



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:
 - 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
 - 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 (3)(c)-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,

A handwritten signature in black ink, appearing to read 'J. Butler', with a long, sweeping horizontal line extending to the right.

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
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
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