ASN Comments on Proposed Rules Governing Payment and Quality Measurement in the ESRD Program

By David L. White

Every summer, the Centers for Medicare & Medicaid Services (CMS) releases the proposed End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Quality Incentive Program (QIP) rule that will govern payment and quality measurement in the ESRD program in the calendar year (CY) ahead. This summer was no different, so ASN recommended adjustments to the proposal during the 60-day comment period required by law under the Administrative Procedure Act, which governs rulemaking at the federal level. Currently, more than 800,000 Americans experience kidney failure, including more than 550,000 receiving dialysis and more than 200,000 living with a kidney transplant.

As always, ASN takes advantage of the open comment process to refocus the administration on the vast impact of kidney diseases on 37 million Americans and their family members. It is also an important opportunity to underscore the fact that kidney diseases and kidney failure disproportionally impact historically marginalized populations and minorities, including those who are American Indian or Alaska Native, Asian, Black, Hispanic or Latinx, and Native Hawaiian and Other Pacific Islander; people with lower incomes; and older adults, underlying and exacerbating existing disparities. These and other factors explain why it is critical that the CMS ESRD program promotes equitable access to optimal kidney care.

The proposals discussed in ASN's letter (1) and this article are expected to be finalized around the same time as Kidney Week 2024.

AKI site of care

After several years of advocacy by ASN, CMS proposed to extend the home dialysis benefit to individuals with acute kidney injury (AKI) for either peritoneal dialysis (PD) or home hemodialysis (HD). For patients with AKI requiring kidney replacement therapy, ASN advocated for allowing home dialysis as patients transition to home (from hospitals or postacute or in-center transitionary dialysis facilities), and the corresponding Medicare payment should be allowed when the nephrologist and patient agree that a particular patient with AKI can safely dialyze at home.

ASN views home therapy as supervised care that is of at least similar quality and intensity to in-center HD and highlighted the commitment to ensuring the success of all patients with AKI requiring dialysis (AKI-D), regardless of whether they are receiving dialysis in the home or in an HD facility. In these circumstances, intensive training for home dialysis should also be reimbursed by Medicare, via the addition of Current Procedural Terminology training codes 90989 and 90933 being added to the telehealth list. (Because there is no relative value unit attached to these codes, clinicians who are dependent on the relative value unit system to quantify their clinical work have a difficult time receiving credit for the work that they perform in the supervision of home dialysis training.)

ASN expressed concerns regarding an Add-on Payment Adjustment for Training of patients with AKI being added to the same payment as the proposed payment amount in 2025 for in-center dialysis: $273.20. However, CMS also proposed to extend an add-on payment adjustment for home and self-dialysis training at the same rate as patients with ESRD, on a budget-neutral basis, which results in a proposed AKI CY 2025 base rate (for all dialysis modalities) of $264.70 ($273.20 – $8.50, with $8.50 being the estimated add-on training adjustment). The problem with the adjustment, ASN pointed out, was CMS' math. The agency assumed that the number of patients with AKI going to home dialysis would be the same rate as all patients with ESRD receiving home dialysis in the fourth quarter of 2022: 15.4%. ASN asserted to CMS that "It is highly unlikely that the AKI home dialysis rate will equal the overall ESRD home dialysis rate, especially not in the first years of this new policy." Nephrologists evaluating the proposed rule felt that it is highly unlikely that there will be a significant number of individuals with AKI initiating home PD. ASN expressed concern that such an out-of-portion payment adjustment could impact modality choices for these patients for whom PD is an important patient-centered option. Patients with AKI-D are reimbursed lower than incident patients with ESRD, reflecting noninclusion of the incident patient modifier. While this is required by law, it emphasizes

that further deductions from the reimbursement for HD for AKI-D would be financially unviable.

ASN volunteered its AKINow Committee to work with CMS on accurate predictions of the uptake of home dialysis for AKI-D. Additionally, CMS correctly pointed out that "ESRD" and "AKI" are not interchangeable and that the Conditions for Coverage (CfCs) for dialysis facilities need to be aligned with the changes proposed in the rule. ASN believes that CfCs need updating (last updated in 2008) and urged CMS to engage the kidney care community in a broader dialogue on a range of potential updates to CfCs.

Dialysis bundled payment shortcomings

ASN expressed strong concern over an inadequate Medicare bundled payment for dialysis. In its March "Report to the Congress," the Medicare Payment Advisory Commission (MedPAC) estimated a margin of zero for 2024 (2). MedPAC's finding means that there are many facilities with a margin below zero. Given the significantly increasing costs, it poses challenges for many facilities to be able to adjust to unexpected events when they occur or, in some cases, to be able to continue providing services at their historic levels. A decrease in access to dialysis presents a grave concern for all patients regardless of payor. Other concerns identified by ASN in the proposed rule include the following:

1. **CMS proposed using the outlier policy as payment policy for innovation**. ASN expressed alarm that CMS' proposal to address innovative payment in the proposed rule by expanding products eligible for outlier payments did not represent a sustainable ESRD PPS policy for adequate funding for innovative drugs, biologics, and devices as covered by the Transitional Drug Add-on Payment Adjustment (TDAPA) under the ESRD PPS for certain new renal dialysis drugs and biological products. As MedPAC stated, the outlier policy is essentially stop-loss insurance, and it is not meant to establish accurate and adequate payment for new medically necessary services.

ASN recommended that CMS support the approach in the proposal outlined in section 201 of Senate bill 4469, the "Chronic Kidney Disease Improvement in Research and Treatment Act of 2024" (3). This proposal would require CMS in a nonbudget neutral manner to:

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- Establish a permanent post-TDAPA to the base rate for a new drug or biological product that comes within an existing functional category.
- Calculate the post-TDAPA using the most recent 12-month period of utilization data for the product and the most recent available full calendar quarter of average sales price (ASP).
- Update the adjustment amount annually to account for inflationary changes.
- Apply the adjustment amount immediately upon the expiration of the TDAPA period.

ASN maintains that the ESRD PPS as currently structured stifles innovation for a population that already experiences extreme health disparities and issues of access. As a result of recent policies, patients with chronic kidney disease-associated pruritus are not able to access the only US Food and Drug Administration-approved treatment indicated specifically to treat this disease. The manufacturer of difelikefalin (Korsuva) has indicated it will cease all research and development in the area of chronic kidney disease, reflecting low use due to payment policy.

2 **Orals in the ESRD PPS bundle present challenges.** ASN has repeatedly voiced its concerns to CMS about including oral-only phosphate binders and other phosphate-lowering drugs in the ESRD PPS for many reasons and supports efforts in Congress to delay that occurrence, but CMS again requested comments on a payment approach. To maintain consistency with the treatment of calcimimetics during their first 2 years of TDAPA, to align with the way Medicare reimburses for drugs and biologics under the Hospital Outpatient PPS's pass-through policy, and to minimize administrative burden on CMS and care facilities, ASN recommended that CMS adopt the methodology outlined in the Social Security Act section 1847A (4). This methodology sets payment at ASP + 6%; if ASP is not available, the payment is based on the wholesale acquisition cost.

ASN has made clear to CMS that it believes that adding phosphate binders and phosphate-lowering drugs to the bundle will have a negative impact on patients. ASN emphasized that phosphate binders and phosphate-lowering drugs must be taken outside of the facility, typically when a patient eats. Congress has recognized the challenges of including these drugs in the ESRD PPS when it has repeatedly restricted CMS from adding them. Furthermore, there will not be an actionable solution present for the distribution of phosphate-lowering agents to patients residing in nursing homes or other facilities.

3 **There is also the problem of no dispensing fees.** CMS recognized in the proposed rule's preamble that "dispensing fees and other costs are not currently included in the ESRD PPS base rate for phosphate binders" (5). As the Government Accountability Office found in its 2023 report, dialysis facilities will incur significant costs that are not included in the base rate if phosphate binders are added to the ESRD PPS bundled reimbursement (6). These costs include the following:

- paying pharmacy charges to obtain the drugs through them
- mailing fees either in terms of obtaining the drugs from pharmacies or sending the drugs directly to patients' homes, which is where they are taken
- incurring storage costs associated with maintaining the drugs at the dialysis facility if the decision is to distribute the drugs to patients during their dialysis treatment sessions
- complying with state pharmacy laws; for example, some states, like Alabama, do not allow dialysis facilities to distribute oral drugs, so there are additional contracting costs incurred
- supporting the provision of a significant volume of pills to patients so that they have the amount they need at every meal and snack
- adjusting drug supplies when a physician changes a patient's prescription to another product (which often occurs)
- absorbing costs of unused medications when patients are hospitalized, transfer to other facilities, die, or receive a kidney transplant

ASN detailed the differing policies within CMS programs and recommended that CMS adopt the straightforward and transparent ASP + 6% policy that it relies on in other parts of the Medicare program. As an alternative, CMS could consider using the same flat rate supply fee used for other oral Part B drugs that are supplied as part of a physician service.

QIP

CMS added three new health equity-focused quality measures in the CY 2024 ESRD PPS final rule (88 FR 76437–76446 and 76466–76480) to ESRD QIP (5). CMS is now soliciting feedback on the creation of a Health Equity Adjustment. ASN applauded CMS for its efforts to improve health equity among the population with ESRD receiving facility-based dialysis, given longstanding disparities among this population. ASN posed questions to CMS about the efficacy and logistics of the proposal. It remains unclear if CMS will delay this effort to provide time to improve the proposal.

ASN supported CMS' proposal to disaggregate the Kt/V Dialysis Adequacy measure into four distinct components, each evaluated against its own performance standards. ASN's analysis found that the approach acknowledges the complexity of dialysis adequacy and allows for a more nuanced assessment. By distinguishing

among various aspects of Kt/V, this proposal facilitates a more accurate reflection of patient-specific needs and treatment efficacy. However, ASN has longstanding concerns about the application of Kt/V in assessing PD adequacy, particularly considering existing guidelines and patient outcomes.

ASN continued to express concern over the number of measures in QIP particularly the following:

1. **In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration (clinical measure).** ASN continues to express concern over the low response rate to ICH CAHPS. To reduce the burden on patients, ASN requested the form be shortened and that CMS field the survey once a year and not twice. Finally, to empower patients, ASN encouraged CMS to allow facilities to see deidentified results of the surveys so that they can respond to the specific patient concerns with some level of patient permission. Patient members of several technical expert panels have recommended this step.
2. **Standard Readmission Ratio (SRR) (clinical measure).** ASN remains concerned that SRR might mislead patients, care partners, and health care practitioners due to its wide confidence interval. This variability can lead to inaccurate facility classifications and fail to accurately reflect actual performance. ASN noted that the current measure also poses challenges for small facilities, as their scores can be heavily influenced by random variability. ASN urged CMS to transition to the use of the underlying readmission rate, which can be properly risk adjusted in the same way that the standardized mortality rate has been and allow within-facility year-to-year comparisons.
3. **Standardized Transfusion Ratio (STrR) (clinical measure).** ASN expressed concerns that the STrR measure lacks validity and believes it should be suppressed. ASN, while appreciative that CMS has acknowledged this concern, remained troubled that CMS has not addressed the low reliability of the data on transfusions.
4. **Standardized Hospitalization Ratio (clinical measure).** ASN agreed that hospitalization rates are crucial indicators of quality for both patients and facilities but also strongly urged CMS to implement a genuinely risk-standardized hospitalization rate measure to prevent misclassifying facilities and misleading patients.
5. **Clinical Depression Screening and Follow-up (reporting measure).** ASN recognized that identifying and treating mental health conditions among patients receiving dialysis are critical to ensuring optimal health and clinical outcomes. ASN expressed major concerns about the ability of dialysis units to treat depression in isolation, without additional support and resources. As a first step, ASN proposed that CMS consider clarifying opportunities for and supporting expanded access to mental health services that can occur either on-site in the dialysis facility (e.g., in a private room before or after treatments) or via telemedicine for patients on dialysis.
6. **National Healthcare Safety Network (NHSN) Dialysis Event (reporting measure).** ASN supports CMS' proposal to remove the NHSN Dialysis Event reporting measure from the ESRD QIP measure set beginning with payment year 2027.
7. **NHSN Bloodstream Infection (BSI) in Patients on HD (clinical measure).** Research from the Centers for Disease Control and Prevention, the measure's developer, as well as from CMS and other sources, indicates that the measure lacks both validity and reliability. Previously, ASN has recommended that CMS transition the NHSN BSI measure to a reporting measure while forming a technical expert panel to address its shortcomings.
8. **Screen Positive Rate for Social Drivers of Health (reporting measure).** ASN applauds CMS' commitment to addressing health care disparities and supporting these measure concepts. ASN strongly supports the implementation of screening measures for social drivers of health for patients on dialysis, recognizing their potential to improve patient care. However, ASN also encouraged CMS to evaluate the impact of public reporting of the percentage of patients in each dialysis facility who screen positive in various domains. ASN fears that this publicity may lead patients to either avoid answering or provide inaccurate responses, especially within the close-knit environment of a dialysis facility.

To keep track of ASN's policy efforts related to these proposals, follow coverage in *Kidney News* and the ASN podcast feed, and visit ASN's policy webpage (http://www.asn-online.org/policy). For real-time updates from ASN Policy, follow @ASNAdvocacy on X. ■

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Summary of ASN recommendations in its CY 2025 comment letter (1)

- Finalize site of care proposal for individuals with AKI.
- Revise proposed Add-on Payment Adjustment for Training.
- Support proposed conditions for coverage for dialysis facilities but need to go further.
- Address dialysis bundled payment shortcomings.
  - Payment policy for innovation does not equate to the outlier policy—do not finalize.
  - Dispensing fees for orals in the bundle are needed if oral-only agents are included in PPS.
  - The policy of the current base rate does not include dispensing fees for phosphate binders.
- Convene community to improve the proposed Health Equity adjustment.
- Support replacing the Kt/V Dialysis Adequacy comprehensive clinical measure (measuring how much urea is removed during dialysis) with four separate measures.
- Address additional ESRD QIP issues.

References

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