March 18, 2020

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
ATTN: CMS-2324-NC
7500 Security Boulevard
Baltimore, MD 21244

Submitted Electronically via http://www.regulations.gov

RE: Coordinating Care from Out-of-State Providers for Medicaid-Eligible Children with Medically Complex Conditions

Dear Administrator Verma,

The American Society of Hematology (ASH) appreciates the opportunity to offer comments in response to the Centers for Medicare and Medicaid Services’ (CMS) request for information on Coordinating Care from Out-of-State Providers for Medicaid-Eligible Children with Medically Complex Conditions.

ASH represents more than 18,000 clinicians and scientists worldwide who are committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as non-malignant conditions such as sickle cell anemia, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the field of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy.

As recognized by CMS, many hematologic diseases and disorders, both benign and malignant, are medically complex. Pediatric patients with these diseases and disorders may seek out-of-state care for a number of reasons – an out-of-state provider is geographically closer, an out-of-state provider has the needed expertise, or the patient cannot access needed care in state. For example, many pediatric patients in need of bone marrow transplants for life-threatening genetic-based diseases such as Adrenoleukodystrophy, Hurler Syndrome, Hunter Syndrome, MPS III, Osteopetrosis, MPS VI, I-cell disease, Tay Sachs Disease, Sandhoff Disease, and Zellweger Syndrome, are likely to travel out-of-state to an institution recognized for having expertise in treating these conditions.

While the diseases listed above are very rare, patients also seek care from out-of-state providers for more common blood diseases and disorders, including sickle cell disease (SCD) and other hemoglobinopathies. Pediatric hematologists with medical expertise in treating SCD and with access to the large, multidisciplinary teams needed to appropriately treat this patient population are rare. Children with sickle cell disease need access to expert ultra-sonographers who can perform transcranial Doppler ultrasounds for stroke risk.
screening; neurologists with expertise in pediatric stroke; orthopedists and other surgical specialists to address avascular necrosis of the hips and intra-abdominal laparoscopic techniques for splenectomy and cholecystectomy; physicians who can provide bone marrow transplants and cellular therapies but that also have expertise in benign (non-malignant) hematology; and, psychologists familiar with the frequent acute recurrent or chronic pain experienced by these patients. While this list is extensive but not exhaustive, it certainly supports the need for timely, affordable access to out-of-state providers who can provide the best “health home” for these children.

Whatever the reason for needing out-of-state care, the most important thing is that the patient can access the most appropriate care possible, in a timely, affordable fashion in consultation with their physician.

**Challenges with Referrals**

CMS asked for comments on challenges with referrals to out-of-state providers for specialty services, including community and social supports, for children with medically complex conditions and the impact of these challenges on access to qualified providers. Common challenges with referrals to out-of-state providers include delayed approvals and need for repeated requests.

For example, a pediatric patient may seek care from an out-of-state provider because they cannot access the needed care or expertise for their specific disease in-state. As explained above, this is common for the extremely rare diseases – such as those listed above – as well as for rare diseases, such as SCD. Unfortunately, many of these life-threatening genetic-based diseases are degenerative creating a need for referrals to be completed urgently. Delays may occur because the payer believes that an in-state center has the expertise to treat the condition; however, unfortunately, because of the rarity of hematologic diseases, many times that is not the case. To disallow families to seek expert advice and treatment on a rare and life-threatening condition is frustrating for referring providers and families alike.

Another hurdle is the requirement for repeated yearly approvals even after the patient has been established in an out-of-state institution. Many times, children with rare, complex diseases require care throughout their lifetime but providers are required to seek approval for coverage of out-of-state patients on a yearly basis again causing delays in scheduling needed care amongst the many specialists involved. A proposed solution would be to approve provision of care one time without requiring yearly approval for children who have established care with an out-of-state provider.

This is a particularly exciting time in hematology clinical practice and research as the community expects multiple approvals in gene therapies and other therapeutics in the coming years. While these new treatments hold great promise for patient care, they will also be very technically challenging and involve, for example, the harvesting of stem cells, making viral vectors, and performing the gene delivery to the cells – this will require institutions and providers who have the needed comprehensive expertise, both technical and clinical, to deliver these types of therapies.

**Barriers Preventing Children from Receiving Care**

CMS is also seeking public comment related to individual financial barriers (for example, costs of travel, lodging, and work hours lost) that prevent children with medically complex conditions from receiving care from out-of-state providers in a timely fashion, as well as examples of successful approaches to reducing those barriers. Out-of-state care involves travel by families to another state. The travel costs can be burdensome and a barrier for many families. A proposed solution would be for Medicaid to cover costs or a portion of the costs associated with travel for families who need to make the journey to an out-of-state institution. This could be solved with some type of cost-sharing program between families and payers. These costs are likely a small fraction of the total medical cost but reimbursing some costs could allow patients to access needed, life-changing care.
Thank you for the opportunity to offer comments in response to this request for information. We welcome the opportunity to discuss these comments with you and your team. If you have any questions or require further clarification, please contact Leslie Brady, ASH Policy and Practice Manager, at lbrady@hematology.org or 202-292-0264.

Sincerely,

Stephanie J. Lee, MD, MPH
President