



January 28, 2021

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Centers for Medicare & Medicaid Services
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Amy Bassano
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Center for Medicare and Medicaid Innovation
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Re: Part D Payment Modernization Model Calendar Year (CY 2022)

Dear Acting Administrator Richter and Acting Director Bassano:

Aimed Alliance is a 501(c)(3) non-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. We appreciate the opportunity to comment on the Part D Payment Modernization Model Calendar Year (CY) 2022 (PDM Model). We are writing to request that this administration undo the recent changes to the PDM Model that undermine the Part D Six Protected Classes and generally reduce drug access to Part D drugs. These changes violate the Social Security Act (SSA); will jeopardize the health of vulnerable patients with chronic, complex diseases; and may not result in significant cost savings to Medicare.

I. Summary of Six Protected Classes and PDM Model

Currently, Part D sponsors are required to include on their formularies “all or substantially all drugs” within six categories or classes of drugs, referred to as the “Six Protected Classes.”¹ These classes include antidepressants, antipsychotics, anticonvulsants, immunosuppressants for treatment of transplant rejection, antiretrovirals, and antineoplastics.² Additionally, Part D sponsors may only impose prior authorization and step therapy requirements for beneficiaries initiating therapy (i.e., new starts) for five of the six protected classes, with no prior authorization or step therapy allowed at all for antiretrovirals.³

On January 19, 2021, the Center for Medicare and Medicaid Innovation (CMMI) launched the PDM Model to voluntarily test a new Part D design. The changes include removing protections for the Six Protected Classes. As of CY 2022, participating Part D sponsors would be

¹ <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>. “Substantially all” means all drugs and unique dosage forms are expected to be included in sponsor formularies with limited exceptions. For example, the requirement does not allow for exclusion of brand drugs where generics are unavailable) *Id.*

² <https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-and-part-d-drug-pricing-final-rule-cms-4180-f>

³ <https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-and-part-d-drug-pricing-final-rule-cms-4180-f>

permitted to “treat five of the six protected classes (anticonvulsants, immunosuppressants, antidepressants, antipsychotics, and antineoplastics) as they would other Part D drug. As of CY 2023, CMS also intends to remove protections for the sixth protected class—antiretrovirals.⁵ Additionally, as of CY 2022, regarding all other classes of drugs aside from the Six Protected Classes, participating Part D sponsors would be permitted to include only one drug per drug class on their formulary rather than a minimum of two drugs per classes, as is currently required.⁶

Taken together, the PDM Model would allow Part D sponsors to exclude all but one drug per class in the Six Protected Classes from their formularies and would also be permitted to implement step therapy and prior authorization requirements beyond those that are currently permitted. As a result, many patients who require medications within the Six Protected Classes may lose access to their medications and also may face further administrative burdens in trying to regain access.

II. CMMI Violated the SSA

CMMI violated the SSA by modifying the Six Protected Classes without 1) establishing that the changes were based on scientific evidence and medical standards of practice; and 2) providing an official public notice and comment period through the Federal Register. The SSA states that Part D sponsors shall be required to include all covered Part D drugs for the Six Protected Classes.⁷ The statute also states that HHS may establish exceptions that permit a sponsor to exclude certain drugs within the protected classes from its formulary.⁸ However, in order to do so, HHS is required to ensure that any exception is 1) based upon scientific evidence and medical standards of practice; and 2) includes a public notice and comment period.⁹ Here, CMMI implemented exceptions to allow sponsors to exclude drugs within the protected classes from their formularies (i.e., by treating the Six Protected Classes like any other class of drugs) without meeting either of these requirements. CMMI made no attempt to show how removing protected status is consistent with scientific evidence and medical standards of practice. Instead, CMMI stated that its decision was based on an attempt to allow sponsors to negotiate drug prices.¹⁰ Additionally, CMMI did not allow for a public notice and comment period. Instead of publishing the Model in the Federal Register and soliciting comments, CMMI released a fact sheet and request for applications, only noting that sponsors could send emails with questions to CMMI.¹¹

⁴ <https://www.cms.gov/newsroom/fact-sheets/part-d-payment-modernization-model-calendar-year-cy-2022-fact-sheet>

⁵ <https://innovation.cms.gov/media/document/partd-payment-modernization-cy22rfa>

⁶ <https://www.cms.gov/newsroom/fact-sheets/part-d-payment-modernization-model-calendar-year-cy-2022-fact-sheet>

⁷ 42 U.S.C. § 1395w-104I (G)(i)(I), (iv)

⁸ 42 U.S.C. § 1395w-104(G)(iii)

⁹ 42 U.S.C. § 1395w-104(G)(iii)

¹⁰ <https://www.cms.gov/newsroom/fact-sheets/part-d-payment-modernization-model-calendar-year-cy-2022-fact-sheet>

¹¹ <https://innovation.cms.gov/media/document/partd-payment-modernization-cy22rfa>;

<https://www.cms.gov/newsroom/fact-sheets/part-d-payment-modernization-model-calendar-year-cy-2022-fact-sheet>

As CMS notes, the agency has attempted to remove some of the Six Protected Classes protections in both 2014 and 2018 through the notice and comment period.¹² Both times, CMS abandoned such proposed changes due to significant backlash from the patient and medical community.¹³ In making these changes through a demonstration project, CMS is attempting to do what it failed to do in the past and is circumventing the legal notice and comment period in the process.

III. The PDM Model Is Harmful to Patients and May Not Result in Cost Savings

The Six Protected Classes include medications for the treatment of patients with depression, schizophrenia, bipolar disorder, epilepsy, kidney disease, HIV/AIDS, and cancer. These conditions often require specialized treatment that is targeted to a patient's specific needs, and the treatments within these classes are often not interchangeable, meaning that if a stable patient is switched, that patient may not achieve the same success on the new medication. Loss of access to a medication or being switched onto something less effective can result in dangerous side effects for the impacted conditions. For example, patients with depression who are switched from one antidepressant to another face a higher risk of relapse, more rapid relapse, increased rate of recurrence, shorter course of well intervals, fewer symptom-free weeks, and increased risk of suicide.¹⁴

Moreover, if the classes are no longer protected, Medicare Part D may see some cost savings; however, there will likely be increased costs in other Medicare parts because, as mentioned, many of the medications within the classes are not interchangeable and have known side effects. Patients may experience adverse events leading to disease progression and increased outpatient visits, emergency room visits, and hospitalization, all of which is costly. Acknowledging these results, CMS previously concluded that removing protected class status would not "strike the balance among beneficiary access, quality assurance, cost-containment, and patient welfare."¹⁵ We ask CMS to now come to the same conclusion.

In sum, we ask CMS to abandon the changes to the Six Protected Classes in the PDM Model. Please contact us at policy@aimedalliance.org if you have any questions.

Sincerely,

Stacey L. Worthy
Counsel

¹² <https://innovation.cms.gov/media/document/partd-payment-modernization-cy22rfa>

¹³ <https://innovation.cms.gov/media/document/partd-payment-modernization-cy22rfa>

¹⁴ <https://ps.psychiatryonline.org/doi/full/10.1176/ps.2009.60.11.1439>

¹⁵ <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/CMS-4159.pdf>