January 25, 2019

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd.
Baltimore, MD 21244

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

Dear Administrator Verma:


APIAHF is the oldest and largest health policy and public health organization working with Asian American (AA), Native Hawaiian and Pacific Islander (NHPI) communities across the nation and its Pacific jurisdictions. With more than 150 community-based organizational partners in over 28 states and territories, APIAHF provides a voice in the nation’s capital for underserved AA and NHPI communities and works toward health equity and health justice for all.

For over 6 years, APIAHF has partnered with organizations helping consumers enroll in health coverage, including Affordable Care Act (ACA) Marketplace plans, Medicaid and the Children’s Health Insurance Program (CHIP). As part of these efforts, we co-founded Action for Health Justice with the Association of Asian Pacific Community Health Centers (AAPCHO), Asian Americans Advancing Justice and Asians Americas Advancing Justice – Los Angeles. As part of Action for Health Justice, we worked with 72 community based organizations and health centers and countless local assistors to inform efforts by the U.S. Department of Health and Human Services to reduce barriers for AA and NHPI individuals navigating an often deeply complex enrollment process. The complexities that exist as part of enrolling in private or public health insurance are multiple for immigrant and limited English proficient (LEP) populations. Through this experience, and others first hand, we know both the importance of health insurance for individuals who have complex chronic conditions, LEP persons, immigrants and their families, as well as the existing institutional problems that they already face in getting and stayed enrolled in the programs they are legally eligible for.

AAs and NHPIs are part of the 45 million Americans who rely on Medicare Part D for access to lifesaving prescription drugs. While the data for Medicare
beneficiaries by race and ethnicity is incomplete for AAs and NHPIs, there are at least 1.8 million AAPIs enrolled in Medicare Part A and/or Part B. The share of AAs over age 65 is expected to rise in the coming years.

**AAs and NHPIs Disproportionately Experience the Disease States Covered by the Protected Classes**

According to the American Cancer Society, age is the single greatest risk factor for cancer. Half of the 1.7 million new cancer cases diagnosed in the U.S. this year are projected to be among people 65 or older. Cancer has a significant disparate impact on communities of color, including AAs and NHPIs. In 2017, AAs were one of the only racial groups where cancer was the leading cause of death compared to heart disease for all others. For Asian American men, the three leading causes of cancer death are lung, liver and colorectal. For AA women, they are lung, breast and colorectal. Vietnamese women have cervical cancer rates five times higher than White women. NHPIs are 30% more likely to be diagnosed with cancer than whites. The indices of liver cancer for Laotian men is 66% compared to 9% for white men. Korean women have a stomach cancer rate of 22% compared to only 4% for white women. These are just some examples of the disparate impact cancer has on AA and NHPI populations and within specific subgroups.

1 in 33 NHPI men will be diagnosed with an HIV infection in their lifetime, compared to 1 in 102 white men. 1 in 5 AAs living with HIV does not know they have it, compared to 1 in 7 for all groups. Of AAs living with HIV in 2014, 57%

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2 Centers for Disease Control and Prevention. In 2015, heart disease was the leading cause of death for all males across all racial groups, other than “Asian/Pacific Islander,” while heart disease was the leading cause of death for all females across all racial groups in 2014 other than “Hispanic” and “Asian/Pacific Islander.” Available at: [https://www.cdc.gov/healthequity/lcod/men/2014/race-ethnicity/index.htm](https://www.cdc.gov/healthequity/lcod/men/2014/race-ethnicity/index.htm).


6 Id.


8 Id.
received HIV medical care, 46% were retained in HIV care, and 51% had achieved viral suppression. As detailed below, the proposed changes would threaten the nation’s public health, particularly with respect to stemming the tide of HIV as treatment is how HIV is managed and rapid linkage from testing to treatment is critical. Indeed, our national effort to make HIV medication accessible is one of the major reasons we have seen declining HIV infections.

**The Six Protected Classes Must Be Maintained (§ 423.120(b)(2)(vi))**

While we appreciate the Administration’s desire to limit out-of-pocket expenses for Medicare beneficiaries, we oppose efforts to limit or otherwise undermine patient access to the drugs covered by the six protected classes. Many of the proposed changes affect benefit design where utilization controls are already employed and can create access barriers to beneficiaries, contributing to delayed or improper adherence to clinical regimes and increased expenses associated with emergency and acute treatment.

Specifically, CMS is proposing to allow Part D sponsors greater flexibility to 1) implement broader use of prior authorization (PA) and step therapy (ST) for protected class drugs; (2) exclude a protected class drug from a formulary if the drug represents only a new formulation of an existing single-source drug or biological product, regardless of whether the older formulation remains on the market; and (3) exclude a protected class drug from a formulary if the price for the drug increased beyond a certain threshold over a specified look-back period.

As we will detail more specifically, taken together, the proposed changes threaten to impede beneficiary access to drugs that are critical components of clinical care.

**The Proposed Changes Run Counter to Congressional Intent**

Since 2008 when Congress established the six protected classes of drugs under Medicare Part D through the Medicare Improvements for Patients and Providers Act (MIPPA) and when Congress reaffirmed its commitment to the protected classes by codifying them in the Affordable Care Act (ACA), Medicare beneficiaries have had the guaranteed right to access all drugs within these six classes and categories. This has given millions of seniors the peace of mind, particularly those with disabilities and chronic conditions such as HIV, transplant recipients, epilepsy and mental illness, that they can access the right drug at the right time regardless of cost. Even in the time since then, however, Medicare Part D Prescription Drug Plans (PDPs) have had the ability to limit access as CMS’ definition of “substantially all” permits plans to limit coverage to one drug of clinical equivalence in each class. For example, according to a study conducted by Avalere in 2018, plan sponsors employ utilization management tools at least 40%

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9 Id.
of the time across the six protected classes. Permitting plans greater flexibility where flexibility is already largely inherit in the system will threaten patient access and medication adherence, leading to worse health outcomes. As such, APIAHF raises serious concerns about changes in formulary design that would result in excluding drugs within the six protected classes from Part D plans based on thresholds related to drug cost that are not related to patient clinical guidelines.

Prior Authorization and Step Therapy (ST) or Fail-First Policies Can Impede Patient Access to Care for Drugs in the Protected Classes

APIAHF opposes the proposed expansion of prior authorization and step therapy for drugs in the protected classes as they could hinder access and patient health outcomes. ST operates as a “fail first” policy, requiring beneficiaries to first “fail” on a less expensive drug than the one recommended by their clinician prior to their plan paying for the original prescription. As described below, particularly in the context of HIV, this can have serious adverse consequences for both the patient and public health.

It is critical that when CMS evaluates whether such forms of utilization management are appropriate for Medicare beneficiaries, that it consider the demographic and diverse makeup of Medicare beneficiaries and those who are eligible. For example, many seniors may have low literacy and/or low health literacy and experience a range of factors, including difficulty speaking and/or reading English that can prevent them from accurately evaluating plans and understanding the impact that PA or ST would have on the medications they currently take. This is particularly problematic in treatments for HIV or mental health where strict adherence to the clinical regimen is critical for either viral suppression or good health outcomes. As such, the proposed changes to the protected classes policy threaten public health and the nation’s efforts to control the HIV epidemic.

In addition, ST fails to consider that different drugs or therapies for clinical conditions may work differently in patients depending on their comorbidities, demographic factors and drug interaction. By requiring patients to try a lower cost medication before the one their physician prescribed, ST does not adequately consider the diverse factors that go into clinical treatment, and particularly their application for racial and ethnic minorities. By interjecting yet another barrier between the patient and their clinical treatment, ST create unnecessary burdens on patient access resulting in delayed care or even increased out-of-pocket costs if a patient decides to avoid ST by paying out-of-pocket or is forced to seek additional physician visits or emergency care. In the case of patients with HIV, ST could result in an entire treatment regime failing if a patient is forced to try a lower cost drug

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prior to continuing on or trying the drug their clinician recommended. Similarly, persons with HIV must be able to readily switch therapies to maintain viral suppression if they develop resistance or complications with a drug, and this must be able to happen quickly and at the clinician’s recommendation. Any disruption or delay in access to treatment for a patient with HIV can threaten viral suppression and result in worse health outcomes, which could ultimately drive health costs up in contrast to the rationales proposed by this policy. In addition, delays in access to drugs can interfere with viral suppression and the ability of a person with HIV to transmit the virus to another individual. As a result of treatment, many people with HIV are able to maintain an undetectable viral load, with very little chance of transmitting the virus to another partner.

Finally, CMS seeks to adopt ST in Part D plans where already nearly half (49%) of plans are already using prior authorization for branded drugs in the protected classes. In summary, we urge CMS to maintain the current requirements and do not permit plans to broaden use of PA or ST in Part D in the protected classes.

Thank you again for the opportunity to comment. Should you have any questions, please contact Amina Ferati, APIAHF Senior Director of Government Relations and Policy at aferati@apiahf.org.

Sincerely,

Kathy Ko Chin
President & CEO