in the IFC. We are pleased that CMS has indicated in the Interim Final Rule that was released on April 30 that CMS would consider additional codes in sub-regulatory guidance. To that end, we ask that CMS add CPT code 90989 for home dialysis training to the approved telehealth list, as well as CPT code 90993, for an incomplete course of treatment. We also ask that CMS allow physicians to bill the provision of AKI services via telehealth using CPT code 90935 during the PHE. As we now know, AKI is increasing due to COVID-19, so having access to telehealth services for these patients is also critically important.

Additionally, KCP also supports efforts on the part of non-profit organizations seeking federal funding to address the needs of patients during the pandemic as well. We understand that this request, which is highlighted in the attached letter, is outside the scope of the IFC, but highlight it to note the important role that these organizations can also play in assisting patients during the pandemic.
II. KCP requests additional flexibility to respond to PHE created by the spread of COVID-19.

A. Clarifying the medical necessity requirements for ground ambulance transport

During several of the kidney care community calls with the Administration, patient advocates, physician, dialysis facilities, and others have raised concerns about COVID-19 positive patients or those patients under investigation (PUI) for COVID-19 who require in-center dialysis to be able to get to their appointments. For these patients, tradition non-medical based modes of transportation are no longer appropriate, because the patients require medical isolation due to their COVID-19 status. The need to isolate these patients is consistent with the CDC guidelines; yet, several Medicare contractors are telling ground ambulance entities that these types of transports are not covered under the Medicare program. There is no consistency in how the contractors are responding. Some acknowledge that ground ambulance transport is medically necessary when a patient has a communicable disease or hazardous material exposure and must be isolated from the public or whose medical condition must be protected from public exposure. Some are silent. Others state that such transports are not covered.

Dialysis patients need to be able to get to their thrice weekly dialysis sessions. If they do not, they will likely require hospitalization due to fluid overload or a cardiac event. Some might die. We need CMS to clarify that MACs should indicate that such transports are covered by Medicare and that medical isolation because of COVID-19 status (positive or suspected) will meet medical necessity to justify payment.

CMS has already indicated in other areas of the Medicare program that medical necessity standards requiring other types of services to be contraindicated can be met if a “physician states that it is medically contraindicated for the patient to leave the home because the patient’s condition may make the patient more susceptible to contracting an infectious, pandemic disease.” Medicare has also stated that such patients would be considered “confined to the home” or “homebound” for purposes of our specimen collection policy.”¹ The rationale that supports this guidance for home testing also supports issuing guidance allowing these same types of patients to qualify for ground ambulance transportation during the PHE.

B. Providing flexibility for treating patients with acute kidney injury (AKI)

During the last few weeks, it has become clear that one of the complications of COVID-19 is acute kidney injury (AKI). The range of patients experiencing AKI is varied. The risk of AKI

is 2-5 percent in certain papers, but as high as 19-23 percent for hospitalized or critically ill patients.²

Current law only allows for AKI patients to be treated in dialysis facilities as in-center patients. However, to maximize resources, some AKI patients are being placed on PD during a COVID-19 hospital stay, because hemodialysis is not available. If the patient recovers from COVID-19, he/she will be discharged from the hospital with a PD catheter in place. KCP members are concerned that if CMS does not provide flexibility to allow for AKI patients to be treated in the home, then these patients will be subjected to a second access surgery to transition them to in-center dialysis during this crisis. Such a step is not only not medically necessary, but it is also likely to create a greater risk of complications for patients who are already in the process of recovering from COVID-19. Therefore, we ask that CMS allow COVID-19 patients who are placed on PD when hospitalized to continue their PD therapy and facilities be reimbursed for providing it during the PHE.

Similarly, some hospitals are discharging COVID-19 patients to skilled nursing facilities. We appreciate the guidance that indicates that dialysis facilities are permitted to provide services within the SNFs, but we want to clarify that this guidance also allows reimbursement for services provided to AKI patients discharged from hospitals and sent to SNFs.

III. Conclusion

Once again, KCP thanks CMS for all of the efforts to address barriers to providing high quality care to patients during the pandemic and PHE. We look forward to continuing to work with you on these remaining issues. Please do not hesitate to contact Kathy Lester if you have any questions or would like more information about our recommendations. She can be reached at 202-534-1773 or klester@lesterhealthlaw.com.

Sincerely,

John Butler
Chairman

Appendix: Kidney Care Partner Members

Akebia Therapeutics
American Kidney Fund
American Nephrology Nurses’ Association
American Renal Associates, Inc.
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
Ardelyx
AstraZeneca
Atlantic Dialysis
Baxter
Board of Nephrology Examiners and Technology
BBraun
Cara Therapeutics
Centers for Dialysis Care
DaVita
DialyzeDirect
Dialysis Patient Citizens
Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Greenfield Health Systems
Kidney Care Council
Medtronic
National Kidney Foundation
Nephrology Nursing Certification Commission
National Renal Administrators Association
Renal Physicians Association
Renal Support Network
Rockwell Medical
Rogosin Institute
Satellite Healthcare
U.S. Renal Care
Vertex
April 16, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Verma:

The members of Kidney Care Partners (KCP) appreciate all that CMS has been doing to address the coronavirus outbreak and remove barriers that will allow dialysis facilities, physicians, nurses, and other health care professionals to respond to the crisis. KCP is an alliance of members of the kidney care community that serves as a forum for patient advocates, health care professionals, providers, and manufacturers to advance policies that support the provision of high quality care for individuals with chronic kidney disease (CKD), including End-Stage Renal Disease (ESRD).

We want to especially thank you for the allocation of funds from the Public Health Emergency Fund that providers and facilities received last week. These funds are extremely helpful. Our members also want to thank you for the various calls and working groups focused on addressing the needs of patients living with kidney disease who are at a higher risk when it comes to COVID-19. KCP submitted several suggestions through these various processes, as well as requests to the CMS team prior to the formation of the working group. We are very grateful that CMS has been able to respond to so many of the requests for relief and waivers during the last few weeks.

There are some additional issues that have arisen and a few that remain unresolved that KCP would like to share with you as well. As the crisis evolves, it is important that we find ways to address these concerns that are creating barriers to providing care to patients. Each of these asks is limited to the duration of the public health emergency (PHE). They are:

**Transportation**

- **Assisting Patients with Transportation:** Provide non-emergency transportation reimbursement and billing options, including coverage of non-emergency ground ambulance transportation of patients with communicable disease exposure and who must be isolated, under Medicare FFS using demonstration authority to create a temporary billing code to assist dialysis patients with getting to and from appointments for the duration of this crisis. Medicare Administrative Contractors could make determinations as to eligibility on a case-by-case basis.
Fraud and Abuse Waivers

- **Assistance for Patients:** Waive Stark and the antikickback restrictions on dialysis facilities and nephrologists to allow them to provide and/or facilitate patient assistance programs for patients who need financial support for transportation, food, medicine, co-payment obligations, or other expenses during the emergency.

Quality Programs

- **Reporting Data to Quality Programs:** Expand the relief provided through the quality waivers facilities to include the full year of 2020 and a grace period (e.g., 30-60 days) after the “end” of the crisis to ramp back up, because areas/states will be hit unevenly. KCP also requests that CMS extend the quality program waivers to eliminate data submission for Q3 and Q4 of 2020 and not apply program penalties for any program penalties based on the year 2020.

- **ESCOs:** Suspend ESCO quality program, consistent with how CMS is treating the fee-for-service quality programs, during the PHE.

- **Networks:** Suspend all ESRD Network projects during the PHE.

Home Dialysis

- **Missed Labs:** Temporarily waive the requirements to include labs on claims during the crisis: (1) if a home patient has not come to the facility because of a shelter-in-place order or self-quarantine or (2) 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. This request is similar to the policy where CMS has allowed facilities to use the previous months BUN test on a claim during previous emergencies (see https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Consolidated_Medicare_FFS_Emergency_QsAs.pdf (Question J-2), but this request would need to extend to other lab results as well. This request is necessary to implement the CMS waiver that allows home dialysis patients to rely upon telehealth services for their monthly required visit. Patients who are medically stable in the judgment of their physician do not need to have monthly labs drawn solely for the purpose of meeting the billing requirement should not be required to take the risk associated with leaving their homes for these tests.

- **Providing flexibility for Home Dialysis Patient Labs.** Reimburse outside of the bundle the cost of laboratory tests performed in a patient’s home during the PHE. Some home dialysis patients who are medically stable do not want to risk infection during the stay-
in-place orders by having to go to a laboratory to obtain their monthly lab work for dialysis. They would prefer to have a technician come to their patient home and draw their blood. The bundle does not include such costs and so Medicare during the PHE to reduce infection should reimburse directly for these services.

- **Facilitating home treatment options:** Provide during PHE coverage under Medicare Part D for oral agents indicated by the FDA to treat conditions associated with CKD in patients not on dialysis, which would allow patients to avoid the need for infusion treatments in hospital outpatient departments and minimize risk of exposure.

- **Recognizing new site of care AKI patients.** Temporarily waive restrictions and allow reimbursement for Acute Kidney Injury patients discharged from hospitals and sent to SNFs.

- **Emergency PD for AKI Patients:** Allow COVID-19 patients who are placed on PD when hospitalized to continue their PD therapy and facilities be reimbursed for providing it during the PHE. To maximize resources, AKI patients are being placed on PD during a COVID-19 hospital stay because hemodialysis is not available. If the patient recovers from COVID-19 and he/she is discharged from the hospital with a PD catheter in place, it does not make sense to subject the patient to a second access surgery and transition them to in-center dialysis during this crisis.

**Telehealth**

- **Facilitating Telehealth Home Dialysis:** Add CPT code 90989 for home dialysis training to the approved telehealth list, as well as CPT code 90993, for an incomplete course of treatment.

- **Telehealth Waiver Clarification:** Allow a phone-only option for patients who do not have access to a video option during the PHE.

- **Expanding options for AKI patients.** Allow physicians to bill the provision of AKI services via telehealth using CPT code 90935 during the PHE.

**Survey and Certification**

- **Avoiding Surveyor Disruption:** Instruct surveyors to minimize disruption caused when they enter facilities during the PHE. We understand that surveyors are supposed to conduct infection control surveys, but facilities are having difficulties when surveyors ask for documentation and other paperwork that takes away from the care being provided. We ask that CMS streamline these surveys to require the minimum amount of engagement and instruct the surveyors accordingly.
• **Addressing Staffing Ratios:** Temporarily waive the staffing ratio requirements (and coordinate with the States to waive any specific staffing ratio requirements).

• **Relaxing Billing Requirements Related to the Location of a Patient:** Provide temporary flexibility to dialysis facilities billing for patient treatments in the following ways:
  
  o Allow facilities to continue to bill in-center patients as in-center patients, even if they receive dialysis via a home hemodialysis machine in a PD or HHD training room to reduce the risk of transmission of the coronavirus; and
  
  o Allow facilities to continue to bill a home dialysis patient as a home dialysis patient, even if the home patient receives his/her monthly visit services in a room of a facility that is not otherwise certified for home, but is otherwise safe and appropriate to treat a patient.

**Lab Testing**

• **Billing:** Allow a laboratory using a third party to perform COVID-19 testing to bill Medicare for the test, even though the specimens were not accessioned by the billing lab.

• **Billing:** Clarify that any type of COVID-19 tests is not a laboratory test for the treatment of ESRD and will be billed separately, which would be consistent with guidance CMS has provided to other providers and suppliers that are permitted to conduct COVID-19 testing and allow COVID-19 tests to be CLIA waived tests to allow the test to be performed at dialysis facilities instead of always having to send them away (when such tests become available).

• **Billing:** Clarify that when ordering a COVID-19 test consistent with CDC guidelines that billing for the (1) “point of care” performance of a test at a facility and (2) the PCR or IGG/IGM test performed at a facility or third party laboratory on the same date of services will not be presumed to be medically unnecessary. Also clarify whether the U0002 reimbursement code for COVID-19 testing covers serum-based COVID IGG/IGM tests used at the point of care or at the laboratory. Similarly, clarify whether the serum-based COVID IGG/IGM POC can be reimbursed without a determination from the FDA as to whether the tests are low complexity/CLIA-waived.

**Miscellaneous**

• **Application of waivers:** Clarify that all PHE-related waivers applicable to dialysis facilities will apply to facilities that are joint ventures as well.
• **ESRD Treatment Choices:** Postpone implementation of the ETC model until after the PHE has ended and there is sufficient time after that to allow for nephrologists and facilities to address the changes required by the new model. KCP also asks that CMS provide additional time related to finalizing the proposal and provide the opportunity for additional comments, given that substantial changes in the model are anticipated. The community needs to stay focused on treating patients and finding ways to continue to treat patients who test positive for COVID-19. If the virus continues to be a problem in the fall (as the CDC suggests), it is also important that nephrologists and providers are not being asked to make changes due to the new model while addressing COVID-19 at that time. Trying to implement a new system in what could include half of the country is not practical at this time.

• **Provide grant funding:** Provide grants to eligible 501(c)(3)-non-profit entities for ESRD patients specifically to enhance COVID-19-specific direct patient financial assistance programs.

On behalf of KCP, we want to again thank you and your team for working closely with the kidney care community as we all try to deal with the pandemic and its impact on individuals with kidney disease. Please do not hesitate to contact Kathy Lester at klester@lesterhealthlaw.com or 202-534-1773 if you have questions or would like more details about any of these recommendations.

Sincerely,

[Signature]

John Butler
Chairman
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Greenfield Health Systems
Kidney Care Council
Nephrology Nursing Certification Commission
National Renal Administrators Association
Renal Physicians Association
Renal Support Network
Rockwell Medical
Rogosin Institute
Satellite Healthcare
U.S. Renal Care
Vertex