January 31, 2023

The Honorable Xavier Becerra  
Secretary of Health and Human Services  
U.S. Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

The Honorable Chiquita Brooks-LaSure  
Administrator Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

Re: Request for Information; Essential Health Benefits- CMS-9898-NC

Dear Secretary Becerra and Administrator Brooks-LaSure,

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 Request for Information (RFI) related to the Essential Health Benefits (EHB) under the Patient Protection and Affordable Care Act (the Affordable Care Act or ACA). Our organizations believe that all coverage for children must ensure access to timely, affordable, high-quality, and age-appropriate health care that meets their unique developmental needs and enables them to meet their full potential as adults. We recognize the agency's continued commitment to promoting coverage, improving access, and eliminating health disparities, and appreciate the opportunity to submit feedback.

As you conduct your review of EHB and consider future rulemaking, we respectfully urge you to consider an essential core principle: **Children are not little adults**; they require services and care specifically suited to their unique developmental needs. Because of their continuous growth and development, children need timely access to a full set of pediatric and age-appropriate and family centered services. Missed screenings, diagnoses, and treatments can result in life-long health consequences that generate extensive and avoidable costs. It is critical that children's health issues are identified as early as possible to avoid the development of more complex and costly issues in the future.

Our organizations remain concerned that the EHB benchmark approach does not ensure children and youth have access to a comprehensive set of benefits that meets their needs. As noted in the RFI, aside from the required preventive services for children, and the identification in section 1302(b)(1)(J) of the ACA for “[p]ediatric services, including oral and vision care” as one of the 10 categories of EHB, the EHB-benchmark plans largely do not differentiate between benefits for adults and benefits for children.

The small group plans that largely serve as the EHB benchmarks were not developed with adequate consideration of children's needs. On the contrary, Medicaid’s Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit guarantees specific benefits designed especially for children. EPSDT is the definitive standard of pediatric care, covering 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. Through EPSDT, children have an array of services including developmental, dental, vision and hearing screenings, mental and behavioral health services, and home and community-based services allowing health problems to be diagnosed and treated appropriately and as early as possible. **As such, our organizations believe that EPSDT should serve as the model for the scope and breadth of EHB for children.**
We applaud CMS for explicitly asking commenters to help address these gaps. Specifically, the RFI asks “Are there differences between adult and pediatric benefits and those populations' needs such that further delineation of pediatric benefits is warranted?” The answer to this question, unequivocally, is “Yes.” Studies have documented the significant gaps in pediatric services covered by plans subject to EHB requirements, especially when compared to the child-appropriate benefits under Medicaid and CHIP.1 2 3 4 Those gaps can be seriously detrimental to a child’s healthy development and well-being.

As such, this comment letter highlights the unique needs of children, the current gaps that exist that prevent children from accessing necessary care, and recommendations that CMS can implement to improve pediatric EHB for children. Our key recommendations are highlighted below, followed by a more detailed analysis.

- **Further Define “Pediatric Services”:** At minimum, access to all needed services under EHB should include all mandatory and optional benefits outlined in the AAP statement “Scope of Health Care Benefits for Neonates, Infants, Children, Adolescents, and Young Adults Through Age 26.”

- **Strengthen EHB Benchmarks to Address Gaps in Pediatric Care:** Medicaid's EPSDT benefit should serve as the model for the scope and breadth of EHB for children. At a minimum, CMS should use each state’s CHIP benefit package as the basis for a crosswalk with the state benchmarks to determine which benefits are included and excluded.

- **Cover Habilitative Services and Devices that Meet Children's Developmental Needs:** CMS should identify a minimum set of basic habilitative services and devices that plans should cover.

- **Establish a Standardized Definition of Medical Necessity:** CMS should develop a standardized definition of medical necessity, including a definition of pediatric medical necessity, based on Medicaid’s EPSDT benefit or the AAP’s recommendations for a comprehensive pediatric benefit package.

- **Limit Insurer Flexibility:** Insurers should not have the authority to substitute or alter the essential health benefits offered, either within or among the ten required categories.

- **Engage in Ongoing Monitoring of EHB:** CMS monitoring and oversight of children’s access to all aspects of EHB is an important tool to assess gaps in services or obstacles to care and determine if further rulemaking or policy changes are warranted in the future.

- **Prioritize Whole-Child Care and Address Social Drivers of Child Health:** A wide variety of community-based services may be appropriate to enable optimal child and family health, particularly for children and youth with special health care needs, and EHB could serve as a facilitator to identify and access these services.

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3 The Wakely Consulting Group, Comparison of Benefits and Cost Sharing in Children’s Health Insurance Programs to Qualified Health Plans (July 2014)

**Further Define Pediatric Services**

The ACA places particular emphasis on children’s needs by making pediatric services, including oral and vision care, one of the ten required categories of essential health benefits. By including it as a required category of benefits, Congress signaled its intention that children should receive an additional set of benefits beyond that provided in the other nine EHB categories. Those additional benefits include, **but are not limited to**, oral and vision care. The ACA’s legislative history makes it clear that oral and vision care were added to supplement other pediatric services provided under the category, not to limit pediatric services to only those two types.

Children depend on other pediatric services that do not fall into the other nine EHB required categories. However, HHS regulations incorrectly require only that the base benchmark for “pediatric services” be adjusted to cover vision and oral health care, both explicitly listed in the statute; the regulations do not further define the meaning of “pediatric services.” As they grow and develop, children’s needs differ from adults. For instance, a growing child may require a new wheelchair or other durable medical equipment on a much more frequent schedule than is provided for in an adult benefit package—a new wheelchair every five years would not be adequate for a child. In addition, children may require speech therapy to ensure that their development is optimized. As they develop, children also need preventive and supportive services more frequently to ensure they have the tools to maintain or improve their health well into adulthood. These include, for example, developmental assessments and screenings, education, counseling, and services such as anticipatory guidance and nutritional counseling.

Consequently, many states have excluded important services that children need to thrive from their plans. As displayed in more detail in the next section, the benchmark plan approach to EHB in the pediatric services benefit has resulted in arbitrary coverage exclusions and limitations of necessary services for children, such as home health services, habilitative services and developmental devices, and—in some cases and contrary to federal law—well-child visits.

Amid the children’s mental health emergency, there is a strong need to reduce the current gaps in coverage related to pediatric mental health services. This includes mental health services that children may need from prevention and early identification through treatment, community-based services, intermediate-level mental health care (i.e., intensive outpatient programs), crisis response, and hospitalization. EHB requirements can play an important role in addressing these coverage gaps by incorporating coverage of pediatric mental health services in the “pediatric services” category.

**Recommendation:** Broadly and comprehensively consider the “pediatric services” category to ensure that children receive the services they need to grow and develop. Pediatric services are not just limited to oral and vision care but include a full range of services from preventive and primary care to ancillary services utilized by children with special health care needs, such as physical, speech and occupational therapy, home health care, durable medical equipment, hearing services, and personal care.

**Recommendation:** At minimum, access to all needed services under EHB should include all mandatory and optional benefits outlined in the AAP statement “Scope of Health Care Benefits for Neonates, Infants, Children, Adolescents, and Young Adults Through Age 26.” These services reflect the latest clinical evidence available regarding effective, appropriate care to ensure the best health outcomes for children.

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**Recommendation:** Prohibit benefit scope, duration, and visit limits that will deny children access to needed care. Many of these limits are particularly harmful for children with disabilities related to mental health and development. While federal law bans lifetime and annual benefit caps, other limits on benefit scope, visits, and duration will effectively deny children access to the care that they need.

**Strengthen EHB Benchmarks to Address Gaps in Pediatric Care**

Congress expressly authorized the Secretary of HHS to implement EHB coverage standards, including the pediatric services. However, rather than establishing a detailed national EHB standard, HHS allowed states to select “benchmark” plans that represent a state’s “typical” employer-sponsored plan, to serve as a template for other health plans to follow. A standard nationwide benchmark of covered pediatric services under EHB that mirrors the Medicaid EPSDT benefit is needed to ensure that all children, regardless of the state, can access covered services, even if that care is in another state.

While CHIP also uses a similar benchmark plan approach, these plans are specifically designed for children. In contrast, the benchmark plan approach to EHB—especially for children under the pediatric services benefit—is not specifically tailored to children and youth and fails to ensure that they have access to benefits that are essential to meeting their needs. Pediatric care typically involves other family members or guardians, and requires extra time, monitoring, specialized medications and equipment, and specially trained health care providers who are compassionate and understand kids of all ages and from all backgrounds. In addition, pediatric specialty care is regionalized in nature requiring cross-state care more frequently for children than adults. This is especially important for children with complex medical conditions, who may need to be treated by a specialist outside of their home state.

The current landscape, according to several academic pediatricians and child health policy experts, is a “state-by-state patchwork of coverage for children and adolescents, with significant exclusions, particularly for children with developmental disabilities and other special health care needs.” Their 2014 analysis found several specific pediatric exclusions within certain treatment categories. These gaps largely continue to exist as states have made very few changes to their benchmark plans:

- Nine states at least partially excluded services for children with autism spectrum disorders.
- Eight states specifically excluded services for children with developmental delays/disabilities.
- Seven states excluded one or more services for children with behavioral problems.
- Six state benchmarks expressly excluded family/parental therapy services.

Our informal review of proposed benchmark plans for the 2017 plan year across EHB categories also revealed numerous instances of inadequate coverage for children, including coverage with arbitrary visit limits or limits on service frequency. Children often need services with greater frequency and intensity than adults, so certain benefit limits (for instance, limits on number of visits, frequency of service or device replacement, etc.) established for adults may be inappropriate for children. We provide you with several illustrative examples of inadequate coverage of important services for children below under EHB:

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8 See Letter to CCHIO from Children’s Health Groups: https://downloads.aap.org/DOFA/Signon%20to%20CCHIO%20on%20EHB%20benchmarks%202017.pdf
**Audiology services**

Many state benchmarks limit hearing screenings to newborns only, even though hearing loss may not be identified until later in the child's development. Additionally, many state benchmarks do not specify whether hearing loss would qualify a child for services such as speech therapy, and if so, what limits would apply to those services. Arbitrary limits on these services could delay language development in a child with hearing loss who may require significantly more speech therapy visits, especially during the critical language development years. Finally, for the state benchmarks that did cover hearing aids for children, some did not cover the associated technologies that are required to make the hearing aids work (such as ear molds).⁹

**Well-baby and well-child visits**

While every state benchmark reviewed clearly covered well-baby visits, the review found coverage of well-child visits much more difficult to assess. For example, several states stopped all well-child visits before age five or ten. And while many benchmark documents reference adherence to a national standard, like the AAP/HRSA promoted Bright Futures Guidelines,¹⁰ they do not always comply with those standards.

**Home health services**

Some state benchmark plans only cover home health services for individuals who are homebound and unable to leave their home. This requirement means that a child with a serious, chronic, or complex condition cannot attend school or engage in other activities and also receive needed home health care services. Additionally, several benchmarks require preauthorization of prescribed home health care services that could be particularly burdensome for both patients and providers.¹¹

**Pediatric dental coverage**

As you know, the initial benchmark selection process led to limited pediatric dental coverage in some instances due to federal flexibility in the imposition of supplementation requirements. Consequently, some states only cover basic preventive dental services for children, leaving families with no coverage for services such as fillings, orthodontics, or other important procedures. If a stand-alone dental plan exists in a given marketplace, qualified health plans are not required to embed pediatric dental services in their basic benefits, despite “pediatric services, including oral and vision care” being required in ACA. This means that families must purchase additional dental coverage, adding further cost burdens for the family. In addition, consumers who purchase stand-alone dental plans do not have access to the same level of affordability and consumer protection standards as those guaranteed by the qualified health plan, including federal subsidies.¹²

**Mental and Behavioral Health Care**

Given the impact of the COVID-19 pandemic on children's mental health, which exacerbated challenges children faced prior to the pandemic, we urge CMS to ensure that the mental health category of EHB include meaningful access to and payment for pediatric mental and behavioral health care across the continuum of care and in a range of settings, including in the pediatric primary care setting. Restrictions on same day billing of medical and mental health services serve as a barrier and should be prohibited. CMS should expand health care coverage and payment to pediatric providers for services related to mental and behavioral health such as integrated mental health care, care coordination, supportive services, and home visiting. Payment for such

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¹⁰ https://www.brightfutures.org/

¹¹ The GAO analysis of health plan coverage compared to CHIP coverage also observed limitations of home health care benefits in the private plans in the states included in the analysis. Children's Health Insurance: Coverage of Services and Costs to Consumers in Selected CHIP and Private Health Plans in Five States (March 2015).

services should be determined based on the functional needs of the child not whether the child has a diagnosis. Additionally, Marketplace plans should cover trauma-informed care services, including screening, diagnosis, office-based management, counseling, case management, community collaboration, and home visiting.

Children’s mental and behavioral health care needs span the continuum of care and include the promotion of mental health, prevention and early identification of behavioral health issues, assessment, referral, treatment across a range of settings, and management/co-management of behavioral health issues. Solutions for adults are not the same as solutions for children. By some estimates, as many as 19% of children have mental health symptoms that impair their functioning without meeting criteria for a disorder. For young people who have experienced significant or complex trauma, such as those in foster care, our current system makes it difficult to access services without applying diagnoses that do not fully capture their needs and can lead to fragmented and unnecessary care that does not address the root need they have.

Similarly, lack of insurance payment for services for children and adolescents whose needs do not yet rise to the level of a diagnosis is a major barrier and contributes to the mental health crisis we are confronting. While some symptoms may ultimately become a diagnosable condition, the rigidity of insurance payment prevents support for those children and adolescents with emerging problems. While more providers are needed to address the mental health needs of the pediatric population, payment rates for these services are a key barrier to building the workforce and must be improved. It is also important to ensure that primary care physicians can be paid for the mental health services they provide. A study in *Pediatrics* found that primary care pediatricians are the sole physician care-managers for approximately one-third of US children with mental health disorders. During the COVID-19 pandemic, pediatric practices reported a decrease in visits for acute physical illnesses, but an increase in visits focused on mental health concerns.

Now more than ever, families and children from infancy through adolescence need access to mental health screening, diagnostics, and a full array of evidence-based therapeutic services to appropriately address their mental and behavioral health needs. It is also important to recognize that a child in need of mental health services typically will need those services more frequently than an adult. In addition, mental health services, particularly for young children, may require the participation of parents/caregivers.

As outlined in a set of Child and Adolescent Mental and Behavioral Health Principles endorsed by many of our organizations, we call on CMS to use every authority possible to increase children's access to mental health services. If enacted in policy, these principles would increase access to evidence-based prevention, early identification, and early intervention; expand mental health services in schools; integrate mental health into pediatric primary care; strengthen the child and adolescent mental health workforce; increase insurance coverage and payment; extend access to telehealth; support children in crisis; and address the mental health needs of justice-involved youth. We recommend the principles document to you as you consider all policies related to coverage and access to care for children and families. Comprehensive pediatric mental health

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coverage in EHB has the potential to play a critical role in addressing the nation’s children’s mental health emergency.

**Recommendation:** Medicaid’s EPSDT benefit should serve as the model for the scope and breadth of EHB for children. At a minimum, CMS should use each state’s CHIP benefit package as the basis for a crosswalk with the state benchmarks to determine which benefits are include and excluded. When benefits for children are more limited or lacking in the benchmark, CMS should require states to ensure that the benchmarks are appropriately supplemented.

**Recommendation:** If the above recommendation is not adopted, states that wish to go beyond the federal floor and promote coordination with other sources of public coverage should have the option to build EHB packages for children around Medicaid’s EPSDT benefit.

**Recommendation:** CMS should provide additional guidance to states regarding the design of the plan summaries and related materials to ensure consistency, accuracy, and clarity. We recommend standardizing the benchmark reporting process to make compliance with EHB requirements clear and to ease the data collection process in the future.

**Recommendation:** Require that “pediatric oral services” provide for comprehensive children’s dental care, including medically necessary orthodontic services. States must take steps to assure that children’s dental coverage is at least as comprehensive as a state’s CHIP dental benefits and is sufficient to fully guarantee children’s oral health.

**Recommendation:** Delineate “pediatric vision services” to include much more than a vision screening, which is already required to be covered as a preventive care benefit, and include the diagnosis, frames, and corrective lenses a child needs.

**Recommendation:** EHB benchmarks should also address current gaps in pediatric care including in audiology services, well-baby and well-child visits, home health services, and others.

**Recommendation:** Require EHB to meet benchmarks for increasing access to mental and behavioral health services for the full continuum of care including how payment to pediatric providers will be sufficient to increase access to services and how a diagnosis is not required for a mental health or substance use disorder in order for there to be payment for services. CMS should incentivize screening for behavioral health needs at well-child visits, the provision of parental supports, and other early intervention services necessary to address needs early.

**Cover Habilitative Services and Devices that Meet Children’s Developmental Needs**

While the ACA specifically recognizes habilitative and rehabilitative services as the seventh of the ten categories of EHB and federal regulations define habilitative services as coverage of “health care services and devices that help a person keep, learn, or improve skills and functioning for daily living,”16 — many health care plans only cover rehabilitative services that aim to restore a lost function. Fewer plans explicitly include habilitative services that facilitate acquisition of a function or skill not yet attained. As medical knowledge has advanced, health care providers have recognized that children who were thought to have limited potential function or to be destined to exhibit functional deterioration over time may improve, or at least maintain, function with a rigorous therapeutic program or with innovative approaches.

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16 42 C.F.R. § 156.115(a)(5).
Furthermore, children continue to gain skills as they advance in age, and therefore, interventions that sustain continued acquisition of developmental milestones are medically necessary, as are interventions that maintain or at least slow the loss of a skill. Children are fundamentally different from adults, who display a static acquisition of skills, and for whom rehabilitation is focused solely on the restoration of prior functionality.\(^{17}\) The only mention of pediatric habilitative services in the federal regulations is an example: therapy for a child who is not walking or talking at the expected age. Otherwise, they do not delineate the types of habilitative items and services that should be covered for children.

We urge CMS to conduct a thorough review of the coverage of habilitative services and devices in the benchmarks to ensure that they include adequate coverage for children, including appropriate services and devices that help a child keep, learn, or improve skills and functioning. Receiving sufficient habilitative services and devices that help the child acquire, improve, or retain a skill or level of functioning that they did not previously possess can mean the difference between having the ability to walk or talk.

In addition, we ask CMS to pay particular attention to any limits that may be imposed on the habilitation benefit. Coverage of habilitative services and devices without arbitrary age, visit or other limits is especially important for children who may acquire a condition at birth (such as cerebral palsy, autism or spina bifida) or from an illness or injury that prevents skills development and functioning. For example, it may be difficult to measure progress for a child who is developing a skill for the first time, and services for that child may be needed for an extended period. For some children with progressive conditions, progress may be measured by a reduced rate of loss of function or maintenance of existing skills.

Furthermore, it is nearly impossible to determine, with certainty, the limits of the child’s capacity – whether, for example, more speech therapy will enable the child to develop stronger verbal skills. In addition, as they grow or their skills develop, children will need frequent replacements of devices, such as wheelchairs, glasses, auditory aids, orthotics, prosthetics, and augmentative communications devices.

Our review of the 2017 proposed benchmark plans raises some serious concerns regarding state implementation of habitation services and devices – a critically important benefit for children and youth with special health care needs.\(^{18}\)

- Several state benchmarks did not include coverage for any habilitation services.
- Most state benchmarks imposed arbitrary visit limits on physical therapy, occupational therapy, and/or speech therapy visits. The allowed number of visits varied widely, signaling the arbitrary nature of the limits, and the lack of a medical necessity standard.
- Some benchmarks only cover habilitation for specific conditions; others impose age limits.
- Coverage of hearing aids and wheelchairs for children is inadequate in most states.

**Recommendation:** CMS should prohibit benefit scope and duration and visit limits that will deny children access to needed care. If service caps in benefits continue to be permitted, there must continue to be separate caps for habilitation and rehabilitation benefits. However, simply importing the limits and exclusions that may exist under a plan’s rehabilitation benefit and applying those same limits and exclusions to the habilitation benefit seriously undermines the ACA’s habilitation mandate.


\(^{18}\) See Letter to CCIIO from Children’s Health Groups: https://downloads.aap.org/DOFA/Signon%20to%20CCIOO%20on%20EHB%20benchmarks%202017.pdf
**Recommendation:** CMS should identify a minimum set of basic habilitative services and devices that plans should cover. Without a minimum set of identified services, there is no firm mechanism for CMS or a state to determine whether a plan’s habilitative services benefit is adequate to meet beneficiaries’ needs.

**Recommendation:** The habilitative services benefit should include, but not be limited to, physical and occupational therapy, speech-language pathology, behavioral health services, audiology, rehabilitation medicine, and developmental pediatrics.

**Recommendation:** The habilitative devices benefit should include, but should not be limited to, durable medical equipment (e.g., wheelchairs and related accessories), orthotics, prosthetics, low vision aids, hearing aids, augmentative communication devices that aid in hearing and speech, and other assistive technologies and supplies.

**Establish a Standardized Definition of Medical Necessity**

Without a federal child health benefit standard, the current system of pediatric coverage in the ACA’s Marketplace is neither comprehensive nor consistent. Our organizations urge the Secretary to develop a standardized definition of medical necessity, including a specific standard of pediatric medical necessity, to assure that children and others can access the essential health benefits meaningfully and consistently.

The definition of medical necessity should not be narrowly defined by acute treatment outcomes but rather be broad enough to include services that improve, maintain, and promote health and function or that prevent deterioration of a child’s capacity to function. As part of the definition, the Secretary should require that plans clearly articulate the scope, process, and information used in applying the definition of medical necessity, including whether some services will require prior authorization or meet other medical management criteria. The value of a treatment may be considered in determining medical necessity, but when considering a treatment’s value, cost effective interventions should not necessarily be interpreted as the lowest price intervention.

A universal definition of pediatric medical necessity would ensure that children can access needed health benefits meaningfully and consistently. The American Academy of Pediatrics recommends the following definition of pediatric medical necessity: “health care interventions that are evidence based, evidence informed, or based on consensus advisory opinion and that are recommended by recognized health care professionals or organizations, such as [those represented by] the AAP, in order to promote optimal growth and development in children and youth and to prevent, detect, diagnose, treat, ameliorate, or palliate the effects of physical, genetic, congenital, developmental, behavioral, or mental conditions, injuries, or disabilities. Furthermore, new evidence, new community influences, and emerging societal changes dictate the form and content of necessary health care for children” 19

This definition appropriately reflects the needs of children in allowing medical professionals flexibility in prescribing health services that consider the evolving needs of the individual child. Furthermore, each state’s process for determining medical necessity should rely on the expertise of pediatricians, pediatric medical subspecialists, pediatric surgical specialists, family physicians, and other health care professionals qualified in pediatric care. All payers should ensure that in the process of making decisions on the basis of medical

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necessity, the physical, mental and behavioral health, and developmental care needs of the child are fully considered and that appropriate comprehensive benefits are available to address the full range of these needs.

**Recommendation:** Develop a standardized definition of medical necessity, including a definition of pediatric medical necessity, based on Medicaid's EPSDT benefit or the AAP's recommendations for a comprehensive pediatric benefit package.

**Limit Insurer Flexibility**

When choosing plans in the individual and small group market, consumers face differences and tradeoffs among the plans' provider networks, premiums, and cost-sharing charges. Allowing insurers to offer different sets of essential health benefits introduces another level of complexity, requiring consumers to consider another dimension of choices and tradeoffs. The result could leave many consumers uncertain of what benefits they are entitled to when they purchase a plan. Because it is impossible to predict exact health care needs, we believe all plans should include strong pediatric benefits and that children should not be excluded from medically necessary benefits because their parents chose the "wrong" benefits package.

We supported the changes made by the agency in the 2023 Payment Notice that amended § 156.115(b)(2) to withdraw the flexibility for health plans to substitute benefits between different EHB categories. We believe that insurer flexibility would invite adverse selection through uneven consumer choice of plans.

**Recommendation:** Insurers should not have the authority to substitute or alter the essential health benefits offered, either within or among the ten required categories.

**Improve Prescription Drug Coverage**

Under the current EHB regulations, plans must comply with § 156.122(a)(1) to cover at least the same number of prescription drugs in every United States Pharmacopeia (USP) category and class as covered by the State's EHB-benchmark plan, or one drug in every category and class, whichever is greater. This prescription drug coverage requirement is not as comprehensive as the one offered in Medicare Part D, which requires plan formularies to include drug classes covering all disease states, and a minimum of two chemically distinct drugs in each class. Part D plans are also required to cover all drugs in six so-called "protected" classes: immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastic.

Our organizations support strengthening EHB prescription drug coverage consistent with EPSDT requirements but at a minimum, to align with Medicare protections. This should also include coverage of pediatric indications/conditions/formulations in existing EHB formulary requirements, such as when a plan covers a drug in a class but not for pediatric utilization. Finally, these protections should also apply under other EHB benefit categories, such as when prescription drugs are administered by a physician or in a hospital.

CMS also seeks feedback on using an alternative prescription drug classification standard for defining the EHB prescription drug category, such as the USP DC or others, in the future. Our organizations note that the USP DC provides no specific classes or categories of drugs for use in children. For example, Nusinersen and Onasemnogene were recently approved to be used in children as young as two months old for Spinal Muscular Atrophy (SMA) and infantile-onset (SMA). These are the only two FDA-approved drugs to manage SMA in

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children. However, in the USP DC, both drugs are included in the broad category “Genetic, Enzyme, or Protein Disorder: Replacement, Modifies, Treatment,” along with 60 other drugs.\textsuperscript{21} This category includes drugs that do not treat SMA or relate to any neurological or spinal disease. Thus, these two drugs may not be covered by insurance formularies, preventing children from receiving clinically effective therapy SMA.

Moreover, pediatric patients, including newborns and young children, often require alternatives to oral solids. These can include liquid forms, as well as buccal, nasal, transdermal, and rectal routes and are often compounded.\textsuperscript{22}

**Recommendation:** As CMS considers using an alternative prescription drug classification standard for defining the EHB prescription drug category, the unique needs of children must be taken into account.

**Engage in Ongoing Monitoring of EHB**

Overall, we are pleased with this effort by CMS to review the EHB to determine:

1. Whether enrollees are facing any difficulty accessing needed services for reasons of coverage or cost,
2. Whether EHB needs to be modified or updated to account for changes in medical evidence or scientific advancement,
3. Information on how EHB will be modified to address any such gaps in access or changes in the evidence base, and
4. The potential of additional or expanded benefits to increase costs and the interactions between the addition or expansion of benefits and reductions in existing benefits to meet actuarial limitations.

As CMS collects data on EHB to help guide any future changes in the implementation of this important aspect of the ACA, we ask that you include specific data collection elements in your evaluation of state implementation to assess children’s coverage, including their access to the habilitation benefit and mental health services. In that regard, we strongly urge CMS to closely monitor and evaluate the implementation of the habilitation benefit to track the types of services and devices covered by plans and the impact of coverage limits on access to appropriate care. Furthermore, CMS should monitor children’s access to mental health services, including monitoring qualified health plan compliance with mental health parity requirements.

CMS monitoring and oversight of children’s access to all aspects of EHB is an important tool to assess gaps in services or obstacles to care and determine if further rulemaking or policy changes are warranted in the future. This type of information also is particularly important to families of children with serious, chronic, or complex medical conditions who need to understand if and how their plan will meet their child’s needs.

**Update EHB to Reflect Changes in Medical Evidence and Scientific Advancement**

The RFI also seeks comment on whether and to what extent EHB needs to be modified or updated to account for changes in medical evidence and scientific advancement. Coverage determinations of existing interventions should be based on evidence of usefulness and understanding of risks. Evolution of health care

\textsuperscript{21} USP. SUMMARY OF CHANGES BETWEEN MMG V7.0 AND MMG V8.0 (2020).

benefit coverage should reflect changes in treatment modalities and should adapt to new evidence and changes in standards of care as well as innovations in care.\textsuperscript{23}

As outlined above, the health care needs of children are drastically different than those of adults. Additionally, changes in the medical evidence and scientific advancement since 2014 warrant a review of additional pediatric benefits that are not reflected in the current EHB-benchmark plans. A couple specific examples are listed below:

**Improved Coverage of Maternal Care, Including Doula Care**

The RFI calls out the reliance on doula services as a cost-effective way to improve maternal and newborn health outcomes. Our organizations applaud this assertion, and further raise the 2019 recommendation from the United States Preventive Services Task Force (USPSTF) that providing or referring pregnant or postpartum women at increased risk to counseling interventions prevents perinatal depression. As such, insurers should cover counseling for perinatal depression to improve maternal and child health in EHB. When appropriate, CMS should allow pediatric providers to administer care to adult parents and caregivers, with adequate payment and without excessive administrative burden. Caring for a parent-child dyad or a child within the family context can lead to the best health outcomes, but often comes with payment denials and other administrative burdens.

CMS should also consider the recommendations for Maternal Health and Infant Health Quality Improvement in Medicaid and CHIP made by an expert advisory panel in 2020, which include ACOG-recommended postpartum services, group prenatal care, and midwife care.\textsuperscript{24}

**Insurance Coverage for Medical Nutrition**

While medically necessary nutrition is sometimes the best or only treatment for a digestive or metabolic condition, insurance companies often deny coverage. Insurance companies will typically cover pharmaceuticals or biologics for treatment of these diseases; however, they are often used off label or may not be recommended by the treating physician as first line therapy. Further, pharmaceuticals and biologics are often costly and can have undesirable risks such as suppression of the immune system, which can increase a patient's risk of infection or cancer. Even when an insurance company does cover medically necessary nutrition, it often comes with the stipulation that the formula be administered through a feeding tube (for example, a nasogastric tube, placed through the nose into the stomach or a gastrostomy tube, surgically placed directly into the stomach). Both public and private insurance should be required to cover medically necessary foods, such as highly specialized formulas, as a treatment option. Congress has previously recognized the importance of providing coverage for medically necessary nutrition and required TRICARE coverage for such therapies in the 2016 National Defense Authorization Act. We urge the CMS to expand this requirement for other insured populations with rare digestive and metabolic conditions.

Additionally, there is no current federal requirement for insurance coverage of donor human milk, which often leaves families, especially families with preterm infants who rely on donor milk, responsible for the costs. Donor milk banks, such as those accredited by the Human Milk Banking Association of North America, represent a safe and effective approach to obtaining, pasteurizing, and dispensing human milk for use in


Neonatal Intensive Care Units and other settings. CMS should ensure that families can access donor human milk on the basis of medical necessity.

**Prioritize Whole-Child Care and Address Social Drivers of Child Health**

Addressing the needs of children in the context of their family and community settings improves the efficacy of services and health outcomes of children and families, as well as making important services including preventive and health promotion services more accessible for children. This requires strategies such as providing early child development support via home visiting and in primary care pediatric practices, implementing two-generation strategies like maternal depression screening, and integrating school-based health and other community resources into the pediatric medical neighborhood. Consequently, the design, financing, and “value equation” of children's health care is more complex than that of adults and must be considered as part of the ongoing CMS review EHB, in addition to all HHS initiatives. A wide variety of community-based services may be appropriate to enable optimal child and family health, particularly for children and youth with special health care needs, and EHB could serve as a facilitator to identify and access these services.

The research on social drivers of health, resiliency, adverse childhood experiences (ACEs), and toxic stress makes clear that healthy child development is dependent upon safety, stability, security, and nurturing in the child's home environment. As CMS explores ways to improve access to care for children and families, the agency should invest in primary care to better address ACEs, including mental health issues, resulting in decreased chronic illness burden. This includes coverage of trauma-informed care services, including all necessary screenings, diagnosis, office-based management, counseling, case management, community collaboration, and home visiting. Investing in these services for children mitigate negative health outcomes and the significant economic burden of ACEs, thereby leading to long-term savings for children and their families. This will also help to reduce stress for families, especially for those with children that have complex medical conditions.

Thus, a comprehensive understanding of what is unique about pediatrics, including the timeframe to expect return on investment/cost-savings, must be woven into the design of a new framework to advance primary care. This framework should also help develop or support accountable resources in communities such as programs involving social services that meet needs relating to housing and nutrition security, literacy, mental health, and others. In short, an ideal pediatric health care financing framework should support seamless coordination between medical and “non-medical” resources.

Again, we thank you for your leadership on the implementation of the ACA. We look forward to working with you to ensure that children's coverage continues to be strengthened as implementation moves forward. If you have any questions or need further information, please contact Stephanie Glier, Director, Federal Advocacy at the American Academy of Pediatrics at sglie@aap.org.

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Sincerely,

American Academy of Pediatrics
Academic Pediatric Association
Alabama Chapter of the American Academy of Pediatrics
Alaska Chapter of the American Academy of Pediatrics
Alaska Children’s Trust
American Academy of Child and Adolescent Psychiatry
American Academy of Family Physicians
American Foundation For Suicide Prevention
American Pediatric Society
American Physical Therapy Association
American Psychiatric Association
Arizona Chapter of the American Academy of Pediatrics
Association of Maternal & Child Health Programs
Association of Medical School Pediatric Department Chairs
California Chapter 1 of the American Academy of Pediatrics
Children Now
Children’s Hospital Association
Colorado Chapter of the American Academy of Pediatrics
Connecticut Chapter of the American Academy of Pediatrics
DC Chapter of the American Academy of Pediatrics
Family Voices
Family Voices Colorado
Family Voices of North Dakota
Federation for Children with Special Needs
First Focus on Children
Florida Chapter of the American Academy of Pediatrics
Georgetown Center for Children and Families
Georgia Chapter of the American Academy of Pediatrics
Illinois Chapter of the American Academy of Pediatrics
Kansas Chapter of the American Academy of Pediatrics
Kentucky Chapter of the American Academy of Pediatrics
March of Dimes
Maryland Chapter of the American Academy of Pediatrics
Massachusetts Chapter of the American Academy of Pediatrics
Maternal Mental Health Leadership Alliance
Mental Health America
Michigan League for Public Policy
Mississippi Center for Justice
Mississippi Chapter of the American Academy of Pediatrics
Missouri Chapter of the American Academy of Pediatrics
National Alliance on Mental Illness
National Association of Pediatric Nurse Practitioners
Nevada Chapter of the American Academy of Pediatrics
New Mexico Voices for Children
New York Chapter 2 of the American Academy of Pediatrics
New York Chapter 3 of the American Academy of Pediatrics
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition
North Carolina Pediatric Society
Ohio Chapter of the American Academy of Pediatrics
Oregon Center for Children and Youth with Special Health Needs
Oregon Family to Family Health Information Center
Pediatric Policy Council
Pennsylvania Chapter of the American Academy of Pediatrics
Prevent Blindness
Raising Special Kids
Rhode Island Chapter of the American Academy of Pediatrics
Rhode Island Parent Information Network
Sandy Hook Promise
School-Based Health Alliance
Schuyler Center for Analysis and Advocacy
Society for Pediatric Research
South Carolina Chapter of the American Academy of Pediatrics
Tennessee Justice Center
Texas Pediatric Society
The National Alliance to Advance Adolescent Health
The Parents’ Place of Maryland
Virginia Chapter of the American Academy of Pediatrics
Voices for Georgia’s Children
Voices for Utah Children
Wisconsin Chapter of the American Academy of Pediatrics
Wyoming Chapter of the American Academy of Pediatrics
Wyoming Family to Family Health Information Center
Wyoming Institute for Disabilities