



January 25, 2019

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4180-P
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Submitted electronically via <http://www.regulations.gov>

Re: Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses (CMS-4180-P)

Dear Secretary Azar:

On behalf of the National Alliance on Mental Illness (NAMI), I am pleased to submit comments on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule entitled, "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses" (the proposed rule). NAMI is very concerned that this proposed rule would significantly affect access to medications, continuity of care, and health outcomes for Medicare beneficiaries living with mental illness.

Millions of people with mental illness rely on Medicare as a lifeline for treatment. Medicare covers both older adults who live with mental health conditions and, frequently, co-occurring chronic medical conditions, as well as younger adults who are disabled by a psychiatric condition. In fact, 37% of all disabled Medicare beneficiaries have a severe mental illness. For these beneficiaries, access to mental health medications is critical for stabilizing conditions and promoting recovery.

Recognizing the vulnerability of beneficiaries with mental illness, the Medicare Part D program has been charged with protecting access to prescription drugs by requiring plans to cover "all or substantially all" drugs in protected classes of clinical concern, including antidepressants and antipsychotics. This requirement and other protections were also intended to ensure that plans did not discourage enrollment of people with mental illness by creating formularies that excluded or covered very few mental health medications or that imposed significant barriers. This is especially important because individuals' responses to specific antidepressants and antipsychotics are unique and vary widely. In fact, many antipsychotics, for example, are prescribed based on their side effect profiles, which may help or exacerbate an individual's unique symptoms.

Given the vulnerabilities and unique medication needs of people with mental illness, NAMI urges CMS to consider the following comments and work to ensure continued access to a wide range of mental health treatment options.

Greater use of prior authorization, including step therapy

The proposed rule would allow Part D plans to impose additional prior authorization requirements – like step therapy – on drugs within the six protected classes.

NAMI has serious concerns with this policy because the very symptoms of mental illness can cause beneficiaries to have challenges with adhering to a medication or navigating administrative barriers. In

addition, antidepressant and antipsychotic medications impact individuals differently and, significantly, often take several weeks of titrated doses to reach a therapeutic effect. If the medication does not work, this process of titrating off a drug and onto another can take weeks or months, during which time a beneficiary is at especially high risk of experiencing poor health outcomes, including emergency department visits, hospitalizations, and even homelessness or justice involvement. Step therapy policies, in particular, can lead to beneficiaries not filling their prescriptions or underutilizing medications,ⁱ which can have a negative impact on adherence to medications. In fact, in previous guidance, CMS has articulated that limiting access to the most appropriate medication can drive higher costs in Medicare Parts A and B by increasing admittance to inpatient care and emergency departments due to the destabilization of individuals' conditions.

Part D plans already have more restrictive formularies for drugs covered under the six protected classes relative to commercial plans,ⁱⁱ which suggest that the current policy does not prevent Part D plans from effectively managing formularies within these drug classes. Notably, 97% of antidepressants and 91% of antipsychotics filled under Part D are generics.ⁱⁱⁱ This data demonstrates that the current regulation protects access for beneficiaries who may benefit from specific mental health drugs while simultaneously allowing plans to incentivize very high use of generics. The Medicare Payment Advisory Commission (MedPAC) notes that the "protected status does not appear to affect plan sponsors' ability to encourage the use of generics."^{iv} Imposing prior authorization requirements also increases administrative costs to providers. According to a 2017 survey of the American Medical Association, 92 percent of respondents reported care delays because of a private health plan's use of prior authorization requirements.^v

While we appreciate that CMS proposes to retain the requirement that Part D sponsors cover at least two drugs per therapeutic category and class, we are concerned that this policy will not provide sufficient access to antidepressants and antipsychotics, which vary widely in their mechanisms of action, side effect profiles, drug interactions, and effectiveness for individual beneficiary's conditions.

While the Medicare appeals and exceptions process will be available to beneficiaries, the Medicare Payment Advisory Commission (MedPAC) has noted that widespread frustration with this process exists among all stakeholders – beneficiary groups, prescribers, plan sponsors, and CMS – and that the process can be frustrating and burdensome for beneficiaries.^{vi} NAMI requests that CMS rescind the proposed rule's expansion of step therapy and prior authorization in Medicare Part D plans.

Exclusions of new drug formulations

The proposed rule would allow Part D plans to exclude new formulations of an existing single-source drug or biologic product and permits this exclusion even if the manufacturer no longer makes the older version of the drug.

NAMI is particularly concerned that this proposal would severely restrict access to new formulations, including formulations that enhance adherence or tolerability for people with mental illness. For example, prescription drugs that are "extended release" differ substantially from an "immediate-release" version of the same drug and can affect symptom management and beneficiary adherence.

In addition, Long-Acting Injectable (LAI) formulations of existing antipsychotic medications are a highly effective innovation in psychiatric treatment that helps beneficiaries who struggle with adherence reach a therapeutic dose and/or maintain treatment. Despite the valuable role LAIs can play in treatment, use of these innovative therapies in the United States lags far behind their use in other countries. NAMI is very concerned that Part D plans would use the new flexibility in the proposed rule to exclude from their formulary any LAI versions of medications, despite their benefit for those who struggle with treatment adherence. NAMI recommends that CMS reject this proposal, particularly in light of the lack of clarity in the definition of "new formulation" and "single source drugs."

Exclusions of drugs based on cost increases

The proposed rule would also allow Part D plans to exclude from their formularies any single source drug or biological product within the protected classes whose price increases beyond the rate of inflation. While we appreciate the Administration's interest in making prescription drugs more affordable for beneficiaries, we believe this proposal is flawed.

Beneficiaries with mental health conditions require continuity in the drug treatment that is found to work best for them. Allowing Part D plans to remove drugs from their formularies because pharmaceutical manufacturers' prices increased beyond an arbitrary threshold could result in harm to beneficiaries who need these medications. If drugs are no longer covered under this policy, Medicare beneficiaries will have to pay out-of-pocket for these products (which can be beyond the means of most beneficiaries) or fail to fill their prescriptions.

CMS is proposing to use Consumer Price Index for All Urban Consumers (CPI-U) to calculate the rate of inflation above the baseline price for a particular drug or product. This flexibility would give Part D plans the opportunity to design discriminatory benefits that could result in significant disruption in clinical care for beneficiaries or could result in discouraging people with mental illness from enrolling in a plan.

NAMI appreciates the underlying intent of providing additional leverage for Part D plan sponsors in negotiating rebates and discounts. However, we are very concerned that the proposed change will result in unintended consequences for beneficiaries with mental illness. NAMI implores CMS to not permit exclusion of drugs based on price increases and, instead, put the health of Medicare beneficiaries first.

Explanation of Benefits Requirements

In this proposed rule, CMS seeks to require plans to communicate negotiated drug pricing information and lower-cost alternatives in the Part D plan's Explanation of Benefits (EOB). NAMI appreciates this step toward greater transparency, but we are concerned that the information would not help beneficiaries make different health care decisions. Instead, NAMI recommends that CMS require plans to use clear and concise language to communicate plan benefits, coverage levels, and out-of-pocket costs, and that this information be included in EOBs in different ways (e.g., using graphs or bullet point summaries) to ensure that beneficiaries better understand their plan benefits.

CMS should also work to improve beneficiaries' online shopping experience and ability to compare formularies and out-of-pocket costs across plans. As recently recommended by the National Council on Aging, Medicare Plan Finder would benefit from a comprehensive redesign and ongoing investment to remain relevant. The Medicare Plan Finder should display costs with more precision, so that enrollees could view actual premium and out-of-pocket costs more accurately.

Pharmacy Price Concessions in the Negotiated Price

In the proposed rule, CMS is considering an option to develop a standard set of metrics from which plans and pharmacies would base their contractual agreements. NAMI recommends that CMS focus its efforts on developing metrics that address the safe and appropriate use of medications in Part D plans. To do so, we urge CMS to seek out an established measure developer with the following experience and capacities:

- 1) Experience in developing evidence-based, clinical quality measures for Medicare Part D that address the safe and appropriate use of medications,
- 2) Capacity to serve as a neutral convener of all relevant stakeholders on this issue, including patient advocates, health plans, pharmacy benefit managers, chain and independent pharmacies, government agencies, specialty pharmacy providers, pharmacist practitioner organizations,
- 3) Experience on developing measures through a fully-transparent consensus-based process, and

- 4) Ability to steward these measures on behalf of CMS, including completing necessary maintenance at least annually.

Application of Step Therapy for Part B Drugs by Medicare Advantage Plans

CMS proposes new requirements for when Medicare Advantage plans may apply utilization management (including step therapy) for Medicare Part B drugs. NAMI has consistently opposed widespread use of step therapy, as it is an impediment to a prescribed therapy, particularly for beneficiaries who require timely and often personalized use of Part B medications. We are disappointed that CMS did not seek any formal or informal stakeholder comments before the release of guidance on August 7, 2018. This is allowing Medicare Advantage plans to use these same tools for Part B drugs in 2019 under certain circumstances. While we appreciate CMS's callout regarding protections currently in place for beneficiaries, we do not believe that these are sufficient to adequately protect beneficiary access.

When Congress enacted the Medicare Modernization Act of 2003 (MMA), it recognized that certain drug classes were vital to Medicare beneficiaries with mental illness. The Conference Report that accompanied the MMA required CMS to "ensure that Medicare beneficiaries have clinically appropriate access to pharmaceutical treatments for mental illness, including but not limited to schizophrenia, bipolar disorder, depression [and other conditions]." While NAMI appreciates the Administration's efforts to lower drug costs and reduce out-of-pocket costs for beneficiaries, we are deeply concerned that the proposed rule would have negative consequences for beneficiaries with mental illness.

Thank you for the opportunity to provide comments and for your commitment to HHS's mission to enhance the health and well-being of all Americans.

Sincerely,



Angela Kimball
National Director
NAMI, National Alliance on Mental Illness

CC: The Honorable Seema Verma, Administrator,
The Centers for Medicare and Medicaid Services

ⁱ Carlton RI, Bramley TJ, Nightengale B, Conner TM, Zacker C. Review of outcomes associated with formulary restrictions: focus on step therapy. *Am J Pharm Benefits*. 2010;2(1):50-58.

ⁱⁱ Kelly Brantley, Jacqueline Wingfield, and Bonnie Washington, "An Analysis of Access to Anticonvulsants in Medicare Part D and Commercial Health Insurance Plans," Avalere Health (2013), http://avalere.com/research/docs/Anticonvulsants_in_Part_D_and_Commercial_Health_Insurance.pdf (finding that on average commercial plans covered 80 percent of anticonvulsant drugs compared to Part D plans which covered on average 62 percent).

ⁱⁱⁱ Partnership for Part D Access, "Medicare Part D's Six Protected Classes Policy" November 29, 2018. http://www.partdpartnership.org/uploads/8/4/2/1/8421729/partnership_for_part_d_report_2018.pdf

^{iv} Medicare Payment Advisory Commission. Report to Congress: Medicare and the health care delivery system. Improving Medicare Part D (2016), at: 191.

^v American Medical Association. 2017 AMA Prior Authorization Physician Survey. Available at <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc/prior-auth-2017.pdf>.

^{vi} Medicare Payment Advisory Commission, *Report to Congress: Medicare Payment Policy*, status report on the Medicare prescription drug program (Part D), March 2017 at 421.