



November 27, 2017

The Honorable Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Re: Comments on HHS Notice of Benefit and Payment Parameters for 2019 Proposed Rule;  
CMS-9930-P

Dear Administrator Verma:

Thank you for the opportunity to comment on the proposed rule, Notice of Benefit and Payment Parameters for 2018. The Epilepsy Foundation is the leading national voluntary health organization that speaks on behalf of at least 3.4 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 compliment the Department of Health and Human Services (HHS) for maintaining critical patient protections previously promulgated, but are very concerned that the proposed changes to how states can select their essential health benefits will diminish patient care and increase beneficiary's out of pocket costs. Therefore, we urge HHS to maintain the current process for states to select their essential health benefits.

Due to the need of patients to access a wide array of health benefits and services, we also are very concerned with the possibility that HHS might propose in the future a "Federal default definition of essential health benefits" which would include a "national prescription drug benefit standard."

We are also disappointed that HHS is abandoning the "standardized plan option" in the federally-facilitated market. Such plans are working well in many states, and allow beneficiaries to access

benefits with set co-pays and often exempt prescription drugs from the deductible or have a separate, lower prescription drug deductible. We also oppose the proposed abandonment of the “meaningful difference” standard.

We reiterate our strong support of including prescription drug utilization in the Risk Adjustment Model. Despite the ACA’s goal to end discrimination based on pre-existing conditions, many health insurance plans currently engage in practices that enable them to avoid patients with serious and chronic conditions. We believe that compensating issuers through mechanisms like risk adjusters for their enrollees who need and use higher-cost prescription medications will encourage issuers to take responsibility for caring for these patients, remove incentives for avoiding the sickest patients, and reduce discriminatory practices that prevent vulnerable populations from accessing care and treatment. We look forward to any reports HHS may conduct on the operation of the risk adjustment model after its first year of operation with prescription drug utilization data included.

We appreciate your consideration of our insights and concerns as we all work to improve the patient experience and health outcomes under the ACA, particularly for those with serious and chronic health conditions.

### **Proposed New Options for States to Develop “Essential Health Benefits”**

We are concerned with the proposal to provide states additional flexibility in defining a state’s “essential health benefits” by allowing additional options from which they can choose. **While the stated goal is “state flexibility,” having an almost endless combination of services creates the opportunity to reduce beneficiary health benefits and increase patient out of pocket cost-sharing. We urge HHS to abandon the proposed options and maintain the current process for states to select their essential health benefits.**

We are concerned that the flexibility allowed under this policy proposal could allow states to design benchmark plans that offer not just less generous coverage, but the least generous coverage of each of the ten essential health benefits available across the country.

Currently, states have 10 benchmark plans to select from each year to help define that state’s essential health benefits package. We believe the current system best meets the ACA legal requirement that the essential health benefits be similar to a typical employer plan operating in the state. The current process provides states sufficient options and reflects the individual needs of the state. In fact, 7 out of the 10 benchmarks from which they can currently select are state-specific plans. Additionally, states can select from the largest three national Federal Employees Health Benefits Program (FEHBP) plan options by enrollment.

Allowing states to select benchmark plans from other states, or to select a benefit category from another state’s benchmark plan runs counter to meeting the needs of beneficiaries in that state. Constructing the benchmark plan by cherry picking benefit categories will create a plan that does not resemble any existing plan in the marketplace today. These options would allow states to reduce or weaken beneficiary benefits because states can find plans – and categories – anywhere in the country and select the least comprehensive suite of benefits to create scaled back coverage requirements. This would particularly be true for the proposed third option, which allows a state

to create a new benchmark plan from scratch that must be less generous than the most generous among a set of comparison plans. These proposals for selecting benchmark plans and categories will discourage states from offering comprehensive coverage because they would be responsible for defraying the costs beyond a minimal threshold of benefits.

New benchmark plans that curtail benefits will mean higher cost-sharing burden and out of pocket expenses for patients. The problem is compounded because benefits that are not covered do not count towards out of pocket maximums. Despite our concerns with the proposals surrounding the benchmark and categories, we are pleased that the Proposed Rule notes that if a plan covers drugs beyond the number of drugs covered by the benchmark, all of these drugs are essential health benefits and must count towards the annual limitation on cost sharing.

### **Future Proposal to Develop a “Federal default definition of essential health benefits”**

We are surprised that at the same time as HHS proposes increased flexibility for states to select their essential health benefits, HHS is also considering developing a “Federal default definition of essential health benefits,” which could include a “national benchmark plan standard for prescription drugs” and thereby limiting state flexibility. Since we have no information on how these national standards would be developed, we are concerned that this would lead to limits in beneficiary benefits and increased patient cost-sharing. States would still be able to select a different benchmark, but they would have to defray the costs that exceed the Federal default. This certainly raises a red flag that the “Federal default” under consideration would not be expansive and meet the needs of people living with serious and chronic conditions.

We note that HHS has previously created certain federal requirements that plans must follow in their plan design regarding prescription drugs. The biggest problems patients are encountering are that some plans are not covering the drugs necessary for beneficiaries to manage their conditions and maintain their quality of life, and that many issuers have extremely large deductibles and very high co-insurance that make it difficult or impossible for beneficiaries to afford their medications. As we discuss below, if the current patient protections are followed and properly enforced, beneficiaries should be able to access their medications and maintain their health and quality of life.

Efforts to create a “national benchmark plan standard for prescription drugs” could lead to the creation of a national formulary. **We strongly oppose a national formulary because this approach would limit access to only a select list of drugs, fail to include new innovative drugs, ignores the individual health care needs of people with serious and chronic conditions, and limits provider options when treating their patients.**

This is especially concerning for people living with epilepsy who much have access to the full array of treatment options because there is no “one size fits all” treatment option for epilepsy, and the response to medications can be different for each person. Maintaining seizure control with minimal side effects requires careful evaluation and monitoring by physicians and their patients. Further, to change, limit, or deny access to a medication that an individual with epilepsy has gained seizure control with could be extremely dangerous and even life-threatening. Limits to physician-directed in the epilepsy space can significantly increase medical costs related to preventable seizures, along with lost wages and productivity, not just for the individuals living

with epilepsy but also their families and communities. The treating physician, relying on their education and experience, is in the best position to make the judgment about which epilepsy medication is most appropriate, rather than the government or an insurer.

### **Proposal to Abandon Standardized Plan Options & Meaningful Difference Standards**

We are disappointed that HHS is proposing to abandon the Standardized Option (Simple Choice plans), and urge the Department to reconsider this proposal. Several states that run their own marketplace have successfully implemented standard plans and while we did not fully support all elements of the federal marketplace “Simple Choice plans,” its basic structure can be useful to beneficiaries.

We believe that consumers can benefit from being able to more easily compare plans across issuers and have some level of protection through cost-sharing limits, particularly for prescription medications, and exempting drugs in most metal levels from the deductible. Deductibles and other patient cost-sharing have increased to such a point that accessing health care, and particularly prescription medications, is becoming almost impossible for many patients. The use of standardized plans can help reduce the cost-sharing burden for patient and allow them to actually utilize their health insurance.

We do not share the Department’s concerns that standardized plans stifle innovation because there is no requirement that issuers offer them and issuers are allowed to offer other plans.

We also oppose the proposal to abandon the “meaningful difference standard.” Shopping and selecting a plan that best meets a patient’s health needs and which they can afford is not an easy process. Ensuring that plans are in fact meaningfully different reduces confusion and helps improve the beneficiary shopping experience. We disagree with the Department’s assertion that the current “meaningful difference standard” limits innovation and believe the existence of such standards encourages greater innovation and differences among plans.

### **Maintaining and Enforcing Patient Protections**

As stated in the Proposed Rule, the ACA contains many important patient protections that help in defining essential health benefits and that all issuers must abide to when designing plan benefits. For example, plans must offer all ten categories of the essential health benefits, the benefits must be equal in scope to a typical employer plan, there must be an appropriate balance across all categories, and plan benefit design cannot discriminate based on an individual’s age or disability. The essential health benefits must also consider the health needs of diverse segments of the population including women, children, persons with disabilities, and other groups.

In previous regulation, HHS has further defined essential health benefits. For example, for prescription medications, every plan must cover at least the greater of one drug per class or the same number of drugs in each category and class as the state’s benchmark plan. Previous regulation also requires plans to be transparent in their coverage of benefits and costs, utilize Pharmacy and Therapeutic Committees, and consider newly approved medications and treatment guidelines. Plans must also not limit delivery of medications to only mail order. Additional regulations have been promulgated to implement Section 1557 of the ACA, which further defines discrimination in health care. HHS has also provided examples of discriminatory benefit

design to include excessive patient cost-sharing, excessive utilization management techniques, such as prior authorizations, and placing every drug to treat a certain condition on the highest tier.

As we wrote in a letter to HHS earlier in the year, continuation of these patient protections is critical so that qualified health plans meet the needs of patients, particularly those with serious and chronic conditions. We thank HHS for recognizing their importance by maintaining them and trust that in the expected Letter to Issuers for 2019 other plan standards and expectations are maintained.

Patient protections are meaningless without proper enforcement. Despite the law or regulation, some insurers still design plans that are discriminatory and limit patient access. Beneficiaries continue to encounter plans that lack meaningful formulary coverage for prescription medications, engage in adverse tiering, have high cost-sharing and burdensome utilization management requirements such as extensive and/or unwarranted prior authorization and step therapy requirements. Beneficiaries also still face midyear formulary changes, and can have their medications switched for non-medical reasons. Current regulations and guidelines must be enforced.

We are concerned that in an effort to provide greater state flexibility, some states will not enforce these important patient protections, eroding beneficiaries' access to quality health care. Many states lack the financial resources and/or legal authority to prospectively review plans and formularies to ensure that they are adequate and do not discriminate against beneficiaries. Some states have stated they have no interest in or a limited capacity to implement plan requirements included in the ACA, including the important patient protections.

**Therefore, we encourage HHS to fully enforce the patient protections contained in the ACA and in regulation, and ensure that if oversight and enforcement responsibilities are assumed by the states, they have the authority and resources necessary to fully address patients' protections, particularly non-discrimination in plan benefit design.**

Thank you again for your consideration of our comments. The Epilepsy Foundation looks forward continuing to work with HHS to improve ACA Marketplace plan benefit design, cost-sharing, and transparency; and maintain existing protections, especially for people with chronic conditions like epilepsy. Please do not hesitate to contact Angela Ostrom, Chief Legal Officer & 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