National Health Council

1730 M Street NW, Suite 500, Washington, DC 20036-4561 ■ 202-785-3910 ■ www.nationalhealthcouncil.org ■ info@nhcouncil.org

November 6, 2014

The Honorable Sylvia Burwell
Secretary, Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Madam Secretary:

The National Health Council (NHC) has been and continues to be a committed supporter of provisions of the Affordable Care Act (ACA) that provide the greatest benefit to people with chronic diseases and disabilities. We are also committed to ensuring that the law is continually enhanced to strengthen these protections.

The NHC is submitting to you the attached model regulatory language that the patient advocacy community believes will strengthen patient protections that were created by the ACA.

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 a business, 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.

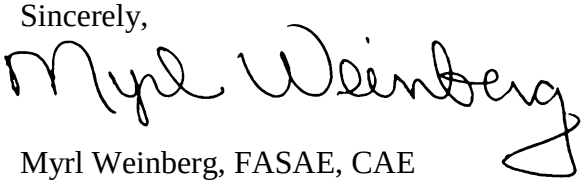
We are submitting the attached recommendations with the aim to

- Ensure that health insurance plan design elements do not discriminate against people with chronic diseases and disabilities;
- Guarantee patient access to needed health care providers;
- Improve plan transparency so that people have the information they need to choose the plan that best meets their individual needs;
- Standardize plan materials to help people do side-by-side comparisons when picking a plan and understand what services their chosen plan offers; and
- Ensure continuity of care when switching plans.

The model language can be used in a variety of HHS' policy making, including a potential update to essential health benefits for 2016 or a draft letter to issuers for the 2016 enrollment period.

Thank you for your consideration of these very important issues, and we look forward to the opportunity to discuss them in greater detail with your staff. If you have any questions, please do not hesitate to contact Eric Gascho, the NHC's Assistant Vice President of Government Affairs, at egascho@nhcouncil.org or 202-973-0545.

Sincerely,



Myrl Weinberg, FASAE, CAE
Chief Executive Officer

Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Proposed Regulatory Language

Preamble

The National Health Council has developed this set of proposed provisions to establish a new layer of protections for patients that would be required of health insurance issuers consistent with Title I of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, referred to collectively as the Affordable Care Act. Specifically, this proposed rule outlines Exchange and issuer standards related to the prohibition of discrimination in cost-sharing structures and other plan design elements; network adequacy requirements and oversight; transparency requirements; and continuity of care protections.

The Prohibition of Discrimination in Cost-Sharing Structures and Other Plan Design Elements section discusses requirements for state and federal oversight to ensure that state-selected benchmark plans and qualified health plans are not designed and do not have the effect of discriminating against any set of individuals. The Network Adequacy Standards section establishes federal oversight of state processes to review qualified health plan networks and ensure that they meet the needs of all enrollees, including those who may need access to providers accepting new patients. The Transparency in Coverage section requires health insurance issuers to standardize processes and information about their qualified health plans, including formularies and the exceptions and appeals processes. The Continuity of Care for Patients Transitioning into New or Changing Coverage section establishes critical protections for patients in need of access to medications while negotiating new coverage through a qualified health plan.

Proposed Language for Regulations Related to Essential Health Benefits

§ 101. Prohibition of Discrimination in Cost-Sharing Structures and Other Plan Design Elements

(a) *Review of State-Selected Benchmark Plans*. State-selected benchmark plans must not employ market practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs. States must establish thorough review of state-selected benchmark plans to ensure the plans meet statutory requirements and are not, in themselves, discriminatory. This includes review of plan design elements and cost-sharing structures with respect to prescription drug coverage, inpatient hospital stays, inpatient mental/behavioral health stays, specialist visits, and emergency room visits.

(1) State oversight requirement. States shall establish oversight mechanisms to review state-selected benchmark plans to ensure such benchmark plans do not discriminate on the basis of race, color, national origin, disability, age, sex, gender identity, sexual orientation, or health needs.

(i) *Enforcement*. States must establish enforcement mechanisms to ensure review of state-selected benchmark plans when those selections are updated. State-selected benchmark plans failing to meet the non-discrimination standard required by 45 CFR 156.125 shall lose status as a state-selected benchmark.

(2) Federal oversight requirement. HHS shall have final authority to approve state oversight programs to ensure appropriate measures are in place to guarantee that plans are meeting the requirements of this section.

(i) Enforcement. State governments are generally responsible for enforcement of reviewing state-selected benchmark plans to ensure that they do not engage in market practices or benefit designs that discourage the enrollment of individuals with significant health needs, with the federal government assuming that role in connection with federal law requirements if a state does not do so.

(3) This provision shall only apply if the Essential Health Benefits are based on state-selected benchmarks

(b) *Review of Qualified Health Plans*. Qualified health plans (QHPs) must not employ market practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs. States must establish thorough review of qualified health plans to ensure the plans meet statutory and relevant regulatory requirements and are not, in themselves, discriminatory. This includes review of plan design elements, cost-sharing structures, and utilization management techniques with respect to prescription drug coverage, inpatient hospital stays, inpatient mental/behavioral health stays, specialist visits, and emergency room visits. In order to ensure that states are able to fully assess QHPs, CMS must provide states with tools to assist with plan reviews. States are required to either use the federal tools or apply an equally thorough assessment that the state has developed.

(1) State Oversight Requirement. States shall review qualified health plans to ensure such benchmark plans do not discriminate on the basis of race, color, national origin, disability, age,

sex, gender identity, sexual orientation, or health needs. These reviews shall be done using comprehensive tools provided by CMS unless the state is using an equally rigorous state standard.

(i) States shall submit to CMS the results of the reviews using either federal or state tools to determine that qualified health plans do not discriminate.

(ii) The plan assessment tools developed by CMS should include, but are not limited to

(1) Examinations of cost-sharing requirements across the benefit design that are more than 10 percentage points higher than the qualified health plan's actuarial value would require (for example, 40% coinsurance in a silver plan with a 70% actuarial value);

(2) Comparisons of medical management techniques across the benefit design among qualified health plans to analyze the comparative use of practices such as prior authorization, step therapy, and quantity limits;

(3) Reviews of formularies to ensure inclusion of drug categories and classes that cover all disease states, accounting for the specific drugs, tiering and utilization management strategies employed in each formulary as well as assurance that sufficient drugs are on the formulary when they offer unique and important therapeutic advantages in terms of safety and efficacy, and their absence from the formulary would substantially discourage enrollment by beneficiaries with certain disease states; and

(4) Inspections of provider networks to include appropriate specialists in their network in accordance with § 156.230.

(iii) *Enforcement*. States must establish enforcement mechanisms to ensure review of qualified health plans when those plans are submitted to the state. Qualified health plans failing to meet the non-discrimination standard required by 45 CFR 156.125 shall lose status as a qualified health plan.

(2) Federal Oversight Requirement. HHS shall have final authority to approve state oversight programs to ensure appropriate measures are in place to guarantee that plans are meeting the requirements of this section.

(i) Enforcement. State governments are generally responsible for enforcement of reviewing qualified health plans to ensure that they do not engage in market practices or benefit designs that discourage the enrollment of individuals with significant health needs, with the federal government assuming that role in connection with federal law requirements if a state does not do so.

Proposed Language for Regulations Related to Essential Health Benefits

§ 156.230 Network Adequacy Standards.

(a) *General Requirement.* A QHP issuer must ensure that the provider network of each of its QHPs, as available to all potential and current enrollees, meets the following standards—

(1) Includes essential community providers in accordance with 156.235;

(2) Maintains a network that is sufficient in number and types of providers in various specialties, including providers that specialize in mental health and substance abuse services, to assure that all services will be accessible without unreasonable delay;

(3) Includes a network that incorporates a sufficient number of providers that are accepting new patients throughout the year;

(4) Provides reasonable access to specialists and other providers who serve the needs of enrollees with rare, chronic, or complex medical conditions;

(5) Assures geographic access to in-network providers, including for individuals in urban, suburban, rural, and frontier areas, based on time and distance standards established by the Exchange; and,

(6) Is consistent with the network adequacy provisions of section 2702(c) of the PHS Act.

(b) *Access to Provider Directory.* A QHP issuer must make its provider directory for a QHP available, in a standardized form and manner specified by HHS, to the Exchange for publication online in accordance with guidance from the Exchange and to potential and current enrollees as described in the following paragraphs. In the provider directory, a QHP issuer must identify providers that are accepting new patients.

(1) A QHP issuer must make its provider directory available to potential and current enrollees in hard copy upon request.

(2) A QHP issuer must maintain a publicly available website, updated no less than quarterly, where potential and current enrollees may access provider network details for each QHP in the Exchange without creating a user account or login.

(3) A QHP issuer shall include in its publicly available provider directory each provider's specialty, network tier, if applicable, and contact information.

(4) A QHP issuer must inform enrollees, in a form and manner specified by HHS, of changes to each of its provider networks.

(c) *Mid-Year Changes to Provider Network*. A QHP provider network is permitted to modify its provider network mid-year but must also maintain network adequacy standards as described in § 156.230(a).

(1) <u>Enrollee Access to Providers Leaving a Network.</u> QHP enrollees receiving care and treatment from a provider that is leaving the network shall have the option to maintain access to that

provider for the remainder of the policy year. Enrollees grandfathered under this provision shall also access the provider under the plan's in-network cost sharing.

(d) *Oversight of Provider Networks.* A QHP provider network must maintain a network that is sufficient in number and types of providers, including providers that specialize in mental health and substance abuse services, to ensure that all services will be accessible to enrollees without unreasonable delay. States are required to conduct reviews of provider networks across a variety of specialties to ensure the needs of enrollees with complex health needs are met.

(1) Criteria for Provider Network Oversight. Reviews of QHP provider networks will include compliance with the Centers for Medicare and Medicaid's "reasonable access" standard across a variety of specialties that have historically raised network adequacy concerns, including but not limited to hospital systems, mental health providers, oncology providers, and primary care providers. To ensure that QHP provider networks do not discriminate against individuals with chronic conditions or impede access to care, the criteria for evaluating QHP provider networks must include the following:

(i) *Network design oversight*. QHPs utilizing a provider network shall be required to demonstrate an adequate number of in-network providers in various specialties corresponding to the ten categories of essential health benefits services. Network designs must encourage a choice of provider networks, promote cost-effective delivery of health care, and assure geographic access.

(ii) *Specialty provider oversight*. QHPs must ensure that enrollees have access to specialty providers that meet the needs of patients. Specialty provider availability must take into account the geographic prevalence of specific conditions.

(iii) *Geographic access oversight*. QHPs must demonstrate that their networks do not unduly burden beneficiaries in terms of travel distance and time to network providers. QHPs must demonstrate that 90% of their provider network meets the time and distance requirements (90% of beneficiaries must have access to at least one provider, for a given specialty, within the time and distance requirements). Time and distance requirements for urban, suburban, rural, and frontier localities shall be established by HHS.

(2) Enforcement. States have primary enforcement authority for conducting QHP provider network reviews. In accordance with federal law, the federal government will conduct reviews for states that fail to perform provider network reviews.

§ 156.220 Transparency in Coverage.

***

(a) *Publication of Single Formulary*. A QHP issuer shall make available, in a standardized form and manner required by HHS, to the Exchange and to potential and current enrollees as described in the

following paragraphs, a single drug formulary for each QHP that includes all pharmacy, provider-administered medical benefit, and specialty drugs.

(1) A QHP issuer must make its single formulary available to potential and current enrollees in hard copy upon request.

(2) A QHP issuer must maintain a publicly available website, updated no less than quarterly, where consumers can access the single formulary for each QHP offered through an Exchange without creating or using a login or user name.

(i) At a minimum, the single formulary must make clear the tier placement of covered drugs, including drugs covered under the medical or specialty benefit; cost-sharing information; and any utilization management protocols that apply to covered drugs.

(3) Notification of Formulary Changes. A QHP issuer must inform enrollees, in a form and manner specified by HHS, of changes to the single formulary. A QHP issuer must make sure that the information submitted under paragraph (a) is provided in plain language as defined under § 155.20 of this subtitle.

(4) Limitation on Negative Formulary Changes. With the exception of products recalled by the Food & Drug Administration (FDA) or a product manufacturer or brand medicines that have lost patent protection and for which the generic is available on the formulary, QHP issuers may make negative formulary changes only if enrollees currently taking the affected drug are exempt from the formulary change for the remainder of the contract year.

(i) Such negative formulary changes include, but are not limited to, removal of a product from a formulary, increased cost-sharing, and increased utilization management techniques.

(b) *Requirements for Appeals and Exceptions Process Materials*. QHP enrollees are entitled to a reasonable opportunity for a full and fair review of an adverse coverage determination. Further, QHP enrollees are entitled to a standard, uniform exceptions process that allows an enrollee to request and gain access to clinically appropriate drugs not covered by the health plan. To comply with the requirements of the Affordable Care Act, QHP issuers shall establish an exceptions and appeals process and are required to design those processes such that they meet the uniform standard process established by HHS.

(1) Cost Sharing under the Exceptions Process. QHP issuers must assign drugs approved under the exceptions process to one of the existing cost-sharing tiers and may not subject it to coinsurance, copayment, or other cost-sharing requirements that exceed the requirements for drugs that are on the QHP's formulary. Cost-sharing paid by an enrollee for a medication covered as a result of the exceptions process shall be counted toward any deductible and maximum out-of-pocket limit established by the QHP.

(2) Expedited Process for Clinically Appropriate Non-Formulary Drugs. QHP issuers are required to establish an expedited process for access to clinically appropriate drugs that are not covered

by the issuer in exigent circumstances, such as when an enrollee is suffering from a serious health condition or an enrollee is in a current course of treatment using a non-formulary drug. QHP issuers shall render decisions regarding formulary exceptions requests and notify the enrollee (and the prescribing physician or other prescriber as appropriate) within 24 hours following the issuers' receipt of the exceptions requests.

(3) Duration of Exception Coverage. Once an exception is granted, the plan sponsor is prohibited from requiring the enrollee to request approval for a refill or new prescription to continue using the prescription drug approved under the exceptions process for the remainder of the plan year, so long as the enrollee remains enrolled in the plan, and the physician or other prescriber continues to prescribe the drug. A plan sponsor may choose not to require an enrollee to resubmit an exception request at the beginning of a new plan year.

§ 103. Continuity of Care for Patients Transitioning into New or Changing Coverage

(a) *Continued Access to Medications for Individuals Changing Plans*. Issuers are required to temporarily cover non-formulary drugs, including drugs that are on the issuer's formulary but require prior authorization, as if they were on the issuer's formulary during the first 30 days of coverage, for coverage beginning on January 1 of each year, starting with the 2016 plan year. This policy allows individuals newly enrolled in a QHP or switching QHPs who are stabilized on specific medications to receive coverage for a non-formulary drug during this time period without using the exceptions process.

(b) *Ensuring appropriate use of step therapy*. Plans are not permitted to require step therapy for patients who are demonstrated to be stable on a medicine. Additionally, patients who have already undergone step therapy should never be required to repeat step therapy in order to obtain coverage for the medicine their doctor has prescribed. When step therapy is required, plans must have a process in place for physicians to override step therapy if the preferred medicine is more clinically appropriate for the patient.