



Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
P.O. Box 8010  
Baltimore, MD 21244-8010

**Attention: CMS-9980-P.**

**Submitted electronically via [www.regulations.gov](http://www.regulations.gov)**

Dear Sir or Madam:

The Essential Health Benefits Coalition (EHBC/Coalition) appreciates the opportunity to submit comments on the proposed rule, “Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation,” issued by the Department of Health and Human Services (Department/HHS), Centers for Medicare & Medicaid Services (CMS) and published in the November 26, 2012 *Federal Register*. The EHBC is a broad-based organization representing small and large employers from various economic sectors, as well as pharmacy benefit managers, providers and health and dental plans operating throughout the nation.

In establishing standards related to essential health benefits (EHB), this proposed rule has significant implications for the Affordable Care Act’s (ACA) principal goal – increasing the number of Americans with health coverage. The EHBC firmly believes that in order to achieve this goal, flexibility in EHB design decisions is critical to ensure that coverage is affordable.

The Coalition commends the Department for including a number of provisions that advance that objective, such as allowing adjustments to deductible limits to ensure the availability of bronze-level plans, permitting plans to apply benefit limitations that differ from the EHB benchmark plan and creating an EHB benchmark selection process designed to more properly reflect coverage in typical employer plans as the statute requires. However, the EHBC remains deeply concerned that unless modified, other major aspects of the proposed rule will override the impact of those provisions and lead to higher premiums and less accessible affordable coverage for employers, employees and individuals.

Below we address issues of key concern to the Coalition, followed by additional comments on other provisions of the proposed rule. The Coalition offers its recommendations in the

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**Essential Health Benefits Coalition**

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spirit of establishing a regulatory environment that promotes the availability of affordable coverage options. We appreciate the Department's consideration of our comments on EHB and look forward to continuing to work together as the effort to implement this aspect of the ACA moves forward. Should you have any questions, please do not hesitate to contact Stacey Rampy at 202-585-0236 or [rampy@mvc-dc.com](mailto:rampy@mvc-dc.com), or Neil Trautwein at 202-626-8170 or [trautweinn@nrf.com](mailto:trautweinn@nrf.com).

Sincerely,

National Retail Federation  
U.S. Chamber of Commerce  
National Federation of Independent Business  
National Association of Manufacturers  
National Association of Wholesaler-Distributors  
National Association of Health Underwriters  
Blue Cross and Blue Shield Association  
Retail Industry Leaders Association  
Prime Therapeutics  
America's Health Insurance Plans  
Express Scripts, Inc.  
Pharmaceutical Care Management Association  
American Osteopathic Association  
American Academy of Ophthalmology  
National Association of Dental Plans  
Delta Dental Plans Association  
Council for Affordable Health Insurance  
Communicating for Agriculture  
The IHC Group

## ISSUES OF KEY CONCERN

### 1. Inclusion of state-mandated benefit in EHB benchmark during transition years

Issue: As HHS well knows, coverage affordability plays a key role in decisions by employers to offer, and individuals to obtain, health care coverage. State mandates – many of which lack strong medical evidence – have driven up the cost of coverage, pricing it out of reach for employers, especially small employers, and individuals. The decision to permit state-mandated benefits enacted as of December 31, 2011 in the EHB benchmark during the 2014 and 2015 transition years perpetuates the current situation. The policy will undermine plans' ability to offer affordable coverage and to achieve the central ACA goal of increasing the number of Americans with health insurance coverage.

Recommendations: The EHBC understands that given the current implementation timeframes and state activities to date, HHS is unlikely to change its policy on state mandates for the transition period. The Coalition believes that this policy is misguided and should be revisited for the 2016 benefit year. At that time, only mandates that states can demonstrate have a strong evidence base should be included in the EHB benchmark. In addition, during the transition period – for reasons presented in a subsequent section of this letter – plans should be allowed to apply any existing annual and/or lifetime limits to state-mandated benefits included in the EHB benchmark. Finally, the EHBC urges HHS to clarify that the transition policy with respect to mandates applies only to benefits and not any other mandates related to providers (e.g., any willing provider) or cost-sharing.

### 2. Prohibition on discrimination

Issue: The Department proposes to implement the statutory prohibitions on discrimination at §156.125. The proposed rule states that an issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on the individual's age, expected length of life, present or predicated disability, degree of medical dependency, quality of life or other health conditions. The preamble states that proposed §156.125 would apply to both benefit designs that limit enrollment, and those that prohibit access to care for enrollees. The preamble further states that the proposed approach would allow states to monitor and identify discriminatory benefit designs, or the implementation thereof, and would not prohibit issuers from applying utilization management techniques as long as such techniques are not discriminatory. The preamble specifically notes that issuers could require prior authorization, but could not do so in a manner that discriminates on factors including age, disability or length of life.

Recommendation: A plain reading of proposed §156.125 along with the preamble language could be interpreted to preclude issuers from applying any medical management techniques that entail factors listed in the proposed rule. As the Department well knows, the evidence base for any number of services, treatments and

screenings assess factors, such as age, when determining the appropriateness of the service, treatment or screening for certain individuals. Consider, for example, the shingles vaccine. Although the vaccine has Food and Drug Administration (FDA) approval for adults between ages 50 and 59, the Centers for Disease Control and Prevention (CDC) recommends it for adults age 60 and older. It is unclear whether or not the Department would consider an issuer that follows the CDC recommendation and requires individuals under age 60, or even under age 50, to obtain prior authorization to be in violation of the non-discrimination policy. At the most extreme, the proposed rule could be read to require that all benefits, regardless of medical evidence otherwise, be available to all enrollees without the application of utilization management (UM) techniques. Such a requirement not only would result in higher premium costs to employers and individuals, but also could cause overuse or inappropriate use of services that could lead to adverse medical events and outcomes.

To address this issue, the EHBC recommends that HHS modify proposed §156.125(a) such that it reads:

“An issuer does not provide EHB if its benefit design, or the implementation of its benefit design, results in services not being covered due to an individual’s age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions; however, nothing in this section shall be construed to prevent an issuer from utilizing medical management techniques that are based on medical evidence; and”

This modification will ensure that the proposed rule does not have the unintended consequence of prohibiting important medical management activities that will ensure that patients receive appropriate care in accordance with recommendations based on medical evidence.

### **3. Prescription drug coverage**

#### *(a) Requirements for number of covered drugs*

Issue: §156.120(a)(1) proposes that to comply with EHB requirements, a plan would have to cover at least the greater of: (1) one drug in every United States Pharmacopeia (USP) category and class or (2) the same number of drugs in each category and class as the EHB benchmark plan.

Recommendation: The EHBC interprets the proposed regulatory language to require that a plan provide the same number of drugs in each category and class as the EHB benchmark plan. Should the EHB benchmark not cover a drug in a specific USP category or class, the plan also must cover one drug in those categories or classes. If this interpretation is correct, the Coalition must express its profound reservations about this approach.

The EHB benchmark selection process is intended to ensure that benefits offered by plans reflect those offered by a typical employer plan. Requiring plans to cover a drug in a category or class not covered by the EHB benchmark plan is wholly inconsistent with that fundamental condition. Although the USP provides a useful classification system, it was never intended to serve as the basis for health plan coverage decisions. Such an approach would usurp the important role of plans' Pharmacy & Therapeutics (P &T) Committees in making coverage decisions based on clinical evidence and advances, and treatment effectiveness.

In addition, some drugs over time have been determined to be superior to others in treating various conditions; it is also possible that an entire class of drugs could be determined obsolete and replaced by more effective drugs in a different class. Requiring plans to cover the same number of drugs in each class and category as the EHB benchmark plan would stifle plans' ability to make coverage decisions based on treatment effectiveness and clinical advances. It will also tie plans to drug coverage decisions largely made in 2011, which could be outdated by the 2014 and 2015 plan years.

Finally, the USP is a classification system that includes all drugs and vaccines, not just those typically covered by employers. For example, it includes lifestyle drugs that treat conditions such as hair loss, weight loss and erectile dysfunction. It also includes all vaccines, not just those recommended by the United States Preventive Task Force.

The EHBC implores HHS to reconsider its approach and allow plans to: (1) use the EHB benchmark plan's classification system and (2) determine the number of drugs to be covered within that classification system based on clinical evidence and treatment effectiveness. The Coalition believes that its recommended approach is more in line not only with principles that underpin the development of formularies, but also with the goals of designing EHB that reflect those typically offered by employer plans and assuring coverage affordability.

*(b) Six protected classes*

Issue: The proposed rule does not recommend adoption of Medicare's "six protected classes" requirement.

Recommendation: The EHBC appreciates that HHS did not propose to apply Medicare's six protected classes requirement to EHB prescription drug coverage. The Coalition believes that the Medicare requirement is inconsistent with the goal of designing prescription drug coverage based on best clinical evidence and effectively eliminates plans' ability to negotiate discounts from manufacturers, resulting in higher coverage costs to employers and individuals. The EHBC urges HHS to remain resolute in its decision on this issue when finalizing the rule.

*(c) Application of generally-recognized prescription drug standards of care and best clinical practices*

Issue: As discussed above, a plain reading of §156.125 (Prohibition on Discrimination) could result in a prohibition on UM strategies that consider factors, such as age, but are intended to assure appropriate clinical use of a medical service or treatment.

Recommendation: The EHBC urges HHS to clarify that plans will not be prohibited from applying prescription drug management strategies that consider factors, such as age, and that are in place to assure appropriate clinical use of a prescription drug. Some drugs, for example, have both medicinal and cosmetic uses with the medicinal use appropriate only for a certain age group. The medicinal use would be covered, but the cosmetic use would not. Making that determination would necessitate that a plan apply an edit based on the enrollee's age. Disallowing such edits could lead to inappropriate use of prescription drugs and lead to higher coverage costs.

*(d) Determination of medical versus pharmacy benefit*

Issue: The proposed rule does not address the fact that in certain situations, some plans elect to cover a prescription drug as a medical benefit as opposed to an outpatient prescription drug and vice versa. For example, plans may cover a drug under a medical benefit when it is administered in a physician's office.

Recommendation: The EHBC recommends that HHS permit plans to continue to determine under which general benefit category (i.e., medical vs. prescription drug) a prescription drug will be covered. Should a plan elect to cover a prescription drug as a medical benefit, even though the EHB benchmark plan covers it as a prescription drug, the plan should be considered to meet the prescription drug requirement for that therapeutic class.

#### **4. Determining habilitative services**

Issue: The preamble notes that many health insurance plans do not identify habilitative services as a distinct group of services and as such, the Department recommends at §156.110(f) a "transitional" policy for determining habilitative benefits. Under the transition policy, a state could define habilitative benefits should the base benchmark plan not include them.

Recommendation: As HHS noted in the preamble, the EHB is intended to reflect those benefits offered by the typical employer in that state. Granting states broad authority to determine habilitative benefits could result in definitions that go far beyond a typical employer plan and violate a fundamental design tenet of EHB.

To ensure that habilitative services reflect the typical employer plan in a given state, the EHBC recommends that states and the Department follow the supplementation processes presented in §156.110(b) and (c). Specifically, should a state-selected base

benchmark plan not include habilitative services, the state must supplement the base benchmark plan by the addition of the entire category of such benefits offered under any other benchmark plan option described in §156.100(a). These options include: (1) the largest health plan by enrollment in any of the three largest small group insurance products; (2) any of the largest three employee health benefit options by enrollment offered and generally available to state employees; (3) any of the largest three national Federal Employees Health Benefits Program (FEHBP) plan options by aggregate enrollment that is offered to all health-benefits eligible federal employees; and (4) the coverage plan with the largest insured commercial non-Medicaid enrollment offered by a health maintenance organization operating in the state.

Should the state not select a benchmark plan and the default base benchmark plan does not include habilitative services, the Department should – in the following order – supplement the category of benefits with those included in: (1) the largest health plan by enrollment in the second largest product in the state’s small group market as specified in §155.20; (2) the largest plan by enrollment in the third largest product in the state’s small group market as specified in §155.20; and (3) the largest national FEHBP plan by enrollment across states that is described in and offered to Federal employees under 5 U.S.C. 8903.

If none of the supplementation options presented in §156.110(b), for a state-selected base benchmark and in §156.110(c), for a default base benchmark include habilitative benefits, then the state may determine the benefits to be included in the category.

## **5. Process for supplementing pediatric vision and oral care services**

Issue: Proposed §156.110(b)(2) and (b)(3) require a state-selected benchmark that lacks pediatric oral or vision care to be supplemented by the addition of the entire category of benefits from either: (1) the Federal Employees Dental and Vision Insurance Plan (FEDVIP) or (2) benefits available under the state’s separate state CHIP plan, if a separate CHIP plan exists, to the eligibility group with the highest enrollment.

Recommendation: While we appreciate the inclusion of the CHIP option as it offers more choices for states, both options for supplementing pediatric oral care and pediatric vision benefits are very comprehensive and go beyond benefits offered in current typical small group or individual plans. Selection of either option for supplementing pediatric oral care and pediatric vision benefits will undermine the goal of keeping coverage affordable for employers, employees and individuals.

The EHBC urges HHS to reconsider its proposed approach for supplementing pediatric oral care and pediatric vision benefits. For both benefit categories, the Coalition recommends allowing supplementation with a benefit that follows American Academy of Pediatrics’ (AAP) and Bright Futures’ recommendations for preventive vision and dental screenings with referral for necessary vision, medical and surgical care for potential problems as needed.

Under this approach, pediatric oral care would include: (1) a risk assessment with appropriate action to follow, if positive, at the six- and nine-month well-baby visits; (2) referral to a dental home if available, otherwise administration of an oral health risk assessment and consideration of oral fluoride supplementation if the primary water source is fluoride deficient at the 12-, 18-, 24- and 30-month well-baby visits; and (3) determining whether or not the patient has a dental home, and if not making a referral to one and consideration of oral fluoride supplementation if the primary water source is fluoride deficient at ages three and six.

For pediatric vision services, the AAP's and Bright Futures' recommendations call for: (1) a risk assessment with appropriate action to follow if positive at the newborn evaluation, three- and five-day follow up visits, and at the one-, two-, four-, six-, nine-, 12-, 15-, 18-, 24- and 30-month well-baby visits; (2) a screen at age three with a rescreen within six-months if the patient is uncooperative; (3) a screen at ages four, five and six with a risk assessment at age seven; and (4) in general, alternating a screen and risk assessment beginning at age eight years. If a risk assessment indicates a potential issue, an eye examination including refraction would occur.

Should HHS retain its proposed approach for pediatric vision, the EHBC recommends that in the final rule HHS clarify that issuers may require a referral from a primary care provider, school or health department prior to receiving FEDVIP or CHIP vision benefits. The referral should identify the need for additional care following a screening/risk-assessment consistent with AAP and Bright Futures guidelines.

## **ADDITIONAL COMMENTS**

### **1. Benchmark selection process**

Issue: The proposed rule establishes a process for states to elect their EHB benchmarks such that a state can choose one of the following: (1) the largest health plan by enrollment in any of the three largest small group insurance products; (2) any of the largest three employee health benefit options by enrollment offered and generally available to state employees; (3) any of the largest three national FEHBP plan options by aggregate enrollment that is offered to all health-benefits eligible federal employees; or (4) the coverage plan with the largest insured commercial non-Medicaid enrollment offered by a health maintenance organization operating in the state.

Recommendation: The EHBC strongly encourages HHS to retain its proposed EHB benchmark selection policy in the final rule. The Coalition believes that the proposed approach offers states a sufficient number of options that will result in an EHB benchmark plan that is generally consistent with plans typically available to employers.

## **2. Allowances for adjustments to annual small group deductible limitations**

Issue: Proposed §156.130 allows flexibility for a health plan that is unable to meet the annual deductible limit (i.e., \$2,000, self-only; \$4,000, other than self-only in 2014) and reasonably reach the actuarial value of a given coverage level (i.e., metal tier).

Recommendation: The EHBC appreciates HHS' recognition that health plan issuers may not be able to develop plans that meet the ACA's actuarial value and cost-sharing parameters, and that it proposed allowing plans ability to use higher deductibles so that bronze plans can be offered to small employers. Retaining this provision in the final rule will be crucial to ensuring that employers and individuals have access to a range of plans, including those at the lowest or bronze level.

## **3. Consideration of employer contribution to a health savings account (HSA) and health reimbursement arrangement (HRA) when determining maximum deductible**

Issue: HSAs and HRAs are important health benefit tools, particularly for small employers seeking to offer affordable benefits that best meet their needs and preferences. Nearly 25 percent of small employers offer either a HSA or HRA, and the number of Americans with HSA/high-deductible health plan (HDHP) coverage more than doubled between January 2008 and January 2012, increasing from 6.1 million to 13.5 million.

Recommendations: To ensure that these benefit tools remain viable well into the future, the Coalition offers two recommendations on this issue:

- (i) In the preamble, HHS indicates that the entire amount of an employer's contribution to a HSA or amounts made available under a HRA will be included in the actuarial value (AV) calculator. The proposed regulatory language at §156.135 could be construed to suggest that HHS is considering applying only the anticipated amount of the contribution to a HSA or amount made available under a HRA. The Coalition urges HHS to clarify the regulatory language such that it aligns with HHS' intent expressed in the preamble on the treatment of employer contributions to a HSA or amounts made available under a HRA.
- (ii) The Coalition recommends that in the final rule, HHS provide that the entire amount contributed by an employer to a HSA and amounts made available under a HRA could be treated as part of the benefit design and allow for an increase in the maximum deductible, including any adjustments allowed under §156.130(b)(3), such that a plan would be in compliance as long as the net deductible equals the maximum deductible. This approach will ensure not only consistency between the proposed rule's treatment of employer contributions to HSAs and HRAs for purposes of calculating AV, but also the availability of plan designs that utilize HSAs and HRAs as a means to provide affordable health care coverage. In response to HHS' request for comments, the Coalition also suggests

that the Department take the same approach with respect to employer contributions to flexible spending accounts (FSAs).

#### **4. Treatment of stand-alone dental plans**

Issue: The proposed rule does not clarify the treatment of stand-alone dental plans outside the Exchange in the small group and individual market. ACA Section 1311(d)(2)(B)(ii) allows “plans that provide limited scope dental benefits” to offer the pediatric dental benefit inside an Exchange, as long as it meets the chosen EHB benchmark. Since 99 percent of dental policies are offered separately from a medical policy, without clarification the dental market will be completely disrupted – allowing for adverse selection on and off the Exchanges, significant disruptions to the private market, and breaking the promise to allow consumers to keep the coverage they have.

Recommendation: The EHBC strongly encourages HHS to clarify through HHS regulations that QHPs can offer the EHB package without pediatric oral services outside Exchanges as long as separate dental policies covering those services are available.

#### **5. Allowance for different coverage limitations**

Issue: Proposed §156.115(a)(1) would allow plans to impose limitations on coverage that differ from the EHB benchmark plan, but covered benefits must be “substantially equal” to the benefits under the EHB benchmark plan. The “substantially equivalent” standard applies to covered benefits, coverage limits, including limits on amount, duration and scope of covered benefits.

Recommendation: The EHBC supports allowing plans to apply limitations that differ from the EHB benchmark plan as long as the limitations meet the substantially equivalent condition. This approach will help plans’ efforts to maintain coverage affordability and to offer employers, employees and individuals innovative coverage options that best meet their needs and preferences.

The Coalition also strongly urges the Department to allow plans to apply any existing annual and/or lifetime limits to benefits included in the EHB benchmark. To ensure that coverage remains affordable, HHS should permit flexibility in applying benefit limitations, including existing annual or lifetime dollar limits in a benchmark plan until at least 2016. From a practical standard, some benefits do not lend themselves to other types of limitations, such as visit limits or medical management.

#### **6. Benefit substitution process**

Issue: The proposed rule allows for plans offering EHB to substitute a benefit or set of benefits for another benefit or similar set of benefits if: (1) the two sets of benefits are actuarially equivalent; (2) the substitution is within a category, not between categories; (3) the benefit is not a prescription drug benefit; and (4) the issuer presents an actuarial certification.

Recommendation: The EHBC appreciates HHS' recognition of the need to permit flexibility in benefit design and in general, supports the proposed approach to benefit substitution, which strikes a good balance between the need to ensure comparability of benefits, plan innovation and benefits choice. However, the Coalition strongly urges HHS to reconsider allowing states authority to impose stricter rules, including outright bans, on benefit substitutions, which could upset the balance achieved by the four-pronged approach outlined in §156.115(b) and result in less innovation and benefits choice for employers and individuals.