

March 7, 2014

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Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-4159-P, Mail Stop C4-26-05
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Submitted via email to AdvanceNotice2015@cms.hhs.gov

RE: Comments on Proposed Changes to Medicare Advantage and Medicare Part D in 2015

Dear Administrator Tavenner:

The Fenway Institute at Fenway Health offers the following public comment on the proposed rule implementing changes to Medicare Advantage and Medicare Part D in 2015. The Fenway Institute is an LGBT-focused, interdisciplinary center for research, training, education and policy development. It is the research division of Fenway Health, a federally qualified health center that serves LGBT people and the broader community. The largest provider of HIV medical care in New England, Fenway has been at the forefront of HIV prevention and care since the emergence of the HIV/AIDS epidemic in 1981.

As you know, the Medicare program is the second largest federal program supporting HIV medical care, covering nearly 100,000 people living with HIV (PLWH). PLWH on Medicare have more complex and serious medical conditions. Most qualify because they have been disabled for at least two years. We are very concerned by the proposal to discontinue protected class status for the anti-depressant and immunosuppressant drug classes, and potentially for anti-psychotics, in 2016. We strongly urge you to remove this provision in the final rule.

We are also concerned that many Medicare Part D plans are placing HIV medications on the highest cost sharing or specialty tiers, excluding them from the exceptions process. The cost sharing required in many of these cases renders the Part D coverage meaningless for beneficiaries with HIV who do not qualify for the low-income subsidy but who live on low incomes (often disability payments). We strongly urge CMS to conduct a stringent review of Part D benefit designs for potentially discriminatory practices.

We also offer the following specific comments on the proposed rule:

423.128(g) Part D Notice of Changes

- **Require Plans to issue Annual Notice of Change Summaries prior to the Open Enrollment Period.**

We support the recommendation to provide beneficiaries with an Annual Notice of Change that provides information about benefit changes, including formulary, premium and cost sharing changes, in the new plan year. Many PLWH on Medicare report serious challenges with accessing their medications through Medicare Part D due to dramatic increases in cost sharing that leave medically necessary medications out of reach of low-income beneficiaries. CMS should perform ongoing monitoring of formulary changes, especially those related to cost sharing, to ensure that changes are justified and not making medications inaccessible to beneficiaries.

423.120(b)(v) and (vi) Drug Classes and Categories or Classes of Clinical Concern and Exceptions

- **Maintain the Current Coverage Requirements for All Six of the Protected Classes**

Since 2006, when CMS created the six protected classes, coverage of these lifesaving medications has been critical to the success of Part D for some of Medicare's most vulnerable beneficiaries, including PLWH. This policy has largely prevented plans from discriminating against vulnerable, low-income populations dependent on these medications.

The proposed new criteria for the classes of clinical concern may create a dangerously high standard for drug classes to continue to receive these critical protections. It is essential that access to the appropriate medications within the immunosuppressant, anti-psychotic, and anti-depressant drug classes not be delayed or denied.

According to the American Psychological Association, nearly half of PLWH have a mental health disorder. Effective treatment of mental health conditions is critical to support the high adherence to care and treatment required for management of HIV infection. People with HIV need access to a range of anti-depressants and anti-psychotic medications. While older, less expensive treatment alternatives may be available, many of them have serious side effects or may have harmful drug interactions with HIV medications.

While CMS is proposing to maintain antiretrovirals as a class of clinical concern in 2015, the proposed criteria could place antiretrovirals and other drug classes at risk in future years. We are particularly concerned by the justification provided by CMS that largely relies on other Medicare Part D safeguards that are insufficient. We strongly urge you to repeal this provision in the final rule. When Congress authorized, through the Affordable Care Act, the classes of clinical concern rulemaking authority, it did not intend to weaken the protections offered for the classes of clinical concern.

423.100, 432.120 Preferred Cost Sharing

- **Enforce the Proposal to Require Lower Cost Sharing at Preferred Pharmacies**

We strongly support the proposal to require Part D plans to pass along savings achieved through preferred pharmacy networks to beneficiaries through reduced cost sharing for all prescription drugs. This proposal is important to lower beneficiary out-of-pocket expenses, which have been rising dramatically for antiretroviral medications.

Thank you for considering these comments. Should you have any questions or require more information on any of the suggestions made here, please contact Sean Cahill at scahill@fenwayhealth.org or 617-927-6016.

Sincerely,

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