Dear Sir/Madam:

As a (practicing nephrologist or other designation), thank you for the opportunity to provide comments on the recently published Local Coverage Determination (LCD) Frequency of Hemodialysis.

As someone who has dedicated their career to helping patients with kidney diseases, I am deeply troubled by your proposed new policy, which, as described below, I believe interferes with the patient-physician relationship, creates unnecessary administrative burden, and is inconsistent with current law.

This LCD needs should be rejected or revised to:

- Protect the physician-patient relationship
- Encourage medically-justified individualized care
- Recognize both acute and chronic conditions and care needs
- Avoid undue administrative burden on physicians
- Conform to current CMS policy

Patients with kidney failure have a variety of often serious comorbidities that impact requirements for dialysis therapy. As their physician, I must approach and design their care with meticulous attention to individual healthcare needs to optimize outcomes, reduce hospitalizations, and control symptoms. These complex patient conditions sometimes demand prescription of dialysis more than three times a week.

As currently written, the draft LCD interferes with the patient-physician relationship in concerning ways. By proposing to establish a blanket denial policy for any claim that is linked to a Plan of Care (POC) that includes a dose of dialysis of more than three treatments per week, and by limiting the conditions that qualify as “medical justification” for more than three treatments per week to only a few acute conditions while excluding chronic conditions, inappropriately infringes upon the physician-patient relationship, establishing substantial barriers to our ability to prescribe what we think is the optimal treatment for individual patients and our ability to prevent future, more severe complications for these already vulnerable patients.

I am also concerned that the LCD limits the conditions for more than three dialysis treatments per week to “acute” clinical conditions, a limitation that is not consistent with the clinical literature. As reflected in the names of conditions such as “Chronic systolic [or diastolic] (congestive) heart failure”, as well as others without the modifier “chronic” many conditions where more frequent hemodialysis is beneficial are chronic rather than acute in nature. Moreover, it is contrary to best practices to treat patients when they have an acute episode, then stop the treatment approach that addressed the issue; such a shortsighted strategy will, predictably, lead to another acute episode for many patients, and risk re-hospitalization and resource use requirements that far exceeds that of an additional weekly dialysis session. If the proposed LCD is finalized as drafted, I believe it would result in increased hospitalizations and lengths of stays.

CMS Administrator Seema Verma recently said that the agency must make it easier for providers to “focus on doing the work that patients and families need them to do without

causing them to be subject to excessive regulatory and administrative burden." [1] Simultaneously, there is an increased—and appropriate—emphasis within the agency on providing patient-centered care, a goal that cannot be met if health professionals spend their time saddled with excess paperwork instead of interfacing with their patients.

The sum impact of the proposed LCD is substantial and unnecessary strain on the patient-physician relationship through the establishment of marked administrative and regulatory barriers to the prescription of appropriate and individualized medical care that will result in fewer medically indicated dialysis sessions being delivered to patients who need them.

Again, thank you for the opportunity to provide comments.

Sincerely,

(Please provide contact information including email and a telephone number.)

[1] https://blog.cms.gov/ August 22, 2017.