

Congress of the United States

Washington, DC 20515

March 3, 2021

The Honorable Norris Cochran
Acting Secretary
U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Ave, S.W.
Washington, DC 20201

The Honorable Elizabeth Richter
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Ave, S.W.
Washington, DC 20201

Dear Acting Secretary Cochran and Acting Administrator Richter,

We write to express our strong opposition to a Centers for Medicare and Medicaid Services (CMS) and Center for Medicare and Medicaid Innovations (CMMI) request for applicants to amend their Part D Payment Modernization (PDM) model for calendar year (CY) 2022. This new model does not fairly take into account the public health implications for patients that utilize drugs under the six protected classes, especially during the COVID-19 pandemic, and we urge the Biden Administration to use their readily available authorities to pull back these changes to the PDM model immediately.

When CMS implemented Medicare Part D fifteen years ago, it identified six classes and categories of medicines where patients could face serious risks, complications, and negative health outcomes without access to these medicines. CMS required Part D plans to cover all or substantially all medications within these six classes, which help treat patients with epilepsy, organ transplants, cancer, HIV, and mental health conditions.

This request by both CMS and CMMI was made in the final hours of the previous administration and would permit participating plans to limit coverage of medications in five of the six protected classes in CY2022 and would move to include antiretrovirals in CY2023. It would also weaken coverage standards for all medicines by providing a waiver to CMS' current two drugs per class requirement and allow participating plans to cover one drug per class. These proposed changes fail to consider the unique needs of patients who need the treatment that is best for their condition, or patients who must try different treatments before finding the right treatment for their needs.

Further, we do not believe these formulary flexibility changes to the model would result in significant cost savings but will instead push access to essential medications out of reach for vulnerable patients. Part D plans are already equipped with tools to manage spending and encourage the use of generics when possible for the six protected classes. According to an

analysis of CMS data by the Pew Charitable Trusts, the generic utilization rate in the protected six classes is as high as 84 percent.¹

We are troubled that for the third time in seven years, CMS is again considering changes to Part D that would strip these critical medicines of their protected status, especially in the middle of a deadly pandemic. Potential changes to the six protected classes have been twice rejected during both the Obama and Trump Administrations after receiving significant opposition from Congress, patient groups, providers, and other stakeholders.²

Given our concerns about the serious public health implications these PDM model changes could have on all Medicare beneficiaries, especially the sickest and most vulnerable patients, we respectfully ask that you remove these dangerous changes from the model.

Thank you for your prompt consideration of this serious matter.

Sincerely,



Grace F. Napolitano
Member of Congress
Co-Chair, Mental Health Caucus



John Katko
Member of Congress
Co-Chair, Mental Health Caucus



Barbara Lee
Member of Congress
Co-Chair, HIV/AIDS Caucus



Jenniffer González Colón
Member of Congress
Co-Chair, HIV/AIDS Caucus

Bonnie Watson Coleman
Member of Congress

Raúl M. Grijalva
Member of Congress

Rodney Davis
Member of Congress

Katie Porter
Member of Congress

Brian Fitzpatrick
Member of Congress

Darren Soto
Member of Congress

¹ The PEW Charitable Trusts. Policy Proposal: Revising Medicare's Protected Classes Policy. March 2018.

² Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses, 84 Fed. Reg. 100,23832 (May 23, 2019); Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 100,29844 (May 23, 2014).

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Member of Congress

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