January 17, 2016

The Honorable Sylvia Mathews Burwell
Secretary of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

Re: Comments on Draft 2017 Letter to Issuers in the Federally-facilitated Marketplaces

Dear Secretary Burwell:

Thank you for the opportunity to comment on the Draft 2017 Letter to Issuers in the Federally-facilitated Marketplaces. The Epilepsy Foundation is the leading national voluntary health organization that speaks on behalf of more than 2.8 million Americans with epilepsy and seizures. We foster the well-being of children and adults affected by seizures through research programs, educational activities, advocacy and direct services. Epilepsy is a medical condition that produces seizures affecting a variety of mental and physical functions. Approximately 1 in 26 Americans will develop epilepsy at some point in their lifetime, and people living with epilepsy must have meaningful and timely access to physician-directed care and specialists, to avoid breakthrough seizures and related complications and costs.

Many individuals living with epilepsy who had been denied access to health insurance in the past due to pre-existing conditions have now gained access to quality and affordable care because of the changes created by the Affordable Care Act (ACA). But many are still facing barriers to care, including discriminatory benefit designs that limit access, such as restrictive formularies and inadequate provider networks; high cost-sharing; and a lack of plan transparency that deprives them of the information that is essential to making informed enrollment choices. We applaud the Department of Health and Human Services (HHS) for proposing increased patient protections, but urge the Secretary to pursue additional protections to ensure meaningful and timely access to quality care for all individuals enrolled in Marketplace plans.

We recently submitted public comments on the 2017 Notice of Benefit and Payment Parameters (NBPP) proposed rule focused on 1) the proposed Standard Benefits Option; 2) protecting access to prescription drugs; 3) continuity of care; and 4) payments made to QHP enrollees on behalf of third parties. Our comments on the 2017 Draft Letter to Issuers complements those comments.

Nondiscrimination & Federal Civil Rights Laws
We are pleased that in the 2017 Draft Letter to Issuers, the Centers for Medicare and Medicaid Services (CMS) reminds issuers that several federal civil rights laws and Section 1557 of the ACA also govern QHPs, and are enforced by the Office of Civil Rights (OCR). CMS notes that OCR proposed the “Nondiscrimination in Health Programs and Activities” rule in September 2015. However, that rule has not been finalized and the proposed rule did not detail which plan benefit design practices constitute discrimination against beneficiaries. We believe that in order to protect beneficiaries and to provide clarity to state and federal regulators, now and in the future, CMS must provide a clear definition of what constitutes discrimination. Enforcement is made more difficult since the rule has not been finalized and the
proposed rule lacks the specifics needed and we urge OCR to move to finalize a rule that includes specific examples of discriminatory plan design so that it can be meaningfully enforced.

**Discriminatory Benefit Design**

We agree with CMS that certain plan designs effectively discriminate against or discourage enrollment by certain beneficiaries, such as those with serious or chronic health condition. This includes when “an issuer places most or all drugs that treat a specific condition on the highest cost formulary tiers.” We urge CMS and the states to pursue greater enforcement to ensure this type of discrimination does not occur. CMS states that “enforcement of this standard is largely conducted by the States,” but in order for the ACA patient protections to be realized, the states need the necessary resources and analytical tools to assist in enforcement. Additionally, it is CMS’ ultimate responsibility to ensure that actual plan review and enforcement occurs, and if it is not happening, to step in to ensure that it does.

We support the proposal to consider a number of plan design elements to determine if an issuer is discriminating against individuals on the basis of their health status and other factors, or “employing marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs pursuant to 45 CFR 156.225.” CMS indicates again that it will analyze outlier tests to examine cost-sharing and out-of-pocket costs associated with standard treatment protocols for certain conditions, and review a plan’s cost-sharing structure. In past years we have noted that an outlier analysis can be faulty if all issuers engage in such practices. Therefore, we are pleased that the Draft Letter to Issuers notes that, “CMS retains the right to identify a benefit design as discriminatory even if it is not flagged in the outlier analysis.”

We support the proposal to review out-of-pocket costs associated with standard treatment protocols of certain chronic and high cost medical conditions. We encourage CMS to expand the list of conditions for which it will conduct a review from the proposed five for 2017 since there are so many more health conditions and patients with those conditions need the same protections.

**Prescription Drugs**

We support the proposal to review adequate prescription drug coverage in QHPs by conducting a 1) formulary outlier review; 2) clinical guidelines-based review; and 3) review of tier placement of prescription drugs recommended of specific medical conditions. While we are pleased CMS will review a plan’s drug coverage in order to determine if it meets clinical guidelines for the treatment of specific medical conditions, it is only doing so for nine conditions. Beneficiaries rely on Marketplace plans for many more health conditions, and adequate drug coverage is necessary for them to have meaningful access to care. We urge CMS to review all plans for adequate drug coverage for all medical conditions.

We are particularly pleased that CMS is “concerned about adverse tiering, which occurs when a formulary benefit design assigns most or all drugs in the same therapeutic class needed to treat a specific chronic, high cost medical condition to a high cost-sharing tier.” We agree that this practice, which is being employed by many issuers across the country, is potentially discriminatory.
**Formulary Drug List and Formulary Lookup Tool**

We support the proposed transparency requirements for all plans to help patients select an appropriate QHP that best meets their needs. This includes an accurate and up-to-date machine readable drug list that includes tiering, utilization management and pharmacy network requirements. We agree with CMS that, “the formulary drug list must be published in a manner that is easily accessible to plan enrollees, prospective enrollees, the state, the Marketplace, CMS, OPM and the general public.”

**Restrictive Formularies**

Some plans limit access to prescription medications through restricted formularies, excessive cost-sharing and medical utilization management tools, such as prior authorizations, step therapy, and others. Some of these practices violate the ACA and are discriminatory, especially against beneficiaries who have chronic or other serious health conditions. We believe that these practices can be eliminated through a meaningful state and federal review processes. CMS and the states must review every QHP and not rely only on patient grievances and complaints.

**Prescription Drug Out-of-Pocket Cost Comparison Tool**

In order for beneficiaries to select a QHP that best meets their health needs and for them to know what their out-of-pocket costs will be for a certain medication or medical service, CMS should require plans to include a true out-of-pocket cost comparison tool. A beneficiary should be able to know what their estimated costs for a specific drug regimen will be in advance. This is particularly important for plans that utilize co-insurance rather than co-pays. A beneficiary has no idea what the patient costs of a drug will be when plans use co-insurance. We believe plans that rely so heavily on co-insurance fail to meet the necessary plan transparency requirements, and may steer beneficiaries to plans that charge patients excessive costs for medications. This could be rectified if the out-of-pocket cost comparison tool was a true cost tool, similar to what is used by Medicare.

**Network Adequacy Standard**

We appreciate the greater detail that CMS provides in the Letter about its approach to determining network adequacy in 2017. In general, we applaud CMS for recognizing the need to strengthen network adequacy standards and for proposing a number of new protections that would apply for the 2017 plan year. While millions of Americans have gained health insurance over the last two years, that coverage is unfortunately hollow if they cannot access the covered benefits promised to them. Even though the National Association of Insurance Commissioners (NAIC) has now completed its work on its updated Health Benefit Plan Network Access and Adequacy Model Act (Model Act), it is not yet clear how many states will adopt it in whole or in part. Therefore, we strongly encourage CMS to move forward with strong network adequacy standards that can serve as a floor of protection for consumers enrolled in QHPs beginning in 2017.

**State Review of Quantitative Network Adequacy Standard**

CMS reiterates its proposal to rely on FFM states to review QHPs for network adequacy, provided those states use an “acceptable quantifiable network adequacy metric commonly used in the health insurance industry”. While we commend CMS for recognizing the need for a quantitative, rather than subjective, approach to determining what constitutes “reasonable access,” we are concerned that relying on a single metric will not be sufficient for measuring network adequacy. Therefore, we recommend that CMS require...
states to use a broad set of metrics that take into account geographic variations, regionalization of specialty care services and utilization and practice patterns. The NAIC’s Model Act includes a list of quantitative criteria that states could use, such as provider-covered person ratios, geographic accessibility (time and distance) standards, and appointment wait time measures. In addition, we want to reinforce our strong support for requiring the use of a minimum set of quantitative measures in all states, including state-based marketplaces (SBMs).

**Federal Default Standard**
We generally support using time and distance standards but these standards alone are not sufficient. There still needs to be minimum provider criteria to ensure that a sufficient number of providers with the required training and expertise are available to actually serve the specific needs of the covered population. Without also specifying and applying minimum provider-to-enrollee standards, consumers, particularly those in densely populated areas, could find themselves within a few miles of a provider but unable to actually get an appointment due to an insufficient quantity of providers. Therefore, we strongly urge CMS to, at a minimum, enumerate and apply minimum provider-to-enrollee standards for QHPs, as is the case for Medicare Advantage (MA) plans. With respect to tiered provider networks, we urge CMS to clarify that only providers in the lowest cost-sharing tier will be counted towards meeting the proposed time and distance standards. Using providers who are assigned to a higher cost-sharing tier can result in significantly more out-of-pocket costs, sometimes akin to using out-of-network providers.

**Distance and Time Requirement Specialty Areas**
CMS solicits comments on both the types of specialties selected and the proposed time and distance standards. Given that neurologists are the physicians that generally care for patients with a wide range of neurological conditions that are likely to be experienced by the QHP population, including concussions, migraines/headaches, epilepsy, multiple sclerosis, and stroke, we support adding neurology to the list of specialty areas for which time and distance standards are established for 2017.

**Distance and Time Requirements Exemptions**
CMS proposes to use a justification process for allowing issuers that do not meet the time and distance requirements to explain why they are unable to do so. Based on its analysis of 2016 QHP issuer network data, CMS estimates that 10 percent of issuers could use this justification process. Unfortunately, such a process does nothing to ensure that consumers enrolled in those plans will have access to an adequate number of providers to provide covered services in a timely manner. Therefore, as part of the justification process, CMS should require issuers to document how they will ensure that enrollees will have access to needed providers without unreasonable delay and at in-network cost-sharing rates. Section 5C of the NAIC’s Model Act requires all health carriers to have such a process in place to assure that a covered person can obtain covered services from an out-of-network provider at in-network levels of cost-sharing when an in-network provider is not available without unreasonable travel or delay.

**Provider Transitions**
We commend HHS for recognizing the need for consumer notification and a transition period when one of their providers is being discontinued from their plan’s network. We generally support these proposals and...
encourage CMS to carefully consider and implement our previous recommendations for improving upon them as you finalize both the Payment Notice rule and the Letter.

Network Transparency
We support the proposal to provide a rating of each QHP’s relative network breadth on HealthCare.gov, and we strongly urge CMS to move forward with implementing this system for the 2017 plan year. Currently, consumers have no way of knowing what the relative breadth of their plan’s network is. Particularly with the growth of plans with narrow networks and no out-of-network coverage, it is critically important that consumers understand the network that comes with the plan they are choosing and the trade-offs that come with that choice. Plans with narrow networks may be an appropriate choice for some consumers, but they should know that is what they are buying and that the choice may result in higher out-of-pocket costs later if they need to go out-of-network.

Provider Out-of-Network Cost Sharing
We appreciate that CMS acknowledges the problems that out-of-network cost-sharing poses for beneficiaries when they receive covered services by an out-of-network provider at an in-network facility, often without their knowledge or control. Unfortunately, we remain very concerned that the remedy being proposed by CMS in the NBPP proposed rule and Draft Letter to Issuers does very little to address the financial harm that consumers experience in these situations and is significantly weaker than the provisions included in the NAIC’s Model Act. We strongly urge CMS to adopt the recommendations we made in our comments with respect to the NBPP when finalizing the rule and this Letter.

The Epilepsy Foundation supports several elements in the Draft Letter to Issuers and we look forward continuing to work with CMS to improve benefit design, cost-sharing, and transparency in Marketplace plans, to ensure that the ACA meets the needs of the millions of individuals who rely upon these plans to access quality health care, especially those living with complex chronic conditions. Please do not hesitate to contact Angela Ostrom, Chief Operating Office & Vice President Public Policy, at 301-918-3766 or aostrom@efa.org with any questions or concerns.

Sincerely,

Philip M. Gattone, M. Ed.
President & CEO
Epilepsy Foundation