



**CONSORTIUM FOR CITIZENS
WITH DISABILITIES**

March 7, 2014

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4159-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Comments on the Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Proposed Rule (CMS-4159-P)

Dear Administrator Tavenner:

On behalf of the Consortium for Citizens With Disabilities (CCD) Health Task Force, we are writing to offer comments on CMS' approach to implementing Section 3307 of the Patient Protection and Affordable Care Act (ACA Section 3307). **We urge CMS rescind this entire section of the proposed rule.**

In our view, CMS has fundamentally misinterpreted Section 3307 of the ACA by weakening the protected classes policy and transforming a legislative directive to identify classes of *clinical* concern into one targeting classes of alleged *cost* concern. The studies cited by the agency do not support its own cost savings assumptions and the rule ignores the substantial spending associated with the destabilization of the individual's health that it may precipitate. In addition, CMS offers little clinical evidences for the new standards it proposes.

Furthermore, the agency falsely assumes that the consumer safeguards embedded in the protected classes policy are no longer necessary and that the fall back consumer protections are adequate. The 6 protected classes policy was developed to help ensure access to needed medications and to prevent health plans from discriminating against people with serious health conditions and disabilities by not including an adequate number of medication on the plan's formulary. The proposed policy significantly weakens the anti-discrimination protections and is a threat to the health and well being of people who need access to these medications. .

By using it as a tool for cutting costs at the expense of the most vulnerable Medicare beneficiaries, CMS has directly contradicted Congress's intent to improve and expand the protected classes policy. CMS must revoke this portion of the Proposed Rule and start again with an approach that, at a minimum, guarantees the same degree of consumer protection that existed prior to its publication.

CMS' New Policy Puts Beneficiaries at Risk and Lacks any Clinical Support

A. First Prong of New Standard Fails to Acknowledge Vulnerability of Individuals Impacted by this Policy

Building on a foundation of inadequate, preexisting protections and a reading of Section 3307 that sharply deviates from Congress's intent to protect beneficiaries, CMS proceeds to specify a new standard for identifying "clinical classes of concern" that can only be justified as an expedient for CMS's underlying goal: restricting access and cutting costs. CMS proposes:

In the case of a typical beneficiary who has a disease or condition treated by drugs in the following category or class, hospitalization, persistent or significant incapacity or disability, or death likely will result if initial administration ... of a drug in the category or class does not occur within 7 days of the date the prescription for the drug was presented to the pharmacy to be filled.¹

However, CMS does not cite a single clinical source for establishing this "seven day rule." Rather, the agency appears to base this arbitrary standard on its false assumptions about the timeline and efficacy of the Medicare appeals process, which is examined in more detail below.²

The first flaw in CMS' development of this new standard relates to orienting the policy toward the needs of a "typical" patient who "has the average clinical presentation of the relevant disease or condition."³ On its face, this standard intentionally puts more vulnerable individuals at risk. Furthermore, no person with mental illness, in need of a transplant, or living with HIV, cancer or epilepsy is typical; they have complex, varying clinical needs that cannot be regressed to a mean.

By isolating its analysis solely to the conditions respectively implicated by the protected classes policy, the Proposed Rule fails to recognize interrelatedness of diseases. For example:

- Nearly half of individuals receiving HIV treatment also have mental illness.⁴
- One in four individuals with cancer has clinical depression.⁵
- Depression is the "most frequent comorbid psychiatric disorder" in epilepsy, with a "risk of suicide [that] has been estimated to be 10 times higher than that in the general population..."⁶
- A systematic evidence review and meta-analysis of 23 articles drawing on 14 data sources found the incidence of active depression in people with epilepsy, on average, to be 23.1%.⁷

¹ 79 Fed. Reg. at 1941.

² Ibid.

³ Ibid.

⁴ EG Bing et al., "Psychiatric Disorders and Drug Use Among Human Immunodeficiency Virus-Infected Adults in the United States," *Archives of General Psychiatry*, August 2001, <http://www.ncbi.nlm.nih.gov/pubmed/11483137>.

⁵ American Cancer Society website, accessed Feb. 14, 2014, <http://www.cancer.org/treatment/treatmentsandsideeffects/physicalsideeffects/dealingwithsymptomsathome/caring-for-the-patient-with-cancer-at-home-depression>.

⁶ AM Kanner, "Depression in Epilepsy: Prevalence, Clinical Semiology, Pathologic Mechanisms and Treatment," *Biological Psychiatry*, August 2003, available at <http://www.ncbi.nlm.nih.gov/pubmed/12893113>.

⁷ KM Feist et al., "Depression in Epilepsy: A Systematic Review and Meta-Analysis," *Neurology*, February 5, 2013, available at <http://www.neurology.org/content/80/6/590.short?sid=8f0120af-36cb-4f15-aa01-da68c578bb47>.

The vital beneficiary protection offered by the protected class policy also provides stability for beneficiaries with serious, chronic medical conditions and often protects those with more than one condition. The proposed narrow application of the term “typical” patient ignores the fact that Medicare beneficiaries taking medications under the protected classes are anything but “typical individuals.” They are beneficiaries often living with multiple, complex chronic conditions, significant disabilities, and complicated comorbidities. The complexity of both physical and mental care required for these beneficiaries is inappropriately ignored by CMS in their proposal to remove antidepressants, immunosuppressants, and potentially antipsychotics from the list of protected classes.

CMS’ most fundamental misstep, though, is assuming that any intentional delay of needed therapies is safe for beneficiaries with conditions covered by the existing protected classes policy. Even minor delays in care can have dire consequences for these individuals ranging from hospitalization to death. While many beneficiaries will face these consequences, that is an unacceptable benchmark for how well Part D is meeting their needs.

The goal of prescription therapies for these populations is to sustain good health, improve functioning and prevent declines that warrant additional care. The current protected classes policy ensures maintenance of this standard. CMS’ proposal would eviscerate it in favor of a minimum standard that would voluntarily upset the balance of these individuals’ treatment in unverified hopes that fallback protections will succeed in avoiding catastrophic outcomes.

B. Second Prong of New Standard is Biased and Contradicts Clinical Standards

1. The Second Prong is Biased in Favor of Restricting Access

After inexplicably stating that CMS’ new “seven day rule” would not do enough to restrict access to medically necessary therapy, the agency imposes an even more vague and arbitrary prong to the new standard. It appears to be added solely to ensure the removal of some of the existing classes. In doing so, CMS abandons sound clinical practice and takes another distinct step afield of Congress’ intent that the agency develop a standard that strengthens existing consumer protections. This prong reads:

More specific CMS formulary requirements will not suffice to meet the universe of clinical drug-and-disease-specific applications due to the diversity of disease or conditions manifestations and associated specificity or variability of drug therapies necessary to treat such manifestations.⁸

Here CMS again reasserts its bias in favor of implementing a policy that restricts access by introducing the requirement that, “in the absence of any specific treatment guidelines to the contrary,” inclusion of all drugs in a class is unnecessary. Yet again, CMS has embedded a presumption that the protected classes policy should be weakened and that some currently covered drugs should be removed. As the agency rationalizes, in the portion of the Rule addressing its consideration of alternative policies, “only narrow criteria would limit the number of categories or classes of clinical concern receiving additional protections under the [ACA].”⁹

1. CMS’ Standard Neglects Variation of Individual Responses to Treatment and is Directly Refuted by the Clinical Sources it Cites

CCD is concerned that CMS is relying on inaccurate characterizations of what constitutes interchangeability and variation of individual response. Individuals benefiting from the protected classes

⁸ 79 Fed. Reg. at 1942.

⁹ Ibid.

policy require access to a broader variety of drugs than individuals with less acute or nuanced illnesses to ensure appropriate care. According to a *Health Affairs* study, “In treating mental illnesses, patients and physicians typically work through a trial-and-error process to identify the best medication or medication combination... This complicates formulary-driven medication switches. Unlike other chronic conditions such as hyperlipidemia, hypertension, and osteoporosis, disrupting psychiatric medications can have immediate health consequences resulting in symptoms, functional impairment, and accelerated use of health services.”¹⁰

Additional research documents that, while a specific medication may help one individual, it may not help another with the same diagnosis. No single mental health medication, for example, works for all individuals and there may be various side effects that one person experiences versus another.¹¹

C. Appeals Processes and other “Protections” are Inadequate

1. Reliance on Flawed Appeals Process Poses Significant Hazards

CMS grievously errs in relying on the *intended* regulatory timeframe for coverage determination and appeals processes to conclude in a satisfactory manner. First of all, there is strong reason to believe existing appeals processes are inadequate to ensure meaningful protections for this vulnerable population, much less within the timeframe CMS presumes. It is telling that the agency provides no data suggesting that the exceptions process works.

In a September 12, 2013, presentation, MedPAC staff identified significant, flaws with Part D exceptions and appeals processes.¹² Among MedPAC’s findings:

- “A majority [of beneficiaries] did not know they had appeal rights ...;”
- Counselors urged beneficiaries to pursue an exception or appeal only as a last result, prioritizing switching plans (if possible), seeking samples, etc., instead ...;
- “CMS’ [own] audit in 2012 found that plans are struggling most with Part D coverage determination, appeals, and grievances ...;”
- “Examples of the kinds of issues identified include:
 - “Failure to make timely coverage determinations;
 - “Failure to notify the beneficiaries of their coverage decisions;
 - “Not making sufficient effort to obtain information needed to make an appropriate clinical decision ...;”
- “A large share of [appeal] dismissals due to technical reasons suggests enrollees may be confused or are having difficulty navigating the appeals process ...;
- “Majority of cases are reversed by the [Independent Review Entity (the 2nd appeal level)] ... suggest[ing] that there may be issues with the process used by plans to verify enrollees’ prior drug coverage status.”¹³

¹⁰ NP Morden and LE Garrison. “Implications of Part D for Mentally Ill Dual Eligibles: A Challenge for Medicare.” *Health Affairs*, 2006 Mar-Apr; 25(2):491-500.

¹¹

http://www.nami.org/Template.cfm?Section=Access_to_Medications&Template=/ContentManagement/ContentDisplay.cfm&ContentID=47683

¹² Sokolovsky, Suzuki and Metayer, “Part D Exceptions and Appeals” (Sept. 12, 2013), *available at* <http://www.medpac.gov/transcripts/part%20d%20exceptions%20&%20appeals.pdf>.

¹³ *Ibid.*

Given the significant flaws in the Medicare Part D appeals process and other fallback protections CMS cites, CCD does not support using them as a replacement for the protected classes policy. Current appeals process failures, in part the result of high volume, also do not account for the inevitable increase in appeals that are certain to happen due to CMS' proposal to restrict access to medically necessary medications under this proposed regulation.

2. Additional Fallback “Protections” CMS Cites are Unsuitable and None Have Ever been Deemed Sufficient for this Population

CCD is concerned that CMS' enumeration of existing additional Part D “protections” in the Proposed Rule is a misinterpretation of Section 3307.¹⁴ The majority of these protections were in place at the time Part D was launched, at which time CMS itself instituted the protected classes policy. Furthermore, they were in place and had been functioning for several years when Congress codified the protected classes policy in MIPPA and reaffirmed it in the ACA. There is no reason to think, and CMS offers no evidence to support, that these protections have ever been deemed sufficient by any policymaker to ensure the safety and quality of care for beneficiaries impacted by the classes policy.

IV. Conclusion

The CCD Health Task Force appreciates this opportunity to respond to CMS' Proposed Rule. Given the serious concerns we have with the portions of the NPRM that address the protected classes policy and the focus on costs over consumer protections, **CCD urges CMS to rescind these components of the Proposed Rule in their entirety and implement section 3307 in a manner that, at minimum, guarantees the same degree of protection present before the Proposed Rule was issued.** If you have questions about our comments please contact Julie Ward, The Arc, (ward@thearc.org).

Sincerely,

The CCD Health Task Force Co-Chairs:

Mary Andrus, Easter Seals,

Lisa Ekman, Health and Disability Advocates

Theresa Morgan, ACCSES

Peter Thomas, Brain Injury Association of America,

Julie Ward, The Arc

¹⁴ 79 Fed. Reg. at 1938-1941.