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December 21, 2012

Marilyn Tavenner

Acting Administrator and Chief Operating Officer

Centers for Medicare & Medicaid Services

Department of Health and Human Services

200 Independence Avenue SW

Washington, DC 20201

**RE: Comments on proposed Essential Health Benefits regulation CMS-9980-P**

Dear Ms. Tavenner:

The Georgetown University Center for Children and Families appreciates the opportunity to provide comment on the proposed rule on essential health benefits, cost-sharing, and actuarial value (CMS-9980-P). The Center for Children and Families is an independent, nonpartisan policy and research center whose mission is to expand and improve health coverage for America's children and families.

For children and families, the proposed rule on essential health benefits reflects important improvements over the approach outlined in previous guidance, but could still be enhanced in several areas. We support establishing a defined age below which children are entitled to pediatric services, greater state authority to define habilitation services and to limit insurer substitution, and the establishment of a mechanism for accessing clinically appropriate drugs that are not on a plan’s drug list. However, we continue to encourage HHS to adopt a comprehensive definition of pediatric services as Congress intended, to provide greater definition of each of the ten categories of required services, and to assure that cost-sharing limits established by the law are not exceeded. In addition we believe that the options to supplement pediatric oral and dental services are too limited.

Some general comments are immediately below, followed by comments on individual sections of the proposed rule.

***Pediatric Services and the Ten Categories***

A key aspect in shaping the essential health benefits is the set of ten categories required to be included by the ACA. HHS has chosen to identify the content of these categories by reference to existing health plans in each state—the benchmark approach. However, the benefits and limits of the benchmark plan will not always define the services available to consumers in individual and small group market plans. If a state supplements benefits or an insurer substitutes them, consumers will receive a different set of benefits that what is in the base benchmark plan. To assure that both supplementation and substitution result in adequate coverage for children and other consumers, HHS must provide further definition of the EHB categories.

We reiterate our view that by including pediatric services as a distinct category, Congress expressed its intent that children receive an additional set of benefits beyond that provided in the other nine categories. Those additional benefits include, but are not limited to, oral and vision care.

As they develop, children also need preventive and supportive services to ensure they have the tools to maintain or improve their health well into adulthood. These services include, for example, developmental assessments and screenings, audiology screenings and hardware, education, counseling, and services such as anticipatory guidance, nutritional counseling, and treatment of pediatric obesity. Pediatric services should be interpreted to include these types of care but we remain unconvinced that the benchmark approach will ensure that children can access medically necessary services regardless of where they live. HHS should define pediatric services to include all medically necessary services for children and require base benchmark plans to be supplemented when they do not cover all essential pediatric services.

*Age definition:* The preamble’s definition of pediatric services is that they are services for individuals under 19 years of age. We support the establishment of a defined age threshold. Some benchmark plans limit pediatric services to a more narrow age range and we believe a federally defined age will help reduce discrimination based on age. Therefore, the pediatric age limit should be codified in regulation with appropriate flexibility for states to increase the age. We recommend that the age be raised to cover those under 21 to align with the ACA’s provision for child-only plans and the child age band proposed in the health insurance market rules (CMS-9972-P).

*Rehabilitation and habilitation services* are also important, especially for vulnerable children, and should be clearly defined. The proposed rule allows states to define habilitation services when they are not present in the base benchmark plan. State flexibility may be appropriate, but insurer flexibility has the potential to limit needed services. An approach that allows insurers to define the habilitation benefit is not acceptable because it would allow insurers to provide a minimal benefit that does not fulfill the ACA’s requirement. Therefore, HHS should establish a fallback definition of habilitation services—if states choose not to define habilitation, the federal definition should be used. A federal definition should define the habilitation benefit to be at least consistent with the HHS Summary of Benefits and Coverage regulation, which was developed by the National Association of Insurance Commissioners.

In addition, the ACA establishes both rehabilitation and habilitation as required benefits. The final rule should specify that plans cover habilitation separate and distinct from rehabilitation. For example, plans should not be allowed to substitute rehabilitation for habilitation or apply only a single visit limit to both benefits. Each benefit must have separate and distinct visit limits which are applied based upon medical necessity, not based upon an arbitrary cap.

***Enforcement, Oversight and Data Collection***

The final rule should set out the process for enforcement of the provisions of the rule, including both EHB selection and non-discrimination provisions. For instance, how will HHS determine that EHB benchmark plans are supplemented in accordance with the rule? How will it monitor insurer substation to assure it is done appropriately? While the preamble contemplates shared authority for enforcement between states and the federal government, the final rule needs more clarity on when and how federal enforcement authority will be used. The rule should also indicate procedures for reporting potentially discriminatory EHB, appealing decisions, and remedying any violations identified.

Further, strong requirements for states to collect and report data on their EHB benchmark packages are essential to understanding whether benchmark plans are serving the needs of maternal and child populations and what, if any, refinements may be necessary. While the Information Collection Request on EHB approved as OMB Control Number 0938-1174 provides a useful starting point for collection of data regarding essential health benefits in the benchmark plans, we reiterate the comments filed in our letter of July 5, 2012 calling for improvements in the data collected. Specifically, we urged HHS to require each issuer to report its definition of medical necessity; to collect information on rider policies; and to collect data elements related to network adequacy.

Along with this information, HHS should collect, analyze, and publish data on consumers’ use of covered benefits and spending on non-covered health services. These data are necessary to evaluate properly the effects of the EHB approach for 2014 and 2015 and to inform the revised approach for 2016. Any evidence of delayed access to care, worsening health outcomes, cost barriers to needed health services, or other detrimental effects on children and families should be considered and addressed as the new EHB approach is developed in 2016.

**§156.110 EHB-benchmark plan standards.**

**Paragraph (b) Coverage in each benefit category.**

The proposed rule holds that supplementation must occur when the base benchmark plan does not offer “any coverage” in one or more of the ACA categories. Some base benchmark plans, however, offer coverage in a category but cannot be said to cover adequately the category of services named in the law. Consistent with state flexibility, states should have the authority to determine that a benefit category in a base benchmark plan is inadequate. HHS has already taken this approach with respect to pediatric oral and vision coverage. Even though some base benchmark plans offer some minimal coverage for eye exams or dental check-ups, HHS determined that this coverage was not sufficient to fulfill the ACA’s requirement for oral and vision care for children. Likewise, states should be able to determine that base benchmark coverage of a certain category is not sufficient. Consistent with the benchmark approach, a state that makes such a determination should have the authority to supplement the inadequate category with the benefits in that category from another allowable benchmark plan. If none of a state’s benchmark plans provide adequate coverage of the category, the state should have authority to define the benefit, as the proposal allows for habilitation services.

**Paragraphs (b)(2) and (3) Supplementation of pediatric oral and vision services**

As mentioned above, we support HHS’ approach that EHBs will generally require supplementation in these areas and have a few specific comments and questions to ensure that adequate supplementation occurs.

Paragraphs (b)(2)(ii) and (b)(3)(ii) which offer states the option of supplementing oral and vision services by using those provided through a state’s separate CHIP program should be revised to offer states the additional options of supplementing with a benefit that would meet the CHIP standard even if it was not already in existence (as previously suggested in HHS guidance) *or* the option of supplementing with Medicaid EPSDT dental or vision services at the state’s option. In light of some states moving away from separate state CHIP programs (such as California) as a result of other aspects of the ACA, it is shortsighted to offer only existing separate CHIP plans as an option to states. In fact we note that Appendix A of the rule lists that California has submitted CHIP benefits as its supplementary plan type, yet at the time that EHB comes into effect California’s separate CHIP program will no longer exist.

A related recommendation is that HHS should make clear in the final rule how it intends to ensure that supplementation is adequate – we note that Utah’s supplementation is likely inadequate and it is unclear how HHS will ensure that a state comes into compliance with this section of the rule.

**§156.115 Provision of EHB.**

The proposed rule allows issuers to make actuarially equivalent substitutions within the EHB categories. While some substitution to allow innovation in benefit design may be appropriate, strict limits on substitution are necessary to fulfill the goals of the ACA. The law establishes essential health benefits to provide a standardized floor for benefits in the individual and small group market. When comparing and purchasing plans, families must be confident that plans are truly comparable and will provide coverage for needed services.

We strongly support the preamble’s clarification that states may limit or prohibit benefit substitution and encourage HHS to codify this language. We further support the limit in paragraph (d) that prohibits issuers from including routine non-pediatric dental services, routine non-pediatric eye exam services, and long term/custodial nursing home care benefits as EHB. This prohibition will prevent issuers from including benefits like dental coverage or eye exams that may give them a marketing advantage over other plans while excluding other essential benefits.

We strongly suggest that HHS take additional steps to prevent issuer abuse of benefit substitution. It seems allowable under the proposed rule for an issuer to substitute out a key benefit, such as wheelchairs for children, and substitute in a different benefit that, while actuarially equivalent, provides lesser medical benefit but gives the issuer an advantage in terms of risk selection or marketing appeal. The proposed rule acknowledges this risk by establishing at (b)(1)(ii) that substitutions be made only within benefit categories. But without a definition of the categories, it cannot be determined whether a proposed substitution falls within the category. To limit this potential for abuse, HHS must define each of the ten benefit categories. When an issuer proposes a benefit substitution, it can then be evaluated as to whether it fits into the category definition. Only substitutions that are actuarially equivalent AND consistent with the category definition should be allowed.

**§156.125 Prohibition on discrimination.**

The proposed rule acknowledges the statutory provisions in the ACA that prohibit issuers from designing an EHB package that may discriminate against various populations on the basis of race, disability, or age, among other factors. The preamble proposes developing “the framework for analysis tools to facilitate testing for discriminatory plan benefits,” and states that such framework will involve “allow[ing] states to monitor and identify discriminatory benefit designs, or the implementation thereof.”

In the final rule HHS should provide a clear standard for evaluating discrimination. The absence of a definition of discrimination in the rule is a fundamental problem that will inevitably lead to uneven enforcement of anti-discrimination provisions. Our organizations submit that the definition of discriminatory benefit design does not and should not vary across states. It is incumbent upon HHS to develop and promulgate a standard definition that will allow states and, when necessary, HHS to evaluate plans uniformly.

In addition, we urge HHS to consider carefully the potentially discriminatory effects of benefit designs. The preamble states “we believe that it is unlikely that an EHB-benchmark plan will include discriminatory benefit offerings.” The proposed EHB benchmark benefits for Utah, however, include a limitation on pediatric dental services that states “Periodic oral exam fees are allowed twice in a plan year age 3-18.” We believe that this clearly demonstrates discrimination on the basis of age for those under 3 years old.

**§156.120 Prescription drug benefits.**

Access to medically necessary prescription drugs is a critical aspect of health care for children. Access to a multiple drugs within the same class is particularly important for children since their health care providers may need to try different drugs as new diagnoses emerge and as children’s bodies grow and develop. Thus, we support the proposed rule’s revision of previous guidance to mirror the number of drugs available in the base benchmark plan as far superior to requiring only one drug per class. Nonetheless, there may still be medications that children require that are not available on their health plan’s drug list. Therefore, we strongly support the provision at paragraph (c) that requires a procedure for requesting clinically appropriate drugs that are not on the plan’s list. This provision should be expanded to clarify and codify that plan decisions on these requests are subject to expedited internal appeals as well as external appeals.

We recommend that the Department look to the exceptions and appeals process under the Medicare Part D drug benefit as a guide in developing standards for procedures to make clinically appropriate drugs available. The Medicare Part D exceptions and appeals process requires plan to make determinations in 72 hours, with an expedited process that requires decisions in 24 hours for serious health conditions. A quick appeals process is necessary to ensure that individuals do not delay care or have a gap in coverage. Any longer wait could result in individuals stopping medication or reducing their dosage in order to save costs. This could result in adverse health impacts. The Department must also make clear, whether through regulation or guidance, the circumstances under which a clinically appropriate drug must be made available.

Further, the final regulations should also make clear that combination therapy will be allowed under the EHB prescription drug policy. Combination therapy can play an important role in treatment, but may not fall into any of the United States Pharmacopeia (USP) categories. For example, combination therapy may be particularly useful for children with asthma who would benefit from the use of both a corticosteroid (used to reduce swelling in the airways) and a bronchodilator (used to open narrowed airways and to prevent nighttime asthma symptoms). Allowing EHB plans to restrict drugs to specific USP categories will unfairly limit drug access to children in need, and we ask HHS to clarify that combination therapies *must* be part of the EHB prescription drug benefit.

Finally, we are concerned that physician-administered drugs are NOT included in USP. As a result, it is unclear whether and how they would be included in the benchmark plans. Physician-administered drugs are important for children with chronic disease. For example, there is a drug approved to treat moderate-to-severe asthma symptoms triggered by allergies, and it is an injection that blocks the body’s reaction to allergens, reducing the immune response that causes asthma symptoms. This injection can be life-saving, but it can only be administered by a healthcare provider, due to risks associated with self-administration. The final rule should clarify that physician-administered drugs will be covered under EHB plans.

**156.130 Cost-sharing requirements**

**Paragraphs (a) Annual limitation on cost sharing. & (b) Annual limitation on deductibles for plans in the small group market.**

We support the requirement to apply cost-sharing and deductible limits applicable to family coverage to all plans other than self-only coverage. This will appropriately cap cost-sharing limits for families. This protection, however, will only be available to the extent that family coverage plans are sold in the individual and small group markets. We strongly urge CMS to adopt our recommendation (in comments to the market reform rule CMS-9972-P) to require family coverage plans to be offered. Still, some families may need to purchase separate plans to cover all of their members, for instance if they live in different geographic areas. CMS should consider developing a method for assuring that these families are protected by the ACA’s cost-sharing and deductible limits.

In addition, the final rule should be made clearer by stating that self-only coverage refers to coverage for one individual, whether that coverage applies to the purchaser him- or herself or to one child in a child-only plan.

**Paragraph (c) Special rule for network plans.**

Children may have health needs that cannot be served adequately by any in-network provider, even if the network meets applicable network adequacy standards. Children who need complex subspecialty pediatric care are most likely to fall into this category. When medically necessary services are not available in-network, a family should remain protected by the ACA’s limits on cost-sharing. Therefore, the final rule should contain an exception that keeps the cost-sharing limit in place for medically necessary out-of-network services that are not reasonably available in-network.

**§156.140 Levels of coverage.**

**Paragraph (c) De minimis variation.**

The +/- 2 percentage point standard for allowable variation could lead to plans in the same metal tier with significantly different cost-sharing amounts. Because the metal tiers are intended to allow consumers to compare plans easily, widely different cost-sharing amounts could lead to consumer confusion and potential adverse selection. HHS should examine the effects of this allowable variation and reduce the allowable amount for a metal tier if it results in plans with deductibles that differ by more than $500. For instance, HHS could allow only +/- 1 percentage point variation for bronze plans, +/- 1.5 percentage points for silver plans, and +/- 2 percentage points for other plans.

**§156.150 Application to stand-alone dental plans inside the Exchange.**

**Paragraph (a) Annual limitation on cost-sharing.**

The cost-sharing limits established in section 156.130 are a critical benefit of the Affordable Care Act for American families. Congress established these limits in the context of the other provisions of the ACA to ensure that families covered in the individual and small group markets have affordable access to essential health benefits. Congress, in turn, identified pediatric dental coverage as an essential health benefit. Therefore, Congressional intent is clear that spending on pediatric dental services should be subject to the same overall limit as other cost-sharing. The cost-sharing limits of the ACA should protect families no matter which of the essential health benefits they need.

Paragraph (a) allows for a separate, reasonable cost-sharing limit for benefits under stand-alone pediatric dental plans. This means that families that approach the cost-sharing limit under their QHP may exceed the limit if their children have dental needs. Because the ACA intents to limit cost-sharing for essential health benefits, this is an unacceptable result.

One cost-sharing limit should apply to all EHBs. HHS should require that health plans and stand alone dental plans track cost-sharing paid by their common members so that they can recognize when the cost-sharing limits of 156.130 are reached. Once they are, the limit should go into effect for all subsequent services, dental and otherwise. Insurers have the capability to coordinate benefits among primary and secondary payers for common members and can use similar systems to track cost-sharing.

**Paragraph (b) Calculation of AV.**

We are concerned that the proposed rule’s treatment of stand alone dental plans, in combination with other federal rules, will inappropriately exclude premiums paid for pediatric dental benefits from the tax credits for which they should be eligible. This is because the rule defines AV levels for stand alone dental coverage that do not correspond to the metal tiers established at 156.140. In paragraph (b), no stand alone dental plan is identified as a silver plan for the purposes of calculating premium tax credits.

Nonetheless, the Affordable Care Act is clear that premiums paid for the pediatric dental benefits in stand alone dental plans are eligible for premium tax credits. ACA section 1401(a) added IRC section 36B(b)(3)(E), which reads:

‘‘(E) SPECIAL RULE FOR PEDIATRIC DENTAL COVERAGE.—For purposes of determining the amount of any monthly premium, if an individual enrolls in both a qualified health plan and a plan described in section 1311(d)(2)(B)(ii)(I) of the Patient Protection and Affordable Care Act for any plan year, the portion of the premium for the plan described in such section that (under regulations prescribed by the Secretary) is properly allocable to pediatric dental benefits which are included in the essential health benefits required to be provided by a qualified health plan under section 1302(b)(1)(J) of such Act shall be treated as a premium payable for a qualified health plan.”

Premium tax credits are determined by the amount of a family’s income and the cost of second lowest cost silver plan available to them, limited by the amount the family pays in premiums. IRS regulations at 26 CFR 1.36B-3(k) appropriately include payments for pediatric dental benefits in the amount families pay in premiums, so their maximum tax credit reflects costs for all EHBs. However, to assure that families get the full tax credit to which they are entitled, the cost of pediatric dental benefits should also be included in computing the cost of the second lowest cost silver plan. If the second lowest cost silver QHP does not include pediatric dental benefits, its cost must be adjusted to include the cost of stand alone pediatric dental benefits. This is consistent with the statutory language cited above, which references “determining the amount of any monthly premium.” “Any monthly premium” should be interpreted to include the “adjusted monthly premium for an applicable second lowest cost silver plan” referenced in 36B(b)(3)(C).

This interpretation should be expressed in section 156.150, in the definition of silver plan at 156.140(b), and/or in IRS regulations at 26 CFR Part 1. Codifying this interpretation will allow families’ premium tax credits to reflect the true cost to families of purchasing coverage for the essential health benefits.

Thank your for considering our comments. Any questions on these comments may be directed to Joe Touschner, Senior Health Policy Analyst, at jdt38@georgetown.edu or 202-687-0331.

Sincerely,

Georgetown University Center for Children and Families.