JUSTICE IN AGING

FIGHTING SENIOR POVERTY THROUGH LAW

January 25, 2019

By electronic delivery to www.regulations.gov

Centers for Medicare & Medicaid Services
Department of Health and Human Services,
Attention: CMS-4180-P
P.O. Box 8013
Baltimore, MD 21244-8013

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

Justice in Aging appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on the above-referenced Notice of Proposed Rulemaking (NPRM).

Justice in Aging is an advocacy organization with the mission of improving the lives of low-income older adults. We use the power of law to fight senior poverty by securing access to affordable health care, economic security and the courts for older adults with limited resources. We have extensive experience with Medicare, Medicaid, and the Affordable Care Act (ACA), with a focus on the needs of low-income beneficiaries and populations that have traditionally lacked legal protection such as women, people of color, LGBT individuals, and people with limited English proficiency.

We appreciate CMS's continued attention to addressing the high costs of prescription drugs, including in Medicare. Prescription drug costs, including out-of-pocket costs, are a growing concern for older adults. In 2015, the average Part D enrollee spent almost $500 on out-of-pocket drug costs, including premiums, while those who reached catastrophic coverage, spent over $3,000.[1] We agree that steps need to be taken to lower the prices of drugs, but this must be done in conjunction with improving beneficiary access. This means that cost sharing must stay low, and that all Medicare beneficiaries, especially those with the most serious health conditions, have access to the prescription drugs they need.

Providing Plan Flexibility to Manage Protected Classes (§ 423.120(b)(2)(vi))

Under current law, Part D standalone and Medicare Advantage prescription drug plans (PDPs) are required, with very limited exceptions, to include all drugs in the six protected classes on their formularies. CMS is proposing to greatly expand the exceptions and provide PDPs broader authority to use prior authorization and step therapy. We disagree with this approach.

[1] Kaiser Family Foundation, 10 Essential Facts about Medicare and Prescription Drug Spending, available at www.kff.org/infographic/10-essential-facts-about-medicare-and-prescription-drug-spending/.

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Congress created the bipartisan protected classes policy to ensure access to critical, often lifesaving, medications that are not interchangeable. It can take years for individuals who need these medications to find a regimen that works well for them, and interrupting regimens in these classes risks significant harm to the individual and even public health. For example, choosing the appropriate regimen for HIV treatment is necessarily individualized to patient- and virus-specific factors. Requiring an individual to demonstrate poor adherence or experience a serious adverse event on a regimen that is not recommended by the clinical provider, or delaying access to treatment by imposing unnecessary prior authorization hurdles, can quickly reverse viral suppression, harming the individual's overall health and unnecessarily creating a public health risk by increasing the chance for transmission. Similarly, not ensuring access to the full range of immunosuppressants for a transplant patient runs the dangerous and costly risk that their body will reject the organ.

Under the proposed rule, plans would also be allowed to exclude a protected class drug from their formularies if the drug were a new formulation of an existing product that lacks a unique route of administration. We recognize the aim is to disincentivize the industry practice of withdrawing older products from the market in order to preserve and extend innovator drug products' monopolies. However, this change would be problematic for Medicare beneficiaries. New drug formulations could be scientifically determined to have superior adherence, safety and/or efficacy, even without unique routes of administration. Rather than allowing plans to decide, coverage of such critical drugs should be based on individual, evidence-based assessments. We support CMS's efforts to work with other agencies to address abuses of patent and drug marketing laws.

CMS cites antipsychotics used for sedation as an example of over-utilization it is purportedly attempting to curb with this proposed rule. While we agree that there is a serious problem with inappropriate prescribing of antipsychotics in nursing facilities as a means of sedation, we do not agree that this issue results from the protected classes policy nor does it justify the proposed changes. Limiting the availability of the full range of antipsychotics would be a barrier to access for those who have a diagnosis requiring such medication but would not stop inappropriate prescribing. Rather than using this broad tool, we recommend that CMS address this issue by targeting the inappropriate prescribing. For example, CMS could specifically amend the Part D rules to require plans to implement prior authorization requirements specifically for antipsychotic drugs for nursing facility residents.

Individuals who need medications in these six classes often have complex and multiple conditions that further necessitate access to the full range of medications because of the potential of negative drug interactions. This issue is of particular concern for beneficiaries dually eligible for Medicaid and Medicare because they are more likely to have chronic and serious health conditions, and their only source of prescription drug coverage is Medicare.

The problems with these proposed changes would be exacerbated by the new limitations on special enrollment periods for low-income subsidy beneficiaries. These individuals would not necessarily be able to switch PDPs to get coverage for a drug in the protected classes if their conditions or regimen changed mid-year or if the plan changed its formulary mid year. Weakening the protected classes policy would add another barrier and layer of complexity for beneficiaries with the most complex health care needs.

CMS suggests that the Part D appeals and exceptions process would be sufficient to protect consumers from the proposed rule's potential access issues. However, the appeals process is deeply flawed, rendering it an inadequate safeguard. There are widespread frustrations with Part D coverage determinations, exceptions, and appeals processes.[2] Moreover, as mentioned previously, individuals who rely on these medications face dangerous consequences if their treatment is interrupted or delayed for even a short time. These proposals impact some of the sickest Medicare beneficiaries, who may not have the wherewithal to engage in a difficult appeals process, even if they know it is an option. An appeals process, especially a cumbersome inadequate one, is slow and cannot address these coverage issues in the time and manner necessary to keep beneficiaries safe. Whether or not these proposals move forward, we encourage CMS to work with stakeholders on improvements to the appeals and exceptions process, such as improving information given to beneficiaries at the point of sale to include the reason for plan denial.

We have particular concerns that, though CMS is proposing that the regulations explicitly exempt from step therapy any Part B drug that is currently used by a beneficiary (with a 180 day look back period),[3] the agency is not proposing a similar provision for drugs in the protected classes. CMS indicates that interrupting a beneficiary's current therapy is not "best practice" and that it is "not likely" to approve a PDP's formulary that requires a beneficiary to switch from a stabilized therapy in order to progress through step therapy.[4] However, we urge CMS not to assume PDPs will follow best practices but instead to require PDPs to follow this best practice. Drugs in protected classes, like Part B drugs, are disproportionately critical to health. If CMS does move forward with its proposal, this protection should extend to all drugs in Part D protected classes.

Finally, while we recognize that PDPs do not have the same tools to negotiate rebates for drugs in the protected classes as they do with other Part D drugs, we disagree that these proposals will significantly lower prescription drug prices or out-of-pocket costs for beneficiaries. Research by Avalere Health[5] and Pew[6] suggest that the opportunity for savings may be limited, given the already prevalent use of generics in the protected classes. Even if the estimated cost savings to Medicare are realized, they do not outweigh the harm to beneficiaries of restricted access to necessary and often life-saving treatment. Therefore, we urge CMS not to move forward with these proposals.

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[2] Medicare Payment Advisory Commission, "Report to Congress: Medicare Payment Policy. Chapter 14: The Medicare Prescription Drug Program (Part D): Status Report" (March 2018), www.medpac.gov/docs/default-source/reports/mar18_medpac_ch14_sec.pdf.

[3] Proposed 42. C.F.R. §422.136(a)(1).

[4] 83 Fed. Reg. at 62163

[5] Partnership for Part D Access, "Medicare Part D's Six Protected Classes Policy: A Balanced Approach to Provide Patients Access to Medications While Allowing Powerful Tools to Control Costs" (2018), www.partdpartnership.org/uploads/8/4/2/1/8421729/partnership_for_part_d_report_2018.pdf.

[6] Pew Charitable Trusts, "Policy Proposal: Revising Medicare's Protected Classes Policy" (March 7, 2018), www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/03/policy-proposal-revising-medicares-protected-classes-policy.

Updating Part D E-Prescribing Standards (§ 423.160)

We support the proposal to adopt a real-time benefit tool as a means to help prescribers choose, on an individualized basis, the medication that meets the beneficiary's needs and minimizes out-of-pocket costs. We encourage CMS to field test and ensure that this tool is usable, up-to-date and accurate for plans and prescribers, and to ensure it is not negatively interfering with prescribing practices. However, we do have concerns about how such a tool would interact with step-therapy, exceptions, and appeals and recommend that CMS require a notice of appeal rights be incorporated into the tool. Moreover, because introducing decision support technology carries a risk of bad actors using the technology to game the system, we urge CMS to engage in robust and frequent evaluation and oversight of these tools and ensure that beneficiaries are still able to access the medications that they need and are in fact seeing lower out of pocket costs.

Medicare Advantage and Step Therapy for Part B Drugs (§§ 422.136, 422.568, 422.570, 422.572, 422.584, 422.590, 422.618-619)

We oppose the proposal to codify MA plans' ability to utilize step therapy for Part B drugs (first announced in August 2018 sub-regulatory guidance). We appreciate CMS's effort to establish more detailed guidelines and safeguards in this proposed rule. However, this policy will limit beneficiaries' access to Part B drugs, including in the treatment of life-threatening conditions like cancer.

As with our concerns about the proposed changes to Part D, we fear the appeals process for MA is similarly inadequate to safeguard the health and wellbeing of beneficiaries facing step therapy in Part B. In a September 2018 report, the HHS Office of Inspector General found there are significant problems with the appeals process and specifically recommends that CMS "address persistent problems related to inappropriate denials and insufficient denial letters in Medicare Advantage."[7] Therefore, we urge CMS to focus on improving the appeals process and other beneficiary protections before implementing this or other coverage restrictions.

Part D Explanation of Benefits (423.128)

CMS is proposing to require PDPs to include information about price changes and lower-cost therapeutic alternatives in the Part D explanation of benefits (EOB) beneficiaries receive summarizing the previous month's use of the prescription drug benefit. While we support increased transparency, beneficiaries need information in real time and need to be able to act on that information. Along with the real-time benefit tool CMS is proposing, pharmacists should be both enabled and encouraged to tell beneficiaries at the point of sale about changes in prices. EOBs, though including important data, are of little value to beneficiaries, particularly because, taken alone, they do not help beneficiaries decide which plan they should join in the next year.

This proposal raises a more basic concern about beneficiary access to needed information that this NPRM does not address. A fundamental assumption of the Part D program is that

[7] OIG, Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials (Sept. 2018), https://oig.hhs.gov/oei/reports/oei-09-16-00410.asp.

beneficiaries shopping among plans will be able to choose a plan that best meet their needs and that their market-based choices will maximize value and act as a brake on costs.
The current design of Part D, however, includes major market distortions. Beneficiaries are supposed to make rational decisions by reviewing comparative costs based on their prescription drug usage. Once they make those choices, they are locked into a plan for a year unless they have a Special Enrollment Period. However, though beneficiaries are locked in, plans are not. Plans' contracts with drug suppliers can—and do—change drug prices as frequently as every two weeks. Those changes are not in lockstep. Prices for a drug can go up substantially for one plan and not for another. An individual who made a careful and rational choice in November during the Annual Enrollment Period can find on January 1 (or in February, May or any other time) that the chosen plan is no longer the most economical for the same drugs. Despite these changes over which they have no control, beneficiaries have no way to respond because they are locked in. It is one thing (though certainly problematic) for a drug's price to go up across the board mid-year, but it is quite another for the drug's relative prices to change significantly between plans with no notice and no recourse for beneficiaries. Moreover, since CMS is prohibited by statute from regulating or even inquiring into pricing relationships between plans and drug manufacturers, there is no regulator looking at how or why these variations occur and providing oversight of this system.

This is the antithesis of an open and transparent market. CMS needs to address the unfairness and opacity of the current system and develop solutions that provide more price stability for beneficiaries and ensure that the market choices they make are meaningful.

Pharmacy Price Concessions to Drug Prices at the Point of Sale

We support the proposal to include Direct and Indirect Renumeration (DIR) in the price at point of sale as a means of increasing transparency. The current inconsistent reporting of DIR makes it difficult for beneficiaries to accurately compare plans in terms of the true costs of their medications. Requiring all fees to be accounted for in negotiated price would enhance the quality of information available to beneficiaries and enable them to better understand their costs as they will progress through the coverage year and evaluate their PDP options in future years.

Conclusion

Thank you for considering our comments. If any questions arise concerning this submission, please contact Natalie Kean, Senior Staff Attorney, at nkean@justiceinaging.org.

Sincerely,

Jennifer Goldberg
Deputy Director