



January 16, 2018

Seema Verma  
Administrator, Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Baltimore, MD 21244-8016

**Re: Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (File Code: CMS-4182-P)**

Dear Administrator Verma:

We are writing on behalf of the HIV Health Care Access Working Group (HHCAWG) – a coalition of more than 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 health care and support services. We appreciate the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) proposed technical changes for Medicare Part D for Contract Year 2019.

The Medicare Program is an important source of health coverage for people with HIV with approximately one quarter of those in care getting coverage through the program.<sup>1</sup> A majority of Medicare beneficiaries with HIV are dually eligible for Medicaid and receive low-income subsidy assistance to purchase drug coverage under Medicare Part D. The benefits and protections offered under Medicare Part D, particularly the Six Protected Classes requirement, have been critical to supporting access for individuals with HIV to current HIV treatment standards as set by the Department of Health and Human Services *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*.

We are writing to express concerns regarding a few policy changes that could adversely impact access to medications for Medicare beneficiaries with HIV as described below.

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<sup>1</sup> Kaiser Family Foundation. Medicare and HIV. October 2016, Online at: <https://www.kff.org/hiv/aids/fact-sheet/medicare-and-hiv/>

- Policy Changes Related to the Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA)

As part of the implementation of CARA, CMS is proposing new regulations to address the appeal process for beneficiaries who would be subject to a Part D pharmacy “lock-in.” We encourage CMS to make appeal processes regarding a Part D pharmacy lock-in as simple as possible for beneficiaries, to ensure that those beneficiaries who need particular drugs can access them. We recommend that CMS implement all of the CARA protections, including automatic escalation for independent review.

- Proposal to Eliminate Continuous Special Enrollment Period for Dual Eligibles

We urge CMS not to eliminate the continuous Special Enrollment Period for dual eligibles and beneficiaries who qualify for the Low-Income Subsidy (LIS). People with disabilities and older adults who count on the LIS do not have the financial resources to respond to any disruption or denial of care. While this option may not be used frequently by beneficiaries, when they use it, they need it to ensure access to their recommended medications.

- Proposal to Expedite Substitutions of Certain Generics

While we support expanded access to generic medications, we are concerned that the proposal to allow Part D sponsors to immediately add generics upon approval and remove brand name drugs (or move the branded to a higher cost-sharing tier) without requiring any approval process or notification period for consultation with a medical provider could lead to medication interruptions or otherwise compromise access to the most appropriate medications for Medicare beneficiaries. Beneficiaries select their plan based on formulary coverage and medication costs. Their health could be negatively impacted if formulary changes including increases in cost-sharing are enacted without notice and without the opportunity to consult with a medical provider to discuss switching to a generic medication. We urge at least a 60-day notification period for the replacement of brand name drugs with generic medications.

- Proposal to Eliminate Meaningful Difference Requirements

We urge CMS to reconsider eliminating the meaningful difference requirements for PDPs offered by a PDP sponsor. This policy is important to ease the burden on beneficiaries of evaluating Part D coverage options and to facilitate the selection of a plan that best meets their prescription drug needs. Ensuring that PDP options offer meaningful differences allows beneficiaries meaningful choices in their coverage options.

- Proposal to Continue Barring Tiering Exceptions for Specialty Drugs

Medicare beneficiaries with chronic conditions like HIV are unfairly penalized by CMS continuing the policy of not allowing beneficiaries and their providers to request lower cost sharing through the

exceptions process for a drug on a specialty tier when there is a medical justification for doing so. We urge CMS to reverse this policy.

- Proposal to eliminate the requirement that PDPs mail benefit package information to beneficiaries 15 days prior to open enrollment.

We recommend that CMS continue the 15-day advance mailing of benefit information and continue to require that beneficiaries receive hard copies by mail. Receiving plan information in advance is important to ensure sufficient time for beneficiaries to review and consider their coverage options given the limited open enrollment period. In addition, relying on electronic communications to disseminate benefits information risks leaving many Medicare beneficiaries without the details they need, and in a format that they can review, to select the most appropriate PDP based on their income and medication needs. Too many seniors and people with disabilities do not have routine access or any access to the Internet to rely solely on electronic distribution of this important information.

- Request for Information Regarding Applying Rebates at the Point of Sale

We strongly agree with the CMS goal of lowering beneficiary out-of-pocket costs and support an evaluation of the impact on total out of pockets of applying rebates at the point of sale for beneficiaries, including those with conditions that rely on higher cost medications like HIV and hepatitis C. In doing so, it will be important to assess total beneficiary costs and how premiums and other costs and fees may be impacted by this change in policy.

Please contact the HHCAWG co-chairs Andrea Weddle with the HIV Medicine Association at [aweddle@hivma.org](mailto:aweddle@hivma.org), Amy Killelea with the National Alliance of State and Territorial AIDS Directors at [akillelea@nastad.org](mailto:akillelea@nastad.org) or Robert Greenwald at [rgreenwa@law.harvard.edu](mailto:rgreenwa@law.harvard.edu) with the Treatment Access Expansion Project with questions regarding our comments.

Submitted on behalf of the undersigned organizations,

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.  
Community Access National Network (CANN)  
Empower U, Inc.

Georgia AIDS Coalition  
Harm Reduction Coalition  
HealthHIV  
HIV Medicine Association  
Housing Works  
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  
The AIDS Institute  
Treatment Access Expansion Project  
Treatment Access Group