American Society of Pediatric Nephrology

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September 4, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1732-P
Mail Stop C4-26-05
7500 Security Blvd
Baltimore, MD 21244-8010

Re: CMS-1732-P: Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program

Dear Administrator Verma:

On behalf of the American Society of Pediatric Nephrology (ASPN), thank you for the opportunity to comment on the proposed rules related to the End Stage Renal Disease (ESRD) prospective payment system (PPS) and Quality Incentive Program (QIP).

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.

As the voice for pediatric kidney disease, ASPN strives to ensure that infants, children, adolescents, and young adults with kidney disease receive appropriate and high-quality care. As such, we offer the following comments to the proposed rule:

- 2021 Prospective Payment System
    - Recommendations to Improve Pediatric ESRD Reimbursement
    - Inclusion of Calcimimetics in the ESRD PPS Base Rate
    - Add-on Payments for Innovative Products

- Quality Incentive Program
    - Pediatric Quality Measurement

Improving Pediatric ESRD Reimbursement

ASPN continues to have significant concerns about the undervaluation of pediatric ESRD care, which we believe requires significantly different staffing and supply needs from those required to deliver ESRD care to adults. Since last year's launch of the Advancing American Kidney Health Initiative, ASPN has appreciated working with the agency to highlight the unique needs of children with kidney disease. We also value the agency's willingness to explore ways to improve collecting pediatric-specific data to better characterize the necessary resources and associated costs of delivering quality pediatric ESRD care. ASPN, however, was extremely disappointed that this CY 2021 proposed rule did not specifically address the needs of the children our members treat. We do look forward, however, to continue working with CMS' representatives to identify ways to appropriately value pediatric ESRD care, including discussing this issue at an upcoming Technical Expert Panel.

CMS staff has asked ASPN to provide options for the agency to consider to ensure more accurate reimbursement for pediatric ESRD facilities, and ASPN respectfully recommends the following three options for CMS to consider implementing in future rulemaking:

- Create pediatric modifiers by age groups <6, 6-11, 12-18 years old to reflect in better detail the extra costs for staffing as well as pediatric-specific equipment and supplies to provide pediatric dialysis treatments. Historical precedent exists for this approach in the previous basic case mix adjustment (BCMA) method.
- Create a pediatric add-on payment by age groups <6, 6-11, 12-18 years old to reflect in better detail the extra costs for staffing as well as pediatric-specific equipment and supplies to provide pediatric dialysis treatments. This option likely would require frequent review and adjustment.
- Create a pediatric-specific ESRD bundle. This would allow for full accounting of costs for pediatric staffing and specialized equipment, and the economic implications of pediatric medical comorbidities that are not addressed in the current PPS. It would also facilitate development of an accompanying pediatric-specific Quality Incentive Program (QIP) that takes into account the barriers implicit in assessing quality in a patient population that will always be very small in number compared to the adult population. The major drawback would be the need for Congress to authorize this pediatric bundle.

Addition of Calcimimetics to the ESRD PPS Base Rate

ASPN supports the agency's proposal to include calcimimetics in the ESRD PPS base rate beginning in CY 2021. Although calcimimetics are less widely used in the pediatric population, they are an important therapy in some children. ASPN believes that this current proposal should make calcimimetics more accessible to pediatric ESRD patients, as many pediatric dialysis units currently limit the stocking of calcimimetics because of their high costs.

ASPN also recommends that CMS consider how to ensure patients have access to compounded versions of calcimimetics. Many children are unable to take medications in pill form and require liquid preparations. Currently liquid forms must be compounded from existing tablets designed for adult dosing, which may make it difficult to dispense in smaller quantities that would require portions of tablets for children. For example, a child might need the equivalent of 2.3 tablets compounded into liquid, but the pharmacist would have to use 3 tablets for safety and accuracy, leading to higher costs.

Current intravenous dosing options may also be difficult to adjust for pediatric patients, resulting in significant amounts of drug wastage. For instance, currently calcimimetics come in vials with concentrations that are aimed for one-time dosing of a typical adult patient. Since pediatric patients may require only a fraction of an adult dose, a good deal of medication is discarded as unused, wasting medication and contributing to higher health care costs. ASPN urges CMS to encourage pharmaceutical companies to increase the dosing options provided for these drugs and to consider development of dosing options appropriate for children or smaller sized adults.

Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES)

ASPN supports CMS' efforts to foster innovation of new dialysis equipment and supplies through the TPNIES. While it is critical to support innovation in kidney care, CMS must also support policies that promote innovation in pediatric kidney care. New equipment and therapies that come to market are not always tested in the pediatric population, even if they may be of the same potential benefit to children as adults. The lack of pediatric testing may complicate regulatory approval of equipment or therapies for use in children and may force clinicians to try to adapt adult care standards without any guiding pediatric data. Additionally, equipment useful only in pediatric patients and not suitable for adults may require testing with fewer numbers of available pediatric study participants than available for study in the adult population.

ASPN emphasizes that children and adolescents are not simply "little adults." Rather, they have unique physiology characterized by maturing organ function, body metabolism, and drug distribution characteristics distinct from adults. Given these differences, the safety and efficacy data of equipment and supplies developed for adults and only studied in adults may not be appropriate for pediatric patients. We recognize that the small number of pediatric patients often complicates conducting safety, efficacy, or interventional trials in children, but the importance of these data is crucial to allow children to benefit from innovation.

We are also concerned that overly restrictive requirements for the TPNIES program may actually stand in the way of any incentive offered by the program to encourage innovation in pediatric and adult kidney care. Specifically, there appears to be confusion about the data needed to support a finding of substantial clinical improvement (SCI) for a manufacturer applying for TPNIES. While the rule acknowledges the utility of small studies and diverse real-world evidence, the rule relies on "blinded" and "large, multicentered trials" to determine if a product qualifies for the incentive. As noted above, this requirement would exclude equipment and supplies in the pediatric kidney space, where multicentered trials are impossible with the small patient population.

As CMS continues to implement this policy moving forward, we urge the agency to keep the special needs of children with ESRD in mind, and foster innovation of new equipment and supplies beneficial across the entire age spectrum of ESRD.

Pediatric Quality Measurement

ASPN shares CMS' goal of improving the quality of patient care and continues to believe that inclusion of pediatric measures will result in enhanced quality care for our patients. We therefore support continued implementation of the QIP, but request that CMS work with the pediatric ESRD community to ensure that sufficient quality measures and benchmarks are adopted to optimize care delivered to this

unique patient population. Specifically, we respectfully request that CMS convene a technical expert panel (TEP) to discuss pediatric quality measures.

We also ask that the agency keep in mind that accessibility to reporting mechanisms in pediatric dialysis facilities may differ from those available to adult facilities. For instance, because of low patient volumes or lack of access to batch data upload, a large proportion of pediatric dialysis units rely on manual entry of data into CROWNWeb. This is clearly a more labor and time-intensive method, and can be a significant burden to small independent units.

We also would like to underscore to the agency that the lack of appropriate pediatric quality metrics limits the ability of pediatric facilities, particularly those not affiliated with adult dialysis facilities, to participate in the QIP and may lead to inappropriately low scores for small pediatric facilities. For example, the current Clinical Care Domain (45 percent of QIP) has 5 measures, but pediatric patients are excluded from 4 of those measures and only Kt/V can be reported to account for the entire 45 percent of QIP. If Kt/V is low in one or two patients in a small unit or if the values are reported improperly due to difficult manual entry into CROWNWeb, the pediatric facility score will be inordinately adversely affected. Moreover, decisions to retire quality metrics applicable to the pediatric population without an available replacement metric for this patient group leads to decreased participation for both pediatric facilities and adult facilities with pediatric patients, and only decreases the scope of coverage of the QIP instead of expanding its breadth.

Conclusion

ASPN appreciates the opportunity to offer comments on CMS's proposed rules for the CY21 ESRD PPS and QIP. Please contact our Washington representative, Erika Miller, at (202) 484-1100 or emiller@dc-crd.com, if we can provide additional information or clarification regarding ASPN's comments.

Sincerely,

Michael JG Somers, MD
President