PINK SHEET
CITELINE REGULATORY

16 Apr 2024 | **Analysis**

Medicare-Negotiated Drugs May Not Get Favorable Coverage In Part D: Will CMS Intervene?

by Cathy Kelly

Insurance plans put on notice that CMS is concerned about restrictions on drugs with negotiated prices, but it's not clear what the agency can or will do about it.

Drugs in the Medicare price negotiation process will be at a disadvantage in Part D plans because their lack of manufacturer rebates and discounts will mean lower profits for plans and more pressure on premiums relative to competitors.

The realization is more dreary news for products that end up in the crosshairs of the Inflation Reduction Act pricing process, even though the law requires Part D plans to cover negotiated drugs. There is no requirement that plans put those products on a preferred formulary tier, nor are there limits on utilization management tools like prior authorization or step therapy that plans can impose.

The US Centers for Medicare and Medicaid Services is aware of the irony that government pricing intervention could lead to less patient access for the affected products. The agency

Key Takeaways

- Negotiated drugs must be covered in Part D, but plans are not prohibited from putting them on non-preferred formulary tiers or imposing prior authorization of step therapy restrictions.
- CMS has stated its concern that plans might be incentivized to disadvantage negotiated drugs and said it will watch for situations that create problems for beneficiaries.

acknowledged that coverage could be limited in its guidance on the negotiation program, which was issued last spring. (Also see "*Medicare Director: 'Bona-Fide' Generic Marketing Likely Product-Specific For IRA*" - Pink Sheet, 10 Jul, 2023.)

- But experts are uncertain about how much CMS can or will do because plans and even the government have incentives to allow formulary decisions to continue to be driven by rebates.
- Those incentives may push Part D plans to continue giving preferential treatment to drugs with high list prices and big rebates.

"CMS is concerned that Part D sponsors might be incentivized in certain circumstances to disadvantage selected MFP [maximum fair price] drugs by placing these drugs on less favorable tiers compared to non-selected drugs," the guidance says, adding that the agency will use its Part D formulary review process to evaluate it.

"They sort of tried to put the plans on notice," Drug Channels Institute president Adam Fein said during a 5 April *webinar* on the impact of the IRA. However, CMS is "pretty overwhelmed. It's not clear what, if anything, they are going to be able to do about this."

And "it does appear [plans] are going to crank up" utilization management "quite a bit" for negotiated drugs, Fein predicted. Patient groups raised that possibility during the "listening sessions" on the drugs up for negotiation that CMS hosted in the fall. (Also see "*Could Government Negotiated Prices Curtail Access? PBMs And Potential Perverse Incentives Dominate First Medicare Listening Session*" - Pink Sheet, 30 Oct, 2023.)

Drugs assigned a maximum fair price by Medicare are not expected to continue to provide rebates, although manufacturers are concerned plans still will demand rebates because they have a vested interest in doing so. Negotiated prices for the first set of drugs to undergo the process will be implemented in 2026.

Most of the drugs undergoing negotiation have been heavily rebated in Part D. (Also see "*Big Rebates Already A Big Factor For Drugs On Medicare Negotiation List*" - Pink Sheet, 29 Aug, 2023.)

"These rebates actually contribute to Part D plan profits," Fein said. "Per the Part D statute … plans get to keep the majority of [rebates] that come in above their projected bids." And "do you want to guess how often they under-forecast … and get the bonus at the end? If you said every single year, you would be right."

In addition to the probability of fewer or no rebates, negotiated drugs also are exempt from the new manufacturer discounts that will be required in Part D beginning in 2025, Fein pointed out. (Also see "*Medicare Part D Redesign: New Discounts Will Not Apply To Drugs With 'Negotiated'*

Prices" - Pink Sheet, 6 Sep, 2022.)

As part of a benefit redesign established by the IRA, manufacturers will provide a 10% discount on drugs in the initial coverage phase and a 20% discount in the catastrophic phase.

Higher Net Revenues For Negotiated Drugs?

The lack of rebates and mandatory discounts will mean costs to the plan and the government "actually go up, because you don't have as much of a contribution from the manufacturer," and "the impact on premiums is higher," Fein said.

"And what's even weirder is the manufacturer's net revenue" on a negotiated drug "is higher than for the high list/high rebate drug" because of the absence of such price concessions, he added. Fein pointed out, however, that the fact that negotiation means a manufacturer has fewer years to sell its drug at a price not controlled by the government would "kind of offset that."

Fein based his conclusion on an analysis of the likely coverage dynamics around a negotiated drug compared to a high list price/highly rebated drug and one with a low list price and low rebates.

"I would say this is an example of an unintended consequence," he observed. "I don't think it was intended that the new Part D benefit design would favor high list price/high rebate products, or that [negotiated] products would be less attractive to the plans and have a bigger premium impact."

But the analysis "gives you some insight into how plans are going to start positioning these products in 2026 on their formularies," Fein said. "And if you're a manufacturer, it could give you some insight into how you might compete in a category in which there is a [negotiated] product on the formulary."

Competing Against Negotiated Drugs

For non-negotiated drugs, the upshot is "if I make my product a high list price/high rebate product, it is more attractive to the plan" and its "premium calculation, which means that I as a Part D plan might actually consider creating parity between the non-negotiated and the negotiated product," Fein suggested.

In addition, "depending on what those numbers are, I as the plan am going to try and get even more rebates out of the non-negotiated product so the gross-to-net pressure on manufacturers is going to increase," he predicted. (Also see "*Medicare Part D Redesign Could Expand Rebate-Driven Formulary Exclusions In Program*" - Pink Sheet, 26 Jan, 2023.)

It "might be expensive," Fein said. "But it means that even if you are in a category with a

[negotiated drug] that is a close competitor, there are still going to be market access strategies that are going to keep you viable."