



January 25, 2019

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-4180-P  
P.O. Box 8013  
Baltimore, MD 21244-8013

Re: Comments to Proposed Rule Modernizing Part D and Medicare Advantage

To Whom It May Concern:

We are writing on behalf of the HIV Health Care Access Working Group (HHCAWG) – a coalition of over 100 national and community-based HIV service organizations representing HIV medical providers, public health professionals, advocates, and people living with HIV who are all committed to ensuring access to critical HIV and hepatitis C-related healthcare and support services. We appreciate the opportunity to provide comments on the proposed rule with regard to modernizing Part D and Medicare Advantage. HHCAWG appreciates the need for greater leverage among Medicare Part D plans to negotiate lower drug prices and to reduce out-of-pocket costs for beneficiaries. However, we are extremely concerned about some provisions in the proposed rule that undermine the intent of the protected classes: to prevent discriminatory risk segmentation and to ensure that all beneficiaries maintain access to certain types of drugs.

The HIV prevention and treatment landscape and standard of care have experienced critical advances over the last 12 years. Many of the newer antiretrovirals achieve more rapid and durable suppression of HIV, have fewer side effects, and can improve adherence through reduced pill burden. Based on a conclusive body of evidence, the recommended standard of care is now to start individuals living with HIV on treatment soon after diagnosis with the most effective, best-tolerated regimen. Not only will this optimize individual health outcomes, but because individuals who are virally suppressed cannot transmit the virus, ensuring early access to the appropriate treatment regimen is critical for public health efforts to end new HIV infections. In addition, the FDA approved the first biomedical intervention using an antiretroviral drug (Pre-Exposure Prophylaxis or PrEP) in 2012. PrEP is highly effective at preventing acquisition of HIV and recently received a draft Grade “A” recommendation from the U.S. Preventive Services Task Force.

Compared to many other classes of drugs, lower-cost multiple-source innovator and non-innovator (“generic”) antiretroviral drug options are limited and therefore not suitable for population-level cost-containment measures. Individualized therapy that requires access to a variety of higher-cost single-source innovator (“brand”) products is still central to best practices toward maximized safety and virologic suppression outcomes. It is unclear when multiple-source antiretrovirals will fully catch up with evolving standards of HIV care and for biomedical HIV prevention through PrEP. In effect, HHCWG questions whether any real cost savings will be achieved within the antiretroviral class, as cost-saving calculations in the proposed rule are predicated on decreased utilization of single-source drugs and increased utilization of generic products.

### **Expanded Use of Step Therapy and Prior Authorization in the Antiretroviral Class (42 CFR § 423.120(b)(2)(vi)(C))**

We strongly oppose eliminating existing protections for HIV medications that have prevented application of step therapy and prior authorization to this class. HIV treatment regimens are complex, involving combinations of multiple medications. Choosing the appropriate regimen is necessarily individualized as a number of patient and virus-specific factors are relevant. Requiring an individual to demonstrate poor adherence, experience a serious adverse event, or experience virologic failure on a regimen not recommended by the clinical provider, or delaying access to treatment by imposing unnecessary prior authorization hurdles, will have disastrous individual and public health effects and will result in additional costs to the healthcare system.<sup>1</sup>

These types of utilization management techniques are particularly inappropriate given the populations who depend on the Medicare program, including individuals who are either low-income and disabled or over the age of 65. These patients are likely to have been living with HIV for many years and necessarily have more complex treatment options because of co-morbid conditions and the development of resistance to some antiretroviral medications. Individualized treatment decisions are critical to ensure appropriate care and treatment for this vulnerable population.

Rolling back this important protection for HIV medications is inconsistent with the federal HIV treatment guidelines<sup>2</sup> cited in the regulation itself (currently at 42 CFR §423.120(b)(2)(vi)(C) and re-designated in the proposed rule to §423.120(b)(2)(vi)(F)) and will lead to harmful treatment disruptions and delays if implemented. Because their use is not justified by the HIV treatment guidelines, prior authorization and step therapy are not currently applied to the antiretroviral class at either treatment initiation or for individuals already on a treatment regimen. The Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.2.5 currently states that: “For HIV/AIDS drugs, utilization management tools such as prior authorization and step therapy

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<sup>1</sup> Studies have found that even when step therapy and prior authorization reduced pharmacy costs, emergency room and hospitalization costs increased. See, e.g., Rashad I. Carlton, “Review of Outcomes Associated with Formulary Restrictions: Focus on Step Therapy,” 2 American Journal of Pharmacy Benefits 50, 56–7 (2010).

<sup>2</sup> Department of Health and Human Services, Federal HIV/AIDS Practice Guidelines, <http://aidsinfo.nih.gov/guidelines>.

are generally not employed in widely used, best practice formulary models.” As stated above, the HIV treatment and biomedical prevention landscape have not changed enough to warrant removing this important protection for the antiretroviral class.

People living with and at high risk for HIV infection depend on access to single-source brand name medications without generic equivalents and applying utilization management techniques such as step therapy and prior authorization to this class is not only dangerous for patients and public health, it is simply not cost effective. CMS itself concedes in the proposed rule’s Preamble that for the antiretroviral class, “the narrower indications and complicating clinical criteria would limit Part D sponsors’ ability to do significant management.” If CMS believes that utilization management is inappropriate for this class, then lifting the protections against applying step therapy and prior authorization to antiretroviral medications will only lead to plan and consumer confusion.

Additionally, we are concerned that the proposed language in § 423.120(b)(2)(vi)(C) allowing prior authorization to be used “to confirm use is intended for a protected class indication” would have unintended consequences in implementation. There is currently only one antiretroviral medication approved for the prevention of HIV (PrEP), a use that is squarely within the protected class indication as it is an antiretroviral approved by the FDA for both treatment and prevention of HIV. There has been a trend in commercial markets to use prior authorization to deny access to the antiretroviral medication when it is prescribed for PrEP, and we urge CMS to develop sub-regulatory guidance to ensure that uses of antiretrovirals for both the treatment and prevention of HIV are protected.

Finally, we have serious concerns regarding the unprecedented proposal to permit step therapy and prior authorization for patients *stable on existing treatments*, across all six protected classes. Many people living with HIV experience co-morbid health conditions. Multiple studies have found that approximately half of those living with HIV have been diagnosed with a comorbid mental health condition.<sup>3</sup> Ensuring that an individual with a mental health condition receives appropriate care and treatment is necessary to achieving positive health outcomes for all people, but especially for people living with HIV. When a mental health issue is controlled, patients will have an easier time treating their HIV and staying adherent to their medications.

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<sup>3</sup> “Public Financing and Delivery of HIV/AIDS Care: Securing the Legacy of Ryan White,” Washington DC: National Academies Press, <http://www.iom.edu/Reports/2004/Public-Financing-and-Delivery-of-HIVAIDS-Care-Securing-the-Legacy-of-Ryan-White.aspx>

Bing, E.G, et al., “Psychiatric disorders and drug use among human immunodeficiency virus-infected adults in the United States,” *Archives of General Psychiatry*. 2001 Aug;58(8):721-8. <http://archpsyc.jamanetwork.com/article.aspx?articleid=205826>; Kates, Jen, Kaiser Family Foundation, “Medicaid and HIV: A National Analysis,” 2011, <http://kaiserfamilyfoundation.files.wordpress.com/2013/01/8218.pdf>.

## **Exclusion of a Drug that Is a New Formulation of an Existing Drug or Biologic without a Unique Route of Administration (Proposed 42 CFR § 423.120(b)(2)(vi)(D))**

While HHCAWG supports regulatory efforts to rein in evergreening and other practices to prolong market monopolies, we believe the proposed provision needs additional safeguards and strongly urge the consideration of additional language to ensure coverage of scientifically validated novel formulations of existing drugs and biologics.

We understand that, under the existing regulation, Part D plans are currently allowed to exclude newer, potentially higher cost versions of older drugs in protected drug classes with the same active ingredient or moiety or extended-release products when the immediate-release product is included. The proposed rule aims to disincentivize the commercial withdrawal of older products as a strategy to preserve and extend innovator drug products' monopolies in the protected classes. Importantly, the proposed rule maintains exceptions for newer versions of older drugs that provide a unique route of administration, which we strongly support.

We also recognize that newer formulations of older drug or biologic products – including those with similar routes of administration, such as oral coformulations and single-tablet regimens – can be clinically important additions to standards of care, including reductions in pill burden. Our support for this provision is therefore dependent on evidence-based determinations conducted by CMS. Any new formulation of older drug or biologic products using the same route of administration should have a superior adherence, safety and/or efficacy, as determined in clinical trials or other scientifically sound prospective studies. We therefore propose the following change to the proposed addition under 42 CFR 423.120(b)(2)(vi):

**(D)** In the case of a single-source drug or biological product for which the manufacturer introduces a new formulation with the same active ingredient or moiety that does not provide a unique route of administration or scientific evidence of superior adherence, safety and/or efficacy for CMS review.

If this provision is finalized, it will also be important to ensure that consumers are aware of and have meaningful access to expedited determination and exception processes when there is no alternative therapy available on the formulary. All HIV medications should automatically qualify for expedited review, similar to how regulations governing the Affordable Care Act Essential Health Benefits are interpreted (45 CFR § 156.122(c)(2)(ii)). The same prescription drug appeals process in place for access to non-formulary drugs should apply in this circumstance, and individuals should have access to clinically appropriate medication. In addition, clinical coverage decisions regarding appeals for antiretrovirals should be reviewed by infectious diseases or HIV experts and adhere to the federal HIV treatment guidelines. The importance of the appeals process in ensuring access to appropriate treatment underscores the need to resolve the current backlog of pending Medicare appeals.

## **Exclusion of a Drug If the Price of the Drug Increased Beyond a Certain Threshold (Proposed 42 CFR § 423.120(b)(2)(vi)(E))**

HHCAGW supports regulatory efforts to curb wholesale acquisition cost (WAC) price increases that exceed average increases in the consumer price index for all urban consumers (CPI-U). Antiretroviral manufacturers frequently take annual WAC price increases of 5% to 9%, which typically exceed annual CPI-U changes.<sup>4</sup> While manufacturers provide significant rebates for Medicaid and other safety net programs, notably AIDS Drug Assistance Programs (ADAPs), it remains unclear to what extent voluntary rebates are being paid to Part D plans and other commercial payers. These price increases are acutely felt by commercial payers and consumers, particularly where negotiations to control net costs are limited and coinsurance amounts are tied to prescription drug costs. Reining in price increases on drugs and biologics would not only provide Part D plans with greater leverage to negotiate rebates on products in the protected classes, but also disincentivize price increases that impact other payer systems.

HHCAGW cannot support formulary exclusions to achieve this goal, however. People living with HIV must have access to all or substantially all commercially available antiretroviral drug products to ensure individualized therapy, as per the comments in response to the first provision of the proposed rule pertaining to the protected classes. Additionally, ADAPs, as payers of last resort, would likely be forced to provide access to high-cost prescription drugs excluded by Part D plans, ultimately shifting costs away from commercial payers and on to a federally funded, safety net program. If this provision is implemented, we reiterate the need for the same drug exceptions policy applied to other non-formulary drugs to ensure consumers have access to the care and treatment they need.

We propose that you consider mandatory rebates being applied to protected class drugs, similar to the inflation penalty statutorily defined for Medicaid, with cost savings accruing to the Medicare trust fund and consumers. The HHS Office of the Inspector General has noted that Medicaid rebates are, on average, three times higher than the privately negotiated rebates paid to Medicare Part D plans and far exceed the average 6% across all protected classes.<sup>5</sup> HHCAGW offers this recommendation with the understanding that such rebates would require an act of Congress.

Alternative regulatory approaches to both shield against WAC price increases unmoored to inflation rates and safeguard against exclusions of critical drugs and biologics include value-based assessments conducted by CMS and/or with the appropriate funding the Agency for Healthcare Research and Quality.

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<sup>4</sup> See summary of price increases in Fair Pricing Coalition, “Open Letter to Manufacturers of HIV and Hepatitis Medications Opposing 2017 Price Increases,” (2016) available at <https://fairpricingcoalition.org/2016/11/16/openletter/>.

<sup>5</sup> HHS Office of the Inspector General, “Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin (2015), available at <https://oig.hhs.gov/oei/reports/oei-03-13-00650.pdf>.

Thank you for the opportunity to comment on this proposed rule. Please contact Amy Killelea with the National Alliance of State and Territorial AIDS Directors at [akillelea@nastad.org](mailto:akillelea@nastad.org), Ramon Gardenhire at [rgardenhire@aidschicago.org](mailto:rgardenhire@aidschicago.org) with the AIDS Foundation of Chicago, or Phil Waters at [pwaters@law.harvard.edu](mailto:pwaters@law.harvard.edu) with the Center for Health Law and Policy Innovation if we can be of assistance.

Respectfully submitted by:

ADAP Educational Initiative | AIDS Alabama | AIDS Action Baltimore AIDS Alliance for Women, Infants, Children, Youth & Families | AIDS Foundation of Chicago | AIDS Research Consortium of Atlanta | AIDS United | American Academy of HIV Medicine | APLA Health AIDS Resource Center of Wisconsin | Bailey House, Inc. | Communities Advocating Emergency AIDS Relief (CAEAR) | Community Access National Network (CANN) | Georgia AIDS Coalition | Harm Reduction Coalition | HealthHIV | HIV Medicine Association | Housing Works | Human Rights Campaign | Legal Council for Health Justice | Michigan Positive Action Coalition | Minnesota AIDS Project | National Alliance of State and Territorial AIDS Directors | National Latino AIDS Action Network | NMAC | Positive Women's Network - USA | Project Inform | Rocky Mountain CARES | San Francisco AIDS Foundation | SisterLove | Southern AIDS Coalition | Southern HIV/AIDS Strategy Initiative | St. Louis Efforts for AIDS | The AIDS Institute | Treatment Access Expansion Project | Thrive Alabama