American Society *of*
Pediatric Nephrology

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April 21, 2025

The Honorable Robert F. Kennedy, Jr.
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Kennedy:

The American Society of Pediatric Nephrology (ASPN) looks forward to working with you and the Department of Health and Human Services (HHS) to advance care for children with kidney disease. 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 scientific discovery of pediatric nephrology. ASPN currently has over 700 members, making it the primary representative of the North American Pediatric Nephrology community and a critical voice for children with kidney disease.

An estimated 150,000 – 260,000 children and adolescents currently suffer from kidney disease; about 10,000 of them suffer from end-stage kidney disease (ESKD) where the kidneys can no longer function on their own, relying on either dialysis or a kidney transplant to survive. Children with ESKD are the only children automatically eligible for Medicare under statute, and approximately one-third are covered by the program with another third covered by Medicaid and the remaining third covered by private insurance. Many children covered by private insurance and Medicare still rely on Medicaid for wraparound coverage to meet their complex health care needs. Children and adolescents undergoing dialysis or kidney transplants are unique and the causes of their kidney disease are very different from the typical causes in adults. While the most common reasons of ESKD in adults are hypertension and diabetes, in children, the kidney disease is predominantly caused by congenital abnormalities (i.e. “birth defects”), glomerular diseases, and rare genetic disorders. Therefore, the incidence of kidney disease in children is not modifiable by changing lifestyle factors such as diet. Children with ESKD also experience their condition during a vulnerable developmental time and thus suffer from impaired growth and neurocognitive development as a result. They also have different drug metabolism, which changes over time as they grow to be adults. Managing and optimizing the health of these children requires different strategies and resources compared to those needed by adults, as well as other pediatric specialists in addition to pediatric nephrologists.

For children, dialysis is typically a temporary therapy, used as a bridge to a transplant. Kidney transplant is preferable to chronic dialysis for children with ESKD because it improves survival in adulthood, optimizes growth, and improves their health-related quality of life. The 10-year patient survival rate after transplantation is 90-95 percent.[1] Most children who receive a transplant will need dialysis again in their lifetime, since a transplanted kidney is estimated to last 15 to 20 years from a living donor and 8 to 12 years from a deceased donor.[2] In 2020 there were 5,519 children living with ESKD, 1,389 of whom were receiving either hemodialysis or peritoneal dialysis as a life-sustaining treatment.[3] Children with kidney disease have extensive and costly health care needs. According to the United States Renal Data System (USRDS), for children with commercial insurance, the cost of pre-dialysis care for CKD is estimated to be $20,764 per year, compared to $2,092 for children without CKD.[4] A recent analysis of children on dialysis showed that mean monthly costs were $3500, for a total of $87,000 for 40 months of treatment. For children who had a kidney transplant, mean monthly costs were $1,900, for a total of $48,000 in 50 months.[5] Thus, kidney transplantation is also the most cost-effective treatment for ESKD.

ASPN appreciates that during the first Trump administration, President Trump signed an Executive Order on Advancing America's Kidney Health. As you set your department's priorities to make American healthy, we urge you to continue your commitment to improving the lives of Americans living with chronic diseases like kidney disease, including children, and incorporate the following policy recommendations to improve outcomes for our pediatric patients with kidney disease.

Add-on Payment for Pediatric Dialysis Services

The Centers for Medicare & Medicaid Services (CMS) has recognized that the End-Stage Renal Disease Prospective Payment System (ESRD PPS) is inadequate to cover the cost of dialysis in children and adolescents. The current reimbursement does not account for the costs associated with the specially trained care team and supplies required to treat pediatric patients as young as several months old or the unique comorbidities and treatment goals in this special patient population. The reimbursement of pediatric dialysis care has been particularly problematic since the implementation of Medicare Improvements for Patients and Providers Act (MIPPA) in 2011 when the pediatric adjustment was eliminated. In the CY 2024 ESRD PPS final rule, CMS finalized the Transitional Pediatric ESRD Add-on Payment Adjustment (TPEAPA) for pediatric patients with ESKD receiving renal dialysis services, which is a 30 percent adjustment for dialysis treatments delivered to patients under 18 years of age for three calendar years effective January 1, 2024. Although this add-on payment is necessary to reimburse for this specialized care accurately, it is only temporary and there needs to be a more permanent solution.

CMS is collecting data on pediatric ESKD and its cost reports and has updated the freestanding dialysis facility form to allow pediatric supplies and staff to be itemized. However, the hospital-based form has not been updated, and the majority of children are dialyzed in children's hospitals. We have worked closely with our members to ensure that they are accurately reporting the cost to provide care to pediatric ESKD patients. However, children's hospitals have significant challenges in reporting this information accurately. Since we recognize that the

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[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6251502/

[2] https://www.kidney.org/kidney-topics/kidney-transplant

[3] https://usrds-adr.niddk.nih.gov/2022/end-stage-renal-disease/8-esrd-among-children-and-adolescents

[4] National Institute of Diabetes and Digestive and Kidney Diseases (U.S.). *USRDS Coordinating Center. U.S. Renal Data System … Annual Data Report, Researcher's Guide, Reference Tables, ADR Slides*. Ann Arbor MI: National Institute of Diabetes and Digestive and Kidney Diseases U.S. Renal Data System Coordinating Center.

[5] Iorembar, Franca and Bamgbola, Oluwatoyin; Structural Inequities and Barriers to Accessing Kidney Healthcare Services in the United States: A Focus on Uninsured and Undocumented Children and Young Adults. Front. Pediatric., April 4, 2022. Volume 10 – 2022. https://doi.org/10.3389/fped.2022.833611.

amount of the add-on payment after TPEAPA expires will depend on this data, we are working closely with CMS to identify a solution. We look forward to working with you and Dr. Mehmet Oz at CMS to ensure that this process continues and that the add-on payment that accurately reflects the cost of pediatric care is finalized after the TPEAPA ends.

Improving Care for Dually Eligible Children

Children with ESKD are the only pediatric population with guaranteed access to Medicare benefits. Given the treatments available for ESKD, it is typical for children with kidney failure to be eligible for Medicare at multiple points in their life: at the initial diagnosis of ESKD until three years after a kidney transplant, when their transplanted kidney fails and they must return to dialysis, if and until they receive a second transplant, etc. Often these children are dually eligible with Medicare as their primary payer and Medicaid as their secondary payer. Children with Medicare as the primary payer have issues accessing other pediatric specialists and services who do not accept Medicare, such as primary pediatricians, pediatric pulmonologists, speech and occupational therapists, and pediatric nurses. In this case, Medicaid should provide coverage and reimbursement as the secondary insurer, but in many cases, states simply follow Medicare's policy and do not offer payment, leading to a lack of required care.

Furthermore, Medicare coverage policies are written to assess what services, devices, and therapies are medically necessary for individuals 65 years of age and older. Since children fall outside of the typical demographic, ASPN requests that services, supplies, and equipment be evaluated specifically for pediatric patients, given the federal commitment to ESKD care. While the population of children who are dually eligible is quite small, it is imperative that Medicare coverage policies and individual case reviews consider the unique needs of these children to help them live the healthiest lives possible. Despite the challenges faced by dually eligible beneficiaries, it is important to maintain Medicare coverage as the higher reimbursement as it more adequately covers the higher cost of ESKD care, and provides greater access to care for pediatric ESKD patients. We look forward to working with you and Dr. Oz to ease the regulatory burden on pediatric patients and their families and care facilities, and ensure that our patients have access to appropriate and medically necessary care.

Additionally, ASPN understands that CMS' Office of Medicare-Medicaid Coordination was moved into the Innovation Center as part of the recent department reorganization. We implore you to ensure that the functions of the office continue unimpeded as part of this change. For the reasons described, better coordination between Medicare and Medicaid is essential to supporting the health of these children who will be eligible for these programs for the majority of their lives, making it in CMS' best interest to adopt policies that support improved health outcomes and access to specialized care and treatments.

Access to Telehealth Services

ASPN appreciates the work that the first Trump administration did to expand access to telehealth services, which has been vital for continued access to nephrology services for our pediatric patients. There is a workforce shortage of pediatric nephrologists across the country, and this has led to difficulties accessing these specialists in many areas. In some states, there are no pediatric nephrologists, forcing children and their families to travel significant distances to receive the specialized care they require. Telehealth has benefitted our pediatric patients who are on dialysis, as well as transplant patients, by connecting them with the care they need, and we look forward to continuing to work with your administration to maintain and expand Medicare telehealth services within the statutory constraints.

Improve Access to Formula

ASPN applauds your recent announcement to create Operation Stork Speed, in order to improve access to safe, affordable and nutritious formula for American families. Pediatric patients with kidney disease often require specialized formulas with reduced electrolytes and altered nutritional components given the complexities of the disease. Diseased kidneys are not able to process the content of standard formulas. We ask that you include access to specialty formulas in the work of Operation Stork Speed, so that children with kidney disease have access to the formulas needed for their unique chronic disease and metabolic needs.

Labeling Phosphates on Nutrition Fact Panel

ASPN requests that you work with the Food and Drug Administration (FDA) to improve nutrition labeling for phosphorous food additives. Currently, 1 in 7 adults, or 36 million people in America have chronic kidney disease (CKD), and phosphate food additives, prevalent in packaged and shelf-stable foods, have a devastating impact on patients with CKD and ESKD. Every year, hyperphosphatemia becomes more prevalent, more severe, and more difficult for pediatric nephrologists to manage. Between 2013 and 2022, the prevalence of severe hyperphosphatemia increased by 50 percent (from 16 percent to 24 percent) among patients on hemodialysis. Similar trends were seen in peritoneal dialysis patients. At the same time, the use and amount of phosphate food additives in the food supply has increased. There is a growing body of evidence that demonstrates associations between phosphate additives and increased risk of morbidity and mortality in the general population, in part due to the association between hyperphosphatemia and vascular calcification, a risk factor cardiovascular disease.

Therefore, it is critical that the FDA require information on the amount of phosphorous in milligrams on food and beverage packaging (both naturally occurring phosphorous in foods including dairy products, and phosphate additive-derived phosphorous). This information should be displayed on the Nutrition Facts Panel. As the FDA reviews generally recognized as safe (GRAS) additives, it is important to note that phosphate food additives were granted GRAS status decades before the effect of these additives on FGF-23 and other hormones was known, and before it became common for one food product to have two or three additives. We recommend that the GRAS status for phosphate food additives be re-evaluated.

Continue to Strengthen the Transplant System

ASPN supported the bipartisan legislation that directed the effort to improve the accountability and transparency of the Organ Procurement and Transplant Network (OPTN) Modernization Initiative. Due to the significant advantages of transplantation over dialysis in a child, dialysis is a temporary bridge to transplant for the majority of children with ESKD, and transplant referral is critical for optimal pediatric ESKD care and growth into the healthiest adults they can be. As you implement the HHS reorganization, we urge you to ensure that the function and expertise of the Health Resources and Services Administration’s (HRSA) Division of Transplantation is preserved and strengthened. ASPN understands that HRSA is being eliminated as a standalone agency and will become part of the new Administration for a Healthy America. Publicly available information about this new entity does not address where the Division of Transplantation and OPTN will be housed. We urge you to provide more detail for the community about where the Division’s functions will be housed and who will be overseeing its work, particularly as the modernization progresses.

While the modernization is being implemented, it is critical that the system continue to function and serve transplant patients with minimal impact on patient care. Ongoing efforts to strengthen the accountability and transparency of the transplant system have the potential to improve the health of this vulnerable patient population. ASPN has asked that HRSA ensure the needs of pediatric patients, their families, pediatric nephrologists, and pediatric centers are considered in the modernization effort. It is critical that pediatric transplant patients and pediatric nephrologists have a voice in any changes made to OPTN.

The existing multidisciplinary committees are a strength of the OPTN; these committees are key to weighing in on allocation priorities and setting policy. ASPN has requested that HRSA maintain this committee structure, and to require a pediatric nephrology representative on each organ-specific committee. This will allow pediatric specialists to have input on allocation changes and ensure that policies protect pediatric patients. The families of children who are eligible for transplants should also be included in these discussions.

ASPN has also requested that HRSA's publicly available data include pediatric data for organ transplantation and waitlists by organ. Transplant requirements and considerations differ between children and adults. Without pediatric data, it is impossible to have a complete picture of how the transplant system is functioning for children with ESKD. We look forward to continuing to work with your administration to ensure that the policies considered reflect the needs of children.

Innovation in Pediatric Nephrology Care

ASPN strongly supported the American Society of Nephrology's partnership with the HHS during the first Trump administration on KidneyX. The Society believes it is critical to support innovation in kidney care, and there must also be a specific focus on innovating in the pediatric space. New products and therapies that come to market are not always tested in the pediatric population or are even appropriate for these patients because of the differences in kidney disease in children and adults. Policies must be put in place to change this moving forward.

Due to the small size of the pediatric population, there has been a lack of high-quality clinical trials in pediatric nephrology. Most studies that are done have been observational and not interventional. There needs to be more focus on the disorders that disproportionately cause childhood kidney disease. Examples include, but are not limited to, congenital abnormalities, autoimmune disorders, nephrotic syndrome, C3 glomerulopathy, IgA nephropathy, FSGS and minimal change nephrotic syndrome. ASPN suggests the following policy recommendations:

- Prioritize clinical trials that focus on these diseases and coordinate collaboration between investigators to increase the numbers of patients included (NIDDK).
- Focus on renal priorities under the Best Pharmaceuticals for Children Act needs to be continued (NICHD).

It is critical that the NIH continue to support meritorious research in pediatric kidney disease, which differs significantly from adult kidney disease. Recent studies funded by NIDDK have found that chronic kidney disease affects brain development and cognition in pediatric patients, and children with chronic kidney disease have unique risk factors for progressing to end-stage kidney disease, and ongoing research is required to identify interventions to reduce the risk for progression.

ASPN is concerned about recent grant cancellations that undermine progress in pediatric kidney disease and the future biomedical research workforce. An ASPN member recently learned that the Pediatric Scientist Development Program (PSDP) funding that supported a fellow at his institution had been canceled with no further justification other than the funding was no longer consistent with the administration's priorities. The Association of Medical School Pediatric Department Chairs, which was awarded the grant and allocated it to research fellows across the country, was not given a chance to appeal the cancellation or revise the program to make it consistent with this administration’s priorities. The $400,000 from the PSDP supported a single pediatric nephrology fellow who was conducting basic science research on why congenital kidney abnormalities lead to increased risk of urinary tract infections, and risk factor for kidney disease progression; after completing this fellowship year, the funding was earmarked to support his first two years on the faculty ensuring adequate time can be spent advancing his research. This is just one example of the grant cancellations that are being issued to researchers across the country. It exemplifies the challenges that physician-scientists are facing, particularly in pediatrics where there is already a shortage of researchers. It takes 10 years for a physician-scientist to complete training and become an early-stage investigator. If these policies are not reversed immediately, the research pipeline will run dry, delaying innovations and new therapies for the children who need them most.

Thank you for your consideration of these recommendations as your department develops your priorities. ASPN stands ready to work with you to improve health outcomes for children with kidney disease and will follow up to request a meeting to discuss how we can work together to improve the health of these children. Please contact Erika Miller, ASPN’s Washington representative, at emiller@dc-crd.com should we be able to provide you with any assistance advancing these goals or if you have any questions.

Sincerely,

Meredith Atkinson
President