July 27, 2015

Andrew Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244
Submitted electronically to http://www.regulations.gov

Re: CMS-2390-P - Medicaid and Children's Health Insurance Program (CHIP) Programs: Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions to Third Party Liability

Dear Mr. Slavitt,

On behalf of over 220 children’s hospitals across the country, the Children’s Hospital Association (CHA) appreciates the opportunity to provide comments on the proposed rule to update the existing Medicaid managed care regulations. Since almost two-thirds of children covered by Medicaid are enrolled in comprehensive risk-based managed care, the proposed rule has implications for children’s hospitals and children’s health.

Though children’s hospitals account for only 5 percent of hospitals in the United States, they provide 47 percent of the hospital care required by children covered by Medicaid. Children’s hospitals are regional centers for children’s health, providing care across large geographic areas and serving Medicaid children across state lines. Children’s hospitals serve the majority of children with serious illnesses and complex chronic conditions and most children in need of major surgical services. In addition, children’s hospitals are engaged in efforts to promote delivery system changes, efficiency and cost savings in Medicaid.

CHA appreciates CMS’s efforts to update the managed care regulations and believes many of the provisions in the proposed rule are a positive step to improving managed care for Medicaid and the Children’s Health Insurance Program (CHIP) to ensure children receive the best quality of care. We applaud your efforts to institute additional guidelines, oversight and accountability in managed care, and we believe these efforts will help ensure children get access to the care they need.

Specifically, we greatly appreciate CMS’s efforts to strengthen guidelines for plans when providing the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit for children in the proposed rule. We are also extremely supportive of efforts to collect additional Medicaid data from plans and states in a consistent manner, which we believe is critical for understanding the quality of care provided to beneficiaries.

Although we support your efforts to set clearer requirements for states and health plans in the rule, we ask you to consider our suggestions from the pediatric perspective. As you know, more than 50 percent of the beneficiaries on Medicaid are children, necessitating a review of the new proposed policies to ensure they work for children as well as the broader Medicaid population. We strongly encourage CMS to consider the unique needs of the pediatric population as the agency develops and implements managed care requirements, particularly when aligning Medicaid and CHIP standards with Medicare Advantage and qualified health plan (QHP) standards. While we are supportive of efforts to align coverage programs when appropriate, children have unique needs for their healthy development and growth that are different than the health needs of the elderly population served by Medicare or adults served by QHPs. Medicare and QHPs do not necessarily include the proper protections for children. To address the needs of children, we ask CMS to consider the following major recommendations:
• **Access to pediatric providers**: We recommend CMS adopt strong pediatric network adequacy standards in Medicaid and CHIP that specifically include access to children’s hospitals along with a full range of pediatric primary, specialty and subspecialty providers to ensure children have timely access to the comprehensive services covered under EPSDT. We also share with you data that raises serious concerns about the use of the Medicare Advantage time and distance standards as the primary standard for access to pediatric specialty providers.

• **Managed care oversight, rates and expenditures**: We appreciate CMS’s efforts to allow states to engage in delivery system initiatives under managed care. We recommend expanding the list of exceptions of special contract procedures so states are able to ensure access to safety net providers and engage in future delivery system initiatives to improve care and efficiency in Medicaid while also incentivizing and retaining providers.

• **Quality**: We are supportive of the development of state comprehensive quality strategies for Medicaid and CHIP, but these efforts should specifically include a pediatric quality strategy that is appropriate for all sub-populations of children, including children with medical complexity. Consumers should also be able to identify whether a particular plan adequately meets the needs of specific subpopulations of Medicaid beneficiaries.

• **Strengthening children’s health**: We believe the rule includes a number of provisions that are positive for children’s hospitals and children’s health, such as requirements related to the 340B drug discount program, coordination of services and continuity of care. We provide recommendations for a number of these provisions to further strengthen the proposed regulations for children.

We respectfully submit the following specific comments and suggestions to ensure the managed care regulations take into account the unique needs of children.

**ACCESS TO PEDIATRIC PROVIDERS**

**Network Adequacy Standards (§438.68)**

We applaud CMS for its recognition that network adequacy is a foundational component of a health plan’s ability and capacity to provide covered services and for proposing minimum standards for network adequacy. We also are pleased that CMS proposes that states must ensure that enrollees have access to all covered services in a manner that meets state accessibility and affordability standards. However, we believe that the proposed federal framework requirements should be strengthened to ensure that children enrolled in Medicaid managed care plans have timely access to all covered services to which they are eligible under EPSDT. Furthermore, we are concerned about the rule’s application of Medicare Advantage standards to the pediatric population. We, therefore, respectfully urge CMS to consider our comments and recommendations below:

• **Provider-specific network adequacy standards (§438.68(b)(1))**
  - **Pediatric-specific standards**: We urge CMS to expand the required types of pediatric providers for whom network adequacy standards should be developed so children’s full scope of health care needs are appropriately addressed. We strongly support the inclusion of pediatric-specific standards in the proposed network adequacy standards to ensure that the large numbers of children enrolled in Medicaid plans actually have access to the specific services they need. However, we believe it is critically important to children’s timely access to care that pediatric-specific standards also be developed and implemented for children’s hospitals, emergency rooms, behavioral health providers, non-physician and physician specialists and subspecialists, and pharmacies, among others, as further discussed below.

  With approximately 1 in 3 children covered by Medicaid and two-thirds of those children enrolled in managed care, it is absolutely imperative that state standards for network adequacy include metrics specifically geared
toward ensuring that children have access to all levels of care, from primary to tertiary and quaternary. Therefore, while we are pleased that CMS proposes to require specific pediatric standards for some aspects of medical care, we urge CMS to require states to develop pediatric network adequacy standards for the full range of primary and specialty pediatric providers. Children’s unique health and developmental needs cannot be addressed through adult-focused standards. They must have access to the spectrum of pediatric-trained health care providers with the specific skills and experience to treat them.

Our specific recommendations include the following:

- Networks must include one or more appropriate pediatric hospital providers that are in the geographic area to ensure children’s access to comprehensive pediatric specialty services. To serve children adequately, the combined services of these hospitals, at a minimum, should include neonatal services, critical and intensive care, surgical, emergency/trauma services, and the relevant range of ancillary supports, such as occupational, physical, and speech therapy services; specialized pharmacies; anesthesia; durable medical equipment; and linguistically and culturally responsive providers/services.

We know that CMS understands children’s hospitals’ unique capabilities to deliver appropriate pediatric care to children covered by Medicaid. For example, CMS indicated in the Final Notice of Benefit and Payment Parameters for 2016 that, given children’s hospitals’ important role as essential community providers (ECPs) in the care of low-income and other vulnerable children, requirements for qualified health plans (QHPs) to contract with children’s hospitals should be strengthened. According to the final rule, new requirements to strengthen ECP standards and improve children’s access to children’s hospitals will be proposed in next year’s rule.1 We urge CMS to align the Medicaid managed care network adequacy standards for pediatric hospital services with those for QHPs, in the event that CMS, in fact, strengthens children’s hospital ECP requirements for QHPs in next year’s rulemaking. These pediatric hospital network adequacy standards under Medicaid would help mitigate the potential effects of churn for those families moving between Medicaid and Marketplace coverage.

We believe the intended change in federal ECP requirements accurately recognizes the unique capabilities and expertise located in children’s hospitals. While all children’s hospitals provide local care, they also excel in specialty care, meaning that children throughout large geographic regions have access to trained pediatric specialists, and the specialized services and technology not found in community or adult hospitals.

A recent CHA analysis2 demonstrates the unique capacity and capabilities of children’s hospitals and reinforces the importance of ensuring that network adequacy standards ensure that children, in fact, have access to the services provided by a children’s hospital. The children’s hospitals in the 13 states studied were found to provide, on average, more than six times the number of selected pediatric services than seen in non-children’s hospitals. Furthermore, they have more than 25 times the number of pediatric-designated beds. In addition, the study found that children’s hospitals in selected states see greater than 60 percent of all occurrences for 21 different pediatric services. These hospitals have the experience to appropriately treat children in need of tertiary and quaternary care, as evidenced by the volume of services they provide. They also have pediatric specialists and subspecialists with the specific expertise and clinical training to meet the needs of children from birth into adulthood for a full range of conditions. Thus, a network that does not include a children’s hospital will not have adequate capacity or the capability to provide the complete spectrum of specialty care that children may need.

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1 See final Notice of Benefit and Payment Parameters for 2016, page 10837
When a network includes providers without the requisite pediatric training, families may be referred to inappropriate providers who, by their own admission, do not have the experience to provide the services needed. In fact, we know that pediatricians, family practice physicians, and adult community hospitals refer their patients to children’s hospitals for treatment of everything from complicated fractures to complex congenital heart conditions, because of the expertise of those working in the hospital.

To illustrate this point, we share the case of a two-year-old child who was in need of hernia repair surgery. The child was referred to an in-network outpatient surgery clinic, rather than the local children’s hospital because that hospital was not in the plan’s network. However, the center told the child’s family that it did not have providers with the appropriate pediatric training and did not treat two-year-olds. The surgical center told the family that the only provider in the community equipped to care for their young child was the children’s hospital. Ultimately, the child was treated at the children’s hospital with good outcomes. Clearly, when a plan has a pediatric-appropriate provider network that includes providers with the requisite training, the delays and frustrations experienced by this family can be prevented and the unnecessary costs of negotiating out-of-network care will be avoided.

- **State network adequacy standards must be developed for all types of pediatric specialties.** Standards are needed for the full range of pediatric specialties and subspecialties, including, but not limited to pediatric cardiology, neurology, nephrology, developmental medicine, psychiatry and other behavioral health services, gastroenterology, orthopedics, pulmonology, oncology and radiology. Children, particularly those with serious, chronic or complex conditions, represent a unique cohort of covered patients and must have access to practitioners with the unique training and experience to meet their needs. Therefore, the network adequacy standards for pediatric specialties must specifically ensure that children have access to board-certified pediatric providers.

In addition, children require access to other types of providers who have the specific clinical expertise, capacity and experience to appropriately diagnose and treat them. Access to a range of pediatric behavioral/mental health and rehabilitative and habilitative services must also be addressed through network adequacy standards. These include, but are not limited to, pediatric physical therapy, occupational therapy, and speech therapy; pediatric audiology services; and pediatric optometry.

- **Tiered networks must be able to deliver all covered health care services under EPSDT.** In the event a plan utilizes tiered networks, access to all covered services must be in the lowest cost sharing tier, without additional administrative delays. A tiered network that is designed such that not all covered services are provided in at least the lowest cost sharing tier results in a potentially discriminatory benefit design for children with serious, chronic or complex health care conditions.

- **Children with special health care needs require a network that can support an appropriate transition to adult care providers.** We know that many children with congenital conditions live well into adulthood. Often those adults continue to receive care from their pediatric specialist or subspecialist because they have the unique training to continue to treat the condition.

  - **Time and distance standards:** We believe that the use of travel time and distance standards, particularly those developed for the Medicare Advantage program, are not appropriate metrics to determine network adequacy for children in need of specialty care. Therefore, we urge CMS to expand the types of quantitative measurements to include those that we highlight below, which states must develop and enforce, at a minimum.
CMS should be very careful not to impose single-faceted metric requirements for states that would not accurately determine beneficiaries’ access to all covered services. While we support the use of time and distance metrics as a generally appropriate measure of a network’s primary care capacity, they should not be used to assess a network’s adequacy in relation to pediatric specialty care. According to an analysis by CHA\(^3\), approximately 50 percent of children nationwide will not have access to the unique services provided by an acute care children’s hospital if Medicare Advantage minimum time and distance standards are the principal determinant of network adequacy. The use of time and distance standards as the sole metric for network adequacy would place children at risk of delayed services or may compel them to seek care in settings ill-equipped to address their pediatric service needs.

We believe that it is absolutely critical that quantitative network adequacy metrics enhance, rather than impede, children’s timely access to the most appropriate provider for the care they need on an in-network basis. Therefore, we recommend that CMS require standards that go beyond time and distance to ensure access to care for children with serious, complex or chronic conditions, many of whom rely on Medicaid for their coverage and care. For instance, as noted above, there may not be an appropriate children’s hospital available within the required time and distance standards. However, if the plan has arranged for access to an appropriate children’s hospital as an in-network provider outside the geographic region, the state should still approve the network. In fact, a state should require plans to arrange for access to an appropriate children’s hospital as an in-network provider when one is not available within the geographic (service area) region.

To comport with the above recommendations, we urge CMS to consider the following changes to its proposed regulatory language under this section [changes in italics]:

“At a minimum, a State must develop network adequacy standards, which may include, but should not be limited to, time and distance standards, when appropriate, and which take into account the regionalization of specialty care for children and adults with serious, chronic or complex conditions for the following provider types, if covered under the contract. State standards should include a broad set of measurable criteria and any other requirements that the state deems appropriate to assure access to all covered services by appropriate in-network providers. When developing quantitative criteria, states should incorporate the following, without relying on a single metric alone to avoid a false assessment of adequacy; factors to consider include, but are not limited to: 1) Enrollee ratios by specialty; 2) Primary care/enrollee ratios; 3) Geographic accessibility, with appropriate adjustments for geographic differences and for the regionalization of specialty care to assure access to all covered services; 4) Geographic population dispersion; 5) Wait times by specialty, based on provider hours and availability; 6) The volume of technological and specialty services available to serve the needs of covered persons requiring technologically advanced or specialty care, diagnostics or ancillary services; 7) Minimum appropriate providers available to meet the needs of children with special health care needs, adults with physical and mental disabilities, and enrollees with limited English proficiency, and diverse cultural and ethnic backgrounds.”

Finally, we respectfully remind CMS that there is no state-of-the-art knowledge regarding network adequacy metrics for pediatrics. Therefore, it may be necessary in the near or distant future to modify the measures and standards for plans to reflect changes in practice patterns, demographics and other factors. In order to ensure that the standards accurately assess children’s access to the most appropriate providers for their care, CMS must implement strong, ongoing monitoring and analytical strategies. Furthermore, the standards development and implementation process must be nimble enough to adapt as health care delivery and population needs change.

- **Long-Term Services and Supports (LTSS) (§438.68(b)(2))**

We are pleased that the proposed rule recognizes that separate network adequacy standards should be developed to ensure access to LTSS and we strongly support the development of pediatric-specific network

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\(^3\) See Children’s Hospital Association’s analysis, *An Examination of Certain Network Adequacy Measures and Their Potential Impact on Children’s Access to a Children’s Hospital*
adequacy standards for these providers. LTSS are an absolutely critical component of care for children with special health care needs. These children must have access to the full range of pediatric therapists, home health care and other providers with the specific expertise and experience to meet their unique needs. Adult LTSS providers do not have the requisite training or capabilities to provide the range of services that will help children acquire their most functional level. The availability of in-network pediatric LTSS providers can mean the difference between a child talking and not talking, walking and not walking, or needing special education and being able to join a regular classroom.

Furthermore, additional metrics beyond or instead of time and distance should be adopted for LTSS, given the unique nature of these services, including availability, service and utilization patterns. At a minimum, the elements included in §438.68(c)(1), along with the additional elements we recommend in our comments on §438.68(c)(1), should be required as well.

- **Scope of network adequacy standards (§438.68(b)(3))**
  We respectfully urge CMS to require, rather than permit, states to develop standards to take into account geographic variations, as well as geographic accessibility of providers, and population dispersion. We agree that network adequacy standards should vary for provider types based on geographic areas and remind CMS that (as noted above) these variations and their impact on beneficiaries’ access to care are particularly pronounced for children in need of the specialty care provided by children’s hospitals.

- **Development of network adequacy standards (§438.68(c)(1))**
  We are pleased that CMS recognizes that there are additional elements which must play into the development of network adequacy standards, but urge the agency to require states to specifically demonstrate that these elements have been incorporated into their standards. As currently proposed, states must “consider” these elements when developing their standards. We strongly believe that these elements are critical aspects of appropriate and robust network adequacy standards, should be part of states’ minimum standards, and be subject to state and CMS review and oversight. Therefore, we urge CMS to clarify that states must include these elements as objective network adequacy measures. As we have noted above, no individual measurement is likely to ensure access, and in fact, if used alone, may provide a false assessment of network adequacy.

  We further recommend that CMS clarify in this section that states must utilize a multi-faceted set of measures specific to each unique cohort of beneficiaries, particularly children with serious, complex or chronic conditions. These metrics should address wait times by specialty, based on provider hours and availability; availability of technological, diagnostic and ancillary services for children; and patient and family feedback on network access.

- **Exceptions process (§438.68(d))**
  We urge CMS to strictly limit a state’s option to permit exceptions to very rare circumstances and health conditions. For example, plans must not be allowed to secure exceptions solely because the appropriate provider is in another state. Reliance on appeals, grievances or other processes to account for access to specialty care reflects an inadequate network, which should not be approved by the state. Plans must be required to design networks that ensure access to appropriate in-network providers for all covered services and must not be allowed to rely on out-of-network arrangements, exceptions processes and other mechanisms that create barriers and burdens for sick children in need of care.

  We, also, respectfully remind CMS that an overly generous exceptions process that impedes access to necessary care could be discriminatory based on health status and violate the non-discrimination provisions of the Affordable Care Act (ACA) and Medicaid access requirements. In order to avoid discriminatory practices, plans must be able to ensure that patients have access to covered health services from a full range of in-network providers, including children’s hospitals and other regional specialty providers.
Therefore, we encourage CMS to disincentive states from allowing plans to have an exceptions process. However, if exceptions processes are permitted, they must be well-documented, timely, and transparent, and must not be utilized as an alternative to the inclusion in networks of the full range of providers to ensure timely access to covered services. We also recommend that the processes be standardized for all MCOs and not be specific to each plan. In addition, there must be established timelines, and processes must be subject to regular review and oversight by the state with regular reports provided to CMS. Oversight of exceptions should be used as a mechanism to identify network inadequacies. When networks are found, through this oversight, to be inadequate, states and plans should be required to offer proof that networks will be supplemented to achieve adequacy. Finally, exceptions processes must include specific reimbursement requirements to require payers to reimburse out-of-network hospitals the reasonable and customary value or other agreed-upon rates for out-of-network services.

Availability of Services (§438.206; §440.262)

We are pleased that the proposed rule specifically identifies the adequacy of the provider network as a required component of a state’s assurance that all services covered in the state plan are available and accessible in a timely manner. We offer several recommendations to further ensure that children have access to available services in a timely and appropriate manner.

- **Delivery network §438.206(b)**
  - We support the proposed rule’s requirement that states ensure that plans maintain and monitor a network of appropriate contracted providers, but recommend that the standard be strengthened.
    - Specifically, we recommend the following changes to §438.206(b)(1)[additional language in *italics*]:
      
      (1) Maintains and monitors a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to all services covered under the contract for all enrollees…

      We make the above recommended changes because we are concerned that the phrase “adequate access” will not, in fact, ensure that the network is sufficient to assure timely access to all covered services. In addition, we recommend that CMS add a requirement that the contract include appropriate payment for all covered services to ensure that providers are, indeed, accessible.

      We emphasize the importance of meeting all the needs of covered children through in-network access to services provided through the EPSDT benefit. To meet the standard under this section, states must review plan networks for their full range of trained and experienced pediatric providers and only allow the use of out-of-network arrangements or procedures under very rare or unanticipated circumstances. A reliance on, or over-use of, out-of-network providers impedes timely and appropriate care, which could be catastrophic for a child’s long-term development and health. Furthermore, as noted in our comments to §438.68(d), inadequate access to providers could be in violation of EPSDT requirements and federal non-discrimination laws.

      - We recognize that out-of-network arrangements may be necessary for very rare conditions or due to a provider shortage and make the following comments and recommendations to ensure that, under those circumstances, children have timely and appropriate access to the care they need:

        - We agree with CMS that the plan must be able to cover out-of-network services in a timely manner and at no greater cost to the enrollee than if that care was provided in-network.

        - We urge CMS to require plans to provide access to out-of-network providers when there is no provider in-network to provide care for a very rare condition or when there is a provider shortage **without** requiring the enrollee to use an appeals process.
- CMS should establish a specific timeliness standard for plan approvals for out-of-network care so care is not delayed inappropriately when it must be provided out-of-network

- Plans should be required to submit to the state for review and approval a well-documented and transparent out-of-network approval process

- States must require plans to monitor and report on the timeliness of reviews for out-of-network and referred services and their disposition, including documentation that appropriate clinical standards are used to evaluate requests

Finally, we strongly recommend that CMS require state payment standards for out-of-network providers that would reimburse the reasonable and customary value for those services, which could be billed charges or an alternative agreed-upon rate. Plans should be prohibited from paying out-of-network providers less than the state’s defined in-network rate.

- Timely access §438.206(c)(1)
  - We agree with CMS that states should establish standards for routine, urgent or emergency care which take into account state patterns of care, availability of providers and geographic variations, as well as other relevant criteria. However, we believe that CMS should strengthen the timely access requirement as follows:
    - CMS should establish minimums or benchmarks for timely access, which state standards must meet or exceed, to ensure that enrollees have access to care when they need it
    - States should be required to confer with clinicians and other providers for their clinical expertise and perspective on appropriate standards
    - States should be required to establish separate standards for primary and specialty care (routine, urgent and emergency)
  
  - We are pleased that CMS recognizes the importance of states taking an active role in overseeing plan’s compliance with timely access and network adequacy standards under §438.206(a) and 438.206(c), as noted in the preamble to the rule. Compliance reviews should start with a state’s direct review of a plan’s network as part of the contract review and approval. States should also be required to audit plan’s provider directories at regular intervals to ensure that networks remain adequate throughout the coverage period and to require the plan to take corrective action in the event a network is determined to be inadequate at any time during the contract period.
  
  - We believe that the mechanisms identified in the preamble to the proposed rule to assess compliance are appropriate, including enrollee surveys, review of encounter data, reporting of HEDIS measures, secret shoppers, and systematic evaluations of consumer service calls. We support a requirement that states use a multi-faceted approach to oversight as there is no single mechanism that will accurately and completely assess enrollees’ access to timely care and plans’ compliance with state and federal standards. In addition, we recommend the inclusion of regular documentation/tracking of appeals for out-of-network providers and the timeliness/disposition of those appeals as an oversight tool. We also strongly believe that requirements for state compliance reviews must include procedures to ensure corrective actions when a plan is not in compliance. Finally, we wish to highlight the importance of the use of quality measurement in the evaluation of plans’ network adequacy.
Assurances of Adequate Capacity and Services (§438.207)

Nature of supporting documentation §438.207(b)
We urge CMS to require plans to specifically address access to pediatric specialty services when filing their provider network information with the state. To do so, states should establish reporting requirements on access to care for children with special health care needs, including access to appropriate children’s hospitals, behavioral health services, and LTSS, to ensure access to all services covered under the EPSDT benefit. Plans should expressly be required to report on the utilization of services by this population, including the nature of the services, their location, and the extent to which these services were provided outside the contracted networks. In addition, plans should be required to submit data on both authorizations and denials of referrals within and outside their network, including specific data on referrals to specialty care for children with serious, chronic or complex health conditions and the disposition of those referrals and any related appeals.

We also ask that CMS require plans to take corrective actions when there is a consistent pattern of referrals to, and utilization of, out-of-network specialty providers. Because a pattern of referrals to out-of-network providers indicates an inadequate network, plans must be required to supplement their networks in a timely manner. Under these circumstances, plans should be required to submit interim reports to the state to demonstrate that they have taken the appropriate steps to strengthen their networks. Furthermore, states should specifically conduct regular reviews, throughout the calendar year, of plan denials of referrals. We respectfully remind CMS that simply including a pediatric specialist, subspecialist or hospital in a network does not guarantee a child will have access to the services promised through EPSDT if a plan denies the referral to those providers. When the state identifies a pattern of denials that may impede a child’s access to appropriate care, corrective action with supplemental documentation should be required immediately.

Timing of documentation §438.207(c)
- We agree that plans should submit documentation of its network’s adequacy when there is a significant change in the plan’s operations that affects its capacity or services, such as changes in its benefits, service area or provider networks. We ask CMS to consider clarifying what would constitute “significant change” to provide guidance to states as they define this standard. At a minimum, we recommend that CMS define “significant change” as “a change in the composition of a plan’s provider network or a change in size or demographic characteristics of the population enrolled that renders the plan’s network non-compliant with one or more of the network adequacy standards set forth in federal and state law and implementing rules.” Examples of a significant change under this definition would include the termination of a contract with a children’s hospital or other specialty provider. We believe that a standard definition of this concept is needed so state assessment of plan compliance is based on generally uniform standards. A minimal framework would also ease CMS review of states’ certifications of plan documentation.

- We agree that plans should submit documentation when new populations are enrolled in the plan. Different populations will have varying health care needs and may utilize different types of providers, which could necessitate changes in health plan networks. States must be able to assess on an ongoing basis whether these changes have impacted access and availability of services.

State review and certification to CMS §438.207(d)
We agree with the continued requirement that plans demonstrate, and states certify to CMS, that their networks include a full range of providers to meet anticipated need and that they are sufficient in number, mix and geographic distribution. We wish to emphasize that determinations of network adequacy are ultimately the responsibility of the state Medicaid agency, not the health plans. Therefore, the documentation that states require of the plans must be robust enough to enable state agencies to independently assess plans’ compliance with the quantitative metrics and other standards established by the state and CMS.
We are extremely pleased that the proposed rule and preamble expressly note that CHIP serves a child-focused population with unique health care needs and requires specific network adequacy standards for pediatric specialists. However, we offer the following recommendations to ensure that children covered by CHIP have access to the care they need when they need it.

- **We seek clarification on the requirement in the proposed rule that states develop these standards “if covered under the contracts.”** We encourage CMS to clarify that covered CHIP services includes inpatient and outpatient services, physician services, clinic services, laboratory and x-ray services, and prescription drug coverage. Thus, CHIP network adequacy standards must ensure that enrolled children have access to the full range of pediatric primary, specialty, and subspecialty services to provide these covered services.

- **We respectfully, but strongly, caution CMS against relying on time and distance standards as indicators of network adequacy.** As we note previously, distance standards alone may provide a false assessment of network adequacy. The limitations of Medicare Advantage distance standards in the assessment of network adequacy for pediatric care are particularly profound. A CHA analysis indicates that almost half of all children nationwide would not have access to the specialty care provided through an acute care children’s hospital if adult distance metrics are used to determine network adequacy, given the regional nature of pediatric specialty care. We, therefore, urge CMS to require the development of a multi-faceted quantitative standard of network adequacy that will evaluate networks for their breadth of providers that have the unique capabilities, expertise and capacity to care for children of all ages and with all health conditions. We also note that plans that have arranged for in-network access to specialized pediatric care outside a geographic region may meet network adequacy requirements.

- **We strongly recommend that CHIP plans be required to meet network adequacy standards specific to children’s hospitals, as well as pediatric behavioral health providers.**
  - To serve children adequately, CHIP plan networks must include one or more appropriate pediatric hospital providers that maintain comprehensive pediatric specialty services. Our recent analysis of the capacity and capability of children’s hospitals in comparison to non-children’s hospitals demonstrates the importance of ensuring timely access for children covered by CHIP to the full continuum of care provided by children’s hospitals. For example, the children’s hospitals included in this analysis provide, on average, more than six-fold the number of selected pediatric services than non-children’s hospitals, and have more than twenty-five-fold the number of pediatric-designated beds. Children’s hospitals located in three states see greater than 60 percent of all occurrences for 21 different pediatric services.

  - Network adequacy standards should include specific standards for pediatric behavioral health providers for CHIP plans that must cover those services under EPSDT, as well as for separate CHIP plans that choose to cover them. Children in lower income households, including those who enroll in CHIP, are at higher risk of mental and behavioral health problems. CHIP plans that cover mental and behavioral health services must ensure access to in-network providers with the clinical training, expertise, and capacity to both diagnose and treat children using developmentally appropriate and evidence-informed practices. However, given the current shortage of mental health services for children, we caution CMS against using time and distance metrics as the sole metric for

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4 See Medicaid and CHIP Payment and Access Commission; Key CHIP design features https://www.macpac.gov/subtopic/key-design-features/

5 See Children’s Hospital Association’s analysis, An Examination of Certain Network Adequacy Measures and Their Potential Impact on Children’s Access to a Children’s Hospital, 2015.

6 Children’s Hospital Association’s analysis, An Examination of Certain Network Adequacy Measures and Their Potential Impact on Children’s Access to a Children’s Hospital, 2015.
determining whether a network provides children with timely access to those services. Instead, we recommend that the agency require a multi-faceted standard per our comments above and on §438.68(b)(1). We also recommend that information on appointment wait times for pediatric mental and behavioral health providers, as well as their areas of expertise, be a required component of provider directories.

To comport with the above recommendations, we urge CMS to consider the following changes to its proposed regulatory language under this section [changes in italics]:

“In addition to developing standards….the state must develop time and distance standards (including, but not limited to time and distance standards, if appropriate) for dental providers and pediatric specialty and subspecialty providers to ensure that children have timely access to all covered services under the plan. The standards should take into account the regionalization of specialty care for children with serious, chronic or complex conditions.

State standards should include a broad set of measurable criteria and any other requirements that the state deems appropriate to assure access to all covered services by appropriate in-network providers. When developing network adequacy criteria, states should incorporate the following, without relying on a single metric alone to avoid a false assessment of adequacy; factors to consider include, but are not limited to: 1) Enrollee ratios by specialty; 2) Primary care/enrollee ratios; 3) Geographic accessibility, with appropriate adjustments for geographic differences and for the regionalization of specialty care to assure access to all covered services; 4) Geographic population dispersion; 5) Wait times by specialty, based on provider hours and availability; 6) The volume of technological and specialty services available to serve the needs of covered persons requiring technologically advanced or specialty care, diagnostics or ancillary services; 7) Minimum appropriate providers available to meet the needs of children with special health care needs, adults with physical and mental disabilities, and enrollees with limited English proficiency, and diverse cultural and ethnic backgrounds.”

Finally, we agree with CMS that, to the extent possible, network adequacy standards should be aligned between Medicaid and CHIP. We refer you to our specific comments and recommendations in this letter, which address the unique needs of children and are intended to ensure that they have timely access to the full range of health care services to support their healthy development. We would also encourage CMS to continue to monitor the National Association of Insurance Commissioners’ work to develop model standards for commercial plans. The alignment of appropriate and robust standards for plans across the public and private insurance markets can offer important protections to children and families who may move between markets as their incomes or family situations fluctuate. Continuity of provider when possible and assurance of timely access are particularly important to children in families with unstable financial situations or who face other stressors.

MANAGED CARE OVERSIGHT, RATES AND EXPENDITURES

CMS Review of Managed Care Plans and Contracts and State Monitoring Systems

We appreciate CMS’s proposed efforts to review and approve Medicaid and CHIP plan contracts and the rates for services provided under managed care. We believe the promise of additional oversight will be helpful to ensure Medicaid beneficiaries have access to a breadth and depth of providers and services to meet their health needs. Meaningful oversight is important to ensuring managed care meets the needs of beneficiaries and assisting with appropriate enforcement of managed care rules. This oversight will likely require additional resources for both states and CMS to ensure the timely negotiation and approval of plan rates and contracts.

While we believe the oversight goals of the proposed rule are achievable, we ask that CMS ensure the agency and states have sufficient resources to implement and oversee implementation of the managed care requirements. We also ask CMS to ensure there are not adverse consequences for beneficiaries and providers if there are not sufficient state and federal resources to complete plan and rate review and approvals in a timely manner. We are concerned that states and CMS may not currently have the capacity to adequately fulfill all of the plan review and approval requirements outlined in the rule by 2017. We recognize that meaningful oversight and review will not be achieved in reality if there is
insufficient capacity to conduct these activities. Furthermore, we are concerned that inadequate oversight resources can result in delays in contract approval to provide states, plans, and providers certainty or lead to lowered standards for the quality of these reviews.

State Contract Requirements and Provider Discrimination Prohibited (§438.3; §438.12)

We have been concerned about access to pediatric specialists even when these specialists are in network due to the inability to refer to these providers. We note that §438.3(l) allows beneficiaries to have a choice of health professionals. We request that CMS expand §438.3(l) to ensure the managed care contract does not discriminate against particular providers or prohibit referrals to providers that serve high-risk populations or specialize in conditions that require costly treatment.

We also request that CMS require plans to include documentation to states of their standards for provider contract terminations. In addition, CMS should require contracts between states and plans to include a process for how plans will handle the termination of providers from their network and allow providers an opportunity to respond to a notice of a termination proceeding or appeal a decision. These standards should include ensuring providers are given written notice of the termination and the reason for the decision. To strengthen these plan contract requirements, we also ask that CMS modify §438.12 to specify that written notice requirements apply to providers seeking to be included in a plan network and those that are terminated from a plan network.

Actuarial Soundness (§438.4)

We believe managed care rates should be actuarially sound so that beneficiaries have access to medically necessary services and a breadth and depth of providers to deliver these services. We strongly agree with CMS that review of actuarially sound rates should include network adequacy. We recommend that that appropriate referral to specialty providers should be a component of any review of actuarial soundness as part of the network adequacy review.

We note that actuarial soundness should take into account rates for specialty hospitals separately from general community hospitals and rates should be appropriately risk adjusted. Aggregating specialty and general care costs, particularly for pediatric care, can be problematic for hospitals that treat large volumes of children with serious, complex or chronic conditions. Rates should be differentiated by the complexity of the medical condition and the population volume seen by certain provider types. We are concerned that rates for specialty pediatric providers may not be representative of the population treated or care provided if they are aggregated with general care provided for adults.

Given that many states are engaged in various delivery system initiatives, we also believe there is a need for CMS to examine actuarial soundness and the long-term opportunities and challenges these initiatives may have on the rate setting process. We encourage CMS to consider how value-based payment and shared savings models affect capitation rates when reviewing actuarial soundness. There is a need for a mechanism to share savings in a capitated system to avoid long-term, unsustainable downward pressure on rates that may not be captured in a single-year rate review. We are concerned that if these initiatives are not considered when looking at a plan’s actuarial soundness, there could be long-term consequences to rates that are not sustainable by plans and providers. This can undermine the success of true delivery system reform.

Special Contract Provisions for Payments (§438.6)

We urge CMS to modify the proposed §438.6(c) to provide additional flexibility for states to direct expenditures to promote access to services from safety net providers, engage in future delivery system efforts and tailor payment models for specific provider types or populations. We are pleased CMS is taking steps to ensure delivery system initiatives can be conducted through managed care as many children's hospitals are actively leading and participating in these efforts. We are supportive of efforts to ensure states are able to use managed care to incentivize and retain providers while also improve care and efficiency in Medicaid. We believe allowing states to set reimbursement standards for particular provider types will be important to improving access to pediatric specialists, reducing provider shortages and maintaining policy to pay primary care
providers and others at Medicare payment levels. However, we believe the current list of exceptions for state-directed expenditures limits states’ ability to achieve the goals CMS outlines in the preamble of the proposed rule. In addition, we believe the section as proposed may inappropriately assume a “one-size-fits-all” model should be applied to all provider types and populations under new Medicaid payment models. Specifically:

- **We recommend a fourth exception under §438.6(c)(1) to allow states to direct managed care payments to promote access to and retain certain types of safety net providers so beneficiaries receive timely and appropriate care.** While CMS states in the preamble it is codifying existing guidance, we believe the proposed rule as written would prevent states from retaining safety net providers by limiting the use of supplemental payments and other payment arrangements and models under managed care. Many states currently provide additional payments to providers through managed care in order to promote access to services and retain providers that treat large volumes of Medicaid patients. These payment arrangements play an important role in Medicaid by ensuring beneficiaries have access to a breadth and depth of providers and unique services while addressing Medicaid underpayment for certain groups of providers. While we recognize the proposed rule intends to improve managed care rates so they account for actual health costs and better relate to quality and delivery system initiatives, we believe that existing payment programs need to continue into the near future without requirements to restructure payments in the prescriptive manner currently described in the proposed rule until the goals of improving payments in Medicaid can be achieved.

In addition, states should be allowed to target these payments to certain provider types or unique services as appropriate, and we would not recommend applying the requirements for approval at §438.6(c)(2)(ii) for the exception we propose. On average, Medicaid reimburses children’s hospitals only 77 percent of the cost of care provided, including Disproportionate Share Hospital payments. Until each state’s Medicaid program payments cover the cost of care, limiting states’ ability to continue various supplemental and other payment arrangements will serve as a barrier to access to care for certain providers and services.

- **We recommend that CMS broaden the exceptions listed in §438.6(c)(1) to accommodate future delivery system initiatives to improve care and efficiency in Medicaid while also incentivizing and retaining providers.** The list of exceptions in the proposed rule is prescriptive and may not encompass all delivery system, population health and quality initiatives currently employed by states. In addition, the rule may not provide enough flexibility for states to use Medicaid and CHIP managed care to engage in future delivery system and population health efforts that have yet to be envisioned. Given the changes to managed care and our health care system over the last decade, it is imperative that states and Medicaid programs are able to evolve to meet unknown future opportunities and challenges of a changing health care landscape. The managed care regulations should allow states using managed care to adapt to new payment models that meet the goals of aligning payment with value-based purchasing and quality initiatives.

- **To fully achieve the goals of improved care and efficiency in Medicaid, we request clarifying language under §438.6(c)(2)(ii) to allow states to engage in initiatives targeted at specific providers or populations and use modified performance measures when appropriate.** CMS proposes contract arrangements that direct certain managed care plan expenditures must extend to all managed care providers participating under the contract. In addition, CMS also proposes that these arrangements must use a common set of performance measures across all payers and providers. While we appreciate CMS’s efforts to provide continuity for these efforts across a state’s Medicaid program, we believe this language may limit state flexibility to engage in multiple payment models based on provider type or population or pilot value-based purchasing and other quality initiatives under managed care for certain populations.

We believe states need the flexibility to target and tailor payment models for various providers and populations, which is especially important for children who have different health needs than adults and their care results in different expenses and costs. Payment models tied to quality initiatives should not be “one-size-fits-all” and multiple models in
a state can align with overall quality goals. For example, several states are proposing bundled payments for public and commercial payers to push systems beyond fee-for-service (FFS). While laudable, at least one state has made appropriate exceptions for calculating specific child or pediatric bundles for some conditions separate from those of adults and for allowing some groups of children in more comprehensive risk-based arrangements like capitation to be exempted from bundling schemes. Other states are testing payment models for pediatric patients instead of relying on models only tested for adult providers or adult populations. We are concerned arrangements that benefit children served by Medicaid may not be developed or continue under the proposed rule if all providers are required to engage in a particular delivery system initiative or payment model.

Similar challenges for pediatrics also exist when requiring a common set of performance measures across all providers. It can be problematic for children’s hospitals to adapt measures designed for care provided to adults in hospitals since children often have different health needs and the epidemiology of disease is often different in children than adults. Requiring a common set of performance measures without considering modifications based on provider type and populations served by different providers under the contract will limit the ability of Medicaid to appropriately improve care for all beneficiaries served.

Medical Loss Ratio (§438.8)

We appreciate that CMS proposes to include activities that improve health care quality in the numerator of the medical loss ratio (MLR) calculation. We believe it is important that managed care plans are able to consider health costs associated with these activities that are integral to improving population health, increasing quality of care and implementing delivery system initiatives. However, we believe additional activities are needed to ensure the MLR calculation reflects services unique to pediatric health and account for a number of population and prevention health activities critical to children. Specifically, we recommend that CMS include prevention activities and interventions in the community for children. The inclusion of these activities will address a range of issues that affect pediatric medicine such as addressing social determinants of health and assisting parents of pediatric patients.

We are also concerned that activity requirements listed under 45 CFR 158.150(b)(iv) may inadvertently prevent managed care from supporting pediatric health care quality related activities. CMS proposes that activities conducted by an issuer to improve quality must “be grounded in evidence-based medicine, widely accepted best clinical practice, or criteria issued by recognized professional medical associations, accreditation bodies, government agencies or other nationally recognized health care quality organizations.” While we believe there should be parameters to ensure activities are evidence informed, we are concerned that limited research in pediatric medicine will preclude plans from supporting pediatric quality activities. Many children’s hospitals are innovating and generating new evidence to support adoption of interventions targeted for children, and additional flexibility is needed in the MLR calculation for pediatric medicine. We also believe the public health community should be added to the list of acceptable criteria as this would capture many of the quality efforts currently aimed at children.

State Monitoring Requirements (§438.66)

We applaud CMS for outlining what must be included in a state’s monitoring system for managed care plans. We specifically support that plan performance must include provider network management, availability and accessibility of services, quality improvement and delivery of long-term services and supports. We urge CMS to also monitor plan performance for pediatric services to better enforce managed care requirements for children.

In addition, we are supportive of efforts to collect additional Medicaid data from plans and states in a consistent manner. The data requirements and analyses that plans and states must provide as part of the state monitoring activities may assist in the development and refinement of delivery system initiatives and improve understanding of Medicaid’s impact on small subpopulations of children. States and plans often inconsistently report data, which can be a barrier to improving care for children with rare or complex conditions. We believe the additional data requirements are a step in the right direction to better understand the quality of care provided by Medicaid for all subpopulations of beneficiaries.
QUALITY

Quality Assessment and Performance Improvement Program (§438.330)

It is critical that CMS differentiate and specify quality assessment and performance improvement programs for children. The health needs of children and services provided for their care are different than those of adults. Appropriate attention should be paid to assessing the quality of care and outcomes for children within specific subpopulations, especially among those where disparities are known to exist.

We are encouraged by and support CMS in identifying important and impactful performance measures. States’ participation in reporting measures in the Child Core Set greatly contributes to understanding how successful Medicaid and CHIP programs are in delivering high-quality care to their enrollees. We encourage CMS to continue to critically examine the existing Medicaid/CHIP Core Set, and replace less impactful measures. To that end, CMS should continue working with the National Quality Forum’s (NQF) Child Medicaid Measure Applications Partnership, which makes recommendations to CMS intended to strengthen the measure set and support CMS’s goals for the Child Core Set reporting program. We encourage CMS to continue their work with states to increase the number reporting Core Set measures, increase the number of measures reported by each state, and increase the number of states using Core Set measures to drive quality improvement. We also encourage CMS to continue to critically examine the existing Medicaid/CHIP Core Set, and replace less impactful measures. Further, while we support the inclusion of preventive care measures, we encourage CMS to include measures for all subpopulations of children; including children with complex conditions who are our most vulnerable and require substantial resources.

We encourage CMS to also clarify and specify required data collection and submission. It is important that the data provided on reported measures in Medicaid and CHIP is consistent to provide a much clearer picture of the quality of care and outcomes for children nationwide. The expectations for the quality of the data submitted should be strengthened so that we can understand the quality of care provided within and across states. This will allow providers, plans, states and CMS to identify gaps and incentivize smarter spending in Medicaid and CHIP.

State Review and Approval of MCOs, PIHPs and PAHPs (§438.332)

We are supportive of CMS’s efforts to align accreditation and review standards to allow for more efficient and effective implementation by managed care organizations (MCOs). However, we have concerns that this alignment will miss necessary differentiating standards to ensure the delivery and outcomes of children are at the highest standard. Medicare Advantage and QHPs were designed for adults, and we strongly urge CMS to ensure the needs of children are reflected in efforts for plan approval and accreditation.

Medicaid Managed Care Quality Rating System (§438.334)

We appreciate the challenge of creating a quality rating system for Medicaid managed care plans that is informative and useable for consumers shopping for a health plan. Given that half of Medicaid beneficiaries are children, any quality rating system should be appropriate and adequate to reflect the care provided to children, including all subpopulations of children. While we are supportive of efforts to align plan rating systems, we request CMS ensure pediatric-specific ratings are available that use underlying measures important and relevant to children and their caretakers.

We believe any rating systems must address all of the populations served and address the care provided by a range of services. We are concerned that combining measures into a star rating system may not adequately reflect the needs of certain patient populations, such as children with medical complexity. Aggregate ratings that do not address critical sub-populations and quality domains may result in insufficient information to guide the choice of plans and prioritization of quality improvement efforts by plans. In addition, the information needs to be clear and useable for a range of consumers who will value certain services and quality improvement efforts differently. For example, a low-income, childless adult will search for a different plan
than a parent of a child with severe asthma. Likewise, the pediatric population is heterogeneous, and a parent with a child diagnosed with cerebral palsy may look for the quality of specialty services provided by a plan that may not be as important to a parent with a child that only requires standard preventive care.

We note that any quality rating system should be dynamic and improved upon over time. We are concerned about the limited scope of measures that address pediatric health care and outcomes to adequately reflect how plans rate for children, particularly children with medical complexity. **We urge CMS to carefully test, evaluate, and refine the rating methodology over time, particularly as new measures become available that better capture the needs of the various subpopulations served by Medicaid.** We further encourage CMS to increase states’ awareness of national-level measure leaders when identifying measures, for example, NQF.

**Managed Care Elements of the State Comprehensive Quality Strategy (§438.340)**

We applaud CMS for requiring states to conduct a comprehensive quality strategy across all aspects of Medicaid and CHIP. We believe this effort can bring a renewed focus on the quality of care provided by Medicaid and CHIP beneficiaries and presents an opportunity for CMS to focus on healthy child development and the needs of children with special health care needs. **We recommend CMS require states to specifically consider pediatric quality improvement in any comprehensive strategy and use a range of pediatric measures that capture the needs of all subpopulations of children, including children with medical complexity.**

We believe the comprehensive quality strategies present an opportunity to spread the use of the pediatric Medicaid/CHIP Core set and continue to leverage and build on the pediatric quality improvement efforts through the Pediatric Quality Measures Program (PQMP). In addition to placing a stronger emphasis on pediatric quality, we encourage CMS to:

- Replace less impactful measures with validated measures coming out of the PQMP and other sources relevant for the various populations served by Medicaid;

- Ensure a pipeline of much needed pediatric quality of care and outcomes (health and costs) measures. Clinical evidence, science, and data availability changes over time, and we want pediatric measures to be responsive to these changes so they accurately reflect the quality of care for children; and

- Require the reporting of a *minimum* core set to move away from voluntary reporting in order to better demonstrate trends and understand how the Medicaid program operates across the country.

We also agree with CMS that network adequacy and availability of service standards are quality measures, and we support CMS’s proposal that states’ comprehensive quality strategies must include these access standards. We encourage CMS to specify that state quality strategies must look at all populations served by Medicaid when reviewing network adequacy and availability of service standards.

We support CMS’s efforts to review state quality strategies. We believe this will assist CMS in ensuring that all states are working toward common national objectives to improve care for all Medicaid beneficiaries. We do want to ensure CMS has sufficient resources to conduct an adequate and thorough review of state quality strategies. We believe appropriate review of these strategies by CMS is important for achieving long-term quality goals of the Medicaid and CHIP programs. We are also supportive of efforts to include CHIP in the state comprehensive strategy. This will help align quality standards for similar populations of children between the two programs. If CHIP is included in the comprehensive strategy, it is even more important that state quality strategies differentiate between pediatric and adult quality efforts and address all subpopulations of children.
**STRENGTHENING CHILDREN’S HEALTH**

**340B Drug Discount Program (§438.3(s)(3))**

We appreciate that the regulation correctly implements the Medicaid rebate statute by maintaining that states, not 340B covered entities, are legally responsible for protecting manufacturers from having to pay both a 340B discount and a Medicaid rebate on a managed care claim. The Affordable Care Act amended the Medicaid rebate statute by requiring manufacturers to provide rebates for drugs dispensed to individuals enrolled in MCOs but specifically excluded 340B MCO drugs from the rebate requirements. Thus, 340B MCO drugs are not subject to rebates. This means that the duplicate discount provision in the 340B statute would not apply to 340B MCO drugs because that provision only applies to 340B drugs that are subject to rebates. Since 340B MCO drugs are not subject to rebates, the provisions of the 340B statute imposing liability on covered entities for creation of duplicate discounts do not apply when the underlying drug is an MCO drug.

In addition, we welcome the flexibility provided by the rule, as a one-size-fits-all solution would not be appropriate given differences between 340B pharmacies. In particular, we appreciate that CMS has not proposed that all pharmacies must identify 340B Medicaid MCO claims at the point of sale (POS). Such a methodology would be impractical given that some covered entity-owned outpatient pharmacies and most contract pharmacies use a virtual 340B inventory. For such pharmacies, 340B patient eligibility determinations are usually made after a drug is dispensed to a patient. The pharmacies do not know at the POS whether a claim is for a 340B drug. Therefore, a single methodology requiring identification of all 340B claims at the POS would not work for these pharmacies. However, we believe CMS could provide further flexibility by permitting states to decide whether it would be better for covered entities to report 340B claims directly to the state or its rebate contractor instead of having the reports go through MCOs.

We are also concerned that, without further guidance from CMS, some MCOs might establish methodologies for identifying 340B claims that could make it difficult or impossible for some entities and contract pharmacies to use 340B for Medicaid managed care patients. Therefore, we ask that CMS protect this right by explicitly acknowledging it in the rule and by including guidelines and limits for how MCOs can implement the rule. Without guidance, there is a risk that states and MCOs could use methodologies for identifying 340B claims that would make it difficult or impossible for covered entities to exercise that right.

**Information Requirements (§438.10)**

We believe the proposed minimum requirements that states and managed care plans must provide potential enrollees about managed care and how to access Medicaid services are a good step for improving transparency for beneficiaries. Particularly, we believe the requirements at §438.10(e) are especially important for children who are entitled to medically necessary services under EPSDT.

To further strengthen §438.10(e) for children, we recommend CMS also specify that states and managed care plans must provide information to families with children about EPSDT and how to access these benefits. We have been concerned that families may not be aware of the range of benefits their child is entitled to under Medicaid and who is responsible for ensuring their child receives those benefits. We believe providing beneficiaries information on the benefits provided by the managed care plans and any benefits provided by the state will help children seamlessly access medically necessary services, particularly when behavioral health and other services are carved out of managed care.

We also believe that enrollees must have the information they need in the provider directories to identify the specific types of hospital in a plan’s network—different hospital types have differing clinical expertise and experience. Accurate, up-to-date and easily accessible provider directories are a critical aspect of ensuring that beneficiaries understand their health plan. The information in the directory, when appropriately specific and up-to-date, will allow beneficiaries to identify the most appropriate providers, including those that have the specialty training, experience and capacity to meet their needs in the event their medical needs change or worsen. In addition, accurate provider directories serve as the fundamental
tool that enables enrollees to determine which providers are in-network when they enroll. Furthermore, providers also need accurate information to allow for in-network referrals when further, specialized treatment is warranted.

Therefore, we strongly suggest that plans include the following additional information in their directories:

- Listings of hospitals by type (e.g. general acute care, children’s, cancer, orthopedic, rehab)
- Hours of operation of provider offices
- Names and locations of the hospital(s) where the physician or other provider has medical staff privileges and whether those hospitals are part of the provider network
- Network tiering of providers (if applicable) and related cost sharing requirements
- Changes in cost sharing and out-of-pocket limit differentials (or other changes) that may result from using a non-participating provider for the pediatric population aged 19-20.

In addition, we support the requirement in the proposed rule that the beneficiary handbook include information about prior authorizations and referral processes. We encourage CMS to consider including information about these processes in the provider directory as well, to ensure that beneficiaries understand that there may be delays in accessing some specialty care and providers.

Finally, we are pleased that the proposed rule requires plans to notify enrollees of a “significant” change in information included in the enrollee handbook at least 30 days prior to the effective date of the changes. We urge CMS to require plans to also notify enrollees when there is a change in the provider network, particularly changes in hospitals or other specialty providers, including network tiering and related changes in cost sharing. The impact of inaccurate provider information on enrollees can be devastating, especially on those consumers who need to carefully examine networks for specific subspecialists, cancer centers, children’s hospitals, and other similar providers.

Continued Services to Enrollees (§438.62)

We thank CMS for its proposal to require states to establish transition of care policies to ensure beneficiaries have continued access to services as they transition between delivery systems or managed care plans within Medicaid. We believe transition of care policies are particularly important for promoting continuity of care for children. Disruptions in care for children can lead to lifelong consequences that affect a child’s quality of life and generate extensive and avoidable costs to the Medicaid and CHIP programs. We believe there are additional reasons why states should establish transition of care policies in addition to the policy outlined in §438.62(b). We recommend CMS modify §438.62 to ensure state transition of care policies also are developed and in effect when:

- **Beneficiaries transition from Medicaid managed care to Medicaid FFS.** While states are trending towards the expansion of Medicaid managed care, there are still times when a beneficiary may transition from managed care to FFS. Examples include children who become disabled or enter the foster care system.

- **States implement delivery system changes for certain populations or their entire Medicaid program.** States have increasingly modified their Medicaid programs to limit the use of FFS and move more beneficiaries into managed care. We believe anytime a state makes a major change in how Medicaid is delivered to beneficiaries that it should apply transition of care policies, regardless if the state is transitioning from FFS to managed care or vice versa.
• Special populations of children switching between plans and specific programs, such as children in foster care and the juvenile justice system. These children, who often have significant physical and behavioral health needs, are particularly vulnerable to coverage disruptions. States should be required to establish separate transition care policies to promote continuity of care and adherence to treatment for these special populations.

• Beneficiaries transitioning from FFS coverage to managed care after plan selection as described in §438.54(c)(2) and §438.54(c)(2). Under §438.54, CMS proposes that states must provide potential managed care enrollees, regardless if the program is voluntary or mandatory, with at least fourteen calendar days of FFS coverage so enrollees have an opportunity to actively select their managed care plan. We are concerned this policy could lead to discontinuity of care, particularly for children with special health care needs and pregnant women who need services during the time period they are enrolled in FFS.

• A provider leaves or is terminated from the enrollee's managed care plan. Managed care plan provider networks can change within and between plan years, which can be problematic for children and families who have developed a trusted relationship with a particular provider.

We also recommend §438.62(b) be modified to better meet the needs of children by requiring transition of care policies for enrollees when a disruption of services will impact the enrollee’s health and well-being, development, ability to maintain their level of functioning or otherwise impact anticipated health outcomes. We are particularly concerned the proposed §438.62(b) to require transition of care policies for circumstances when “in the absence of continued services, [the enrollee] would suffer serious detriment to their health or be at risk of hospitalization or institutionalization” is too limiting and may not appropriately protect children who may transition between providers, managed care plans or delivery systems. This language does not account for children who are in a course of treatment during the transition where disruption could impact or delay the expected outcome or those at risk of prolonged hospitalization and institutionalization. In addition, children with chronic conditions often have long-term relationships with their provider and could physically and mentally benefit from a transition of care policy even though they are not at risk of suffering a “serious detriment to their health.”

We are concerned the limitations of the proposed §438.62(b) would force children to leave a trusted provider or interrupt a course of treatment in many situations that would impact their health and well-being but not necessarily rise to the level of a serious health detriment or risk of hospitalization. We encourage CMS to modify the language to better promote continuity of care and ask CMS to consider recent draft language developed by the National Association of Insurance Commissioners that allows for transition of care policies when discontinued care would “interfere with anticipated outcomes.”

We note that transition of care policies should also take into account whether the patient’s old plan or new plan is responsible for care provided during a transition period. We believe CMS should require all transition care policies to specify the financially responsible party for the patient’s care during the transition, particularly if the patient is in the middle of an inpatient stay or course of treatment during the transition. We believe clear guidance is needed in these policies to determine when the original plan’s financial obligations end and when the new plan’s financial obligations begin to prevent confusion and undue burden on both patients and providers.

Beneficiary Support System (§438.71)

We support the establishment of a beneficiary support system to assist enrollees in understanding managed care and identifying an appropriate health plan. However, we are concerned that the conflict of interest provisions, as proposed, would prevent children’s hospital staff from providing this important information to the families they serve. As you know, children’s hospitals and other health care providers serving low-income and disadvantaged populations have historically played a critical role in assisting with Medicaid applications utilizing out-stationed eligibility workers or application assisters. We believe that CMS can maintain program integrity and ensure a robust beneficiary support program by allowing choice counseling by non-profit community-based health care providers. We recommend the implementation of measures such as those that were
adopted under federal rules governing Navigators and in-person assisters for the Marketplaces. In particular, we ask that CMS adopt clarifications similar to those under federal rules for Navigators, which stipulate that payment for the provision of medical services is not a prohibited conflict of interest.

We also urge CMS to consider the following recommendations to ensure that all choice counsellors are trained to address the unique coverage needs of children, particularly children with special health care needs. Specifically, counsellors should be trained to: 1) understand and explain the differences in health plans and provider networks and how these differences impact children; and 2) understand the service needs of children with complex and chronic conditions and provider-relevant network differences among plan choices. These children often need specialized medical and therapeutic services for which provider networks may differ among health plans.

**Coordination and Continuity of Care (§438.209)**

We applaud CMS for specifying that certain beneficiaries with special health care needs should have direct access to specialists. We are extremely supportive of efforts to improve coordination and continuity of care, and this provision is particularly important for children with medical complexity who receive the majority of their care from pediatric specialists.

**We recommend that §438.209(c) clarify that “persons with special health care needs” include children.** While children have assurances of access to all medically necessary services through EPSDT, plans should conduct assessments for children with special health care needs to ensure they can access needed services in a timely and efficient manner. We believe this clarification will help improve access to care for this vulnerable population and strengthen pediatric coverage under Medicaid managed care.

**We also recommend that §438.209(c) require managed care plans to conduct assessments and develop contingency plans for children “aging out” of pediatric care.** As children with special health care needs covered by Medicaid transition from childhood to adulthood, they will also transition from the EPSDT benefit to the state’s Medicaid benefit package for adults. Children with serious, complex or chronic conditions may instantly lose access to some medically necessary services as they age even though their medical needs remain the same. Managed care plans should conduct assessments and develop contingency plans for these children before they age out of pediatric care to assist families in identifying how to best manage and treat their child’s ongoing health needs. Any specific treatment and transition plan designed for these children should be developed by the enrollee’s provider or team of providers.

**In addition, we recommend that CMS clarify §438.209(c)(4) to ensure plans provide children “aging out” of pediatric care direct access to pediatric providers in adulthood when appropriate for the child's condition.** Some children with congenital or other pediatric-specific conditions who transition into adulthood may require continued access to pediatric specialists. As medical improvements allow children with congenital or other pediatric conditions to live into adulthood, many adult health care providers do not have the expertise to provide ongoing care for their adult patients with those conditions.

**Coverage and Authorization of Services (§438.210)**

We applaud CMS’s proposed clarification that plans must meet the requirements under EPSDT when determining what constitutes medically necessary services. We believe this clarification will help ensure plans consider the unique health needs of child enrollees when determining their appropriate and timely access to services. We believe plans are not always familiar with the obligations under EPSDT, and we commend CMS for its efforts to strengthen Medicaid managed care for children.

**Continuation of Benefits While the MCO, PIHP, or PAHP Appeal and State Fair Hearing are Pending (§438.420)**

We appreciate CMS’s clarification that plans must continue benefits for beneficiaries who are appealing certain benefit denials, but we believe the proposal to allow plans to recoup costs for services is not realistic for the Medicaid population and could
leave providers with additional costs. Medicaid serves the lowest income individuals and most medically needy patients. Out-of-pocket health care costs, such as cost sharing, disproportionately impact beneficiaries and serve as barriers to accessing care. It is unrealistic to expect these beneficiaries to significantly contribute to the cost of services provided. It is especially unrealistic and unfair to expect them to bear the cost when the program allowed for them to receive benefits during the appeals process. **CMS should specify MCO standards for any recoupment of costs to prevent undue burden on vulnerable beneficiaries in the event of an adverse appeal decision. Those standards should also ensure MCOs do not deny payment to providers for services rendered.**

### Utilization Management Tools and Appeals

It is common practice for MCOs to use utilization management tools, such as approval of referrals or prior authorization for out-of-network care or to ensure Medicaid is covering services that are medically appropriate. We understand MCOs have a responsibility to the Medicaid program, and we appreciate their efforts to ensure they are good stewards of federal and state health care dollars. However, we are concerned that MCOs are increasingly using these tools to deny allowable services, particularly access to specialists that may be higher cost than primary care providers. We are also aware of a growing number of instances when plans initially deny needed care, but later approve the care through an appeals process.

Requiring beneficiaries to needlessly go through the appeals process can delay access to specialized pediatric care for children, create unnecessary stress for families, and result in less than optimal health outcomes. These practices can easily transition from effective plan oversight to tools that deny or delay care, which is counterintuitive to Medicaid’s responsibility to provide timely access to medically necessary services to children. Furthermore, it increases administrative costs for providers, for plans, and for states. We believe CMS and states should monitor how MCOs rely on utilization management tools and track administrative denials. Specifically, CMS in collaboration with the states should review the number of administrative-related denials, grievances and appeals and the outcomes associated with the grievance and appeals process. We also believe that CMS should establish additional guidance to limit unnecessary administrative denials and ensure providers are paid upon approval of an appeal if the only reason for that appeal was due to an administrative denial.

### Behavioral Health

We recommend that CMS consider the behavioral health needs of the Medicaid population, particularly the unique needs of children, as it finalizes and implements this rule. We believe children should have seamless access to all medically necessary services, including mental health and substance use disorder services, regardless of the delivery system through which they are receiving care. We submitted comments to proposed rule CMS-2333-P: Medicaid and the Children’s Health Insurance Program; Mental Health Parity and Addiction Equity Act of 2008; the Application of Mental Health Parity Requirements to Coverage Offered by Medicaid Managed Care Organizations, the Children’s Health Insurance Program (CHIP), and Alternative Benefit Plans, and we refer CMS to those comments for a more detailed description of issues related to behavioral health services for children under Medicaid and CHIP managed care.

### CHIP Requirements

We support the appropriate alignment of CHIP managed care standards with those of Medicaid and believe in many areas CMS has proposed to appropriately extend Medicaid requirements to CHIP managed care. Since our comments to the managed care proposed rule reflect the need to strengthen managed care to meet the needs of children, we refer CMS to the recommendations included in this letter for Medicaid and suggest that they also apply to CHIP when CMS proposes to align Medicaid managed care and CHIP standards. We particularly want to highlight our comments related to the inclusion of CHIP in quality strategies and improvement areas and the development of network adequacy standards in CHIP.

We note that the proposed rule does not include a provision requiring a beneficiary support system in CHIP like the one in Medicaid at §438.71. While we recognize that CHIP does not always provide beneficiaries with more than one plan option at enrollment, we believe that a beneficiary support system is still applicable for this population, particularly when children...
transition between Medicaid and CHIP or when families are new to managed care. We recommend that CMS expand §438.71 to ensure the program also includes CHIP and extend the program requirements to CHIP when states provide beneficiaries with more than one choice. We also recommend that CMS ensure either choice counselors or a modified CHIP-specific beneficiary support system are available and equipped to help families — regardless of plan options — understand managed care, outreach activities promoting enrollment, and the grievance and appeals processes.

We appreciate the opportunity to provide comments on the proposed regulation. We look forward to working with CMS to advance the needs of children, particularly as CMS looks to finalize and implement the managed care regulation. If you have questions or need additional information, please contact Shannon Lovejoy at (202) 753-5385 or shannon.lovejoy@childrenshospitals.org.

Sincerely,

M. James Kaufman, PhD
Vice President, Public Policy