American Society of Pediatric Nephrology
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August 26, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CY 2025 Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, Conditions for Coverage for End-Stage Renal Disease Facilities, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model (CMS-1805-P)

Dear Administrator Brooks-LaSure:

The American Society of Pediatric Nephrology (ASPN) is pleased to provide these comments on the CY 2025 End-Stage Renal Disease (ESRD) Prospective Payment System and Quality Payment Program (ESRD PPS & QIP) proposed rule. Founded in 1969, ASPN is a professional society composed of pediatric nephrologists whose goal is to promote optimal care for children with kidney disease and to disseminate advances in the clinical practice and basic science of pediatric nephrology. ASPN currently has over 700 members, making it the primary representative of the Pediatric Nephrology community in North America.

We will be providing comments on the following provisions of the rule:

- Proposed Expansion of ESRD Outlier Services
- Inclusion of Oral-Only Drugs into the ESRD PPS Bundled Payment
- AKI Provisions
- Proposal to Replace the Kt/V Dialysis Adequacy Comprehensive Clinical Measure with a new Kt/V Dialysis Adequacy Measure Topic
- Future of the ETC Model

Proposed Expansion of ESRD Outlier Services

ASPN supports the agency's proposed changes to the outlier policy as it will result in increased value in outlier payments for pediatric patients who qualify. We thank the Centers for Medicare & Medicaid Services (CMS) for advancing a policy that recognizes the unique and costly requirements to deliver high-quality care to children with ESRD. As we have shared with the agency in previous comments, the root causes, co-morbidities, and treatment for ESRD differs between children and adults. ASPN appreciates that the agency took this opportunity to recognize these unique costs and reimburse for them appropriately. We welcome the

opportunity to continue to work with CMS to identify other areas where the ESRD Prospective Payment System can support the delivery of the specialized pediatric ESRD care that children require.

While we support this proposed change to the outlier policy, we do want to emphasize that CMS should not fully rely on changes to the outlier policy to pay for new and innovative drugs; changes still need to be made to fix the base rate and support innovation in new drugs, biologicals and devices for pediatric kidney patients.

If this policy is finalized, ASPN will educate our members about this change and the importance of pediatric dialysis units appropriately billing for use of alteplase and other qualifying drugs to collect the outlier payment when appropriate. We would appreciate it if CMS would highlight this change, if finalized, and any specific requirements for billing.

Inclusion of Oral-Only Drugs into the ESRD PPS Bundled Payment
While ASPN appreciates that adding oral-only drugs to the bundled payment will improve patient access, we are concerned that these drugs are expensive and pediatric centers will not be able to afford them. Pediatric patients with kidney disease are mainly dialyzed in pediatric hospitals, which are not able to get bulk pricing deals for these drugs. By adding oral-only to the bundle without an appropriate increase in reimbursement, it will be a huge cost to the pediatric hospitals that they cannot absorb. There are additional concerns about access, as these are not first line drugs for pediatrics and there is often significant prior authorization involved in procuring these drugs for our patients. Another barrier is that in-hospital pharmacies at children's hospitals often do not have a license to dispense for Medicare.

There are additional costs that are not accounted for by 100 percent of ASP. This includes compounding charges as needed for pediatric patients, dispensary costs, and syringes, among others. Therefore, ASPN recommends that the agency considers reimbursing these drugs at ASP plus 6% consistent with other payment systems to better reflect the costs of these drugs in the ESRD Prospective Payment System.

AKI Provisions
ASPN supports the agency's proposal to provide coverage and reimbursement for home dialysis modalities when used by beneficiaries with AKI. We are pleased that the agency will offer reimbursement for home dialysis for patients with AKI as this will prevent pediatric patients from having to go in-center for dialysis when home dialysis is medically appropriate.
We request that the agency provide guidance on how CPT codes 90945 (*Dialysis procedure other than hemodialysis (e.g. peritoneal dialysis, hemofiltration, or other continuous renal replacement therapies) with single evaluation by a physician or other qualified health care professional*) and 90947 (*Dialysis procedure other than hemodialysis (e.g. peritoneal dialysis, hemofiltration, or other continuous renal replacement therapies) requiring repeated evaluations by a physician or other qualified health care professional, with or without substantial revisions of dialysis prescription*) should be used when billing home dialysis for a patient with AKI.

Proposal to Replace the Kt/V Dialysis Adequacy Comprehensive Clinical Measure with a new Kt/V Dialysis Adequacy Measure Topic

ASPN supports the agency's proposal to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Adequacy Measure Topic that is comprised of four individual Kt/V measures, including two pediatric measures: pediatric HD Kt/V and pediatric PD Kt/V. This new measure will allow for more accurate comparisons across patient populations and across modalities. This new measure will allow for another meaningful option for pediatric nephrologists to report on quality. Measures do not apply to pediatric and adult ESRD patients in the same way, given the meaningful differences in these two patient populations and we appreciate that CMS proposed a meaningful quality measure for pediatric patients.

RFI on the Future of the ETC Model

ASPN appreciates that children under 18 have not been included in the ETC Model. While we support the goals of the ETC Model to increase the rates of kidney transplantation and home dialysis, we continue to believe that any future model should exclude all patients treated at pediatric centers. This would also allow for the exclusion of a sub-population of young adults 18 years of age and older who still receive treatment at pediatric centers.

The young adults who continue to be treated by pediatric nephrologists in pediatric facilities once they turn 18 years old are a particularly complex group of patients who have not met the medical requirements to transition to adult care. They often have significant neurocognitive and developmental issues, both mental and physical, which necessitate continued access to care only available in pediatric dialysis centers such as child life specialists and specialized nursing or specialized pediatric equipment. These young patients face chronic health challenges more similar to patients in skilled nursing facilities than either the typical pediatric or adult ESRD patient. They, however, are able to remain at home in the care of their families because of their younger age and the availability of a caregiver in the home setting who is willing and physically able to commit the time and effort to provide care.

With respect to kidney transplant and home dialysis, these young adults also differ in meaningful ways from typical pediatric patients. Dialysis is a bridge to transplant for the overwhelming majority of pediatric patients, but many of these young adults may not be transplant candidates related to their medical complexity or family preference. Moreover, although ASPN agrees home dialysis is preferable to in-center dialysis when possible, many of these young adults have already had long courses of ESRD care and typically already been on home dialysis but returned to in-center treatment because of challenges with their peritoneal membrane.

As CMS considers future models to incentivize home dialysis and transplantation, we ask that a representative of the pediatric nephrology community be involved in these discussions to ensure that our patients are not negatively impacted by policy decisions.

ASPN appreciates the opportunity to offer comments on CMS' CY 2025 ESRD PPS & QIP proposed rule. Please contact our Washington representative Erika Miller at emiller@dc-crd.com if we can provide additional information or clarification regarding these comments.

Sincerely,

Meredith Atkinson, MD
President