American Society of Pediatric Nephrology

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September 26, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1713-P
Mail Stop C4-26-05
7500 Security Blvd
Baltimore, MD 21244-8010

Re: CMS-1713-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, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements

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:

- 2020 Prospective Payment System
    - Pediatric Case Mix Adjuster
    - Pediatric Outlier Payments
    - Add-on Payments for Innovative Products

- Quality Incentive Program
    - Pediatric Quality Measurement
    - Proposed Changes to Measures

- Request for Information related to the Technical Expert Panel on Improving the Reporting of Composite Rate Costs under the ESRD PPS

Pediatric Case Mix Adjuster

ASPN continues to have significant concerns about the pediatric case mix adjuster and the undervaluation of pediatric ESRD supplies and services. We have previously requested that the Centers for Medicare and Medicaid Services (CMS) evaluate pediatric facility Medicare cost reports and ensure that the Medicare claims forms and CROWNWeb data accurately reflect what is required to deliver quality care to pediatric patients. ASPN believes that the data CMS is using fail to reflect the necessary resources and associated costs of delivering pediatric ESRD care. In particular, there is not a good mechanism to report some of the costs uniquely associated with pediatric patients, such as costs associated with the allied health team. ASPN recommends that CMS look beyond the currently required report data and consider what expenses unique to pediatric dialysis should be included to appropriately reflect the costs of pediatric ESRD care.

ASPN stands ready to work with CMS to improve the completeness and accuracy of pediatric data being reported and offers CMS the following list of unique expenses related to pediatric dialysis care that should be reflected in any pediatric ESRD facility payment formula:

- Need for increased reliance on registered nurses to provide dialysis care, especially for smaller, younger pediatric hemodialysis patients, leading to higher personnel coats compared to adult dialysis facilities
- Need for developmental/behavioral specialists, including Child Life Specialists and Child Psychologists, given the cognitive and developmental issues associated with pediatric ESRD
- Need for more frequent assessment by pediatric dieticians to adjust diet and feeding regimens to meet the specialized growth and nutrition requirements of children treated with dialysis
- Need for social workers, teachers, and designated liaisons to interface regularly with schools to optimize school attendance and performance among pediatric dialysis patients
- Need for a broad array of dialysis supplies, despite a typically small patient census, to accommodate patients who range in size from infants to young adults. Pediatric facilities must stock a broader range of dialyzers, tubing, HD catheters, PD catheters and peritoneal fluid bags than an average adult dialysis unit.

Without accurate reimbursement to pediatric facilities, those who are specially trained to care for this unique patient population, as well as pediatric ESRD patients themselves, face an uncertain future. There is already a shortage of pediatric nephrologists and we believe that inadequate reimbursement will further exacerbate this shortage and result in limited access of pediatric dialysis patients to specialized facilities with pediatric personnel trained to care for their unique needs. The result will likely be worse health outcomes for children with ESRD, with the potential for higher costs of care when these children mature to adulthood. The ultimate goal should be to ensure that reimbursement is appropriate so that pediatric facilities and providers can continue to provide high quality services to those in need.

Pediatric Adjustment for Outlier Payments

CMS proposed to update the outlier services fixed-dollar loss (FDL) amounts for adult and pediatric patients and the Medicare Allowable Payment (MAP) for adult and pediatric patients for CY 2020. Based on CMS analysis of the latest available data, the following would apply to pediatric beneficiaries:

- The proposed FDL amount would decrease from $57.14 to $44.91;
- The MAP amount would decrease from $35.18 to $33.82; and
- The percentage of pediatric patients qualifying for outlier payments would be 8.2%.

The agency explains that the pediatric outlier amount is decreasing as a result of a decrease in utilization of these services in the pediatric population. ASPN is concerned that the outlier calculation does not currently capture all of the services pediatric ESRD patients require, including management of co-morbidities seen in many pediatric dialysis patients such as failure to thrive and seizure disorder. Additional unique costs are for care coordination, as the pediatric dialysis unit frequently functions as the child's medical home. CMS should ensure that the pediatric outlier recognizes conditions and services unique to the pediatric population, and we request that CMS examine the accuracy of its data in capturing pediatric co-morbidities before implementing any cuts to the pediatric outlier services.

ASPN also believes that any pediatric modifiers should be based on actual cost data from pediatric dialysis facilities for recent years. Without adjustments based on accurate cost data, the long-term economic viability of pediatric dialysis units will be jeopardized, and adult units will be further disincentivized to meet the special needs of their pediatric patients who are unable to access specialized pediatric dialysis units.

Proposed Add-on Payments for Innovative Equipment and Supplies

In order to incentivize ESRD facility use of innovative dialysis equipment and supplies, CMS proposed providing additional payment for new and innovative renal dialysis equipment and supplies furnished by ESRD facilities through a transitional add-on payment adjustment. ASPN supports the agency's efforts to foster innovation of new renal dialysis equipment and supplies by revising the Transitional Drug Add-on Payment Adjustment (TDAPA) policy. ASPN believes that it is critical to support innovation in kidney care, but we would also point out that there must also be a specific focus on innovations that also pertain to the pediatric space. New products and therapies that come to market are not always tested in the pediatric population or are even appropriate for children, and. policies must be put in place to change this moving forward.

ASPN continues to emphasize that children and adolescents are not simply "little adults." Rather, they have a unique physiology characterized by maturing organ function, body metabolism, and body distribution characteristics distinct from what adults manifest. Due to 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 complicates conducting safety, efficacy, or interventional trials in children, but the importance of this data is crucial to allow children to also benefit from innovation.

We offer two examples of innovative products in the renal dialysis field that have not been designed for use in pediatric ESRD patients because of the lack of such data:

- Baxter's new AMIA automated peritoneal dialysis (APD) system is transformative for improving home dialysis, but the manual states that it is not appropriate to be used on patients weighing less than 20 kg.
- Outset's Tablo unit, with innovations that facilitate self-care for dialysis, is similarly designed to meet adult needs and is not advised for pediatric patients even though some degree of self-care might help older pediatric patients better tolerate chronic dialysis.

As this policy for additional payment is implemented, we urge CMS 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 the appropriate number of quality measures and most applicable benchmarks are implemented to optimize care delivered to this unique patient population.

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, currently a large proportion of pediatric dialysis units rely on manual entry of data into CROWNWeb, a more labor and time-intensive method, but often the only option ultimately available 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. Moreover, decisions to retire pediatric quality metrics without an available replacement metric for the pediatric population 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.

Comments on Specific Quality Measures Included in the QIP

Percentage of Prevalent Patients Waitlisted, Clinical Measure

While ASPN supports the goal of increasing transplant referrals and rates of transplantation, we are concerned about the specifications of one of the new measures for the PY 2022 measure list, "Percentage of Prevalent Patients Waitlisted, clinical measure." Not all patients are medically appropriate candidates for transplant and should not, therefore, be wait-listed. For example, the majority of children under 2 years of age are not physically large enough for successful transplant surgery, and it would not make sense to put them on a waitlist. In addition, many pediatric patients have social situations precluding transplant that they are unable to overcome due to their age, as well as transportation and financial restraints.

Older children may have medical conditions that preclude or contraindicate transplant, such as active malignancy, and similarly should not be waitlisted. Some patients may become appropriate candidates at a later time, when medical conditions change or improve. For example, for patients with a higher risk for glomerulonephritis (GN) recurrence, a period of dialysis is recommended prior to transplantation to allow for the recurrence to end. Similar scenarios would also apply to adult patients with medical contraindications. We recommend that CMS amend the measure to apply specifically to patients who are medically appropriate candidates to be waitlisted for a transplant. Furthermore, we note that the dialysis facility has control over referral for transplant evaluation but do not actually waitlist patients for transplant; this is done by the transplant team. CMS should clarify this in the PPPW measure as well.

Pediatric ESRD patients are waitlisted and transplanted at higher rates than adult patients.[1] The primary goal of dialysis in most children is to provide a bridge to transplantation. The high rates of waitlisting and transplantation in pediatric patients also stem from the frequent unified location and overlap in medical staff between pediatric transplant centers and pediatric dialysis units, facilitating, better coordination of care and interdisciplinary communication. This coordinated care approach could be a model for CMS to examine when addressing barriers to successful referral and transplantation in adults.

In considering potential dialysis facility measures that relate to transplantation, ASPN further recommends that CMS place more focus on the dialysis facility's responsibility to educate patients about the benefits and advantages of transplantation. Because dialysis is typically viewed for most children as a short-term bridge to transplantation, pediatric dialysis facilities provide significant education and counseling to patients and families about transplantation as the preferred renal replacement therapy modality, and we believe these interactions account in part for why higher percentages of pediatric patients are referred for transplant evaluation and successfully placed on the waitlist. For these reasons, ASPN urges the agency to prioritize the value of education about transplantation for dialysis patients and encourage that education be sensitive to cultural and literacy differences in the target population.

(Kt/v) Dialysis Adequacy Comprehensive, clinical measure

ASPN is concerned that CMS has included the (Kt/V) Dialysis Adequacy Comprehensive measure in the QIP, which the National Quality Forum (NQF) and its Renal Committee rejected as part of its endorsement process. Particularly of note, the NQF Renal Committee found that this measure did not pass NQF's "Importance" criterion, which is a threshold requirement for further discussion on factors such as validity and reliability. The pooled measure approach used in this measure results in all dialysis patients (pediatric and adults, as well as both peritoneal and hemodialysis) being combined in a single denominator, with scores calculated as would be done for a single measure. This results in the elimination of the ability to see performance on any specific patient population, such as pediatric dialysis patients.

NQF has endorsed several other measures in the domain of dialysis adequacy, including two related to pediatric patients (NQF #1432 Minimum spKt/V for Pediatric HD Patients; NQF #2706 Pediatric PD Adequacy---Achievement of Target Kt/V). We recommend that CMS use these NQF-endorsed measures,

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[1] Reese PP, Hwang H, Potluri V, et al. Geographic determinants of access to pediatric deceased donor kidney transplantation. J Am Soc Nephrol. 2014;25:827–835.

which would be consistent with the statutory mandate and ensure that patients have accurate information on facility's actual performance on the different dialysis modalities.

Standardized Readmission Ratio, clinical measure

ASPN believes that the Standardized Readmission Ration (SHR) clinical measure is not reliable for pediatric centers based on the small number of patients treated in those facilities. Furthermore, the measure does not accurately account for the complexity of pediatric patients, including their age, unique underlying diagnoses and co-morbid conditions. Until the measure is reliable across all dialysis facilities, we urge CMS to not include it in the ESRD QIP.

Request for Information related to the Technical Expert Panel on Improving the Reporting of Composite Rate Costs under the ESRD PPS

A CMS contractor conducted a Technical Expert Panel (TEP) on December 6, 2018 to discuss options for improving data collection to refine the ESRD PPS case-mix adjustment model. CMS requested information on several areas included in the TEP recommendations on ways to improve the ESRD PPS case-mix adjustment model.

ASPN appreciates that the TEP identified "treatment and care for pediatric patients" as a source of composite rate cost variation associated with providing care to more complex patients. One rationale given is that pediatric patients require more intense use of labor, particularly direct patient care staff and highly-specialized nursing or social work care.

In refining the case-mix adjustment model, we recommend that CMS consider improving the scope of pediatric data collected, as outlined in detail above in the section labeled "Pediatric Case Mix Adjuster." CMS should consider these additional factors related to pediatric dialysis care costs as well as capital costs and labor associated with pediatric patients, with the agency then formulating a more robust pediatric ESRD facility payment formula.

CMS requested input on several specific focus areas identified by the TEP. In response to the first focus area, "Improving the Reporting of Composite Cost Rates for the ESRD PPS," ASPN notes that the majority of pediatric dialysis facilities are administered by children's hospitals with limited familiarity with the nuances involved in Medicare billing and reporting, since pediatric ESRD patients are essentially the only Medicare-eligible patients treated in these facilities. While a pediatric dialysis facility affiliated with an LDO is well equipped to interface with Medicare, an independent dialysis unit housed in a free-standing pediatric institution often lacks the institutional infrastructure to bill or provide needed data appropriately. A recent example from one of the larger pediatric hospital-based dialysis facilities illustrates this issue: a hospital initiative to provide free influenza vaccines to all pediatric ESRD patients resulted in removal from Medicare billing of the documentation of a vaccine being delivered, so the pediatric dialysis unit did not receive credit in billing-derived metrics for having actually vaccinated their dialysis patients.

The agency also needs an easier way for dialysis units to report Medicare data to CMS other than CROWNWeb, which is harder for smaller units with limited infrastructure like pediatric units. We also request that CMS be transparent about where they pull data for quality review and that units have an opportunity to correct any errors prior to it being used to calculate quality performance scores. Pediatric dialysis units have discovered after the fact that some of their data for required activities is missing by the current process and has led to the dialysis unit being penalized in error for not completing activities that were actually done.

For the third focus area, “Collection of Data to Identify Sources of Variation in Treatment Costs Associated with Complex Patients,” ASPN notes that staffing practices for pediatric units are different than for adult units. Besides increased direct involvement of the pediatric nephrologist, pediatric dialysis unit staffing involves more nursing personnel due to lower patient: nurse ratios as well as more direct dietitian and social worker interventions given issues of growth, development, and psychosocial well being. In terms of treatment frequency, small children often require more than three hemodialysis sessions/week to prevent evolving volume overload. This need is not reported accurately in the current system. Although pediatric dialysis patients are more likely to receive home dialysis than adults, the costs of a facility providing home dialysis for children with ESRD -- similar to those for in-center pediatric hemodialysis -- are higher than that for adults, due to the additional costs associated with equipment, supplies, and staff.

For the fourth focus area, “Collection of Facility-level Data,” CMS requested information on the costs incurred by pediatric dialysis units that do not vary at the patient-level. As detailed above, there are several staffing positions, including child life specialists and other non-nursing personnel such as psychologists, pediatric renal dietitians, social workers, and school teachers who come to the unit several times per week and work with the patients and their families to address the ramifications of ESRD on growth, physical and cognitive development, and school attendance and psychosocial adjustment to chronic disease as a child. Also as detailed above, facilities must maintain adequate supplies of dialysis equipment to cover the possible range of size of a pediatric patient from infancy to young adulthood. Other costs incurred with some frequency by pediatric units include addressing food insecurity in the family with provision of meals to the child with ESRD before and/or following dialysis while also sending food home. Many pediatric units also absorb costs associated with summer camps for dialysis patients that allow children with ESRD on dialysis to have a summer camp experience and undergo dialysis while at camp.

Conclusion

ASPN appreciates the opportunity to offer comments on CMS’s proposed ESRD PPS and QIP rules, as well as the request for information on the TEP. 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,

Patrick Brophy, MD, MHCDS

President