November 1, 2017

Noridian Healthcare Solutions, LLC
JE Part B
Attn: Charles Haley, MD, MS, FACP
PO Box 6700
Fargo, ND 58108-6700

**RE: Noridian Hemodialysis Frequency LCD (DL37502)**

Dear Dr. Haley:

The Renal Physicians Association (RPA) is the professional organization of nephrologists whose goals are to ensure optimal care under the highest standards of medical practice for patients with kidney disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with kidney disease. RPA leaders serve as Carrier Advisory Committee (CAC) members for all Medicare Administrative Contractors (MACs).

RPA welcomes the opportunity to provide comments on the proposed draft local coverage determination (LCD) policies on frequency of dialysis. We appreciate the addition of ICD-10 codes to the list of diagnosis codes that support medical necessity for more frequent dialysis and applaud the MACs for recognizing the breadth of comorbid conditions that impact the treatment of kidney failure. We remain deeply concerned, however, that while this LCD addresses extra treatments for patients who have an infrequent dialysis-requiring event, it does not address care of patients who need more frequent dialysis on a chronic basis for conditions that may be acute and/or life threatening and **medically appropriate**. RPA recognizes that the MACs believe they are constrained in addressing policies that are separately promulgated in the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), but we would urge you to seek solutions that allow chronic patients who definitively need extra dialysis treatments within a month to receive them in a covered and compliant manner.

As noted, RPA believes that this LCD, if implemented, will negatively impact the contingent of ESRD kidney patients who require extra dialysis treatments on a routine rather than infrequent basis. Our comments below discuss:

- Development of the LCD in the Broader Context of the ESRD Program
- Potential of the LCD to Negatively Affect the Quality of Care Provided to Kidney Patients
- Potential to Restrict Patient Modality Choice
- Likely Disadvantage Posed to Medicare Beneficiaries with Kidney Disease
- Planned Inadequate Dialysis Heightens Risk to Patients and Implies Ethical Misconduct
- Fiscal Ramifications of the LCD on the Medicare System

Development of the LCD in the Broader Context of the ESRD Program

As indicated above, RPA acknowledges that the MACs must develop coverage policies on a wide spectrum of issues in a way that is coordinated with national payment policy as seamlessly as possible, and that the MACs with this LCD have sought to do that. However, we would also posit that the entire reason for the existence of the Medicare ESRD benefit is to cover and pay for dialysis for those Medicare ESRD beneficiaries who need this unique, life-sustaining therapy to live. RPA recognizes that a thrice-weekly dialysis regimen will be sufficient for many if not most dialysis patients, but there will still be a subpopulation who experience acute problems that occur on a chronic basis (the signature example of which is fluid overload, discussed below), and we believe policy such as set forth in this LCD creates a restriction that is counter to the underlying purpose of the ESRD program.

Again, RPA appreciates the expanded list of diagnoses that will medically justify additional dialysis sessions, and we believe that this reflects an understanding on the part of the MACs that it is necessary to recognize important clinical situations that warrant coverage for extra dialysis sessions. RPA believes, however, that coverage by the MACs is medically appropriate for conditions or events that are chronically occurring, in addition to those acute events that infrequently require an extra dialysis treatment.

Potential of the LCD to Negatively Affect the Quality of Care Provided to Kidney Patients

RPA believes the proposed LCD will artificially constrain the nephrologist's ability to effectively provide high quality and safe patient care. Recent concerns that aggressive ultrafiltration (fluid removal) that negatively impacts the heart has led to efforts to limit the magnitude of ultrafiltration that can occur in a single dialysis treatment. Thus, for patients whose fluid volumes exceed that which is safely removed in a single session (or those who have

hemodynamic instability that precludes removal of the needed amount of fluid), additional sessions or extended treatments will be needed. Many patients do not have the physical stamina to undergo an extended dialysis treatment, thus if additional dialysis sessions cannot be covered by Medicare, these beneficiaries will be forced to seek treatment in the emergency department or be hospitalized. The lack of a mechanism for treating these patients with chronically occurring acute problems limits the nephrologist's options, but more importantly, is a threat to their survival.

In the draft LCD, Noridian outlines a series of diagnoses under which hemodialysis performed or billed more than three times per week is deemed to be reasonable and medically necessary. RPA appreciates the expanded list of diagnoses being offered but respectfully points out that the majority of these represent conditions or events that do not occur in isolation or as a solitary event but rather, as a recurring and possibly, frequent complication of a chronic condition. The indications for more frequent dialysis may be acute conditions that are symptom-driven (e.g., chronic fluid overload, hyperkalemia) and of an emergent nature such that hospitalization or death is likely to ensue without dialysis. Less emergent but equally important is the provision of sufficient dialysis to achieve patient well-being by reducing the burdens associated with longer thrice weekly dialysis. Relevant examples include the quality of life benefits that result from taking fewer medications, having less fluctuant volume status, and the shortening of the interdialytic interval, the benefits of which cannot be overemphasized. As physicians, we strive to provide patients with care and treatments that improve quality in addition to prolongation of life. Patients with ESRD are forced to live their lives around dialysis; more frequent hemodialysis allows patients to incorporate dialysis into their lives with less disruption.

Additionally, many pediatric patients, particularly infants and young children, frequently require more than 3 dialysis sessions per week so that they can receive sufficient formula/feedings to promote normal growth and development. Limiting the number of dialysis sessions could have a negative impact on the long-term outcomes of such patients as it might discourage dialysis providers from providing the additional treatments needed to remove the fluid necessary for their nutritional support.

On an issue related to the quality of kidney care, as you know nephrologists and dialysis facilities are appropriately subject to an array of care delivery quality measures, under the Medicare Incentive Payment System (MIPS) for nephrologists and the Quality Incentive Program (QIP) and the Dialysis Facility Compare (DFC) Star Ratings for dialysis facilities. RPA is concerned that an unintended consequence of the LCD is that limiting the number of dialysis sessions for the ESRD patient subpopulation under discussion will confound the ability of providers to successfully achieve the quality goals set forth by CMS.

Potential to Restrict Patient Modality Choice

At a time when CMS is encouraging the use of home dialysis, RPA believes that the draft LCD will in a real-world, point-of- contact sense create a significant disincentive to the prescribing of home hemodialysis. Indeed, it was originally anticipated that patients with ESRD, if treated, would return to work, and for patients who continue to work, home hemodialysis allows for a more flexible schedule and the opportunity to tailor their treatments in a way that optimizes their well-being. Further, nephrologist medical directors and dialysis providers are evaluated by the ESRD Networks and required by the Conditions for Coverage for Dialysis Facilities to educate patients on the advantages and disadvantages of all dialysis treatment options.

This LCD would effectively eliminate a major advantage of doing hemodialysis at home – the opportunity to do more frequent dialysis—and could inhibit its use overall by discouraging both nephrologists from offering it and patients from selecting it.

Likely Disadvantage Posed to Medicare Beneficiaries with Kidney Disease

Given that a preponderance of commercial insurers cover dialysis sessions for ESRD patients at frequencies of greater than the conventional thrice weekly, RPA is concerned that limiting payment for more frequent dialysis will substantially disadvantage Medicare beneficiaries with ESRD, effectively creating two tiers of coverage for these services (with Medicare beneficiaries clearly in the lesser tier). We are mindful of Noridian' s obligation to fulfill its fiduciary responsibility in administering the Medicare Trust Fund, but we would argue that a parallel charge is to ensure that Medicare beneficiaries receive optimal health care including that which fosters prevention of avoidable acute events whether these be new or acute exacerbation of chronic conditions. RPA recognizes that the creation of a disparity between the care that individuals with private insurance receive in comparison to that of Medicare beneficiaries would be unintended, but we do believe that such a disparity has and will continue to occur as a result if this policy as currently written is implemented.

Further, RPA believes that the LCD does not account for the importance of Medicare beneficiaries' patient experience. The availability of coverage for additional dialysis sessions increases the likelihood of an ESRD patient being able to dialyze at home, which in turn enhances the possibility of an ESRD patient resuming normal life activities and even return-to-work when applicable which as noted was an objective of the original legislation. In these cases, a more flexible policy would not only improve the care that a dialysis patient receives but would

also likely have financial benefit for the health system broadly. Noridian's LCD should not pose a barrier to this positive global potential.

Planned Inadequate Dialysis Heightens Risk to Patients and Implies Ethical Misconduct

RPA has significant concerns regarding clinical impact of the LCD. Noteworthy research by Zoccali, et al, on *Chronic Fluid Overload and Mortality in ESRD* points to chronic exposure to fluid overload being a strong risk factor for death[1], and results from a study by Foley, et al indicate that a long interdialytic interval (2 days or more) is a time of heightened risk among patients receiving hemodialysis.[2] This research illuminates the need to promptly and effectively address chronic complications of ESRD that can be worsened by the traditional two-day dialysis treatment interval, efforts which we believe would be hampered by the implementation of the LCD.

Limiting coverage of extra treatments except on an infrequent non-routine basis poses an ethical dilemma for physicians caring for those patients whose "conditions benefit from more than 3 HD sessions per week" (as most recently outlined in the final rule for the 2017 ESRD Prospective Payment System)[3] and whose plan of care warrants the prescription of more frequent dialysis treatments.

We concur with a comment developed by Kidney Care Partners (KCP) in reference to planned inadequate treatments which states:

> *The language in the draft LCD that references "planned inadequate" treatments is problematic because it implies that physicians are not meeting their ethical obligations to patients. We do not agree that a physician who prescribes a therapy for ESRD would write a prescription that was designed to deliver an inadequate weekly Standardized Kt/V. Any decision to regularly perform more than three treatments per week is a direct result of shared decision-making resulting in a chronic plan of care that meets the patient's documented medical needs. As with the POC, the physician uses his/her best judgment to prescribe the course of dialysis treatment. What constitutes the dialysis prescription is the practice of medicine and should remain in the hands of the prescribing physician.*

Financial Ramifications of the LCD

[1] J Am Soc Nephrol 28: ccc–ccc, 2017. doi: 10.1681/ASN.2016121341
[2] N Engl J Med 2011; 365:1099-1107September 22, 2011DOI: 10.1056/NEJMoa1103313
[3] 81 Fed Reg 77843

RPA urges Noridian, and CMS, to consider the possible downstream financial impact of the draft LCD. If, for example, a patient with fluid overload experiences a complication that requires an emergency room visit or hospitalization, the expense of that ER visit or hospitalization will far outweigh the cost to the Medicare program compared to that of an ongoing dialysis treatment regimen that could have likely addressed the patient's condition. The likelihood of overutilization in this regard is minimal in that patients are generally not interested in increasing the time or number of times they are tethered to a dialysis machine unless they recognize the derived benefit. RPA supports the intent of Noridian's prudent interpretation of medical necessity in order to be fiscally responsible with Medicare resources, but we urge Noridian to **not exclude patients with chronically occurring acute complications of kidney failure, and to cover all medically appropriate dialysis treatments, whether isolated or routine.**

Summary

RPA appreciates that the MACs have a responsibility to adhere to the limits posed by CMS ESRD Payment Policy. However, we strongly believe that this LCD, while an incrementally positive step, could have a detrimental effect on the health outcomes of a substantial segment of the ESRD beneficiary population. Further, to limit coverage to extra treatments occurring on an infrequent rather than non-routine basis seems counter to CMS' recognition that "some patient conditions benefit from more than 3 HD sessions per week…"[4] and the directive to "the MACs to pay for medically justified additional treatments when appropriate documentation is provided." Finally, this LCD would place facilities and nephrologists in an untenable position of constraint in their ability to appropriately and ethically choose the best plan of care for their patients.

RPA is committed to working with our physician colleagues in the carrier medical director community to finding a workable solution that honors Noridian's fiduciary responsibilities, while ensuring that all Medicare ESRD beneficiaries receive the level of care that is medically necessary and appropriate for treatment of their individual condition. We urge you to view this comment as part of an ongoing dialogue among clinicians to finalize an LCD that ensures all patients who medically require additional dialysis receive these services in a manner that is consistent with CMS' intent.

[4] 81 Fed Reg 77843

As always, RPA welcomes the opportunity to work collaboratively with Noridian in its efforts to improve the quality of care provided to the kidney patients within its jurisdictions, and we stand ready as a resource to Noridian in its future work in the kidney disease care arena. Any questions or comments regarding this correspondence should be directed to RPA's Director of Public Policy, Rob Blaser, at 301-468-3515, or by email at rblaser@renalmd.org.

Sincerely,

Michael D. Shapiro, MD, MBA, FACP, CPE
RPA President