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July 21, 2011

Donald Berwick, MD

Administrator, Centers for Medicare and Medicaid Services

Department of Health and Human Services

Hubert H. Humphrey Building

200 Independence Avenue SW

Washington, D.C. 20201

RE: CMS-9993-IFC2. Amendment to Interim Final Rule; Group Health Plans and Health Insurance Issuers: Rules Relating to Internal Claims and Appeals and External Review Processes.

Dear Dr. Berwick:

The American Academy of Pediatrics (AAP), a non-profit professional organization of 60,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults, appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services Amendment to the Interim Final Rules Relating to Internal Claims and Appeals and External Review Processes, as published in the Federal Register on June 24, 2011 (the "Amendment").

The Academy would like to thank the Departments for reversing, in the Amendment, the provision in the Interim Final Rule requiring all health plans and insurers to automatically include detailed diagnostic and treatment information in all adverse benefit determinations. The Academy and other groups had requested that this requirement be changed to protect adolescent and young adult confidentiality expectations regarding sensitive health services. The AAP thanks the Departments for making this change in the Amendment.

The Academy is disappointed, however, that the Amendment changes a number of provisions the Academy supported in the Interim Final Rule, namely: the threshold for plans in the group market to provide non-English language services; the duration of the transition period for state external review processes; and the broad scope of claims eligible for the federal external review process.

The Academy is also disappointed that the Amendment does not discuss any of the other changes the Academy suggested to the Interim Final Rule, most importantly that pediatric experts be consulted in internal appeals and external reviews and also that a child's medical home or primary care physician be informed of appeals and review results and other changes.

Thank you for the opportunity to comment on the Amendment. If the AAP may be of any assistance, please do not hesitate to contact Robert Hall in our Washington, D.C. office at 202-347-8600 or rhall@aap.org.

Sincerely,

A handwritten signature in cursive script that reads "O. Marion Burton MD".

President
OMB:rh

American Academy of Pediatrics (AAP or the Academy) Comments in Response to U.S. Department of Health and Human Services (HHS), Centers for Medicare and Medicaid Services (CMS), Amendment to the Interim Final Rules Relating to Internal Claims and Appeals and External Review Processes with request for comments (CMS-9993-IFC2). June 24, 2011.

On July 23, 2010, the Departments of Health and Human Services (HHS), Labor, and the Treasury (the Departments) issued Interim Final Rules implementing Public Health Service Act (PHSA) Section 2719, as added by Section 1001 of the Affordable Care Act, at 75 FR 43330, regarding internal claims and appeals and external review processes for group health plans and health insurance issuers offering coverage in the group and individual markets.

PHSA Section 2719 subjects health plans to additional claims appeals procedures, which must include, at a minimum, the following: an established internal claims appeal process; a notice to participants, in a “culturally and linguistically appropriate manner,” of available internal and external appeals processes; and a provision allowing an enrollee to review his or her file, to present evidence and testimony as part of the appeals process, and to receive continued coverage during the appeals process. Group health plans and insurers have two options regarding the implementation of external reviews: 1) they must comply with state external review requirements that are binding and at a minimum include the consumer protections in the Uniform External Review Model Act from NAIC; or 2) if state requirements do not meet the above minimums or if the plan is self-funded and not subject to state insurance regulations, then the plan must implement an external review process that is similar to that in the Uniform External Review Model Act and that meets standards established by the Department of Health and Human Services. The Secretary of HHS has the authority to determine whether the external review process of a plan or insurer that is in operation as of the date of enactment is in compliance.

The AAP responded to the Interim Final Rule on September 21, 2010 in a group comment letter. In the letter, the AAP, along with Easter Seals, Family Voices, First Focus, March of Dimes Foundation, and Voices for America’s Children, suggested the following changes to improve the Rule’s impact on children:

- require that pediatric experts be consulted in internal appeals and external reviews;
- require that a child’s medical home or primary care physician be informed of appeals and review results (as long as the family permits);
- include all consumer protections from the NAIC Model Act;
- update NAIC Model Act Section 4B (“Applicability”) to include dental and vision in the definition of insurance so that beneficiaries can access external review for such coverage;
- require that *all* plans provide access to external review; and
- apply a more stringent standard than the Medicare Advantage threshold for providing culturally and linguistically appropriate services.

The letter also expressed strong support for the consumer protections included in the Interim Final Rule, specifically, requirements to:

- shift the burden to the insurer to comply with all rules related to internal appeals before triggering an external review;
- continue coverage pending the outcome of an internal appeal; and

- allow only one level of internal appeals before triggering external review in the individual market.

The AAP and another set of groups submitted another letter to the Interim Final Rule on May 2, 2011, requesting that the provision mandating all health plans and insurers to automatically include detailed diagnostic and treatment information in all adverse benefit notifications be changed in order to protect adolescent and young adults' confidentiality for sensitive health services. The AAP thanks the Departments for including this change in the Amendment. The Amendment now requires that notification of the opportunity to request this information be included in all adverse benefit notifications while requiring that the information itself be provided by the plan or issuer only upon request.

In regards to the recommendations the AAP made in its September 21, 2010 comments, the Academy is disappointed that the Amendment does not include, in particular, the requirement that pediatric experts be consulted in internal appeals and external reviews. The AAP believes that the need for pediatric expert review is paramount to a plan's credibility and should be pursued strongly.

The Amendment also changes a number of the Interim Final Rule provisions that the AAP supported in its September 21, 2010 comments. The Amendment changes:

- the 25% of all plan participants threshold for plans in the group market that cover fewer than 100 participants and the 10% of all plan participants threshold for plans in the group market that cover 100 or more participants;
- the duration of the transition period for state external review processes; and
- the broad scope of claims eligible for external review for plans using a Federal external review process.

The Academy urges the Departments to lower the threshold for insurers to be required to provide services in non-English languages. Including a lower threshold in the final rule will maintain the intent of the Departments, as apparent by the July Interim Final Rule, to ensure that linguistically and culturally appropriate outreach to non-English-speaking participants in the group market is adequate by establishing a 25% threshold (25% of the number of all plan participants being literate only in the same non-English language) for a plan that covers fewer than 100 participants and the lesser of 500 participants or 10% of all plan participants for a plan that covers 100 or more participants. The Amendment reduces these thresholds to a uniform threshold of 10% or more of the population residing in the claimant's county. This would adversely affect non-English-speaking participants who, for instance, reside in a largely English-speaking county but who work for an employer with a large non-English-speaking population. In response to the July Interim Final Rule, the Academy had written that the Departments should apply a more stringent standard even to the individual market than the Medicare Advantage threshold of 10% of the population residing in the county. Instead the Amendment applies the Medicare Advantage threshold to not only individual market plans but also to group market plans. The Academy is disappointed in this decision and urges that if the Departments do proceed to adopt these new thresholds as proposed in the Amendment, they also include the provision discussed above.

The Academy has previously commented that children are in proportionately non-English speaking households more often than any other age cohort, and they often are called upon to serve as translators for parents. This can have lasting impacts on a child called upon to translate medical problems, and even bad news, between health care providers and caregivers or family members. In addition, children in U.S. households where English is not the primary language experience multiple disparities in health care. Children in non-English primary language families are almost three times more likely to have had no usual source of care (USC), and their parents are more likely to report that their child's USC never/sometimes spends enough time with the child, never/sometimes explained things in an understandable way, and never/sometimes was able to provide needed telephone help or advice. Perhaps of greatest significance in regards to internal appeals and external reviews is that these children already have significantly more difficulty accessing specialty care, presumably the most common type of coverage denied leading to appeal and review. As was noted in the Academy's previous comment, this difficulty in obtaining specialty care affected approximately two thirds of Asian/Pacific Islander children, half of white children, and one third of Latino children.¹

Application of the Medicare Advantage standard to this population becomes even more difficult to justify as pediatric enrollees in Medicare Advantage are likely non-existent. Clearly, the special needs of this population call for a more stringent standard to allow families a reasonable chance to succeed in appealing an adverse determination. We would urge that the proposed standard be lowered significantly to give children that are denied coverage a chance to have their parents/guardians and their medical homes (or primary care physicians) more effectively advocate on their behalf.

The Departments have also changed course to limit the scope of appeals/review to rescissions and questions of medical judgment. The Academy urges the Departments to re-examine the earlier application of the Interim Final Rule to a larger set of denials. In the September comments to the Internal Final Rule, the Academy urged the Departments to apply all of the consumer protections from the NAIC Model Act to state external review laws because we can think of no reason that some of these structures should be excluded and others included. In particular, requiring that insurers produce reports on the frequency and type of internal appeals and external reviews (as required by Sec. 15(B)) would be an important component of plan quality. Consumers may wish to access this information through the state web portals associated with Exchanges in order to make better-informed decisions regarding which insurance plan to select for their families.

Additionally, it was unclear to the Academy why there were no references in the Interim Final Rule to the utilization management, preauthorization, and the applicable medical necessity criteria used by many insurers. Appropriate references to these common insurance structures would benefit children as these structures may give families the peace of mind that their children will get the services they need prospectively. Finally, it may be appropriate to request that Independent Review Organizations submit their reports to HHS as well as to State Insurance Commissioners. By providing these materials to HHS, the Secretary (and in particular the Office

¹ Flores, Glenn, MD and Sandra C. Tomany-Korman, MS, "The Language Spoken at Home and Disparities in Medical and Dental Health, Access to Care, and Use of Services in US Children," PEDIATRICS, Vol. 121, No. 6 June 2008, pp. e1703-e1714 (doi:10.1542/peds.2007-2906)

of Consumer Information and Insurance Oversight) would have the data needed to reflect appropriate information for consumer use.

Thank you very much again for the opportunity to comment. If you have any questions regarding this comment, please contact Robert Hall with the American Academy of Pediatrics at 202-724-3301 or RHall@aap.org.