National Health Council

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February 25, 2014

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

Re: Urgent Need for Increased Network Adequacy Standards and Patient Protections against Discriminatory Plan Designs

Dear Secretary Sebelius:

The National Health Council (NHC) appreciates the opportunity to submit comments on the draft letter to issuers in the federally-facilitated marketplace (FFM) for the 2015 plan year. We are writing this letter to raise concern about the insufficient network adequacy and patient protection requirements for health plans in the FFM.

While we applaud the Department of Health and Human Services (HHS) for increasing several network adequacy and patient protection standards from last year, we believe that it is important to increase the issuer requirements further to protect vulnerable patient populations, particularly those living with chronic diseases and conditions. Our recommendations are organized according to the following sections of the letter:

- Chapter 2, Section 3: Network Adequacy
- Chapter 2, Section 4: Essential Community Providers
- Chapter 3, Section 1: Discriminatory Benefit Design: 2015 Approach
- Chapter 3, Section 7: Coverage of Primary Care
- Chapter 6, Section 1: Provider Directory
- Chapter 6, Section 3: Coverage Appeals
- Additional Oversight and Protections

The NHC is the only organization 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 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.

Chapter 2, Section 3: Network Adequacy

We support the requirement that issuers submit a provider list that includes all providers and facilities in the plan's network. CMS will review the provider list to evaluate provider networks using a "reasonable access" standard. HHS guidance defining the bounds of "reasonable access" will have important implications for patients with chronic diseases and disabilities who need access to in-network providers.

- **We recommend that HHS have more stringent requirements to review network adequacy and to issue further guidance regarding the definition of "reasonable access."**

Specifically, we recommend that CMS consider the long-established network adequacy standards for the Medicare Advantage (MA) program as a reference point for qualified health plans (QHP) standards. The time and distance standards in the MA program are based on provider specialty as well as county population density characteristics. The MA standard could serve as a useful baseline for CMS to develop more specific time and distance standards for the provider networks in FFM QHPs.

Chapter 2, Section 4: Essential Community Providers

We support the proposed increase in the Essential Community Providers (ECPs) requirements standard to require QHP issuers to include at least 30% of all ECPs in their service area as part of their provider network.

- **We oppose the proposed exception to this ECP standard to allow a plan to cover less than the required 30%.**

This could leave the most vulnerable patients, those who are low-income and underserved, without the proper patient protections in place to ensure that they have necessary access to critical care.

Chapter 3, Section 1: Discriminatory Benefit Design: 2015 Approach

We support the proposed policy requiring states and health plans to ensure that benefits do not discriminate against any category of people or enrollees. We are encouraged that the Draft Letter to Issuers recommended that all formularies be publically available and linked directly from shopping and enrollment websites as well as the summary of benefits and coverage, so that consumers can clearly identify the formulary for each QHP.

As the agency acknowledges, this proposed draft letter and current regulations do not go far enough to ensure adequate protections against discrimination.

- **We recommend that CMS implement a more detailed process for review of plan benefits design to avoid discrimination, beyond an outlier test of QHP plan design and cost sharing.**

Outlier tests can be useful when discriminatory benefit design is the exception, rather than the rule. Common practices, such as higher cost sharing for certain medications or treatments may not be identified in an outlier analysis. Such practices serve equally to discourage individuals with one or more chronic conditions from enrolling and thus are clearly discriminatory. Reviews of cost sharing should be thorough enough to ensure that such practices do not occur in the QHPs.

- **We recommend the CMS establish 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.**
- **We recommend that CMS develop and implement 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 are also available.[3]

- **We recommend that plans offer formulary transition coverage of drugs for new enrollees.**

We strongly encourage CMS to enforce that QHPs in the FFM require issuers to temporarily cover non-formulary drugs, including drugs on formulary with utilization management, as if they were on the issuer's formulary during at least the first 30 days of coverage, starting January 1, 2015. This is critical for patients with chronic conditions who depend upon stable access to life-saving medications and will allow patients a reasonable period of time to navigate new coverage options and requirements.

We support CMS' recommendation that all formularies be publically available and linked directly from shopping and enrollment websites as well as the summary of benefits and coverage, so that consumers can clearly identify the formulary for each QHP.

- **We recommend that exchange websites contain a searchable formulary tool – similar to the Medicare Part D plan finder – that facilitates comparison of QHPs by drug coverage and cost-sharing.**

Currently the FFM site is designed to show four tiers of drug cost-sharing, even for plans with five-tier formularies. Consumers must open the Summary of Benefits and Claims (SBC) to understand five-tier structure and costs, without any indication that a plan has more than four

[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.

tiers. Shopping and enrollment portals should accurately reflect formulary structure and pharmacy networks.

- **We recommend that formularies contain comprehensive information on drug benefits and adhere to a standard format that**
  - **Includes all pharmacy, medical benefit, and specialty drugs on a single, integrated drug list;**
  - **Provides specific information on tier placement and cost sharing;**
  - **Designates which drugs are subject to utilization management and link to more detailed utilization management criteria;**
  - **Articulates generic substitution policies, requirements around specialty and/or mail-order pharmacy, and coverage for off-label use; and**
  - **Designates clearly which drugs are covered under the medical benefit.**

Chapter 3, Section 7: Coverage of Primary Care

We support CMS consideration of whether to require through rulemaking that all plans, or at least one plan at each metal level per issuer, cover three primary care office visits prior to meeting any deductible.

- **We recommend QHP issuers in the FFM cover three primary care office visits prior to meeting any deductible in order to allow patients affordable access to provider services. Further, CMS should review cost-sharing requirements for these three primary care visits to ensure that the costs associated with such visits are not burdensome or discriminatory.**

Chapter 6, Section 1: Provider Directory

We support linking all provider directories directly from shopping and enrollment websites.

- **We recommend having national standards for the format of provider directories to make the process of shopping and enrolling in a QHP as straightforward as possible.**

Chapter 6, Section 3: Coverage Appeals

We support establishing requirements on coverage appeals. 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.

- **We recommend CMS create a standardized process for people to file grievances with their plans and to appeal adverse plan coverage determinations.**

Without adequate protections and a standardized process, 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.[4]

Additional Oversight and Protections

- **We recommend enhanced federal monitoring and oversight to ensure that states not enforcing any provision or requirement are discovered.**

Without appropriate 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. As evidenced by current ACA implementation and based on the fact that states are engaged in widely different levels of exchange activity, with some state governors refusing all participation in exchange development, it is important to ensure proper oversight. 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.[5]

- **We recommend the development of baseline criteria for qualified health plans to ensure that minimum patient protections exist in all state exchange plans.**

Plans should be examined to ensure that they cover the ten categories of benefits mandated by the ACA, as well as proper network adequacy and formulary transparency. 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.

- **We recommend the creation of a single, unified medical necessity standard.**

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

[4] 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.

[5] 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.

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.[6]

Conclusion

The National Health Council believes that, with some important modifications, the approach outlined in the 2015 Draft Letter to Issuers is a marked improvement from the 2014 Draft Letter to Issuers. However, we stress that in order for QHP plans to work to meet the needs of the millions of people who will rely upon the benefits and services covered, some provisions need to be strengthened and important details must be clarified in the forthcoming regulations.

As the voice for people 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 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 exchange plans meet the intended objectives of improving and standardizing health care coverage.

Please do not hesitate to contact Eric Gascho, our Assistant Vice President 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

Myrl Weinberg, FASAE, CAE
Chief Executive Officer

[6] 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.