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March 7, 2014

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
P.O. Box 8013
Baltimore, MD 21244–8013

Submitted electronically to <http://www.regulations.gov>.

Re: CMS–4159–P

Dear Administrator Tavenner:

The National Health Council (NHC) appreciates the opportunity to submit comments on the proposed rule – Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs.

As a voice for people with complex health needs, the NHC has a long history of advocating for better access to prescription medications, including in the Medicare prescription drug program.

We are particularly interested in commenting on two major provisions of the proposed rule:

- Changes to the classes of clinical concern
- The proposed meaningful differences policy as it relates to enhanced plans

We strongly advise that the Centers for Medicare and Medicaid Services (CMS) reverse its proposed changes to the classes of clinical concern and work with the patient community to first address existing discriminatory benefit designs in the Part D program. Additionally, we encourage CMS to revise its proposed meaningful differences policy to ensure access to more generous enhanced plans.

The NHC is the only organization that brings together all segments of the health community to provide a united voice for the more than 133 million people living with chronic diseases and disabilities as well as their family caregivers. Made up of more than 100 national health-related organizations and businesses, its core membership includes the nation's leading patient advocacy groups, which control its governance. Other members include professional societies and membership associations, nonprofit organizations with an interest in health, and major pharmaceutical, medical device, biotechnology, and insurance companies.

Classes of Clinical Concern

We strongly advise that the Centers for Medicare and Medicaid Services (CMS) reverse its proposed changes to the classes of clinical concern and work with the patient community to first address existing discriminatory benefit designs in the Part D program. Patients, particularly those with complex and chronic conditions, have relied on the protections afforded by the classes of clinical concern since the Part D program's inception in 2006. The aim of this protection is to increase patient access to needed prescription medications for certain conditions, while decreasing the likelihood that plans would be able to structure their formularies to discourage enrollment by Medicare beneficiaries with particular chronic and disabling conditions that may be expensive to treat. We understand the need for the Medicare program, including Part D plans, to balance the needs of all Medicare beneficiaries with appropriate costs for the program. However, this two-fold assurance — increased access and decreased discrimination — has served as a model for appropriate patient protections, even outside of the Medicare program.

Per § 423.272(b)(2), CMS may not approve a Part D plan that is “likely to substantially discourage enrollment by certain Part D eligible individuals under the plan.” While informal analyses have shown that Part D plans offer fairly comprehensive coverage of medications within the classes of clinical concern, coverage is not the only measure of access to medications. Tier placement, cost sharing, and utilization management techniques must all be considered, in combination with coverage, as factors affecting access. The protected classes policy has, arguably, not offered adequate protections to access when measured across all these factors.

As a result, we believe that additional non-discrimination standards must be introduced to ensure that no Medicare beneficiary enrolled in Part D is discouraged from selecting any Part D plan on the basis of formulary breadth or affordability. To that end, CMS should:

- Introduce additional reviews to test all Part D plans for benefit designs (including formulary breadth, specialty tier placement, cost sharing, and utilization management with particular attention to medications classified as antidepressants or immunosuppressants) that have the effect of discouraging the enrollment of individuals with significant health needs;
- Require Part D plans to provide written notice to affected beneficiaries about any change to their coverage;
- Extend policies, such as a Special Enrollment Period (SEP) and an enhanced transition policy, specifically to patients affected by any change to the protected classes to allow them temporary access and the opportunity either to change plans or request and secure an exception; and
- Tighten oversight of grievances and exceptions requests to ensure meaningful access to medically necessary drugs

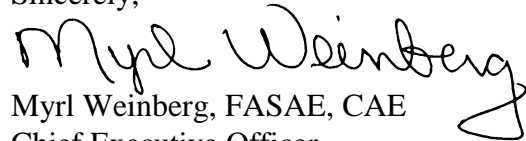
Without first addressing discriminatory benefit designs in the Part D program, the proposed changes to the protected classes policy would only exacerbate the existing challenges faced by those most in need of Medicare Part D – people with chronic diseases and disabilities.

Meaningful Differences

In addition to our comments on the proposed changes to the protected classes policy, we also urge CMS to revise its proposed meaningful differences policy to ensure access to more generous enhanced plans. Recent analysis suggests that that the proposed change could require 39 percent of the total number of enhanced Part D plans to be terminated or consolidated with another plan.¹ The argument could be made that additional choices for Medicare beneficiaries do not directly correlate to more meaningful coverage. Even so, affected issuers may respond to such a policy change by eliminating its more generous enhanced plan in favor of the lower value-enhanced plan option. Should this prove to be true, beneficiaries with chronic or disabling conditions, who would be most in need of access to more comprehensive coverage offered by generous enhanced plans might struggle to find a stand-alone Part D plan that meets their health care needs. We urge CMS to reconsider the effect of the proposed change in policy in light of the needs of those beneficiaries who are most in need of comprehensive Part D coverage.

We thank you again for this opportunity to share our comments. Please do not hesitate to contact Eric Gascho, our Assistant Vice President of Government Affairs, if you or your staff would like to discuss these issues in greater detail. He is reachable by phone at 202-973-0545 or via e-mail at egascho@nhcouncil.org. You may also reach me on my direct, private line at 202-973-0546 or via e-mail at mweinberg@nhcouncil.org.

Sincerely,



Myrl Weinberg, FASAE, CAE
Chief Executive Officer

¹ Avalere Health. Impact of Proposed Meaningful Differences Policy Change on Number of PDPs and Affected Enrollees. (2014). Available at: <http://avalerehealth.net/expertise/managed-care/insights/7.4m-medicare-beneficiaries-could-be-affected-by-proposed-meaningful-differ>.