



THE AIDS INSTITUTE

March 6, 2014

The Honorable Marilyn Tavenner  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
200 Independence Ave, SW  
Washington, DC 20201

**Re: Comments on the Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Proposed Rule**

Dear Administrator Tavenner:

The AIDS Institute, a national public policy, research, advocacy, and education organization, is pleased to offer our views on the Centers for Medicare and Medicaid Services' (CMS) proposed rule: *Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs*. Since we believe aspects of the proposed rule would erode a patient's ability to obtain the medications that their providers prescribe, we are urging CMS to abandon its proposal to change the "six protected classes." Frankly, we were rather surprised the Administration would propose such a rule given its strong commitment to quality health care, including mental health, and to people living with HIV/AIDS and other illnesses and diseases.

For people with HIV and so many others, new drug therapies have saved millions of lives and prolonged millions more. The advent of antiretroviral medications in the late '90s turned HIV from a near certain death to a more manageable disease if patients have access to quality care and medications. We know that all medications are not the same and each person reacts differently to a particular medication. Doctors and patients together make careful decisions about which therapies are most appropriate on a case by case basis. Some individuals may develop side-effects to a particular drug, while another person may need a certain therapy to avoid a harmful interaction with a drug being taken for another health condition. Drug resistance can occur in people with HIV, requiring them to have the ability to switch to another drug without interruption.

It was for these reasons that when Medicare Part D was first implemented, CMS determined that a minimum of only two drugs in a class was simply not enough for certain patients, including those with HIV, mental illness, cancer, epilepsy, and those undergoing organ transplantation. The "six protected classes" was created so that patients could have access to all the drugs in these classes.

## **Medicare Part D Program is Working**

The Part D program is working and is costing the government far less money than ever anticipated. However implementing these changes would undermine its success. For the past 10 years, Medicare Part D has been working for millions of seniors and people with disabilities, including over 100,000 people with HIV. As part of the Affordable Care Act (ACA), Congress even further codified the “six protected classes.” We see no reason why the protected classes should be changed, and if they were, we would like to see more classes of drugs gain “protected” status rather than reducing them so that more patients can gain access to the medications that are prescribed by their providers.

The vast majority of Medicare beneficiaries report they are satisfied with Part D as is. A 2013 national survey found that an astounding 92 percent of Medicare beneficiaries are satisfied with their Part D coverage, up from 78 percent from when the program was first implemented in 2006.<sup>1</sup> Among those that were not satisfied, a primary reason named was limited coverage. It is hard to understand why CMS is proposing changes to further limit drug access in a highly successful program.

In the proposed rule, CMS states “...the circumstances that existed when this policy was originally implemented have changed dramatically.” It is not at all clear as to what this statement is referring. Further, we do not believe there have been changes that would negate the therapeutic rationale for identifying these classes as protected and ensuring a broad range of access. The very point of the six protected classes was to ensure beneficiary access to all or substantially all drugs in certain therapeutic classes or categories where it is known that complete formulary access is essential to successful treatment. CMS has not described what dramatic changes have occurred that would negate this original thinking.

## **Proposal Not Based on Clear Evidence**

We fail to see the basis for this proposed rule, believe it lacks scientific grounding, and is arbitrary. In fact, one of the pieces of evidence of cost savings cited in the rule is a Milliman report that was commissioned by The Academy of Managed Care Pharmacy, a group that is opposed to the “protected classes” and has a significant financial stake in the matter. The report’s findings focus exclusively on those costs associated with reduced drug access and in no way account for the clinical outcomes. We believe CMS did not consider the evidence of the benefits of the “six protected classes” and the clinical outcomes. Nor did they fully consider the associated medical costs if this rule were finalized. For example, did CMS consider the risks and costs related to a failed transplant as a result of a beneficiary lacking access to an appropriate immunosuppressant therapy? Similarly, one can envision the extraordinary costs and harm that could occur should someone not have access to the antipsychotic that works best for them with the least debilitating side-effects.

We are also very concerned about the process by which this proposal came to be. At the very least, it lacks transparency. The proposed rule describes a consensus panel that was convened consisting of CMS

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<sup>1</sup> Medicare Today. Press Release and link to survey data: Survey: Medicare Prescription Drug Benefit Earns High Marks 10 Years After Enactment [http://www.medicaretoday.org/MT2013/pdfs/2013%20Part%20D%20Survey%20Press%20Release\\_FINAL.pdf](http://www.medicaretoday.org/MT2013/pdfs/2013%20Part%20D%20Survey%20Press%20Release_FINAL.pdf)

pharmacists and the CMS Chief Medical Officer to identify classes of drugs that should be removed from protective status. The rule also states that the panel was supported by a contractor. We believe that a process that has such profound impact on vulnerable beneficiaries' access to essential medicines should be convened in a public forum with identifiable panelists, adequate public comment, include clinical evidence, and should incorporate witnesses from impacted stakeholders groups, including patient advocates and physicians.

The Secretary used the authority granted to her under the ACA to develop criteria to alter the "six protected classes" and at the same time, proposed to eliminate three of the six classes. One would think that if the Administration was contemplating any changes, the criteria for class review would be developed first with adequate public comment before it was applied. Instead a very arbitrary criterion was developed in secret and then arbitrarily applied at the same time.

### **Congressional Intent Supports the "Six Protected Classes"**

In addition, The AIDS Institute believes the proposed rule violates the Affordable Care Act (ACA) which codifies the six-protected classes. Section 3307 of the ACA is titled "*Improving* formulary requirements for prescription drug plans..." The section gives the Secretary authority to identify classes and categories of clinical concern and details the existing protected classes. We do not believe the intent of the law was to diminish the existing classes. Rather, we believe it was to give the Secretary authority to improve upon the existing classes by introducing additional classes of clinical concern.

### **Appeals Process is Inadequate**

The proposed rule suggests that existing Medicare appeals and exceptions processes will function to allow beneficiaries access to necessary drugs, but this is far from reality. CMS has not released data on the appeals processes. Yet the patient advocacy community knows from those patients we represent that there are backlogs and that this process is insufficient to ensure access to essential therapies. While the Office of Medicare Hearings and Appeals (OMHA), has committed to being responsible to beneficiary initiated appeals, other types of appeals have created a backlog of nearly 375,000 claims.<sup>2</sup> This raises serious concerns about CMS' ability to manage the existing appeals process.

We have grave concerns about the ability of patients with mental health conditions and transplant patients to navigate an already backlogged appeals process. Medicare Part D beneficiaries, on average, represent vulnerable groups, made up of seniors and those with significant disabilities. For example, 29 percent of beneficiaries have a mental health issue or cognitive impairment and more than 4 in 10 live with three or more multiple chronic conditions.<sup>3</sup>

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<sup>2</sup> Jaffe, Susan. *As HHS Moves To End Overload Of Medicare Claims Appeals, Beneficiaries Will Get Top Priority*. Kaiser Health News. <http://www.kaiserhealthnews.org/stories/2014/january/21/medicare-claims-appeals-backlog-after-suspension.aspx>

<sup>3</sup> Kaiser Family Foundation. *Medicare: A Primer*. April, 2010.

## **Impact of Proposal on People with HIV & Hepatitis**

While The AIDS Institute holds these concerns with respect to all beneficiaries, we have some key concerns related specifically to those living with HIV and hepatitis B and C. Multiple studies have found that approximately half of those living with HIV have been diagnosed with a comorbid mental health condition.<sup>4</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. We know that when an individual is treated through antiretroviral therapy and achieves undetectable viral loads they not only benefit personally but also are 96 percent less likely to transmit HIV to others. Therefore, ensuring that those living with HIV are adherent to both mental health drugs and HIV drugs is especially important. Part of encouraging adherence to mental health drugs (both antidepressants and antipsychotics) is ensuring that patients have access to the drugs that work best for them and have the least challenging side effects. Removing antidepressant and antipsychotic drug classes from protected status will limit beneficiary ability to access the most clinically appropriate drugs.

About one quarter of those infected with HIV are co-infected with hepatitis C, while 10 percent have hepatitis B. The CDC estimates that between 5 and 20 percent of those infected with HCV will develop cirrhosis. Chronic hepatitis C infection is the leading indication for liver transplants in the United States. We are therefore highly concerned about the proposal to remove immunosuppressants from protected status. It is hard to imagine a scenario in which it is any more critical that a drug work as it should than an immunosuppressant being used to ensure a transplanted organ is successful. The financial and human cost of just a handful of individuals failing to receive the most effective immunosuppressant would be huge. We believe that removing this class of drugs from protected status is short sighted.

## **Protections for Antiretrovirals**

Despite our grave concerns related to changing the “six protected classes,” we do appreciate CMS’ intent that they will continue to afford protected status for antiretrovirals and continuing several other protections for antiretrovirals. We appreciate and support the proposal to explicitly exclude antiretrovirals from the proposed exception regarding fixed-combination drugs. As the rule points out, fixed-dose combination products simplify the dosing and pill regime for people living with HIV. Further, these fixed-dose products are considered the standard of care.

We also strongly support the proposal not to allow prior authorization and step-therapy for antiretrovirals. These utilization management techniques can lead to poor adherence and create an

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<sup>4</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. Kasier Family Foundation. Medicaid And HIV: A National Analysis. 2011. <http://kaiserfamilyfoundation.files.wordpress.com/2013/01/8218.pdf>

unnecessary obstacle for beneficiaries with HIV. With respect to both of these proposals, we appreciate the steps CMS is taking to ensure that HIV positive beneficiaries have access to the medicines they need to be healthy. As previously discussed, this has ramifications not only for the individual's health, but also for the public's health.

### **Conclusion**

The AIDS Institute strongly opposes CMS' proposal to dismantle the "six-protected classes." The original purpose of the classes of clinical concern was to protect categories and classes of drugs in which it was clinically essential that beneficiaries have access to the full breadth of available therapies. When the classes of clinical concern were adopted, six classes of drugs were identified as fitting this profile. There have not been any developments that would warrant removing the antidepressant, antipsychotic, or immunosuppressant classes from protected status and doing so could only bring harm to beneficiaries. We urge CMS to reverse this proposal and maintain the critical protections around these six classes, as has been the case since Medicare Part D was first implemented and as was codified in the ACA.

Thank you very much.

Sincerely,

A handwritten signature in blue ink, appearing to read "Carl E. Schmid II".

Carl E. Schmid II  
Deputy Executive Director