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December 22, 2014

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

Re: Proposed Rule on HHS Notice of Benefit and Payment Parameters for 2016

The National Health Council (NHC) appreciates the opportunity to submit comments on the Proposed Rule on the Notice of Benefit and Payment Parameters for 2016. We are submitting this letter to ensure that patients have access to appropriate coverage in upcoming plan years.

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.

We applaud the Department of Health and Human Services (HHS) for working to improve patient protections for those who are served through the exchange market. The NHC has worked closely with HHS to advocate for modifications to regulations that will support the needs of patients in exchange plans and other health insurance coverage affected by the Affordable Care Act (ACA). We continue to believe that the success of exchanges depends on appropriate protections for patients enrolled in these plans, particularly for those living with chronic diseases and disabilities. Over the past year, the NHC has focused ACA-related advocacy efforts on five key priorities:

1. Ensure cost-sharing structures and other plan design elements do not discriminate against people with chronic conditions and impede access to care.
2. Create transparency standards to ensure patients have access to complete details about coverage and costs of health insurance exchange plans.

3. Make insurance exchange plan materials easier for patients to understand by creating uniformity of content and design.
4. Establish continuity of care requirements that protect patients transitioning into new coverage.
5. Ensure that all health insurance exchange plans meet federal requirements.

We strongly believe that many of the changes included in this proposed rule will increase patient protections according to the principles outlined above. Even so, the NHC remains concerned about certain elements of the proposed rule. Below we outline our support for certain provisions and discuss changes to the proposed rule that will help to ensure that patients have access to health coverage that addresses their medical needs at the most affordable price in 2016.

Annual Eligibility Redeterminations (§ 155.335)

The NHC supports a re-enrollment process that allows enrollees the option to re-enroll according to their own preferences for the following year, whether that preference is to keep the same carrier, a similar premium, or some other standard. However, because premium changes from year to year are not evenly distributed among the plans, one patient enrolled in a plan may experience a year-to-year increase of 2%, while another patient will face an increase of 20%. Creating a system that allows people to select their preferred approach to re-enrollment certainly would protect many enrollees from unexpected premium increases.

The NHC believes that the re-enrollment process should grant the enrollee as much controls is possible. For example, the proposed rule states that a trigger—such as any premium increase, or a premium increase higher than the rate increase seen by other plans, or a premium increase that meets a threshold—would instigate the process. It should be possible to build a system that allows enrollees to select their own trigger; likewise, they should be able to select their own outcome, whether it is the lowest premium plan in the same metal level or some other approach. A system with example scenarios could offer enough explanation to shoppers that allows them to make an informed decision about the next year's re-enrollment, should they not happen to actively select a plan. Such sample scenarios should make it clear to shoppers how auto-reenrollment might affect their care, such as changes to their premium and cost-sharing responsibilities as well as potential changes to the drug formulary and provider network.

Annual Open Enrollment Period (§ 155.410)

The NHC supports HHS' proposal to shift the annual open enrollment period to October 1 through December 15 of the calendar year preceding the benefit year. We agree that this change will reduce confusion and align, for most enrollees, their maximum out-of-pocket limit accrual with the calendar year.

Provision of EHB (§ 156.115)

The NHC supports the proposal to define habilitative services. However, we believe that a more comprehensive definition would better support the patients in need of such services. We recommend that HHS adopt the definition of habilitation services and devices developed by the National Association of Insurance Commissioners (NAIC), as recommended by the Habilitation Benefits Coalition and the Consortium of Citizens with Disabilities. Further, the NHC supports the proposal to forbid plans to impose limits on such services that are less favorable than limits placed on rehabilitative services. We believe that HHS should examine coverage of and any limits placed on habilitative and rehabilitative services to determine not only whether they are at

parity with each other, but also if they discriminate against people with need of these particular services. Finally, HHS should continue to assess coverage of these services to ensure that people have appropriate access to habilitation services.

Collection of Data to Define Essential Health Benefits (§ 156.120)

The NHC supports the requirement that the issuer of a state's benchmark plan submit data about its coverage to HHS according to the timelines in the proposed rule. However, this section of the proposed rule leaves many questions unanswered. First, though states would be permitted to select a new benchmark plan for 2017, the rule is silent on benchmark plans for 2016. The current benchmark was selected for plan years 2014 and 2015, with assurance from HHS that an update to EHB for years 2016 and beyond would be forthcoming. Second, the proposed rule does not offer a default benchmark plan for states failing to select a benchmark for 2017. HHS should define a new default benchmark plan from 2014 that is compliant with ACA of its own accord, not through supplementation. Third, the proposed rule is silent on the application of state benefit mandates. One assumes that mandates passed prior January 1, 2012 will continue to be considered essential health benefits if the benchmark plan covers those mandated items and services. However, it is entirely unclear what happens to applicable benefit mandates passed after that initial deadline.

Prescription Drug Benefits (§ 156.122)

The NHC expresses support for the proposed standardized exceptions process for non-exigent circumstances. We also support the proposed requirement that medications accessed through the exceptions process be considered EHB and therefore count toward a plan's benefit structure, including the maximum out-of-pocket limit. This is crucial to ensure affordability of care.

Further, we appreciate the requirement that formularies must be easily accessible—without requiring the creation of an account or other patient hurdles—and machine readable. However, we argue that plans should be required to list all of their covered medications on a single formulary. Currently, some plans have multiple formulary documents for circumstances including the standard formulary, formulary updates, specialty medications covered, and medical benefit coverage, etc. We encourage the agency to consider methods to make formularies available in a standardized template that could be used, in the future, for a “plan finder” type tool on healthcare.gov. Additionally, we strongly support the requirement that tier placement and utilization management details be included in the formulary.

However, the NHC believes that the changes proposed to the prescription drug benefits within EHB are insufficient to provide access to comprehensive drug coverage that is similar in nature and scope to employer-sponsored coverage—a requirement defined by statute. The rule proposes that the drug counting methodology based on the USP Medicare Model Guidelines is replaced entirely by an issuer's use of a P&T committee. A P&T committee alone will not ensure adequate protections for formulary breadth and depth; HHS must develop, and implement in regulation, some level of minimum standard formulary coverage requirements to establish a baseline for health plans. These two elements, taken together with comprehensive reviews for non-discrimination, could help resolve some of the issues surrounding the continued development of exchange plans seeking to avoid risk by attracting enrollees with less-than-ideal health profiles.

The NHC is also concerned that this approach only requires plans to have such a committee—not to abide by its decisions. One assumes this is an oversight, however, the final regulation should clarify that plans must both have a P&T committee meeting the standards established by the federal government and abide by the decisions of said group. The rule also establishes some standards for membership, frequency of meetings, and development of a formulary. These standards are not sufficient for the purpose of designing an appropriate formulary for all enrollees, particularly those with chronic or disabling conditions. First, there is no minimum for the required number of P&T members—only that the committee needs to include experts from a sufficient number of clinical specialties to represent adequately the needs of enrollees, including experts in chronic diseases and disabilities. While this requirement is an important point, the proposed rule does not include enough specifications about the structure or function of the P&T committee. For example, the rule should stipulate a minimum number of P&T committee members who are specialists versus generalists. We also recommend that committees should include patients and family caregivers. The final rule should require plans to maintain a publicly available list of all P&T members, subject to review both by federal oversight activities and the general public. Finally, the regulation should require that plans seek outside expertise on any uncommon or rare conditions one or more enrollees might have to ensure appropriate coverage for any enrolled patient.

That said, the NHC supports a few notable points in this area. First, we agree that P&T committees should review for coverage both newly FDA-approved drugs and new uses for existing drugs. Also, we support the requirement that P&T committees review whether formularies cover a range of drugs across a broad distribution of therapeutic areas and recommended treatment regimens for all disease states and do not discourage enrollment by any group. We appreciate the inclusion of requirements that treatment guidelines should be reflected in coverage policies. The NHC believes that the final rule should specify requirements for consideration of both newly FDA-approved drugs and new uses for existing drugs with a specified time period, such as the 180-day timeline already in effect for the Medicare Part D Program.

In short, use of a P&T committee by exchange plans can provide benefit; however, as proposed, these requirements fall far short of ensuring adequate access to medications for patients in these plans.

The proposed rule also considers a potential new standard to replace the USP-based drug counting requirement with one based on AHFS. As stated in previous comments to HHS on the topic, the NHC agrees that the AHFS classification system, particularly if all four tiers are used, has advantages over USP. However, moving to AHFS is not a straightforward process, and HHS should consider the implications of such a change without appropriate guidance on the approach. In general, the AHFS has much more granular classification data across all drugs. However, the system also classifies over-the-counter medicines, devices, diagnostics, and other products not likely to be included in a plan's formulary. Should HHS proceed with an AHFS-based structure, the first step would be to acknowledge the list of products and types of products that would not be included in requirements. Should a minimum standard be established for AHFS, a one drug per class requirement would be insufficient. First, it likely would not ensure a range of drugs across a broad distribution of therapeutic areas. The other major concern with a one drug per AHFS class minimum is the fact that some medicines in AHFS are classified in a single class rather than multiple classes, such as in USP. One notable example of this issue is for cancer

medications (AHFS 10.00), rather than the 11 classes of medications in the antineoplastics category in USP v.6. Since cancer medications are often uniquely tailored to one or a few particular types of cancers, any minimum number of medications in this class will likely be insufficient for people with all cancers. We recommend, therefore, that for antineoplastics—and potentially other therapeutic areas so affected—HHS consider a more nuanced approach than a per-class minimum, based on AHFS.

Prohibition on Discrimination (§ 156.125)

The NHC believes that access to therapies considered the standard of care is key for patients with chronic conditions. As such, we support HHS' proposal to consider discriminatory those plans that do not cover single tablet regimens or extended-release products when those are the customarily prescribed therapy. We also strongly support the prohibition on plans that place most or all drugs for a specific condition on their highest cost formulary tiers. We urge HHS list these and other examples of discriminatory practices in regulation, as opposed to relying on preamble language.

Though we agree with the HHS approach that any plans identified using such practices would be asked to submit justification for their coverage policies, we believe this policy could be strengthened with a few key changes. First, HHS should establish a minimum list of formulary coverage and access tests for all plan formularies and apply these tests across all plans in the federally facilitated marketplace. These reviews should be similar to the internal process used by CMS to evaluate formulary drug lists submitted by Medicare Part D plans. Second, HHS should develop a standard to use to determine whether the justification is appropriate. Third, HHS should consider alternative remedies if a plan justification is not appropriate and the plan does not remedy the situation.

HHS also should develop a set of tests for discrimination outside of the drug benefit. An example of such a review could include examinations of any plan's cost-sharing requirements across the entire spectrum of services 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). Another example of such a test could be for silver plan variations that provide reduced cost sharing for people with limited income. A study released earlier this year examined the percent of silver plan variations that reduce cost sharing for key services and determined that many of these variations, for 2014, do not reduce cost sharing for key services, such as specialist care or brand medications. This trend was even prevalent for 94% actuarial value (AV) variations. About half of these 94% AV plans did not reduce cost sharing for fourth-tier medications from the standard silver cost sharing.¹ With such flexibility awarded to plan issuers to design silver plan variations, it is likely that this trend will continue. The data in this analysis indicate that such variations discriminate against patients who need expensive or specialty medications.

Cost-Sharing Requirements (§ 156.130)

The NHC appreciates the updates proposed to cost-sharing requirements, as described in this proposed regulation. Our support extends to the proposed updates to the maximum out-of-pocket

¹ Avalere Health. Analysis of Benefit Design in Silver Plan Variations. June 2014. Accessed at: http://avalere-health-production.s3.amazonaws.com/uploads/pdfs/1401801935_AH_CHPA.pdf.

limit that would require plans to apply this limit to the calendar year in which the plan began and not allow non-calendar year plans to “reset” the annual limit at the end of the calendar year when such plans overlap multiple calendar years. We also support the proposal to allow health plans to count services received out-of-network toward the maximum out-of-pocket limit. Finally, this rule introduces a new patient protection that the NHC believes will be of great benefit to patients, particularly those with complex conditions requiring expensive care. The proposal to apply the self-only annual limit on out-of-pocket costs for individuals covered by plans that are not self-only will definitely provide protection for patients, regardless of the type of plan in which they enroll. This will undoubtedly protect patients with the most complex conditions from having out-of-pocket expenses that are up to double what they would be, had they enrolled in self-only coverage.

Network Adequacy Standards (§ 156.230)

We understand the HHS perspective to limit formal rulemaking on network adequacy requirements until the National Association of Insurance Commissioners workgroup completes development of their model act related to network adequacy. As this model act is finalized, the NHC urges HHS to consider how well the NAIC requirements measure against the eleven elements of network adequacy standards identified by Families USA as key standards for successful network requirements across states: 1) Accurate Information about Providers; 2) Timely Access to Care; 3) Adequate Numbers of Providers; 4) Adequate Types of Providers; 5) Inclusion of Essential Community Providers; 6) Adequate Geographic Distribution of Providers; 7) Access to Out-of-State Providers; 8) Accessible Hours; 9) Language-Accessible and Culturally-Competent Care; 10) Rights to Go Out-of-Network; and 11) Continuity of Care.²

The proposed rule, however, also introduces a new suggestion for plans to have at least a 30-day transition period for new enrollees in an ongoing course of treatment. The NHC argues that this proposal should be both strengthened and finalized. First, health plans are under no obligation to retain the same set of providers in their network throughout the plan year. Therefore, at any time a provider is removed from the plan’s network, an individual undergoing an ongoing course of treatment should be permitted at least a 30-day transition period to allow the individual time to conclude their therapy and/or find a new network provider. This transition period should be extended, as needed, for patients who cannot find a network provider who is accepting new patients and can continue the individual’s course of treatment without delay. People who enroll in health plans by aligning their providers with a plan’s network should not be harmed by a plan or provider’s decision to end their contracting arrangement. Adequate, flexible transition requirements for health plans will minimize the disruption that patients might experience in such situations.

The NHC also strongly supports the proposed requirements that health plans must make available accurate, timely, machine readable provider directories to the public. We also encourage the agency to consider methods to make provider directories available in a standardized template that could be used, in the future, for a “plan finder” type tool on healthcare.gov.

² Families USA. Standards for Health Insurance Provider Networks: Examples from the States. November 2014.

Accessed at:

http://familiesusa.org/sites/default/files/product_documents/ACT_Network%20Adequacy%20Brief_final_web.pdf.

Essential Community Providers (§ 156.235)

In general, the NHC supports the inclusion of essential community providers (ECPs) in health plan networks. Therefore, the proposal to expand the types of providers considered as ECPs should be a welcome change for patients who access health care from these types of providers. We also support the proposal to require plans to demonstrate they have met the ECP standard defined by HHS for the QHP to be approved through the certification process. The NHC does caution that expanded standards to include additional ECPs in a plan's network should not reduce any requirement related to network adequacy that a state may require of health plans. In other words, a plan that has more ECPs in network should not be able to reduce the number of non-ECP providers that would have otherwise been required according to state law or regulation.

Plan Variations (§ 156.420)

The NHC supports the requirement that health plans provide Summaries of Benefits and Coverage (SBC) documents that accurately represent the cost-sharing reductions available to individuals and families with limited income through silver plan variations. We recommend that SBCs be standardized and machine readable.


Quality Improvement Strategy (§ 156.1130)

The NHC has long supported efforts to encourage value-based purchasing in health plans. Accordingly, we support requirements for health plans to create quality improvement strategies (QIS) that structure payments that incentivized improved health outcomes, reduced readmissions, better patient safety, and reduced medical errors, among other quality improvements. The NHC agrees with the proposal to require issuers participating in an exchange for at least two years to implement QIS and to submit data on the QIS annually. During this important establishment phase, NHC urges HHS to review QIS developed by health plans to ensure that such strategies do not discriminate, either by design or by effect, against any one group of individuals. Additionally, we encourage HHS to consider, for future years, evaluation of the QIS programs established by health plans in order to improve QIS across issuers nationwide and develop a set of quality performance data upon which plans might be assessed and compared.

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 HHS finalizes the notice of benefit and payment parameters for 2016, the NHC strongly encourages the agency to include in its final regulations the above-referenced levels of patient protections supported in our previous communications with the agency.

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, FASAE, CAE
Chief Executive Officer