Feb. 19, 2019

VIA ELECTRONIC SUBMISSION

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Agency of Health and Human Services
Attn: CMS-926-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020

Dear Ms. Verma,

As organizations that share a strong commitment to the health of our nation's children, we appreciate the opportunity to provide comments in response to the Proposed 2020 Notice of Benefit and Payment Parameters (Notice). Overall, more than one-half of all children are covered by commercial plans with more than one million children enrolled in Qualified Health Plans (QHPs) to date. Commercial coverage, whether through an employer plan or a QHP, must ensure that covered children have access to timely, affordable, high-quality and age-appropriate care that meets their unique developmental needs and enables them to meet their full potential as adults. All plans should also promote the health of women before, during and between pregnancies. Access to health care for children and their families is vital to long-term health, well-being and productivity.

We respectfully submit the following comments on ways we believe the Notice can be strengthened to ensure that access to timely and appropriate treatment for pregnant women and children, particularly those with serious, chronic or complex conditions, is as seamless as possible.

Prescription Drug Coverage

- **Changes to guaranteed renewability to allow mid-year formulary changes (§147.106; §146.152; §148.122); Cost-sharing requirements and generic drugs (§156.130)**
  We appreciate the efforts by CMS to address the affordability of prescription drugs in the Notice. However, we caution that there may be unintended negative implications of the proposals to emphasize the use of generic rather than brand-name drugs. Without sufficient guardrails, including fair and timely exceptions, streamlined appeals processes and stringent plan oversight, these proposals could compromise a child patient's health, development and future productivity, and result in short and long-term financial burden and emotional stress for their families.

  Successful use of generic drugs by children, particularly those with serious, chronic or complex conditions, is dependent on a number of factors. Prescribers, let alone insurers, cannot predict who will or won't respond well to a particular generic, even though that drug has been determined to be equivalent to the brand-name. For example, generic stimulant medications for children with Attention Deficit and Hyperactive Disorder (particularly extended release versions), some generic medications for

children with seizures, as well as generic blood thinners and thyroid preparations, may not always be as effective as the brand-name version for some children. Other children may have an adverse reaction to the new generic drug. And, as the child grows, the effect of a generic on a child may change, and fine-tuning or substitution may be needed yet again.

Furthermore, children often are unable to swallow a medication in oral solid form. Providers often work closely with their pediatric patients and their families on an appropriate formulation of the drug (liquid, chewable, etc.) for that child. The generic may come in such a form, but it also must be available in child-appropriate flavorings, which can be key to the successful administration of the drug in the pediatric population.

It is imperative that the agency's well-intentioned goal of reducing the costs of drugs does not compromise children's health. Given the unique nature of, and challenges with, pediatric pharmaceutical administration, particularly for children with a serious, chronic or complex condition, we strongly recommend that the final Notice:

- **Clarify that a generic is not considered equivalent if it is not available as a solution, suspension, and/or chewable in the same form and child-appropriate flavor as the brand-name version.** As noted above, the formulation of the drug can be foundational to the successful administration of that drug. Therefore, the absence of a comparable child-appropriate version should result in the retention of the brand-name on the formulary for that child.
- **Further define the specific parameters and procedures for insurers' exceptions processes under §156.122(c) to ensure that exceptions requests are reviewed and adjudicated with the utmost attention to timeliness, and without administrative burden for the provider or the family.** Those parameters should include specific circumstances under which exceptions must be granted, including the lack of a comparable child-appropriate formulation of the drug. High priority should be given to the provider's recommendations and justifications for exceptions.
- **Specify that an insurer's decision to exclude a brand-name drug from the list of drugs covered under the essential health benefits (EHBs) would trigger an enrollee's right to appeal.** In the event an appeal is filed, it should be the insurer's responsibility to justify its decision to remove the drug and any denials of exceptions requests. The final rule should also specify that the final appeals decision must be based on a full review of the provider's medical opinion and evidence, not solely on the evidence provided by the insurer.
- **Clarify that an insurer must return a brand-name drug to the formulary for an enrollee for whom the generic version no longer works or results in adverse events.** As noted above, some drugs that once worked may not be as effective as a child grows, despite dosing changes. The final rule should include a requirement and process by which insurers must add a brand-name drug back to a formulary after it has been removed in response to a medically necessary request by a provider.
- **Clarify that a positive determination of an exceptions request or an appeal for a specific brand-name drug should be effective for the full plan year, regardless of the number of drug refills during that year.** Children with a serious, chronic or complex medical condition may rely on multiple medications over a long period of time. Any requirement by the insurer that exception requests must be submitted for each refill or on a periodic basis throughout the plan year is unnecessary, resource-intensive, costly, and stressful for the provider and family, and represents an additional administrative cost for the insurer. A plan-year exceptions standard saves money and time and reduces the risk of adverse harm to patients who will be protected from potential gaps in their medication cycle.
- **Include strong oversight and monitoring and public disclosure provisions.** It is critical that CMS, states, providers, and families have timely information and data about plan design changes,

and exceptions processes and outcomes to help them identify unnecessary barriers to medically appropriate brand-name drugs for their children, as well as any unique challenges that children may have in the use of generics versus brand-name drugs and for which conditions. Monitoring and oversight of children's ability to access needed drugs will be an important tool to help the agency determine if further policy changes are warranted to ensure that access. This type of information is also critical to families of children with serious, chronic or complex medical conditions who need to understand if and how a particular plan's formulary will meet their child's needs.

Insurers should be required to provide their state insurance departments and CMS with a detailed overview of their exceptions processes, and to make that information readily and easily available to the public in all plan materials. Insurers should also be required to provide data to CMS and state regulators on the number of enrolled individuals who request exceptions and for which drugs, how many were granted, plans' annual and lifetime limits on brand-name drugs that are not covered as an EHB, the number of enrollees who reach an annual or lifetime limit on a non-EHB brand-name drug, and the number of enrollees for whom the maximum out-of-pocket limit protection does not apply as a result of their use of a brand-name rather than a generic drug. In addition, we urge CMS to collaborate with states on the tracking of exceptions and appeals in order to identify problematic trends in formulary design and to address those concerns in a timely fashion.

- **CMS request for comment on therapeutic substitution and reference-based pricing**
  In response to the agency's request for comment on whether to pursue therapeutic substitution and reference-based pricing in the future, we caution that, like the generic equivalent policies in the proposed rules, these policies could have serious unintended consequences for children.

  It is critical that any future policymaking that might allow therapeutic substitution include strong guardrails to ensure that drugs, particularly for unique populations such as neonates, continue to be available. In particular, therapeutic substitution related to antibiotics could be problematic for children who may not be able to interchange one antibiotic for another within the class of antibiotics. For example, the antibiotic, IE Cefatoxamine, which is critical to babies in the neonatal intensive care unit, cannot be substituted for other cephalosporins.

  CMS is also considering a structure that would allow the insurer to set a reference price for a class of drugs and effectively require the enrollee to pay any amount that exceeds that price (with such cost-sharing not counting towards the annual out-of-pocket limit). However, reference-based pricing could result in significant financial hardship for families if the pricing structure does not address the unique medication needs of children. In particular, the families of children with a serious, chronic or complex condition who rely on specialty drugs as part of their care should not be burdened with greater financial obligations if their child has a clinical need for a more expensive drug within a class of drugs. Specialty pediatric drugs may have different mechanisms of action, modes of administration, or other features that make it difficult to switch among them and to find an alternative that is below the reference-based price. In addition, as noted previously, many children are unable to take their medication in an oral solid form. In the event a liquid form is not available, pharmacies will manipulate the drug to create an oral liquid. The additional time and technology needed to safely prep the drug must be taken into consideration when establishing a reference price, and patient families should not be charged more because their child needs the liquid formulation. Otherwise, families may face exorbitant out-of-pocket costs, making their child's needed drug unaffordable, which could result in poorer health outcomes.

Navigator Program Standards (§155.210)
We encourage the agency to increase and expand its support of Navigators, rather than continuing to cut their funds and functions. In particular, we ask CMS to ensure that Navigators retain their important role in post-enrollment counseling. Post-enrollment assistance can help families, particularly families of children and youth with special health care needs, understand and appropriately use their health insurance coverage. This population may have unique challenges navigating the health care system and may need intensive guidance, support and assistance to also navigate their insurance coverage choices. For example, a family of a child with spina bifida might need intensive assistance to identify appropriate in-network pediatric providers and understand the specific health plan limitations related to coverage of wheelchairs, their replacement, and related costs. They also might need assistance understanding the variation among plans for coverage of a range of therapies – both numbers of visits and cost-sharing requirements. Post-enrollment assistance by Navigators can help families become empowered consumers with the core understanding of their plan that is needed to make reasonable and cost-effective health care purchasing decisions.

Essential Health Benefits (§156.111 and §156.115)
We continue to be very concerned about the revisions to the EHB benchmark selection process, which were adopted in the final 2019 Notice of Benefit and Payment Parameters and urge you to reconsider this approach. As we articulated in our comments on the proposed 2019 Notice[1], the new flexibilities afforded to states and insurers related to benchmark selection could leave children, particularly those with serious, chronic or complex conditions, worse off and their families with higher out-of-pocket costs.

Children are not little adults; they require services and care specifically suited to their unique development and growth needs. Because of their continuous growth and development, children's need for a full set of pediatric and age-appropriate benefits is particularly acute, and gaps in benefits can result in life-long health consequences that generate extensive and avoidable costs. Essential pediatric benefits must include all preventive, diagnostic, and treatment services that are medically necessary for children, including those who have a chronic condition, functional impairment, or significant or multiple health risks. They also include key therapies and devices that are now included in the habilitative services category of the EHBs. Receiving sufficient habilitative services that helps a child *acquire*, improve, or retain a skill or level of functioning that s/he did not previously possess can mean the difference between talking and not talking, walking and not walking, or needing special education and being able to join a regular classroom.

We hope you agree that it is vitally important that families are protected from the bankrupting out-of-pocket costs that can occur when their health plan does not appropriately cover the services they need.
Without stronger parameters for states that design their own EHB package from scratch or choose a full benchmark or parts of a benchmark from another state, it is very possible that a state could limit or drop certain benefits of particular importance for children in the interest of lowering premiums. Those changes could expose consumers throughout the commercial market to annual and lifetime limits on any covered services in their plan that are not an EHB and eliminate the protection of the out-of-pocket maximum for any non-EHB service that is covered by their plan. As a result, children with serious, chronic or complex conditions who get their coverage through the employer market could face gaps in coverage and their families could be confronted with exorbitant out-of-pocket costs.

[1] See Nov. 27, 2017 letter to Seema Verma re: CMS-9930-P. CMS Notice of Benefit and Payment Parameters for 2019.

Premium Adjustment Percentage (§156.130)
We strongly urge the agency to reconsider its proposal to incorporate individual market premiums into the formula for the premium adjustment factor for the 2020 benefit year and beyond. The proposed change would have a significant financial impact on QHP enrollees and their families who are eligible for premium tax credits, as well as the broader commercially covered population who would experience higher out-of-pocket costs. At least 7.3 million QHP enrollees would experience an increase in premiums due to the reduction in the premium tax credit amounts that would result from this formula change. Furthermore, as CMS estimates in the Notice, the revised formula would cause 100,000 fewer people to enroll in QHPs on a permanent basis because they would not be eligible for subsidies. Without alternative coverage options, many of those individuals would likely end up uninsured, which would leave the Exchange risk pool less healthy and drive up marketplace premiums further.

The formula change would also increase out-of-pocket costs throughout the commercial market by raising the annual maximum out-of-pocket limits. Families could see an additional $400 in annual out-of-pocket bills in 2020, relative to current policy. The higher out-of-pocket cap would be especially harmful for families of children with a serious, chronic or complex condition who require frequent health care interventions throughout the year.

We note that the proposed formula changes are not the result of a statutory requirement under the Affordable Care Act and that the current formula better protects families from financial instability and challenges. Therefore, we urge CMS to use its discretion and not incorporate individual market premium costs into the formula, as it proposes.

Network Adequacy (§156.230)
We urge CMS to restore the federal role in plan network adequacy oversight and assessment. As we note in our comments on the 2019 Notice,[2] children must have access to in-network pediatric primary, tertiary and quaternary care providers with the requisite training and expertise to meet their unique health care needs, regardless of the state in which they live. The absence of a federal minimum set of standards for provider networks will lead to a patchwork of state standards and processes, and will likely reduce children's access to needed pediatric specialty care. Furthermore, the ongoing trend toward more limited (and inadequate) networks may leave families with exorbitant out-of-pocket expenses when they must seek out-of-network care for their child because there is no appropriate in-network provider.

In the absence of action by CMS to reinstate a stronger federal role in network adequacy, we strongly recommend that you stringently monitor provider networks and provider and consumer complaints, in coordination with states. In addition, we continue to strongly recommend that CMS clarify the procedures for, and respective roles of, the agency and states to follow up on complaints that indicate a network gap. Those procedures must include the identification of needed specialists to fill the gaps.

CMS Request for Comment on Auto-reenrollment and "Silver-loading
CMS retains current policies and practices, but seeks comment on potential future policy and program changes, related to auto-reenrollment and "silver loading." We appreciate that the proposed Notice leaves the current policies in place for plan year 2020 and strongly recommend that such policies be maintained for 2021 and beyond. Auto-reenrollment and silver loading are critical to ensuring that individuals and families remain enrolled and that QHP coverage remains affordable, which will result in greater access to needed care and more stable marketplaces.

[2] See Nov. 27, 2017 letter to Seema Verma.

In conclusion, the undersigned organizations appreciate this opportunity to share our views regarding the proposed Notice. We look forward to working with you to ensure that the unique health care needs of pregnant women, children and families are met in the individual and larger group markets. If we may provide further information or otherwise be of assistance, please contact Jan Kaplan at the Children's Hospital Association, at 202-753-5384 or jan.kaplan@childrenshospitals.org.

Sincerely,

American Academy of Pediatrics
Children's Defense Fund
Children's Hospital Association
Family Voices
First Focus
Georgetown University Center for Children and Families
National Association of Pediatric Nurse Practitioners