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# **Patient Impact of the Inflation Reduction Act**

## **Administrative Options to Address Changed Incentives for Formulary and Utilization Management**



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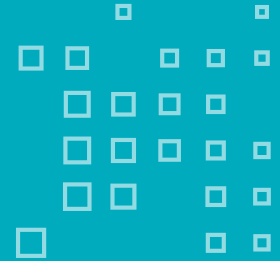
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# Patient Impact of the Inflation Reduction Act

Administrative Options to Address  
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## Executive Summary

The Inflation Reduction Act (IRA) makes significant changes to the Medicare Part D prescription drug benefit and also directs the Centers for Medicare and Medicaid Services (CMS) to enforce government-negotiated prices for the drugs with the most Medicare spending.

However, some of the potential benefits of the IRA for Medicare beneficiaries, such as the new cap on out-of-pocket costs, may be squandered if CMS does not act to protect beneficiaries. Part D prescription drug plan (PDP) sponsors face heightened costs as they bear more risk under IRA's benefit changes, and they will lose manufacturer rebate revenue when CMS negotiates the prices of drugs selected for negotiation. These factors may prompt plans to protect their financial margins by limiting access to drugs through narrower formularies, adopting more rigorous utilization management strategies like prior authorization or step therapy that will delay or deny access to therapy, or promoting drugs through formulary placement other than those CMS has selected for negotiation so as to protect revenue earned from rebates.

As part of IRA implementation and in advance of calendar year 2025, which is when the implementation of Part D redesign changes accelerate, CMS could take steps to protect beneficiaries by preserving access and increasing transparency. CMS has already warned PDP sponsors not to place drugs selected for negotiation on non-preferred formulary tiers without clinical justification. But it can do more under its current legal authority, including:

- Adopt a public “watchlist” for specific adverse formulary decisions that CMS will not approve, to keep PDP sponsors from excessive narrowing of formularies.
- Commit additional resources to formulary reviews to identify access issues before such issues can harm beneficiaries.
- Explicitly and publicly identify more situations where plans must cover more than two drugs per category or class to ensure that formularies provide adequate coverage of drugs commonly used by beneficiaries.
- Require that drugs selected for negotiation—for which CMS has established a maximum fair price—be given preferred formulary status, without utilization management.
- Improve plan transparency so beneficiaries can more easily see when drugs have utilization management restrictions.
- Enforce minimum payment rates to pharmacies, to prevent sponsors from diverting patients away from community pharmacies.
- Actively monitor appeals, grievances and exception requests filed by beneficiaries with their plans, to have near real-time view of access issues.
- Improve appeals and grievance processes, to reduce the burden of challenging a plan's coverage decision.
- Adopt new actuarial equivalence tests to more accurately and quantitatively track whether plan sponsors are offering sufficient coverage of drugs selected for negotiation.

This paper discusses in detail the coming changes to Part D, some of the risks faced by beneficiaries as a result of plan sponsors changing behaviors in response to the IRA, the initial measures taken by CMS to date to protect beneficiaries, and steps CMS could take under its current legal authority to better protect timely beneficiary access to therapy.

Changes From the Inflation Reduction Act Likely to Have Myriad Impacts on Medicare Part D Beneficiaries



## Introduction

The Inflation Reduction Act (IRA) sets forth sweeping reforms for the Medicare program. Under the IRA, the price Medicare pays for the most costly drugs will be set substantially below current benchmarks.<sup>1</sup> Inflation rebates limit to the rate of inflation price growth for drugs covered by Medicare Parts B and D.<sup>2</sup> Additionally, the Medicare Part D prescription drug benefit has been redesigned, most notably by imposing more risk on prescription drug plan (PDP) sponsors for the costs of drugs, and giving beneficiaries an absolute cap on their annual out-of-pocket costs.<sup>3</sup>

While the IRA has the **potential** to lower out-of-pocket costs Medicare beneficiaries pay for prescription drugs, CMS may need to take additional steps to ensure this potential is realized and is not counteracted by harmful loss of access to treatments. The incentives created by the IRA are likely to push PDP sponsors to curtail patients' access to therapies. PDP sponsors will face additional liability for the cost of drugs, particularly in the Part D benefit's catastrophic phase, which may drive them to cut costs. Sponsors may narrow formularies or make tiering changes, limiting the scope of treatments available or they may impose utilization management such as strict prior authorization requirements, step therapy, or other cost containment tools.<sup>4</sup> PDP sponsors may also face a loss of rebate revenue when drugs are subject to government price negotiation, which could cause sponsors to shift their formulary composition in unpredictable ways.

This paper describes how CMS can leverage its existing legal authority and build on protections already in place to preserve beneficiaries' access to prescription drugs and ensure they directly benefit from lower prices for drugs. Through its formulary review, plan monitoring and member transparency authorities, CMS has tools to oversee PDP sponsors to maintain adequate access so that PDPs do not inappropriately narrow formularies or manage utilization in overly restrictive ways.

## Overview of the Inflation Reduction Act's Medicare Drug Price Negotiation and Part D Redesign Provisions

This paper explores the potential impact of two IRA features: the Medicare drug price negotiation program and Part D redesign.

### Medicare Drug Price Negotiation

CMS is required to set the price of certain selected drugs for Medicare beneficiaries through what is called the "Drug Price Negotiation Program." CMS must establish a "maximum fair price" (MFP) for drugs that meet specific eligibility criteria and are selected for negotiation. The MFP must be less than a ceiling price set in the statute, which is tied to the drug's historical pricing and inflation, but there is no "floor," or minimum price, established in the statute. These prices will first apply to Medicare Part D drugs selected for negotiation in 2026 and starting in 2028, to both Part B and D drugs. CMS will announce the first MFPs, applicable for contract year 2026, by September 1, 2024.

Once an MFP is established, the MFP will be the maximum price (plus a dispensing fee) that a Part D drug costs at the pharmacy counter, and the basis upon which beneficiary cost sharing is calculated. The IRA requires manufacturers to provide access to MFP drugs to pharmacies, mail-order services, other drug dispensers, hospitals, physicians, other providers, and suppliers, with respect to Medicare beneficiaries.

To ensure access to drugs selected for negotiation, the IRA requires that PDP sponsors include on their formularies any Part D covered drugs subject to a negotiated price. A plan may remove such a drug from its formulary if the plan adds a therapeutically equivalent generic drug and such removal otherwise complies with applicable requirements. The IRA does not specify whether PDP sponsors can negotiate additional rebates, impose drug utilization management policies, or put such drugs on a non-preferred cost-sharing tier and, to date, CMS has provided limited guidance on these important topics.

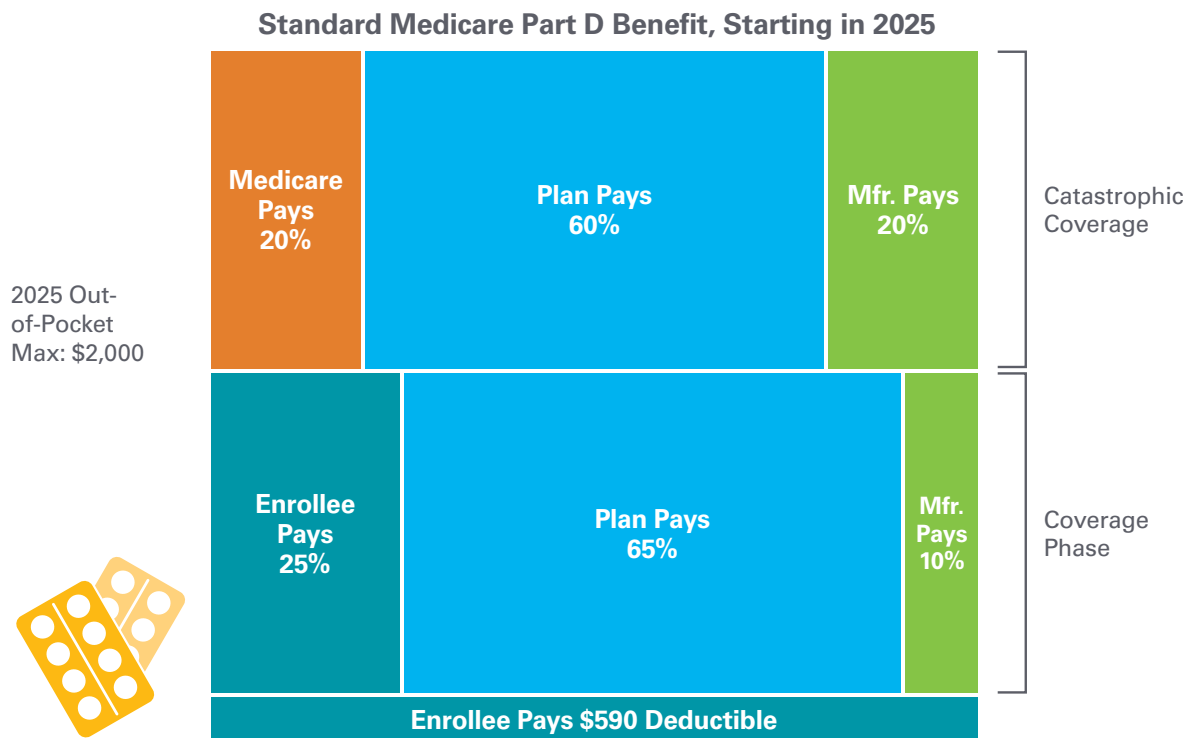
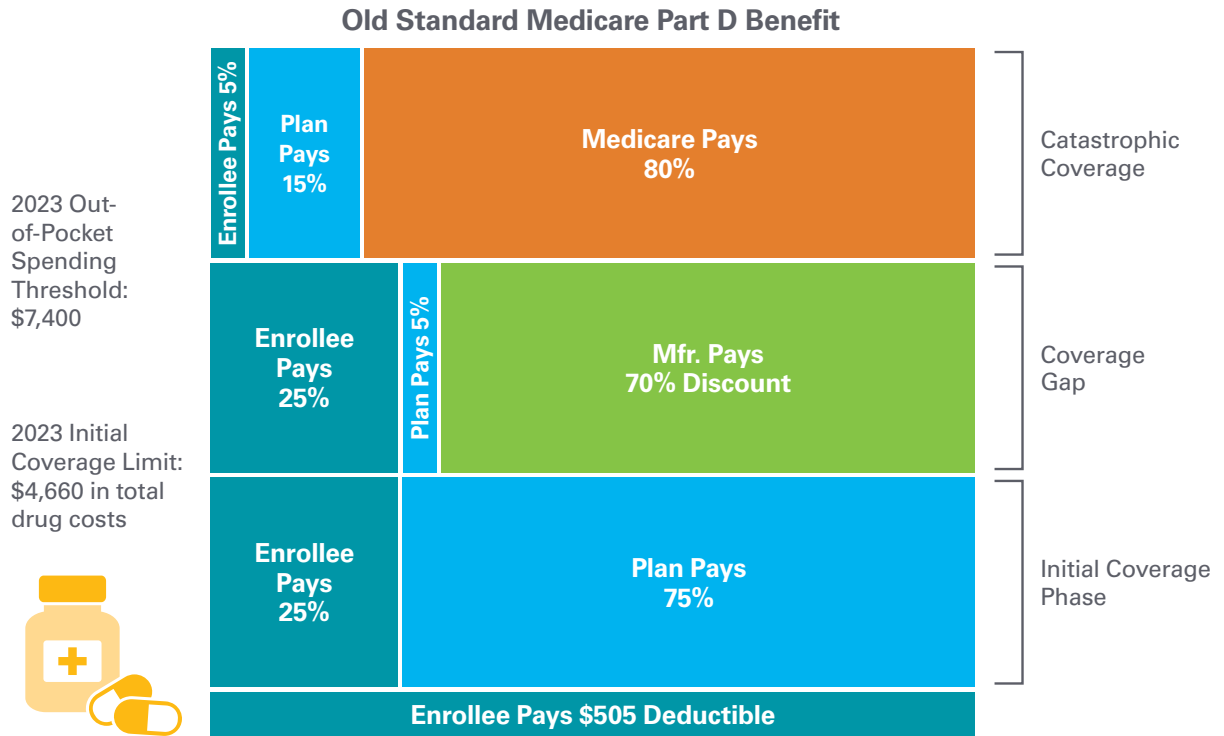
## Medicare Part D Redesign

Another significant feature of IRA is the Medicare Part D benefit redesign. The IRA makes major changes to the Part D benefit that shifts liability for the costs of Part D drugs away from beneficiaries and the government and onto PDP sponsors. A major part of these changes will begin in 2025, but there are some transitional changes that take place before then, particularly in 2024.

A major component of the change is an annual \$2,000 out-of-pocket cap for beneficiaries. Prior to 2024, the Part D benefit had no out-of-pocket cap. Under the defined standard benefit, beneficiaries had a deductible and then post-deductible cost-sharing of roughly 25% for each brand drug's negotiated price, followed by a catastrophic benefit where the beneficiary still needed to pay 5% of the drug's negotiated cost after spending thousands of dollars out-of-pocket during the calendar year. However, under the IRA beginning in 2024, Part D beneficiaries began to benefit from a transitional policy that created a limit of \$8,000 in out-of-pocket spending.<sup>5</sup> Once reaching that limit and entering the catastrophic phase of coverage, beneficiaries no longer have any out-of-pocket expenses, where they used to pay 5%. Beginning in 2025, IRA makes further, permanent changes to the catastrophic benefit: a beneficiary will have an even lower annual out-of-pocket maximum of \$2,000, after which the beneficiary is free of liability for further Part D costs. This maximum will adjust each year by the percentage change in overall Part D spending. Group health plan coverage and supplemental Part D benefits that reduce cost sharing will accrue toward the \$2,000 limit beginning in 2025, further limiting the amount that beneficiaries may spend.<sup>6</sup>

The IRA also provides a new option for Part D beneficiaries, referred to by CMS as the Medicare Prescription Payment Plan. In this program, beneficiaries may spread out their cost-sharing obligations over the course of a plan year into monthly payments, further insulating some beneficiaries from large out-of-pocket payments that may deter medication adherence.

A second major component of IRA's Part D redesign is a shift in liability between plans, manufacturers and the government that imposes increased costs on plans. During the 2024 transitional year, PDP sponsors are responsible for the 5% cost sharing that beneficiaries used to pay in the catastrophic phase. Then, beginning in 2025, the IRA further changes the financial responsibility for each part of the Part D benefit to (1) shift more financial responsibility for catastrophic costs from the government to the plan and (2) broaden manufacturer responsibility from the Coverage Gap Discount Program (CGDP) to a series of discounts throughout the Part D benefit. Once a beneficiary reaches the catastrophic phase, where PDP sponsors previously bore only 15% of costs (and 20% in 2024), the PDP will now bear 60% of the costs of brand drugs, while government reinsurance payments will shrink from 80% of costs to 20%.<sup>7</sup>





# Impact of Negotiation and Part D Redesign on Plan Behavior

Both the new Part D benefit parameters and the imposition of MFPs on Part D drugs could change incentives PDP sponsors have to manage utilization. This section explores the interactions between these features of the IRA and how they are likely to affect plan behavior.

## Plan Cost Control Activities

As noted above, the redesigned Medicare Part D benefit shifts a larger share of costs to plans than in the current standard benefit design, particularly in the Part D benefit's catastrophic phase. Plan liability in the catastrophic phase increases from 15% in 2023, to 20% in 2024, to 60% in 2025. Further, beneficiaries will move through the Part D benefit phase and reach the out-of-pocket cap more quickly, increasing the number

### Examples of Changes in Rebate and Tiering Structure: Example 1

- Sponsors narrow formularies as a cost cutting measure. Example:

#### Example 1

Sponsors narrow formularies as a cost cutting measure

<b>Drug A</b> Cost: \$500	<b>Before IRA</b> Beneficiaries might pick less efficacious Drug A to avoid out-of-pocket cost burden associated with more expensive Drug B.
<b>Drug B: "Next Generation" Therapy</b> Cost: \$10,000	
<b>After IRA</b> <ul style="list-style-type: none"><li>• With its \$2,000 out-of-pocket cap, more may pick and benefit from Drug B.</li><li>• As more pick Drug B, PDP sponsors are responsible for the increased costs.</li><li>• PDP sponsor might require first use of Drug A through step therapy, or drop Drug B from its formulary altogether.</li></ul>	

- Drugs A and B are competing therapies in the same category or class. Drug A has a price of \$500 and Drug B has a price of \$10,000. Drug B is a "next generation" therapy that is much more efficacious than Drug A.
- Before IRA, beneficiaries might pick less efficacious Drug A to avoid the out-of-pocket cost burden associated with the more expensive Drug B. After IRA, with its \$2,000 out-of-pocket cap, more may pick and benefit from Drug B.
- As more pick Drug B, PDP sponsors are responsible for the increased costs.
- In response, PDP sponsor might require that beneficiaries first use of Drug A prior to being approved for Drug B (step therapy), or drop Drug B from its formulary altogether.

of beneficiaries who reach and remain in the catastrophic phase. As the Congressional Budget Office (CBO) succinctly predicts, “plans will have a stronger incentive to control costs because they will be responsible for a greater percentage of costs.”<sup>8</sup> At the same time, beneficiaries will have no liability in the catastrophic phase, and can pay their out-of-pocket drug costs in monthly payments. This will mean beneficiary cost-sharing will be a less effective means for PDP sponsors to limit utilization, particularly of drugs whose higher costs fall in the catastrophic phase.

CMS has, at least subtly, acknowledged this issue, noting in recent guidance that the 2025 Part D benefit changes will alter “the structure of liabilities of all Part D sponsors, which may result in impact to their benefit offerings.”<sup>9</sup> Actuaries at Milliman have speculated that the impact may be more pronounced in standalone PDPs, offered to beneficiaries who enroll in Original Medicare, as compared to Medicare Advantage Prescription Drug (MAPD) plans, which combine Part A, B and D benefits, because MAPD plans have a broader benefit package and therefore more flexibility to manage risk.<sup>10</sup> Since MAPD plans are responsible for their enrollees’ Part A and B medical claims in addition to prescription drugs, the plans have increased financial incentive to provide access to drugs that may prevent hospitalizations or the need for outpatient care.

PDP sponsors are also expected to impose more aggressive utilization management tactics. This is supported by a recent survey of senior executives of health plans who indicated most of them expect this to occur.<sup>11</sup> Commentators have noted that this could take the form of increasingly stringent and burdensome prior authorization requirements, under which beneficiaries must meet strict clinical criteria before the plan will cover a drug.<sup>12</sup> Or plans could impose new step therapy rules, requiring beneficiaries to “fail” on lower cost generic therapies before they may be treated with a higher cost one. A 2023 study found that coverage policies for specialty drugs applied at least one utilization management restriction and the number of coverage policies with multiple restrictions increased between 2017 and 2021.<sup>13</sup> The IRA’s change to the Part D benefit is likely to accelerate these trends.

A separate response that PDPs may contemplate is an overall narrowing of formularies.<sup>14</sup> PDPs might limit the number of drugs available to beneficiaries, keeping only lower cost, older and less effective products on formulary, while eschewing higher cost, newer generation and more effective therapies. This might cause plans to jettison brand-name drugs even in situations they are superior or more effective than a generic therapy of a previous generation.<sup>15</sup> Plans have already been on this path, restricting an average of 44.7 percent of brand-name-only drugs from formularies by 2020.<sup>16</sup> The IRA could accelerate this trend as well.

A third response that PDP sponsors might take is to restrict the places where beneficiaries can acquire certain drugs to place additional barriers to utilization. For example, a PDP sponsor might lower the retail price it is willing to pay pharmacies for covered Part D drugs, narrowing the number of pharmacies, particularly smaller independent ones, who are capable of dispensing that product in practice. Similarly, PDP sponsors might steer beneficiaries to a plan-affiliated mail order pharmacy, preventing them from conveniently filling prescriptions locally. Patient steering can not only impact patient access to prescription drugs, it can also lead to significant loss of business for community pharmacies.<sup>17</sup>

## Plans' Attempts to Maximize Rebate Revenue

In addition to designing formularies to manage utilization, plans may also prioritize drugs on formularies that command significant manufacturer rebates. The introduction of MFP pricing could impact plan behavior to maximize rebates.

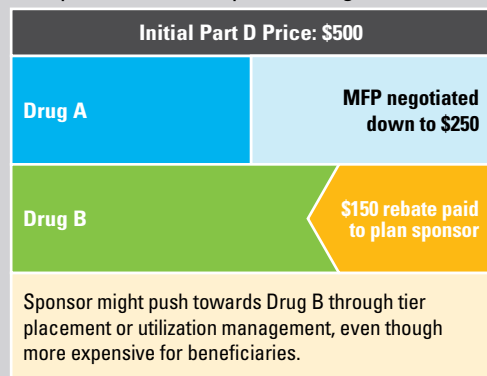
A plan's preference for higher rebate drugs stems from the possibility that plans may find it more profitable to earn a rebate on a drug after the point of sale rather than negotiate a low point-of-sale price. If a drug has a low point-of-sale price, beneficiaries share in the savings of a low point-of-sale price through lower cost sharing because their coinsurance is based on the point-of-sale price. But if a drug has a high point-of-sale price with rebates paid after the sale, the beneficiary may pay a higher cost sharing amount, while the rebates paid after the sale are mostly kept by the PDP sponsor (the sponsor shares a portion of those rebates with the Medicare program).<sup>18</sup> Broadly, plans may steer beneficiaries to the drug that is most profitable to them through formulary placement and other utilization management tools. One commentator has attributed this dynamic as the cause of slow uptake of biosimilars to Humira, despite their lower price, noting "payers may prefer higher-priced treatments. This is often because the rebates accruing to payers . . . are larger."<sup>19</sup>

### Examples of Changes in Rebate and Tiering Structure: Example 2

- Sponsors can leverage negotiated prices to extract rebates from manufacturers of competitors to MFP-priced drugs. Example:
  - Drugs A and B are competing therapies in the same category or class, each with a net Part D price of \$500.
  - Drug A, a drug selected for negotiation, has a Maximum Fair Price negotiated down to \$250.
  - A PDP sponsor can then demand that the manufacturer of Drug B lower its own price to remain competitive, extracting an additional \$150 post-point-of-sale rebate/DIR. Drug A may be less willing to negotiate additional rebates for formulary placement, given the mandatory price concessions under the MFP.
  - Drug B is still more expensive than Drug A (\$350 vs \$250). Beneficiaries will pay higher cost sharing for Drug B and not benefit from a low point-of-sale price, since rebates are reconciled after the sale. But the PDP sponsor may prefer the higher net price of Drug B because it will retain DIR, sharing only a small portion of it with Medicare.
- The sponsor might push beneficiaries towards Drug B through tier placement or utilization management, even though it may be more expensive for beneficiaries and add costs to the Part D program overall.

#### Example 2

Sponsors leverage negotiated prices to extract rebates from manufacturers of competitors to MFP-priced drugs



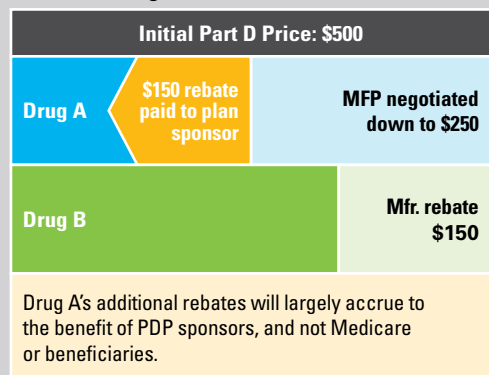
Plans may lose rebate revenue from formerly high-priced drugs once Medicare negotiates an MFP that effectively incorporates those rebates into the negotiated prices paid by beneficiaries.<sup>20</sup> Research indicates that more exposure to the Part D market is associated with greater differences between list and net prices of drugs.<sup>21</sup> As one commenter has noted, “plans will prefer a high-list/high-rebate product over its low-list/low-rebate counterpart,” even more than previously, because IRA’s changes to manufacturer liability mean “a higher share of manufacturers’ rebates will be applied to the plans’ obligations.”<sup>22</sup> This could also lead PDPs to leverage CMS-negotiated prices of selected drugs by extracting additional rebates from drugs not selected for negotiation that are substitutes for the selected ones. This may lead to adverse tiering in plan formulary design, where sponsors place negotiated drugs on non-preferred tiers and try to steer beneficiaries away from them towards non-negotiated drugs with higher prices.<sup>23</sup>

**Examples of Changes in Rebate and Tiering Structure: Example 3**

- Sponsors can leverage negotiated prices to extract rebates from manufacturers of drugs selected for negotiation. Example:
  - Drugs A and B are competing therapies in the same category or class, each with a net Part D price of \$500.
  - Drug A, a drug selected for negotiation, has a Maximum Fair Price negotiated down to \$250. Drug B offers a rebate of \$150, which the plan might prefer.
  - Rather than incentivizing the use of Drug B, the PDP sponsor attempts to leverage Drug B’s rebate to extract further rebates from the manufacturer of Drug A below the MFP.
  - Drug A’s additional rebates will largely accrue to the benefit of PDP sponsors, and not Medicare or beneficiaries.

**Example 3**

Sponsors leverage negotiated prices to extract rebates from manufacturers of selected drugs



# Potential CMS Actions To Ensure Plan Reactions to the IRA Do Not Worsen Prescription Drug Access

While CMS has recognized some of the implications of the IRA rollout this paper identifies, it has taken very limited steps to address them. This section describes CMS's actions to date, as well as additional opportunities for more rigorous oversight and engagement on these issues.

## CMS Current Formulary Review Process

CMS's current processes for reviews of PDP formularies can provide the basis for additional action to protect beneficiaries from unintended consequences of IRA.

Prior to each plan year, CMS requires PDP sponsors to submit formulary files for review that identify the drugs the plan will cover, specifies which drugs are on preferred and non-preferred tiers, and lays out any required utilization management or step therapy associated with the drugs.<sup>24</sup> A team of pharmacists and other clinical professionals at CMS reviews each formulary to determine whether the formulary meets the minimum criteria for access to covered drugs. This review encompasses checks under the basic rule that plans cover in most cases at least two drugs per category and class, or all drugs in the six "protected classes."<sup>25</sup> The reviews also have a qualitative component, designed to determine whether a formulary is so deficient that it is "likely to substantially discourage enrollment by certain Part D eligible individuals under the plan" or lacks "adequate coverage of the types of drugs most commonly needed by Part D enrollees."<sup>26</sup> CMS staff use automated and manual processes to spot deficiencies in formularies, and scan for formularies that are outliers compared to most other plans.<sup>27</sup>

### Select Legal Authorities for CMS Review of Plan Benefit Design

**Non-Discrimination:** By law, CMS cannot allow PDP sponsors to adopt any plan design, "including any formulary and tiered formulary structure" that is "likely to substantially discourage enrollment by certain Part D eligible individuals under the plan."<sup>28</sup>

**Adequate Formularies:** The Part D statute requires that a plan include on formulary all drugs in six protected classes, and otherwise "must include drugs within each therapeutic category and class of covered Part D drugs, although not necessarily all drugs within such categories and classes."<sup>29</sup> CMS has interpreted this to require at least two drugs per category and class on a formulary, but also "adequate coverage of the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines."<sup>30</sup> This authority is limited by a statutory clause that CMS may not "require a particular formulary."<sup>31</sup>

**Specialty Tier:** CMS has traditionally permitted PDP sponsors to place high-cost drugs on a specialty tier that would not be subject to tiering exceptions. Only drugs whose costs are "very high" may be placed on the tier.<sup>32</sup> CMS's authority to regulate specialty tiers arises from its ability to regulate the coverage determination and exceptions process under Section 1860D-4(g).<sup>33</sup>

Throughout these reviews, CMS uses widely accepted national treatment guidelines as its touchstone for determining whether a formulary contains adequate coverage.<sup>34</sup> For example, CMS may initially reject a formulary—and require a PDP sponsor to include additional drugs in order to obtain approval—when comparison of the formulary to those treatment guidelines suggest a lack of appropriate drug classes to treat certain diseases or missing drugs that could discourage certain types of beneficiaries from enrolling in the plan. CMS also uses treatment guidelines to evaluate the appropriateness of plans' tiering decisions. CMS does not publish a specific list of the treatment guidelines it relies on for this purpose, making it difficult to know which guidelines it finds meaningful.

## Initial Steps to Protect Beneficiaries Under IRA

CMS has acknowledged the risks presented but taken few concrete steps to protect beneficiaries from potential adverse impact of the IRA.

CMS said it would generally “continue to maintain a robust clinical formulary review process” of the type described above and to “monitor year-over-year formulary and utilization management changes to assess if these changes have the potential to reduce access to vital medications.”<sup>35</sup>

For the IRA negotiation program, IRA generally requires that PDP sponsors place each drug selected for negotiation on formulary while it has no generic equivalent.<sup>36</sup> But the law is silent on whether sponsors must give such drugs preferential status, and what types of utilization management may be applied. In response, CMS has stated that sponsors are free to place drugs selected for negotiation where they wish on formulary and that there are no “explicit tier placement or utilization management requirements” for these drugs.<sup>37</sup> CMS nonetheless

### Select Legal Authorities for CMS Review of Plan Benefit Design (cont'd)

**Actuarial Equivalence:** The Part D statute permits PDP sponsors to use formulary tiers only if the overall tiering structure is actuarially equivalent to 25% cost sharing across the entire formulary.<sup>38</sup>

**Exception to Non-Interference:** CMS ordinarily does not “interfere” in the negotiations between PDP sponsors, manufacturers and pharmacies, pursuant to a provision that prohibits CMS from instituting “a price structure for the reimbursement of covered Part D drugs.” That clause carries an exception that allows CMS to “interfere” with respect to the Medicare drug price negotiation program “as provided under” the statute setting forth the negotiation program.<sup>39</sup>

**Any Willing Pharmacy:** A Part D prescription drug plan must permit “the participation of any pharmacy that meets the terms and conditions under the plan.”<sup>40</sup> Accordingly, CMS requires that PDP sponsors offer any willing pharmacy a contract that contains “reasonable and relevant terms and conditions of participation.”<sup>41</sup> In sub-regulatory guidance, CMS has suggested that this requirement requires PDP sponsors to pay reasonable reimbursement rates, since “offering pharmacies unreasonably low reimbursement rates for certain ‘specialty’ drugs may not be used to subvert the convenient access standards. In other words, Part D sponsors must offer reasonable and relevant reimbursement terms for all Part D drugs as required by” regulation.<sup>42</sup>

**Authority to Set Minimum Standards:** Congress gave CMS the authority to “negotiate the terms and conditions of [a plan’s] proposed bid submitted and other terms and conditions of a proposed plan,” and to have authority similar to that of the Office of Personnel Management with respect to the FEHB program for setting “reasonable minimum standards” for health benefits plans.<sup>43</sup>

recognizes the potential that “Part D sponsors may be incentivized in certain circumstances to disadvantage drugs selected for negotiation by placing them on less favorable tiers compared to drugs not selected for negotiation, or by applying utilization management that is not based on medical appropriateness to steer Part D beneficiaries away from drugs selected for negotiation in favor of other drugs.”<sup>44</sup> Accordingly, CMS will conduct a review of the formularies submitted by plans during the annual plan bid review cycle prior to 2026.<sup>45</sup> When drugs selected for negotiation on those formularies are placed on non-preferred or higher tiered than other drugs in the same class, have step therapy imposed, or more restrictive utilization management than a drug in the same class, CMS will require sponsors to provide a “reasonable justification” based on clinical factors such as “clinical superiority, non-inferiority, or equivalence of the selected and non-selected drugs, as well as the plan design’s compliance with applicable statutory and regulatory requirements.”<sup>46</sup> Beyond this, CMS has not specified what it will consider to be “reasonable,” or how much deference it will extend to plans in reviewing their clinical justifications.

These general statements from CMS show an acknowledgement of the issues facing beneficiaries but a reluctance to take significant advance action in response. There are factors that might make CMS reluctant to do more at this time: CMS’s potential concern, not universally accepted, over whether the Part D “noninterference” statutory provision prevents CMS action; desire to see what formulary decisions are made, including negotiating positions by manufacturers of drugs selected for negotiation and drugs not selected; and hesitancy to establish bright-line rules for the first year of MFP pricing when the number of drugs subject to MFP will increase rapidly in subsequent years. However, CMS may well be acting in preparation “behind the scenes,” taking measures it has not announced.

Yet given the PDP incentives the IRA establishes, and the risks to beneficiaries, CMS could leverage its legal authority to do more, and do more publicly. The additional steps would place CMS in a less reactive posture and take action to prevent issues before they arise and harm beneficiaries. Public announcements could dissuade plans from limiting access by demonstrating CMS’s commitment to beneficiary protection and plan transparency.

There is also urgency to take action sooner rather than later. There is a shrinking window of time available for CMS to act before the IRA’s changes for the first applicable plan year could cause potential harm to beneficiaries. The interim Part D out-of-pocket cap for 2024 is already in place, and plan sponsors will see an even more significant increase in liability for the catastrophic phase in 2025. Plans will submit proposed formularies for 2025, when the major Part D changes will be implemented, in the summer of 2024, and advertise those plans in fall 2024. Thus, if CMS is going to get ahead of potential adverse impacts to beneficiaries, and not merely react to remedy and prevent further harms once they have taken place in the initial and subsequent plan years reflecting IRA’s reforms, the agency needs to take more immediate action.

## Further Steps to Protect Beneficiaries

CMS could improve on its current rules and procedures to specifically protect beneficiaries from potential adverse impacts of the IRA.

The following are strategies that CMS could consider:

<p><b>Require Drugs Selected for Negotiation Be Given Preferred Formulary Status and No Utilization Management</b></p>	<p>Current CMS rules only encourage placement of drugs selected for negotiation on preferred tiers with limited utilization management, by requiring plans to submit a clinical justification if they attempt otherwise. However, this provides no guarantees, and it would have CMS resource implications for reviewing each submitted justification. Moreover, CMS’s guidance on reviewing clinical justifications is vague. Instead, CMS could adopt a blanket rule protecting drugs selected for negotiation. This could be supported by CMS’s authority to disapprove plan designs likely to discourage enrollment. A plan tiering design that steers beneficiaries away from drugs selected for negotiation and towards drugs not selected with higher out-of-pocket costs to the beneficiary is likely to discourage enrollment of beneficiaries who need a particular drug that has been selected for negotiation. CMS could also justify this under its authority to set reasonable minimum standards for plans.</p> <p>CMS could also give additional guidance on the clinical justifications it will require for non-preferred treatment or utilization management of drugs selected for negotiation. This guidance could address more directly what a might constitute a valid justification.</p>
<p><b>Adopt a Public “Watchlist” for Specific Adverse Formulary Decisions</b></p>	<p>When CMS disapproves a formulary design or utilization management practice, it could do more than simply require the sponsor to correct it. Instead, CMS could publicly announce to all sponsors that it has identified that specific practice as an issue, and that it will be on the lookout for it going forward. This could create clarity for plans and discourage the submission of similar plan designs. It could also give CMS an opportunity to demonstrate that the agency is being proactive in addressing noncompliance with formulary requirements. PDP sponsors who repeatedly submit formularies that require correction could be required to implement a corrective action plan to better consider their formularies before submission.</p>
<p><b>Commit Additional Resources to Reviews</b></p>	<p>The importance of protecting beneficiaries through the first few years of IRA’s implementation suggest CMS should devote additional resources specifically to formulary reviews and PDP sponsor monitoring. The IRA appropriates \$341 million to CMS to implement the IRA’s Part D improvements.<sup>47</sup> It would be prudent to devote some of those funds to expand the teams and tools used for the ordinary annual formulary review process and Part D plan monitoring functions.</p>
<p><b>Set an Explicit Requirement for Where Plans Must Cover More than Two Drugs Per Category or Class</b></p>	<p>Current CMS policy is that it follows “widely accepted treatment guidelines” and “general best practice” to determine whether a formulary has adequate coverage.<sup>48</sup> It also published a list of commonly prescribed drug classes in 2010 for use in formulary reviews. This guidance is vague and out of date. Instead, CMS could publish more detailed lists of key areas where it demands adequate coverage on formularies, including specific minimum numbers and types of medications.</p>
<p><b>Improve Transparency of Utilization Management and Coverage Limitations</b></p>	<p>Beneficiaries shopping for coverage may struggle to easily identify when a plan they are considering has a utilization management restriction for a drug they take. Likewise, they may not know to look and see if a plan disfavors drugs selected for negotiation. CMS could adopt rules and improve transparency of this information by including it prominently in the Medicare Plan Finder and make specific utilization management policies easily searchable and accessible. Likewise, CMS could place a flag in the Plan Finder on plans that disfavor drugs selected for negotiation, to alert beneficiaries in advance.</p> <p>CMS could also ensure that non-electronic beneficiary-facing promotional materials from participating plans disclose use of utilization management practices and encourage beneficiaries to contact the plan to confirm medication coverage details before finalizing their insurance selection.</p>



<p><b>Enforce Minimum Payment Rates to Pharmacies</b></p>	<p>CMS could ensure broad access to covered Part D drugs at beneficiaries’ chosen pharmacy by requiring that PDP sponsors pay at least the pharmacy’s acquisition cost for covered drugs. While CMS ordinarily does not “interfere” in the negotiations between plans and pharmacies, this could be construed as falling within CMS’s authority to set “reasonable and relevant” reimbursement terms plans must meet to satisfy the “any willing pharmacy” rule.</p>
<p><b>Monitor and Improve Appeals, Grievances and Exception Requests</b></p>	<p>CMS could closely monitor rates of beneficiary appeals of coverage denials, complaints to plans about coverage and exception requests for coverage of drugs not on formulary or for preferred status of a non-preferred drug. Upticks in these processes could be leading indicators of specific problems on specific plan formularies that CMS could act on quickly. CMS currently collects this data on a quarterly basis, and perhaps not in sufficient detail to identify specific drug products or policies that trigger additional appeals.<sup>49</sup> By increasing the pace and detail of this collection, CMS could improve its visibility and act more quickly. Additional regular audits of plans would demonstrate situations where plans are inadequately processing and reviewing appeals and exceptions. Publication of this data and CMS’s enforcement activity could demonstrate that the agency is acting proactively.</p>
<p><b>Improve Appeals and Exception Request Processes</b></p>	<p>CMS might also consider taking steps to improve the efficiency of the appeals process to relieve patients and providers of the burden of filing an appeal or a formulary or tiering exception request. These processes are the best immediate mechanism available to beneficiaries facing challenges with coverage or authorizations, and having them run smoothly is an important protection for 2025 and beyond. For example, CMS could consider requirements for seamless electronic prior authorization, appeals and exception requests. CMS could also ensure that beneficiaries are aware of these processes through better communication and education on rights to appeal or request an exception. Finally, CMS could make exception requests easier to obtain, such as by adopting a presumption in favor of granting an exception. This would support a reduction of administrative burden, as data has shown that millions of prior authorization requests are submitted annually, with most appeals of prior authorization denials being overturned.<sup>50</sup></p>
<p><b>New Actuarial Equivalence Tests</b></p>	<p>To protect beneficiaries in 2025, CMS could improve the sensitivity of its actuarial equivalence test to protect against adverse formulary tiering of drugs selected for negotiation. Beginning in 2026, CMS could separately test the actuarial equivalence of out-of-pocket costs of drugs selected for negotiation to ensure that sponsors are actually offering an actuarially equivalent benefit for these drugs. In so doing, CMS will likely prevent PDP sponsors from quietly inflating the out-of-pocket costs for drugs selected for negotiation through inferior formulary tiers.</p>

## Conclusion

The changes to Medicare Part D will inject uncertainty into a program that has, by many measures, succeeded over the past two decades. The incentives the IRA creates pose challenges for CMS, beneficiaries, prescribers, and PDP sponsors. CMS has tools it can use to proactively manage formularies and utilization management practices so that the coming transition does not adversely disrupt beneficiary access while providing clarity and predictability to PDP sponsors. A more proactive posture by CMS on Part D benefit redesign implementation and issuing clear guidance about CMS’s formulary review approach could maintain a more level playing field among Part D sponsors, provide beneficiaries and stakeholders an important opportunity to provide input, and ultimately help ensure that beneficiaries do not experience harm as a result of PDP sponsors’ responses to the implementation of the IRA.

1. Social Security Act § 1194.
2. *Id.* §§ 1847A(i), 1860D-14B.
3. Pub. L. No. 117–169, § 11201, 136 Stat. 1817, 1877 (2022).
4. Joyce G, Blaylock B, Chen J, Van Nuys K. Medicare Part D Plans Greatly Increased Utilization Restrictions On Prescription Drugs, 2011–20. *Health Affairs* 2024 43:3, 391–397. Available [here](#).
5. SSA 1860D-2(b)(4)(A)(i)(II). Beneficiaries may reach this point with as little as about \$3,300 in actual out-of-pocket spending for brand drugs, because in 2024 manufacturers' Coverage Gap Discount Program payments and other payments from qualifying third parties are treated as beneficiary out-of-pocket spending.
6. Centers for Medicare and Medicaid Services. "Contract Year (CY) 2025 Final Part D Bidding Instructions" (Feb. 1, 2024). Available [here](#).
7. At the same time the CGDP will be fully eliminated and replaced with new discounts beginning in 2025. Under this new "manufacturer discount program," manufacturers of brand drugs must pay a 10% discount for such drugs in the coverage phase (after the deductible) and a 20% discount for those drugs when they are dispensed in the catastrophic phase.
8. Congressional Budget Office. How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act. Available [here](#). See also Jennifer Carioto et al., Milliman, Financial Implications of the Inflation Reduction Act Are Expected To Lead to a Reassessment of Formulary Strategies by Part D Plans. (2023) Available [here](#).
9. Centers for Medicare and Medicaid Services. "Contract Year (CY) 2025 Final Part D Bidding Instructions" (Feb. 1, 2024). Available [here](#).
10. Carioto et al., *supra* note, at 8.
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20. Malhotra, Y. The AMJEVITA impact: Innovative U.S. biosimilar pricing models. *Clarivate*, July 2023. Available [here](#).
21. Ippolito BN, Levy JF. The influence of Medicare Part D on the list pricing of brand drugs. *Health Serv Res*. 2023 Aug;58(4):948–952. Available [here](#).
22. Fein, AJ. Drug Channels. Surprise! Thanks to the IRA, Part D Plans Will Prefer High-List, High-Rebate Drugs. February 2024. Available [here](#). PDP sponsors are required to divide rebates between themselves and CMS in rough proportion to each's responsibility for the cost of covered drugs. After CMS's reinsurance obligations decrease in 2025, plans will carry more responsibility for drug costs, and therefore retain a bigger share of the rebate allocation.

23. Alternatively, it is possible MFP-priced drugs will be attractive to PDP sponsors and be placed on lower formulary tiers with minimal utilization management without further CMS intervention. The possibility of that outcome need not foreclose CMS’s attention to other potential consequences of IRA’s implementation.
24. Centers for Medicare and Medicaid Services. “Contract Year (CY) 2025 Final Part D Bidding Instructions” (Feb. 1, 2024). Available [here](#).
25. 42 C.F.R. § 423.120(b)(2).
26. 42 C.F.R. § 423.272(b)(2)(i), (iii).
27. “Medicare Modernization Act Final Guidelines—Formularies. CMS Strategy for Affordable Access to Comprehensive Drug Coverage.” Available [here](#).
28. SSA 1860D-11(e)(2)(D)(i).
29. SSA 1860D-4(b)(3)(C).
30. 42 C.F.R. § 423.120(b)(2)(iii).
31. SSA 1860D-11(i)(2).
32. Medicare Prescription Drug Benefit Manual, Ch. 6 Section 30.2.4.
33. See, e.g., 70 Fed. Reg. 4194, 4354 (Jan. 28, 2005).
34. Medicare Prescription Drug Benefit Manual, Ch. 6 Section 30.2.7.
35. Centers for Medicare and Medicaid Services. “Contract Year (CY) 2025 Final Part D Bidding Instructions” (Feb. 1, 2024). Available [here](#).
36. SSA 111860D-4(b)(3)(I).
37. Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2026 at Section 110. Available [here](#).
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