



National Health Council

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December 19, 2012

The Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8010

Attn: CMS-9980-P

Submitted electronically at <http://www.regulations.gov>

Dear Secretary Sebelius:

The National Health Council (NHC) appreciates the opportunity to submit comments on the pre-regulatory regulation, "Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation." Since the passage of the Affordable Care Act, the NHC has prioritized ensuring that the essential health benefits (EHB) package provides access to affordable and adequate coverage. 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 the perspective of the patient community as the agency drafts guidance on EHB.

The NHC is the only organization of its kind that brings together all segments of the health community to provide a united voice for the more than 133 million people with chronic diseases and disabilities as well as 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.

Support for Key Components

The NHC recognizes the challenge of establishing a standard health benefits package that is adequate across the spectrum of patient needs while remaining affordable. The NHC supports three key components of the proposed rule:

1. Expanded Minimum Formulary Standard
2. Limited Benefit Substitutions
3. Mention of Anti-discrimination

1. Expanded Minimum Formulary Standard

As an organization voicing the needs of people with complex health care needs, the NHC is concerned about patients having access to needed therapies. We appreciate CMS' proposal to increase minimum formulary requirements beyond the one drug per class minimum proposed initially in the EHB Bulletin. As we have stated in the past, a one drug per class minimum would not adequately support the health care needs of patients, especially those with chronic diseases and disabilities. For people stabilized on a particular medication regime, it is vital for those individuals to continue to have access to their particular medications. As the NHC has discussed with CCIIO, establishing formulary requirements that more closely resemble typical employer-sponsored health insurance or the state-selected benchmark plan improves access to needed medications and will contribute to the better health of this population. All in all, the NHC supports the proposed rule requiring coverage of the greater of 1) one drug in every therapeutic class or 2) the same number of prescription drugs in each category and class as the EHB-benchmark plan. Additionally, the NHC supports the proposed requirement that health plans have exceptions processes in place to permit enrollees to access medications not on their plan's formulary. With adequate enforcement of these provisions both at the state and federal level, the Council offers its support of this proposed policy.

2. Limited Benefit Substitutions

The NHC also supports the change from the policy presented in the EHB Bulletin that would have permitted substitution of benefits not only within each of the ten ACA-defined categories of benefits but also across benefit categories. The NHC continues to believe that any regulation that permits plans to cover benefits that are "substantially equal" to a benchmark plan must be limited only to flexibility within a category of benefits and that substitutions within categories should be subject to strict federal guidelines and oversight. Standards and oversight mechanisms must require that any substitutions meet any federal and state standards for non-discrimination. We encourage CMS to provide examples of appropriate and inappropriate benefit substitutions in the final rule and in any future sub-regulatory guidance on non-discrimination.

3. Anti-discrimination

The NHC appreciates the acknowledgment that states and health plans are required by the ACA to ensure that benefits do not discriminate against any category of people or enrollees. As the agency acknowledges, this proposed regulation alone does not go far enough to ensure adequate protections against discrimination. Specific recommendations for consideration in the promised non-discrimination guidance may be found in the section below.

Needed Enhancements

While we acknowledge and appreciate the inclusion of the three elements above, the NHC recommends that CMS consider expanding upon the regulation to better meet the needs of patients, especially those with chronic and/or high-cost health care needs in two ways:

1. Further Definition of Anti-discrimination
2. Creation of a Uniform Medical Necessity Definition

1. Further Definition of Anti-discrimination

Though the NHC appreciates that states and health plans are required by the ACA to ensure that benefits do not discriminate against any category of people or enrollees, the NHC would encourage CMS to include in its forthcoming sub-regulatory guidance on non-discrimination standards the following requirements:

- Processes for review of plan benefits design to avoid discrimination caused by unfair utilization management (UM) techniques or other plan design elements, including the structure of the formulary (e.g., use of specialty tiers) and cost sharing requirements.
- Requirements for plans to disclose to all prospective and current members all utilization management techniques as well as all limits on services.
- Final authority at the federal level to approve any state non-discrimination review processes to ensure appropriate measures are in place to guarantee that plans are meeting the requirements of this section.
- Federal monitoring programs to ensure appropriate checks are in place to guarantee that plans are meeting federal requirements.¹

For more details on non-discrimination standards, please see the NHC's proposed regulatory language for a model comprehensive set of patient protections.² Additional details on prohibiting specialty tiers and ensuring non-discriminatory cost-sharing practices is also available.³

2. Uniform Medical Necessity Definition

The lack of transparent, uniform standards for determining medical necessity causes unneeded complications for patients across the country. The creation of a single, unified medical necessity standard not only would help patients understand the coverage criteria necessary for specific items and services, but it also would ease the burden on navigators and assisters who work with patients to navigate their health plans in this new coverage environment. Specifically, CMS should 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 for appealing a decision should also be clearly communicated.⁴

¹ 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.

² *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.

³ See § 103: Requiring Cost-Sharing Protections in *A United Patient Voice on Essential Health Benefits*, available at: http://www.nationalhealthcouncil.org/NHC_Files/files/EHB_UnitedPatientVoice.pdf.

⁴ 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.

Responses to Specific Questions in Proposed Rule

The NHC also offers the following specific recommendations for consideration in the final regulation:

1. Requirements for Exceptions and Appeals Processes
2. Additional Oversight Processes for Federal and State Governments
3. USP Classification System
4. Strengthening Actuarial Value (AV)

1. Requirements for Exceptions and Appeals Processes

The proposed EHB regulation would require plans to have procedures in place allowing enrollees to request clinically appropriate drugs not covered by their health plan. The NHC supports this requirement but believes that additional details would improve patient protections in health plans. The NHC recommends that the final EHB regulation address the following concerns of the patient community.

First, the EHB regulation should outline clear and straightforward processes for people to file grievances with their plans and to appeal adverse plan coverage determinations. Successful navigation of health coverage often requires members and their providers to understand the standards that plans use in making coverage decisions, as well as how to appeal adverse decisions. The final regulation should clarify and simplify these processes to make it easier for patients and providers to actively participate in health plan decisions. Without adequate protections, patients with complex health needs, including and especially those with chronic health conditions, may find it difficult to obtain coverage for certain health services. Timely access to medical treatments is critically important and often life-saving. Finally, a clear grievance process gives plan members a voice to bring to light their concerns and ask their plans to change.⁵

The exceptions process should borrow many of the requirements of Medicare Part D, a federally regulated, nationwide program that has established requirements for participating plans. Part D plans must describe for patients in detail the exceptions and appeals processes and must utilize a standardized grievance process. To implement the Part D system in this new covered population, the federal government should first establish uniform exceptions and appeals processes and requirements for states to perform plan oversight. Additionally, easy to access plan grievances processes and a system to track grievances and oversee plan responses to grievances filed would ensure that plans are meeting their requirements and are accountable to their enrollees. At the same time, the NHC specifies that the exceptions process for EHB should not permit any exemptions as the Part D program allows for specialty tiers. Further, the NHC reiterates its concern about the use of specialty tiers in EHB and refers CCIIO to its previous recommendations to ban the use of specialty tiers and include cost sharing protections for patients.⁶

⁵ See § 201: Patient Protections, General in *A United Patient Voice on Essential Health Benefits*, available at: http://www.nationalhealthcouncil.org/NHC_Files/files/EHB_UnitedPatientVoice.pdf.

⁶ See § 103: Requiring Cost-Sharing Protections in *A United Patient Voice on Essential Health Benefits*, available at: http://www.nationalhealthcouncil.org/NHC_Files/files/EHB_UnitedPatientVoice.pdf.

2. Additional Oversight Processes for Federal and State Governments

The NHC urges CMS to include specific federal and state oversight requirements in the final EHB regulation. The proposed rule leaves most enforcement activities to states. While states should indeed be the first to act in such cases, the role for federal oversight of state enforcement appears to be insufficient. Specifically, the proposed regulation allows HHS to take enforcement actions in two non-specific circumstances—1) if a state notifies the agency that it has not enacted enforcement legislation or that it is not otherwise using its enforcement powers and 2) when the agency determines that a state is not substantially enforcing one or more requirements.

The NHC believes that federal oversight, as described in the proposed rule, would need additional monitoring by the federal government to ensure that states not enforcing any provision or requirement are discovered. Without monitoring processes in place, the federal government's ability to ensure that states are properly enforcing the requirement that qualified health plans meet all appropriate and necessary criteria will be limited. Based on the fact that states are engaged in widely different levels of exchange implementation activity, with some state governors refusing all participation in exchange development, it is expected that some states will not comply with oversight and enforcement activities. A federal monitoring system, such as the system used in the Medicare Advantage program, would be an appropriate tool to ensure adequate patient protections are enforced.⁷

Federal and state oversight requirements should include the development of baseline criteria for qualified health plans to ensure that minimum patient protections exist in all state exchange plans, regardless of the state. Plans should also be examined to ensure that they cover the ten categories of benefits mandated by the ACA. Of particular concern are services such as habilitation that are likely to not be included in a state's benchmark plan. Additionally, the final regulation, or sub-regulatory guidance on this topic, should include federal fallback processes for states not performing adequate oversight of exchange plans.

Federal and state oversight of EHB must include specific processes to review the benchmark plan selected in a state and the EHB package itself. Criteria should be established for oversight of specific elements of plan design, such as UM or cost sharing, as well as for formulary adequacy.

Further, particular oversight mechanisms should be in place in states that select a benchmark plan with coverage—either of medical or pharmacy benefits—that is an outlier from the coverage seen in other state-selected benchmarks. For example, an HMO plan with limited coverage may currently provide adequate access due to its low use of utilization management, but plans subsequently modeled after the benchmark will be permitted to use a higher level of utilization management increasing the likelihood of limited access to benefits.

Shared federal and state oversight programs should resemble the processes used in the Medicare Advantage (MA) program. Specifically, federal oversight for MA programs consists of the following components: 1) Oversight—rigorous, proactive, data-driven, and targeted to known risks; 2) Audits—timely, targeted to known risks, outcome-based, and integrated into a methods for oversight; and 3) Compliance plans/programs—targeted reviews of all programs to ensure proper oversight and outcomes. Additionally, the federal government offers guidance for MA plans to ensure that these plans have functional and effective compliance programs to meet requirements placed on those plans.

⁷ See § 302. Ensuring Access to Essential Health Benefits through Exchanges in *A United Patient Voice on Essential Health Benefits*, available at: http://www.nationalhealthcouncil.org/NHC_Files/files/EHB_UnitedPatientVoice.pdf.

3. USP Classification System

The NHC encourages CMS to consider a hybrid approach to the particular formulary classification system for the purpose of formulary review in EHB. While the proposed regulation recommends the USP classification system, there are particular weaknesses of the system. In particular, USP was designed for a Medicare population; it includes only Part D drugs; it does not include combination products; and, most importantly, USP is updated only every three years. Alternative classification systems, such as the American Society of Health-System Pharmacists (AHFS) classification system have some advantages over the USP system. In particular, AHFS has more detailed information with evidence-based support, is more granular than USP, and is updated at least annually. On the other hand, there are particular downsides to the AHFS system. Specifically, in addition to classifying all prescription drugs, AHFS also includes over-the-counter products and vitamins. Also, AHFS is available only in print, which further limits efforts to access it.

Based on the advantages and disadvantages of these two classification systems, the NHC encourages CMS to consider a hybrid approach to formulary review of plan formularies. A system that includes all prescription medications, is sufficiently detailed to ensure appropriate medication access, is updated regularly, and accommodates the quickly changing landscape of prescription medications is an approach that the NHC would support without hesitation. Further, any classification system to ensure adequate formularies in health plans should be flexible enough to accommodate new medications that become available after mid-year.

4. Strengthening Actuarial Value (AV)

Based on the definition included in the proposed regulation, actuarial value is intended to be a measure that allows patients to make broad comparisons between different cost-sharing policies of plans. The NHC appreciates that the AV Calculator uses a standard national population that closely matches the expected enrollees in the individual and small group market. However, we remain concerned that plan structures (e.g., through use of utilization management) will lower actual utilization of services in these plans and that actual utilization will not match the utilization rates seen in the continuance tables.

Accuracy of AV is a concern for patients as they compare and shop for health plans; patients should be able to expect that one gold plan on average covers as much costs as another. If one of these plans is artificially driving down utilization rates, then the comparison is far less valid. For this reason, the NHC recommends that CMS introduce a policy to perform an annual check on the accuracy of the continuance tables by comparing aggregated actual plan utilization rates to the continuance tables. Should these analyses uncover discrepancies, CMS should address the situation through changes to the continuance tables. Further, as CMS' data source for the continuance tables can access real utilization data from enrolled populations, these data should be integrated into the process of updating the data driving the AV Calculator, when possible.

Conclusion

The National Health Council believes that, with some important modifications, the approach to essential health benefits outlined in this proposed regulation is a marked improvement over the bulletin released in December 2011. However, we stress that in order for EHB benchmark plans to work to meet the needs of

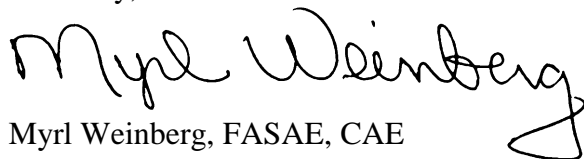
the millions of people who will rely upon the benefits and services covered under EHB, some provisions need to be strengthened and important details must be clarified in the final regulation.

In particular, we believe the final regulation must include clear details about federal and state oversight that will ensure that establishment of the EHB package in states does not lead to discrimination. Further, the regulation must define a uniform exceptions process for patients across all EHB benchmark plans to access medications not on their particular plan's formulary. Further, the classification system used by the federal government to review plan formularies should be comprehensive, flexible, and granular to ensure patients have access to robust formularies that meet their needs. Finally, the NHC believes the data underlying the AV Calculator should reflect, to the extent possible as actual data become available, real utilization rates of health services and demographics of enrollees in EHB benchmark plans.

As the voice for those with chronic diseases and disabilities, NHC believes that broad patient protections are critical to the success of qualified health plans and exchanges. As CMS finalizes the establishment of the EHB, the NHC strongly encourages the agency to include in its final regulations and any sub-regulatory guidance the above-referenced levels of patient protections supported in our previous communications with the agency.

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,

A handwritten signature in black ink that reads "Myrl Weinberg". The signature is written in a cursive, flowing style.

Myrl Weinberg, FASAE, CAE
President