December 21, 2012

The Honorable Kathleen Sebelius, Secretary  
U.S. Department of Health and Human Services   
Hubert H. Humphrey Building  
200 Independence Ave., SW  
Washington, DC 20201

Re: (CMS-9980-P) Patient Protection and Affordable Care Act Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation  
Submitted electronically at http://www.regulations.gov

Dear Secretary Sebelius:

The Epilepsy Foundation appreciates the opportunity to comment on the proposed rule, “Patient Protection and Affordable Care Act (ACA); Standards Related to Essential Health Benefits (EHB), Actuarial Value, and Accreditation” published November 26, 2012, in the Federal Register (Vol. 77, No. 227).

The Epilepsy Foundation is the leading voluntary health agency working on behalf of people with epilepsy. We are a patient resource on safety, information on treatment options, and a leading advocate for research. The organization works to ensure that people with seizures are able to participate in all life experiences; to improve how people with epilepsy are perceived, accepted and valued in society; and to promote research for a cure. In addition to programs conducted at the national level, epilepsy clients throughout the United States are served by 48 Epilepsy Foundation affiliates around the country.

The Foundation recognizes the design of the EHB will have a direct impact on the ability of millions of Americans to access necessary health care services to improve their health and well-being. As a central component of the ACA, we believe the EHB must provide meaningful and affordable coverage for all plan enrollees, including children and adults with chronic conditions and disabilities like epilepsy. The Foundation supported comprehensive healthcare reform and believes the health care needs of individuals living with epilepsy and seizures, including access to neurologists and all medically necessary epilepsy treatments, must be adequately met through strong implementing regulations.

The EHB proposed rule, like the December 2011 EHB Bulletin, departs from a national standard and extends wide flexibility to states and insurers on providing an EHB package to consumers...
based on a benchmark plan approach. We continue to have concerns with the benchmark approach and the ability of states to offer fair insurance coverage, particularly with a limited federal role in evaluating, approving, enforcing and updating the EHB package. We submit comments on the below areas of the proposed rule, and call on HHS to issue a final rule with clear protections against discriminatory insurance practices and strong federal and state oversight and enforcement.

**Prescription Drug Benefits**

The Epilepsy Foundation appreciates the change from the EHB Bulletin that permitted plans to cover only a single drug in each therapeutic category. The spectrum of epilepsy is complex, people with epilepsy vary in seizure types and severity, and this means that the management of epilepsy requires an individualized approach based on etiology as well as co morbidities. In many cases, access to appropriate medications is paramount to controlling seizures and can be a lifesaving treatment regime allowing individuals to thrive in, social, educational and employment settings.

People with epilepsy must have access to and coverage for the physician directed care and treatment that works best for them. The Foundation believes that discrimination could occur in plans that do not offer adequate prescription drug formularies for antiepilepsy medications or disrupt a patient’s ability to maintain access to therapies that work for their unique condition. We are concerned about mandatory substitution of antiepilepsy medications — within the same drug class, various manufacturers, and across drug categories and classes. Differences in therapeutic benefits of antiepilepsy medications can result in a host of adverse consequences, including loss of seizure control, increased seizure activity, and the development of toxic side effects. It is paramount that both physicians and patients have notice of and approve medication changes critical to the successful management of epilepsy.

Patients with epilepsy and other chronic conditions need access to a robust range of medications. In comments to HHS on the December 2011 EHB Bulletin, the Foundation joined a number of patient advocacy organizations in support of Medicare Part D rules that set aside six therapeutic categories — antidepressants, antipsychotics, anticonvulsants, antineoplastics, immunosuppressants and antiretrovirals — and require plans to include “all or substantially all” of these drugs on their formularies. We recommend HHS include the Medicare Part D requirement to cover “all or substantially all” of the drugs in six protected classes of drugs in the final rules. Though positive changes were made related to prescription drugs, we strongly believe the proposed EHB rule continues to fall short on ensuring patients have access to a full range of medicines, including new therapies. The proposed standard emphasizes a minimum number of drugs in a class without regard to the type of covered drugs, thereby potentially excluding certain drugs that may provide important therapeutic benefits. The quality of medications must also be emphasized in plan formularies.

We support the requirement that health plans must have procedures in place that allow an enrollee to request clinically appropriate drugs not covered by the health plan. Additionally, we recommend patients’ rights and safeguards, such as grievances and appeals processes, are incorporated into the final EHB rule.
The Epilepsy Foundation urges HHS to adopt a more comprehensive standard for prescription drugs that will provide critical access to medically necessary medications. At a minimum, HHS must not go below the proposed standard of “at least the greater of 1) one drug in every United States Pharmacopeia (USP) category or class; or 2) the same number of drugs in each category and class as the EHB benchmark plan. Additionally, HHS must work to ensure any future changes to the benchmark plans does not result in a reduction in scope of prescription coverage so that one drug in every category or class becomes the standard.

**Standard for Medical Necessity**

We strongly urge HHS to issue a clear and understandable standard for medical necessity determinations by a health plan so patients are not unduly denied or delayed access to needed medications and other health care treatment through restrictive utilization management practices. To make these processes transparent, the final rule must require plans to use medical necessity criteria that are objective, clinically valid, and compatible with generally accepted principles of care.

The Foundation believes that evidence based medicine or comparative effectiveness research should be applied in a manner that does not lead to inappropriate restrictions in coverage of and access to therapies, treatments, medications, or other services directed by medical professionals for people with epilepsy and other chronic health conditions or disabilities. A lack of medical evidence itself should not be determinative of a finding a service or device is unnecessary or ineffective. Medical necessity should be coupled with a directive to apply it to a patient’s individual medical needs.

**Nondiscrimination**

We are concerned that the proposed rule simply restates the nondiscrimination provision in the ACA and does not identify a standard to determine whether coverage provided complies with those specific provisions of the law.

The Foundation urges HHS to provide a standard for the nondiscrimination requirements imposed on the EHB that includes strong federal enforcement provisions and penalties for violations. We support the comments of the National Health Council to strengthen antidiscrimination provisions and urge HHS to consider developing the following recommendations:

- 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.

These provisions would be critical to ensuring that plan design meets the needs of patients with chronic health conditions like epilepsy, and ensures adequate, uniform oversight of plans for patients and consumers.

Preventive and Wellness Services and Chronic Disease Management

All non-grandfathered individual and group market plans (which are not exempt from the EHB coverage requirement) must offer certain preventive and wellness services without cost-sharing, however, the proposed rule does not fully address the ACA-mandated benefit of chronic disease management. This is a major new benefit that has significant implications on people with disabilities and chronic conditions like epilepsy, but without further guidance, the benefit may be highly restricted under the EHB packages.

We join the Consortium for Citizens with Disabilities in recommending that:

• HHS explicitly state in the final rule that it will collect data on chronic disease management services in order to evaluate the benefit in 2016.

Affordability, Out of Pocket Costs & Impact on Nondiscrimination

The Foundation is concerned that the lack of adequate coverage could lead to high costs for individuals with epilepsy and that plan benefit design can make physician directed care unaffordable, leading to discrimination based on health status. For instance, if enrollee’s expenses for out-of-network physician directed care are not considered part of the annual out-of-pocket maximum and deductible, plans may offer coverage that is unaffordable. Network design, the robust inclusion of specialists, and true consumer costs should be evaluated by HHS. Further, HHS should monitor what plans consider completely outside of their benefit design, costs for care that are not “out of network,” but uncovered services. Patients and consumers will rely on HHS to monitor uncovered services and treatments to ensure nondiscrimination in plan design and implementation. HHS may also want to consider how to reflect out of pocket costs for physician directed care that is not covered by benefit plans as it monitors not only the nondiscrimination provisions (and perhaps leads plans to re-evaluate their coverage), but also the affordability of plans. If a plan is not discriminatory in its design and coverage, provides meaningful access to clinically appropriate care, and maintains a clear and efficient appeals; then it is our hope that no physician directed care would be an uncovered service. The Foundation urges HHS to monitor patient costs and use of any uncovered service.

We share the comment and recommendation of the National Association of Epilepsy Centers in urging HHS to consider that people with epilepsy can face high cost-sharing requirements to access out-of-network care, and disallowing this spending for purposes of the out-of-pocket maximum and deductible will severely limit the benefit of coverage under the ACA. Please reconsider this policy, so that people with epilepsy will not face exorbitant out-of-pocket costs when accessing necessary treatment.
Benefit Substitution & State Required Benefits

We support the proposal prohibiting substitution of benefits across the ten EHB categories and recommend HHS further limit substitution of benefits within EHB categories. At a minimum, strict federal guidelines and oversight is needed to ensure that plans do not undermine coverage and avoid high-cost populations, many of whom have disabilities and chronic conditions like epilepsy.

We support the proposal to include all state-required benefits enacted on or before December 31, 2011, in the EHB package.

Mental Health and Habilitation and Rehabilitative Services

A significant number of people with epilepsy have co-morbid mental health conditions and other neurological conditions. Research indicates a history of depression is a risk factor for developing epilepsy, and disorders such as autism and cerebral palsy are casual factors for developing epilepsy. Rehabilitative, habilitative and mental health services can be vital to persons with epilepsy with co-occurring mental and or physical disabilities. These services are necessary to restore functional capacity, minimize functional limitations, and maintain or prevent deterioration of functioning as a result of an illness, injury, disorder or other health condition. The Epilepsy Foundation supports the explicit recognition that mental health services must be provided under the EHB packages in a manner that complies with the federal parity standards detailed in the Mental Health Parity and Addiction Equity Act of 2008. However, for the rule to be meaningful, sufficient clarity must be provided about how these parity requirements apply and what the process to supplement inadequate coverage is. Without complete, detailed plan information about benefit coverage in each of the base-benchmark plans, it is not possible to fully determine whether mental health coverage in each of the State complies with parity. We recommend HHS provide a framework for States, insurance commissioners, exchanges, consumers, providers, and other stakeholders to detail the process for supplementing plans with deficient mental health coverage to ensure that the EHB meets parity requirements.

We are concerned about the transitional policy allowing the state to determine which services are included in the habilitative services category if the base-benchmark plan does not include coverage. Despite this category of services being historically ignored in health coverage, adequate coverage is critical to many individuals living with chronic disabilities and illnesses. At a minimum, the standard must cover habilitation separate and distinct from rehabilitation and cover habilitation in the same settings and including the same types of providers and specialists as covered in the rehabilitation benefit. We recommend HHS take a stronger role in defining habilitative services.

Conclusion:

While we appreciate the improvements on the language in the December 2011 EHB Bulletin regarding the prescription drug category, we urge careful consideration of our recommendations to ensure children and adults with epilepsy and seizure disorders have access to a meaningful
EHB package. At this critical juncture in implementing the ACA, we are reminded of the goal of assuring all Americans have access to quality, accessible and affordable health care.

Thank you for your consideration of our comments. We look forward to further development and implementation of the EHB and related requirements of the ACA. If you have any questions or would like to discuss our comments, please contact Laurel Stine at lstine@efa.org or (301) 918-3764.

Sincerely,

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