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January 23, 2012

Mr. Steve Larsen
Deputy Administrator and Director
Center for Consumer Information and Insurance Oversight
Centers for Medicare and Medicaid Services

Re: "Essential Health Benefits Bulletin"

Submitted electronically to EssentialHealthBenefits@cms.hhs.gov

Dear Mr. Larsen:

The National Health Council (NHC) appreciates the opportunity to submit comments on the pre-regulatory guidance, "Essential Health Benefits Bulletin." The success of designing the essential health benefits (EHB) package with the level of flexibility prescribed in the Bulletin requires substantial patient protections that will result in a true benefits package — one that will safeguard people as they navigate and enroll in qualified health plans that best meet their health care needs.

The NHC believes that a modified state benchmark approach has the potential to address the needs of people with chronic diseases and disabilities but only if combined with specific protections against discrimination, patient support services, and strong federal and state oversight. These comments will address three critical issues not yet addressed by the Secretary, three specific concerns about the proposed Bulletin, and, lastly, affordability.

The NHC has regularly engaged with the Center for Consumer Information and Insurance Oversight (CCIIO) at the Centers for Medicare and Medicaid Services (CMS) to share its perspective as a voice for the patient community as the agency drafts guidance on essential health benefits.

The NHC is the only organization of its kind that brings together all segments of the health care community to provide a united voice for the more than 133 million people with chronic diseases and disabilities and their family caregivers. Made up of more than 100 national health-related organizations and businesses, its core membership includes approximately 50 of the nation's leading patient advocacy groups, which control its governance. Other members include professional societies and membership associations, nonprofit organizations with an interest in health, and major pharmaceutical, medical device, biotechnology, and insurance companies.

Throughout our communications with CCIIO, the NHC has expressed its recognition of the challenge of establishing a standard health benefits package that is adequate across the spectrum of patient needs while remaining affordable for those who will need health insurance coverage.

Offering each state a set of plan options from which to select a benchmark is a model already used by the Children's Health Insurance Program. Our members have worked tirelessly to obtain state benefit mandates to better serve the health care needs of patients, and the proposed approach maintains flexibility for states to include state mandates within their chosen benchmark plan. If a state selects a benchmark that does include state mandates, it will not be responsible for the costs of those mandates. If the state chooses a benchmark that does not include the state mandates, it will have to cover the cost of its mandates beginning in 2016.

The flexibility of the process outlined in the Bulletin allows states to keep their mandates and gives patient advocacy organizations time to work with state legislatures to advocate for the continued necessity of state mandates post-2016. However, the Secretary must ensure adequate federal oversight of benchmark selection and should monitor the selection effect on state mandates and the populations they were intended to serve.

CRITICAL ISSUES NOT ADDRESSED IN THE BULLETIN

Patient Protections

The NHC has developed and shared with CMS model regulatory language for its envisioned set of patient protections.[1] Specifically, the NHC recommends two coordinating layers of patient protections:

1) transparent medical necessity processes
2) assurance of non-discrimination

First, the EHB regulation must outline clear, understandable standards for plan medical necessity determinations. To make these processes transparent, the regulation should require plans to use medical necessity criteria that are objective, clinically valid, and compatible with generally accepted principles of care. A health intervention should be covered if it is an otherwise covered category of service, not specifically excluded, recommended by the treating health care professional recognized under state or federal law, and determined by the health plan's medical director to be medically necessary. Any denials issued by a plan based on lack of medical necessity must explain to the patient in clear language the criteria used to make the determination, and the process of appealing a decision should also be clearly communicated.[2] While important to all patients with chronic conditions, proper medical necessity criteria is particularly crucial for people living with rare diseases, such as Alpha-1 Antitrypsin Deficiency, ectodermal dysplasias, or hydrocephalus, where treatments are often not covered or utilization is limited.

Second, the EHB regulation must provide for state and federal oversight of plan benefits design to avoid discrimination caused by unfair utilization management (UM) techniques or other plan design elements. To ensure non-discriminatory utilization management, the regulation should include specific oversight mechanisms for states to use in reviewing plan UM policies to ensure practices are neither unfair nor

[1] *A United Patient Voice on Essential Health Benefits* is available at the National Health Council website at: http://www.nationalhealthcouncil.org/NHC_Files/files/EHB_UnitedPatientVoice.pdf.

[2] See § 301: Medical Necessity Decision Making & Appeals Processes in *A United Patient Voice on Essential Health Benefits*, available at: http://www.nationalhealthcouncil.org/NHC_Files/files/EHB_UnitedPatientVoice.pdf.

discriminatory. Further, the Department of Health and Human Services (HHS) should have final approval authority of state oversight programs to ensure plans are meeting the requirements of this section. There also should be requirements for plans to disclose to all prospective and current members their utilization management techniques, as well as all limits on services. Finally, federal monitoring programs should be established to guarantee that plans are meeting federal requirements.[3]

Patient Services

In addition, the EHB regulation must contain specific requirements for state Navigator programs. These programs are fundamental to assist patients in identifying appropriate plans for enrollment, as well as navigating the enrollment and other key plan processes. Even with the EHB service categories clearly defined, plans will still have coverage and cost variations. For this reason, it will be critical for patients, especially those with multiple chronic conditions, to be able to identify the plan that best meets their specific needs. Effective Navigator programs should include assistance with all aspects of plan processes, from selecting a plan to accessing health care benefits during the plan year.[4] The EHB regulation should also include language related to other patient services such as those that help patients navigate complicated claims and appeals processes.

These patient protections are vital to ensuring that qualified health plans and exchanges best meet the health needs of the many people who will rely on EHB.

Federal Oversight

The EHB regulation must include specific federal oversight requirements to ensure that qualified health plans meet all appropriate and necessary criteria. The Affordable Care Act (ACA) leaves substantial discretion to states to oversee qualified health plans operating in state exchanges. Currently, states are engaged in widely different levels of exchange implementation activity, with some state governors refusing all participation in exchange development.

SPECIFIC CONCERNS ABOUT ELEMENTS IN THE BULLETIN

State Benchmarks

In addition to general federal oversight of state implementation activities, the federal government should review each state's selected benchmark plan to ensure that it meets the ACA-defined requirements for balance and non-discrimination highlighted in the previous section. Though the NHC understands CMS' rationale in its decision to allow states to choose a benchmark that meets the needs of its residents, there is a risk that this permitted flexibility could result in a benchmark plan whose design discriminates against certain groups of individuals.

Most potential state benchmarks do not include or inadequately address four ACA-required categories: rehabilitation and habilitation services and devices; mental health and substance use disorder services, including behavioral health treatment; pediatric services, including oral and vision care; and preventive and wellness services and chronic disease management. Because the benchmarks do not adequately address these statutorily required mandates, the Secretary must provide further guidance and exercise oversight to ensure that these and other services mandated by ACA are adequately included in state benchmark plans.

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[3] See § 101: Barring Discrimination in Utilization Management in *A United Patient Voice on Essential Health Benefits*, available at: http://www.nationalhealthcouncil.org/NHC_Files/files/EHB_UnitedPatientVoice.pdf.

[4] See § 202: Education and Coordination through Navigators in *A United Patient Voice on Essential Health Benefits*, available at: http://www.nationalhealthcouncil.org/NHC_Files/files/EHB_UnitedPatientVoice.pdf.

Further, plans that have large statewide enrollment are not necessarily or inherently adequate, balanced, or non-discriminating; large enrollment in a state could be the result of myriad factors (e.g., an inexpensive premium or a good network of providers). Such factors may not be relevant to any plan using an EHB benchmark; for example, premiums will continue to vary from plan to plan, even among those using the EHB benchmark. The NHC believes that the ACA clearly defines a role for the federal government to ensure a fair and balanced EHB product. To meet this requirement, the federal government should review all states' selected benchmark plans against the ACA-established criteria.

Permitted Substitutions

The NHC is very concerned about open-ended flexibility with no clear oversight mechanism. As the Bulletin states, "HHS intends to require that a health plan offer benefits that are 'substantially equal' to the benefits of the benchmark plan" chosen by a state. We understand that some level of flexibility within plans could lead to greater competition, more choice, and better innovation. However, the NHC believes that any permitted flexibility should be subject to strict federally defined boundaries as well as considerable oversight to ensure non-discrimination against any group of potential enrollees.

Further, the Bulletin states that CCIIO is considering such flexibility not only within each of the ten ACA-defined categories of benefits but also across benefit categories. The NHC strongly believes that such flexibility should not be afforded across benefit categories. In any case of allowed substitution, the regulations must require a level of oversight to ensure that changes made to a plan do not create unbalance among benefit categories or the potential to discriminate. Finally, we believe that CMS must clarify whether this flexibility to substitute benefits, either within or among benefit categories, is afforded only to states as they develop an EHB benchmark, to plans once a benchmark is selected by a state, or to both.

Formulary Structure

We believe that CCIIO must reconsider the level of benefit flexibility afforded to plan formulary design. The Bulletin states, "If a benchmark plan offers a drug in a certain category or class, all plans must offer at least one drug in that same category or class, even though the specific drugs on the formulary may vary." This statement conflicts directly with the ACA requirement that essential health benefits be modeled after typical employer-sponsored insurance plans. Most employer-sponsored insurance plans, even when limited to small group employer-sponsored insurance, cover far more than one drug per class and category of drugs. Further, the entire concept of a benchmark is moot if plans are permitted to meet only the most minimal standards within a benchmark, as would be the case in this situation.

To actually meet the standard established by a state-selected benchmark, plans should be required to cover the same breadth and depth of the benchmark's formulary. For example, if the benchmark plan covers two brand-name drugs and three generic drugs in a single class or category, all plans must cover at least two brand-name drugs and three generic drugs in the same class or category. Additionally, requiring an equivalent breadth and depth across all classes and categories in a formulary would help minimize any potential discrimination against enrollees with particular health conditions. Since most potential benchmark plans meet more than minimal formulary standards, the NHC believes that the EHB regulation should not require any specific minimum number of drugs to be covered by a plan. A weak prescription drug formulary counters the federal government's minimum protections within most public plans and the Medicare Prescription Drug Formulary.

AFFORDABILITY

While the Bulletin specifically states that any guidance on costs would not be included in a regulation on essential health benefits, the NHC believes that affordability goes hand-in-hand with access to adequate coverage of benefits. For this reason, we outline an approach developed by the NHC after careful examination of affordability. In past work, the NHC commissioned an actuarial analysis to examine the cost of a comprehensive health benefits package, using an often mentioned benchmark standard for adequate coverage — the Blue Cross Blue Shield Standard Option (BCBS-SO) plan offered under the Federal Employees' Health Benefit Program (FEHBP). The NHC strongly believes that a process similar to this analysis should guide the cost of the EHB package.

The NHC analysis used 2011 National Health Accounts projections, standard administrative expenses, and other assumptions to estimate a cost for covered charges (i.e., cost of benefits) for the average person.[5] The NHC encourages CCIIO to focus its cost consciousness on this measure of a plan's benefit, rather than a plan's premium. A plan's premium is based on the cost of benefits, but that cost is adjusted to account for assumptions that differ among plans. Such assumptions include administrative expenses, risk premiums, adjustments for in-network and out-of-network utilization patterns, as well as provider networks. Because of the variations in assumptions used by plans in developing premiums, defining a premium target would result in plans that offer sets of benefits that are not comparable to one another.

In contrast, a cost of benefit measure is a more standard measure of the actual cost of services that are covered under a plan. It is also the basis for the actuarial value calculation. The agency could specify and standardize assumptions needed to calculate the cost of benefit measure to further increase the stability of the measure. Such assumptions include utilization estimates of the covered population as well as standards for reimbursement.

The NHC analysis of the BCBS-SO plan resulted in a cost of benefit that equaled $4,659 per year for an average person. The BCBS-SO has been cited as a model for the EHB plan design and is considered by many to be a standard for a comprehensive health benefit plan. For these reasons, the NHC believes that the cost of benefit for the EHB package designed by CCIIO should fall within a sensible range of the result of this cost-of-benefit analysis (e.g., $3,500 to $6,000 per person per year). This cost-of-benefit target would be used as the standard for all plans within the exchange — from bronze to platinum. Coverage under the metal levels of plans would vary based on the amount of the cost of benefit that is covered by the plan.

CONCLUSION

The National Health Council believes that **only** with important, necessary modifications will the approach to essential health benefits outlined in this Bulletin be an appropriate starting point. We stress that in order for state-selected benchmark plans to meet the needs of the millions of people who will rely upon EHB, some provisions need to be strengthened and important details must be clarified in regulation. We believe the final regulation must include clear details about the federal oversight that will ensure that benchmark selection in states does not lead to discrimination. In addition, the NHC believes that regulation must define any flexibility afforded to states and/or plans in substituting benefits to meet a "substantially equal" test.

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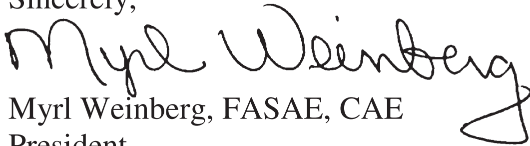
[5] Actuarial analysis performed by Actuarial Research Corporation and Avalere Health and is available at the National Health Council website at: http://www.nationalhealthcouncil.org/NHC_Files/files/EHB_ActuarialAnalysis.pdf.

Finally, as the voice for those with chronic diseases and disabilities, the NHC believes that broad patient protections are critical to the success of qualified health plans and exchanges. As CMS finalizes the establishment of the essential health benefits, the NHC strongly encourages the agency to include in its regulations and guidance the above-referenced levels of patient protections supported in our previous communications with the agency. The NHC also encourages the agency to pursue a cost savings mechanism as a means to address affordability.

We would like to thank you for this opportunity to share our comments. The NHC supports your efforts to ensure that EHB meets the intended objectives of improving and standardizing health care coverage. Please do not hesitate to contact Eric Gascho, our Director of Government Affairs, if you or your staff would like to discuss these issues in greater detail. He is reachable by phone at 202-973-0545 or via e-mail at egascho@nhcouncil.org. You may also reach me on my direct, private line at 202-973-0546 or via e-mail at mweinberg@nhcouncil.org.

Sincerely,



Myrl Weinberg, FASAE, CAE
President