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Re: Part D Payment Modernization Model Calendar Year (CY 2022)

Dear Acting Administrator Richter and Acting Director Bassano:

Patients Rising Now is a national nonprofit organization dedicated to advocating for the rights of patients with chronic and life-threatening illnesses. We support policies aimed at advancing patient access to and affordability of healthcare. We are writing to ask that CMS abandon recent changes to the Part D Payment Modernization Model Calendar Year 2022 (PDM Model) that we believe will reduce access to Part D drugs and place at risk the health of patients with serious, complex diseases.

I. Background

A. Current Requirements Under Part D

As you know, Part D sponsors currently are required to include on their drug formularies "all or substantially all drugs" within the following six classes or categories of drugs, often referred to as the "six protected classes":

- Antidepressants
- Antipsychotics
- Anticonvulsants
- Immunosuppressants for treatment of transplant rejection
- Antiretrovirals
- Antineoplastics

The six protected classes were put in place to protect the most vulnerable beneficiaries with serious, complex health conditions, by ensuring that these patients can access prescribed medications without having to jump through administrative hoops. As such, CMS also limits Part D sponsors in their use of prior authorization[1] and step therapy[2] requirements for the six protected classes. Specifically, sponsors (1) cannot require prior authorization or step therapy at all for antiretrovirals, and (2) may only implement such requirements for new patients for the other five protected classes.

Additionally, sponsors must include at least two drugs on their formularies for each Part D drug class or category, with limited exceptions (e.g., only one drug is available in a particular class).[3] This requirement applies to all Part D drug classes and categories; it is not limited to the six protected classes.

B. PDM Model Changes to Part D

The Center for Medicare and Medicaid Innovation (CMMI) implemented the PDM Model to test changes to the Part D program design that are intended in part to reduce overall Part D prescription drug spending. Unfortunately, the new program design removes important protections for drugs in the six protected classes, which may put many of the most vulnerable beneficiaries at risk.

Beginning in calendar year 2022, Part D sponsors that voluntarily participate in the PDM Model may "treat five of the six protected classes (anticonvulsants, immunosuppressants, antidepressants, antipsychotics, and antineoplastics) as they would other Part D drug classes..."[4] Beginning in calendar year 2023, CMS similarly will permit participating Part D sponsors to treat drugs in the sixth protected class—antiretrovirals—as they would other Part D drugs.[5] In addition, CMS will waive the two-drugs-per-class requirement applicable to all Part D drugs, allowing sponsors to include only one drug per drug class on their formularies.[6]

Therefore, the PDM Model will soon allow participating sponsors to (1) exclude all but one drug per class in the six protected classes from their formularies, and (2) put in place prior authorization or step therapy requirements for drugs in any of the six protected classes, regardless of whether a patient is stable on current therapy. Consequently, some patients who are prescribed medications within these classes could lose access to their treatments altogether and

[1] Prior Authorization is a practice whereby the insurer requires the plan enrollee or provider to obtain the health plan's advance approval before prescribing a particular medication or medical service.
[2] Step therapy is a practice whereby the insurer requires a plan enrollee to try and fail on a medication before the enrollee can access a prescribed medication.
[3] https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf
[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

then be forced to jump through burdensome administrative hoops in trying to restart their treatments.

II. The PDM Model Could Have Devastating Effects for Some Beneficiaries

The six protected classes include medications that treat chronic and complex conditions. Examples include:

- Depression and anxiety disorders
- Schizophrenia, bipolar disorder
- Epilepsy and other seizure disorders
- Kidney disease, liver disease
- HIV/AIDS
- Cancer

Patients with serious conditions like these often present with complex cases and require highly individualized treatment. Health care providers must work closely and carefully with patients, often for extended periods of time, to find a therapy that stabilizes patients' conditions. Even minor medication variations can lead to adverse reactions and negatively impact a patient's quality of life. Given the severity of many of the conditions treated with medications in the six protected classes, any initial medication choice or subsequent change should be carefully considered by the prescriber and the patient. Further, many of the medications within these classes are not interchangeable, meaning that they do not "produce the same clinical results as the reference product in any given patient."[7] Therefore, if a patient is stable on an established treatment plan but suddenly loses access to a medication or is otherwise forced to switch medications as a result health care coverage changes, they might find that their new medication is not as effective.

Yet, the PDM Model will permit participating sponsors to essentially interfere with the patient-doctor relationship by including on their formularies only one drug per class, requiring patients to first try and fail on one or more treatments before covering the medication originally prescribed, or implementing new prior authorization requirements. The Model thus could result in delays in access to care or interruptions in established care, which could lead to increased adverse events, disease progression, increased visits to the physicians' office or emergency room, and hospitalizations for those with conditions treated by drugs in the six protected classes.

Such consequences could be particularly devastating for these vulnerable beneficiaries. For example, patients prescribed antidepressants are advised to only change their medication regimens cautiously and under close observation of their health care providers. Otherwise, switching antidepressant medications can result in a higher risk of recurrence or more rapid

[7] https://pubmed.ncbi.nlm.nih.gov/10520974/#:%7E:text=The%20SSRIs%20appear%20to%20be,be%20treated%20effectively%20with%20another

recurrence of depression and increased risk of suicide.[8] For patients with cancer, lack of immediate access to specific treatments that work best for their individualized needs could result not only in disease progression but death.[9] The same risks exist for patients who have had an organ transplant. According to the National Kidney Foundation, "kidney transplant patients must take immunosuppressive drugs for the life of their transplant to help prevent organ rejection. Skipping even one dose will increase the chance of organ failure."[10]

Given the potentially serious health risks that can result from interruptions in care for those who are prescribed medications in the six protected classes, CMS has previously decided not to implement the types of changes that will be tested through the PDM Model. In a Final Rule in 2018, CMS stated "we conclude that the risks associated with inappropriately interrupting therapy for stabilized patients receiving protected class drugs for protected class indications by potentially subjecting them to [prior authorization] or [step therapy] requirements outweighs the potential clinical benefits that some enrollees could gain from switching therapies that might be more appropriate and the potential cost savings that would accompany the additional formulary management flexibility."[11]

Three years later, the "risks associated with inappropriately interrupting therapy" remain unchanged. Therefore, given the potential harm that the PDM Model could have on vulnerable seniors with serious and complex conditions, we ask CMS to amend the PDM Model by abandoning the changes discussed above.

Sincerely,

Terry Wilcox

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[8] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4919171/
[9] https://www.asrs.org/advocacy/step-therapy
[10] https://www.kidney.org/news/national-kidney-foundation-applauds-landmark-immunosuppressive-drug-coverage-legislation-passed
[11] https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-10521.pdf