March 7, 2014

Marilyn Tavenner, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-4159-P  
P.O. Box 8013  
Baltimore, MD 21244-8013

Dear Administrator Tavenner:

The Epilepsy Foundation (EF), the American Epilepsy Society (AES), and the American Academy of Neurology (AAN) write to offer comment to the Centers for Medicare & Medicaid Services (CMS) and urges the agency to reconsider proposed changes to the Medicare Part D classes of clinical concern, also known as the six protected class policy. This policy has been a safety net for some of the most medically fragile Medicare beneficiaries by requiring plans to cover “all or substantially all drugs” for six critical lifesaving drug classes, successfully protecting patients who need access to non-interchangeable medications to treat and manage serious and often life-threatening conditions, such as epilepsy. This policy has been a weapon against discriminatory plan design and a true protective measure for patient access to physician directed care. EF, AES, and AAN have championed this policy as model guidance for all health insurance formulary designs, including the essential health benefits under the Affordable Care Act. It is disappointing that a narrowly designed policy that is a strong protection against discrimination in plan design would be threatened by CMS. Although anticonvulsants remain protected, EF, AES, and AAN fear the precedent of allowing the Department of Health and Human Services (HHS) to make such a change, which is not patient-centered, with questionable clinical basis, and which appears to be focused on short-sighted financial considerations that ignore other health care and individual costs.

- While the Secretary has discretion, we believe that Congress’ intent with the current protected classes should remain and discretion used to expand only at this time.
- The clinical distinction of 7 days in the proposed criteria is concerning, and we do not see clear clinical guidance for its use.
- An over reliance on limited economic impact is dangerous, and we question the overall savings to Medicare Part D and all other areas of Medicare spending.
- This policy design is critical to maintaining protections against discrimination in benefit design, costs, and access.
- The current exception and appeals process does not sufficiently protect meaningful beneficiary access to needed physician-directed care as is evidences in the Medicare Payment Advisory Commission’s comments on this proposed rule.
The Epilepsy Foundation (EF) is the leading national voluntary health organization that speaks on behalf of more than 2.8 million Americans with epilepsy. EF fosters the well-being of children and adults affected by seizures through research programs, educational activities, advocacy, and direct services. The American Epilepsy Society (AES) is one of the oldest neurological professional organizations in the country and seeks to promote interdisciplinary communications, scientific investigation and exchange of clinical information about epilepsy. The American Academy of Neurology (AAN) is the world's largest professional association of neurologists dedicated to promoting the highest quality patient-centered neurologic care. Epilepsy is a medical condition that produces seizures affecting a variety of mental and physical functions; 1 in 26 Americans will develop epilepsy in their lifetime. About two-thirds of people diagnosed with epilepsy will become seizure free on the first or second anti-epilepsy drug (AED) used, the most common and most cost-effective treatment for controlling and/or reducing seizures. People living with epilepsy must have meaningful and timely access to physician-directed care to avoid breakthrough seizures and related complications and costs. Epilepsy is associated with substantially higher rates of mortality than experienced in the population as a whole, with Sudden Unexpected Death in Epilepsy (SUDEP) being the most common cause of epilepsy-related deaths. The proposed policy change fails to recognize the interrelatedness among complicated conditions. Many epilepsy patients need access to the full range of treatment options for mental health conditions.

While we applaud the recognition that anticonvulsants remain a class that meets the new criteria, we are concerned that the criteria were not determined through clinical guidelines and relies on questionable economic research. The proposed rule focuses on “typical individuals” yet Medicare beneficiaries, especially those living with epilepsy, are not “typical.” They are elderly persons, often with severe disabilities, multiple co-morbidities, and very complex healthcare needs. Limiting access to the most appropriate medications will drive up costs in Medicare Part A and Part B and Medicaid by increasing admittance to in-patient care and emergency departments due to the destabilization of patients’ conditions. For these reasons, we strongly urge CMS to reconsider this misguided effort and to support the long-standing patient protections.

The Part D six protected classes policy has enjoyed strong, bipartisan support since its inception in 2006 and both CMS and Congress have affirmed it as a critical protection mechanism for the most vulnerable and medically fragile Medicare beneficiaries. The policy, intended to ensure additional protections beyond the statutory minimum of two drugs per therapeutic class, has also been cost-effective. Recent data show that Part D costs are less than the original Congressional Budget Office (CBO) score projected. CMS's plans to scale back this lifesaving Medicare Part D policy by limiting and redefining the Part D program’s protected drug classes to exclude antidepressants and immunosuppressants for the 2015 coverage year, and antipsychotics in 2016, would be devastating for vulnerable patients—and costly to our healthcare system.
For the vulnerable patients that rely on therapies in the six protected classes, including epilepsy patients, it is essential that physicians be able to prescribe the medications that are best for the patient. Access to physician-directed care should be based on independent clinical judgment and patients should have access to these medications under Part D plan coverage. Failure to effectively manage these conditions will result in decreased quality of life and health complications for patients, as well as higher costs to the Medicare program and society, through increased hospitalizations, relapses, deteriorating conditions which necessitate additional and expensive care and cause loss in productivity.

For epilepsy, the costs associated with just one seizure (e.g., emergency room visit, ambulance transport, lab tests, hospitalization stay) far outweigh the marginal costs of starting patients on newer AEDs that provide better control with fewer side effects. Furthermore, newer AEDs are not necessarily more costly. Second, cognitive impairments in persons with disabilities and the elderly make it harder for these individuals to articulate problems with side effects. It is critical that a physician be able to prescribe the best medication for a Medicare beneficiary from the outset. This should include alternative formulations of a drug, such as extended release versions that are particularly important for disease management and patient compliance among the elderly.

In addition, many epilepsy drugs have a narrow therapeutic index (NTI), so access to brand name medications should be available to patients without undue financial burden if they are prescribed by the physician as necessary. Beneficiaries must also be protected from tiered cost-sharing that creates insurmountable financial barriers to accessing needed medications. For these reasons EF, AES, and AAN strongly encourage continued protection for epilepsy patients in Medicare drug plans by mandating and protecting access to an open, unrestricted formulary for certain targeted beneficiaries with pharmacologically-complex health conditions.

We strongly question the soundness of the economic analysis in the proposed rule because it does not take into account health care costs due to disruptions to physician-directed care and medication adherence. The Milliman report cited in the proposed rule focused solely on the cost of drugs for Medicare Part D plan administrators, and not improved clinical outcomes and decreased health care costs associated with the appropriate use of the therapies in the six protected classes. Limiting access to the most appropriate medications will lead to higher overall costs to the Medicare program, including higher out-of-pocket costs for beneficiaries and increased costs in Medicare Part A and Part B and Medicaid, due to the destabilization of patients’ conditions and increased physician visits and hospitalizations. CMS is already able to contain costs and steer patients toward lower cost options in Part D Plans through tiered cost for medications. Research by the Government Accountability Office (GAO) has shown that generic medication utilization rates among the Low Income Subsidy (LIS) beneficiaries are comparable to rates among non-LIS beneficiaries.
The existing Part D classes of clinical concern must remain intact in order to provide appropriate health care to vulnerable patient populations. Clinical decisions must continue to be made by the patients’ health care providers—the medical experts who have direct contact with the patients—and these clinical decisions should not be impaired unreasonably by burdensome barriers to access. Medication restrictions or interruptions are harmful and ultimately are not cost-effective. Preserving and strengthening the existing Part D classes of clinical concern is vitally important to both protect vulnerable Medicare beneficiaries and to contain health care costs. Thank you for your attention to this very important issue. We look forward to discussing this matter with you in more detail as you consider changes to the Medicare program.

Sincerely,

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