AUCD
ASSOCIATION OF UNIVERSITY CENTERS ON DISABILITIES
RESEARCH, EDUCATION, SERVICE

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

Dear Administrator Tavenner,

The Association of University Centers on Disabilities is very concerned about the Centers for Medicare and Medicaid Services (CMS) proposal regarding Medicare Part D prescription drug program. We urge CMS to maintain the current six classes and avoid jeopardizing access to these crucial and non-interchangeable medications.

The Association of University Centers on Disabilities (AUCD) is a national non-profit organization and network of interdisciplinary programs made up of 67 University Centers for Excellence in Developmental Disabilities funded by the Administration on Intellectual and Developmental Disabilities, 43 Leadership Education in Neurodevelopmental Disabilities programs funded by the Maternal and Child Health Bureau, and 15 Intellectual and Developmental Disability Research Centers funded by the National Institute for Child Health and Development. These programs are located in every state and territory and serve as a bridge between the university and community, working with people with disabilities, families, and communities to promote policy and practice. Our comments represent the clinical expertise of our members.

According to the Kaiser Family Foundation, 16% of all Medicare beneficiaries are eligible based on disability; 39% of all Medicaid beneficiaries with disabilities are dually eligible for Medicare and therefore receive prescription drug coverage through Medicare Part D.[1] People with disabilities under age 65 participating in the Medicare program have needs unique from elderly beneficiaries that must be considered in regulatory changes. Many people with disabilities have multiple chronic conditions and must manage multiple medications while mitigating adverse interactions and side-effects.

We believe that CMS has 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. CMS offers little clinical evidences for the new standards it proposes and the proposed policy significantly weakens the anti-discrimination protection provided by the six protected classes policy. We are concerned that 1) CMS has inaccurately characterized the interchangeability of medications within classes or sub-classes, 2) that CMS has not taken into account the potential for hospitalization or placement in less-integrated settings for individuals whose health has been destabilized, and 3) the inadequacy of consumer protections and safeguards.

[1] http://kff.org/medicaid/state-indicator/ageddisabled-medicaid-beneficiaries/

Medications in Proposed Classes are Not Interchangeable; Limiting Access Could Result in Destabilizing Health and Hospitalization/Institutionalization

AUCD is primarily concerned that CMS is relying on inaccurate characterizations of what constitutes interchangeability and variation of individual response. In the case of individuals prescribed immunosuppressant and/or antipsychotic medications, CMS states in the proposed rule that protection of sub-categories within these classes is sufficient to protect beneficiaries. We believe that this rule does not take into account the potential for interactions between medications, mitigation of side-effects, and beneficiary protections necessary for this population. Individuals benefiting from the protected classes policy require access to a broader variety of drugs than individuals with less acute or nuanced illnesses to ensure appropriate care.

Antipsychotic Medications

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."[2] 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.[3]

According to the preamble of the proposed rule, the panel convened by CMS to study these issues "concluded that antipsychotics did not have unique effects that distinguished one drug from another for the purpose of choosing the appropriate drug to initiate therapy" and that several drugs within a sub-class can be used to initiate therapy. However, this fails to take into account the highly individualized nature of treatment through antipsychotic medications: that a patient must often try several drugs to determine both the optimal benefits and minimal side-effects. There is significant variation in how individuals respond to antipsychotic medications, and it is common for several to be tried at different doses before the optimal benefit is obtained.

Within our constituencies, these drugs are also part of the therapeutic options to reduce self-injurious behavior in children and adults with autism and other intellectual and developmental disabilities, and are also used in multi-component approaches to management of severe aggressive behavior to others (e.g, caregivers). The alternative to these drugs has historically been institutionalization. This rule as such has the potential to threaten the values of inclusion, independent living, and self-determination that CMS and the disability community have worked to promote for decades.

AUCD appreciates that CMS is attuned to the problem of over-prescription of antipsychotic medication, particularly in nursing homes and for people with dementia. However, restricting access to needed medications has the potential create more problems than it solves. In fact, this rule would likely have the unintended effect of increasing the improper utilization of antipsychotics as providers who prescribe antipsychotics inappropriately may simply shift utilization to those drugs used in the formulary, prescribing with even less attention to medical necessity or side-effects. CMS should undertake other efforts to reduce the over-prescription of antipsychotic medications.

Immunosuppressant Medications

In the case of immunosuppressant medications, the difference between access to the appropriate medication(s) and the inappropriate medication(s) could often be death. Similar to antipsychotic medications, patients respond differently to different immunosuppressant medications and a few drugs cannot be expected to serve all patients. If an approach of "treat until failure" is used before allowing an alternative, the outcome will most likely be the loss of the transplanted organ and death of the recipient. Failure of a transplant comes at huge financial and human cost. Ethics committees have historically found that providing organ transplants to individuals who do not have the resources to sustain immunosuppression therapy after discharge is not ethical

[2] 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.

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

because its' likely outcome is the loss of the transplanted organ due to inadequate immunosuppression. The proposed protection of sub-classes is insufficient to address this ethical and treatment issue.

Beneficiary Protections Are Not Adequate

According to the preamble of the proposed rule, CMS originally implemented the six protected classes as a transitional policy when Medicare-Medicaid enrollees first transitioned from state Medicaid program formularies to Part D plans. Enrollees were expected to be unaccustomed to drug utilization and management techniques. We believe that Part D enrollees, particularly the Medicare-Medicaid enrollees widely considered to be the most vulnerable and high-need beneficiaries, will remain confused by the drug formularies of private plans and their plan selection options. Families navigating Medicaid and Medicare face confusing and program rules, contradictory policies caught between the state and federal systems, and often interact with this system when handling stressful life events. Loss of these protections increases potential for unacceptably frequent beneficiary and family crises given these circumstances.

CMS also errs in relying on the *intended* regulatory timeframe for coverage determination and appeals processes to conclude in a satisfactory manner. In a September 12, 2013, presentation, MedPAC staff identified significant, flaws with Part D exceptions and appeals processes.[4] 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."[5]

Given the significant flaws in the Medicare Part D appeals process and other fallback protections CMS cites, AUCD 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.

AUCD appreciates this opportunity to comment to the 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, we urge 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.

Sincerely,

Leslie Cohen, JD

AUCD President

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[4] 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.

[5] Ibid.