



August 25, 2017

Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-5522-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: CMS-1674-P: Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program

Dear Administrator Verma:

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. We are writing to provide comments on the ESRD PPS Proposed Rule, and specifically on CMS' solicitation of comments on the inclusion of acute kidney injury (AKI) patients in the ESRD Quality Incentive Program (QIP).

We are writing to provide comments on the following areas:

- Etiology and Natural History of AKI
- Methodological Concerns
- Review of QIP Measures' Applicability to AKI Patients
- Possible Areas for Future Development

Etiology and Natural History

Acute kidney injury requiring dialysis (AKI-D) is the abrupt loss of kidney function, resulting in the retention of urea and other nitrogenous waste products and in the dysregulation of extracellular volume and electrolytes. Patient risk factors for development of AKI-D include older age; underlying chronic kidney disease (CKD), with increased risk associated with both lower baseline glomerular filtration rate (GFR) and greater severity of proteinuria; comorbidities including congestive heart failure (CHF), peripheral vascular disease, and diabetes mellitus; medication use, including use of inhibitors of the renin-angiotensin system such as angiotensin converting enzyme inhibitors (ACEI) and angiotensin receptor blockers (ARB), and non-

steroidal-anti-inflammatory drugs (NSAIDs). AKI-D is common in patients admitted to the ICU with a primary diagnosis of infection or sepsis and in post-surgical patients, particularly after cardiothoracic and vascular surgical procedures and after non-renal solid organ transplantation.

The most common histologic manifestation of AKI-D is acute tubular necrosis (ATN), from ischemic, septic or toxic causes; acute interstitial renal disease, intrinsic glomerular diseases and small and large vessel disease are uncommon causes of AKI-D. A recent study utilizing the USRDS database showed that in 2009-2010 ATN (presumably associated with AKI-D) accounted for 3.5% of incident ESRD patients. Data on the natural history of AKI-D are limited, and characterized by substantial variability. Among the areas of concern are lack of information on baseline renal function before the onset of AKI-D; wide variation in the cause and severity of the AKI-D; selection bias, in that some studies are limited to patients with critical illness, or use of continuous renal replacement therapy; incomplete data due to patient death; and use of the USRDS data base, in which entry may be delayed for 45 days after starting outpatient dialysis, and which classifies patients by cause of renal failure, but does not specifically identify AKI-D.

Methodological Concerns

RPA agrees with CMS' efforts to support "measures that matter" to patients and providers. However, given the unique nature of AKI patients, the RPA does not believe the existing QIP measures are appropriate for AKI patients. The next section of our document provides a measure-by-measure review of the QIP measures' applicability to AKI patients.

By definition, AKI patients are seen in outpatient dialysis facilities for a limited time, usually less than three months. Frequently, the patients have been recently discharged from the hospital resulting in low hemoglobin, have low serum albumin reflecting protein malnutrition, and have multiple active medical conditions which may result in re-hospitalization. Unlike patients who start dialysis electively as outpatients with the benefit of being educated about access and treatment options, AKI patients often "crash land" into dialysis with little to no time for the advance work needed to mentally and physically prepare to have a functional access in place. Furthermore, AKI patients may be in transition in terms of their goals of care – they may recover kidney function or decide to withdraw from dialysis.

Since any dialysis unit is unlikely to have many AKI patients over the course of a year, the denominator in any individual dialysis unit will be extremely low, making meaningful evaluation of quality metrics in these patients difficult. The nature of the patients discharged from hospitals with AKI is so heterogeneous that data could not be interpreted as to quality of care.

Review of QIP Measures' Applicability to AKI Patients

Standard Infection Ratio – AKI patients may be at increased risk of blood stream infection due to the underlying condition that resulted in AKI or continued comorbidities that will be difficult to risk adjust. The patients will have increased risk of infection due to catheter use, but as previously stated, duration of exposure may be short, making meaningful data at the unit level difficult to assess. Therefore, **RPA does not believe this measure can be appropriately applied to AKI patients.**

In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey – Given the short duration in the facility as an AKI patient (<90 days), **AKI patients are excluded from the survey.**

Standardized Readmission Ratio (SRR) – The reason for patient readmission is likely to be related to the underlying condition/comorbidity associated with AKI and not under the control of the dialysis facility. Therefore, **RPA believes this would not be an appropriate measure.**

Standardized Transfusion Ratio (STrR) – Given that patients with AKI are at increased risk for transfusion and are generally not started on ESA therapy in the acute phase (and are unlikely to respond to ESA therapy in the acute phase) **this would not be an appropriate measure.**

Kt/V Dialysis Adequacy – While the same target Kt/V applies to AKI, **the measure's denominator is duration of ESRD >90 days, which would exclude the AKI patient.**

Vascular Access Type (VAT) (including Arteriovenous Fistula (AVF); Catheter > 90 Days) – RPA believes including AKI patients in this measure might restrict access to care. A functional arteriovenous (AV) fistula or graft requires clinic visits ahead of time with a nephrologist, evaluation by a surgeon, scheduling the procedure, and recovery time, a process which often takes longer than 90 days. Furthermore, RPA believes the patients should be excluded from the measure for an additional 90 days after they are declared ESRD if they do not recover kidney function. RPA also believes that having such a metric for AKI patients is directly counter to a goal of being patient-centered, in that attempting to commit patients to and proceed with a surgical procedure for access when they may recover is clinically inappropriate at best. **Given the increased likelihood of recovery of kidney function, these patients must be excluded from this measures.**

Hypercalcemia – The measure excludes patients on dialysis for <90 days. **Patients with AKI may have other reasons for hypercalcemia, so this would not be an appropriate measure.**

Mineral metabolism reporting – The measure excludes patients on dialysis for <90 days so **this would not be an appropriate measure.**

Anemia Management –The evidence supporting anemia management with ESAs in AKI patients is lacking and therefore **not appropriately applied to AKI patients.**

Pain Assessment and Follow-Up – While it is not unreasonable to assess pain, the measure excludes patients treated at the facility for <90 days, so **AKI patients would be excluded due to short duration of care.**

Clinical Depression Screening and Follow-Up – Given the prevalence of comorbidities experienced by AKI patients, **this is not clearly meaningful, but the measure also has a treatment at facility for <90 days exclusion that will exclude AKI patients.**

NHSN Dialysis Event Reporting – RPA is concerned that given the fact that **AKI patients are at increased risk for BSI, including them in the reporting could adversely impact access to care.**

In summary, *RPA believes that AKI patients should continue to be excluded from QIP reporting for the many reasons enumerated above.*

Areas for Future Development

RPA believes the paucity of AKI data must be addressed before appropriate, feasible and valid AKI measures can be developed. Given the variability of AKI patients as well as the lack of clinical practice guidelines related to AKI, it will be challenging to develop outcome measures. In future years, CMS should consider focusing on AKI protocols, such as frequency of assessment of renal function or methods to assess status of renal function or avoidance of hypotension.

As always, RPA welcomes the opportunity to work collaboratively with CMS in its efforts to improve the quality of care provided to the nation's kidney patients, and we stand ready as a resource to CMS in its future work on the ESD PPS. 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