

CMS Releases Final Part Two Guidance on the Medicare Prescription Payment Plan: What's Changed for Part D Plans?

July 22, 2024

The Centers for Medicare & Medicaid Services (CMS) updated its guidance on the Inflation Reduction Act of 2022's (P.L. 117-169) (IRA) Medicare Prescription Payment Plan (M3P) with its release of the Final Part Two Guidance on July 16, 2024. The Final Part Two Guidance provides an update to the Draft Part Two Guidance released by CMS on February 15, 2024, regarding plan outreach and education for the M3P. The motivator behind these updates is to ensure that people with Medicare prescription drug coverage, especially those most likely to benefit, are aware of the payment option.

On July 16, 2024, CMS also issued six newly developed model documents for the M3P program following the Information Collection Requests (ICR) comment process, which Part D sponsors can use to meet the education, communications, and outreach requirements included in the Final Part Two Guidance.

M3P Implementation and Timeline Updates

Starting in 2025, the M3P program provides the option to individuals with Medicare prescription drug coverage to spread the costs of their prescription drugs over the calendar year, rather than paying upfront in full each time they fill a prescription. Individuals with Medicare must opt into the M3P program to utilize the new benefit. The M3P program is scheduled to launch at the same time that all individuals with Medicare prescription drug coverage will begin to have their annual out-of-pocket prescription drug costs capped at \$2,000. The final steps of the M3P program implementation are as follows:

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- October 15, 2024: During Medicare Open Enrollment, Medicare Part D enrollees will be able to opt into the Medicare Prescription Payment Plan for the 2025 plan year. Part D enrollees will also have the opportunity to opt in throughout the year.
- January 1, 2025: The Medicare Prescription Payment Plan launches.

What's Changed for Part D Plans?

The Final Part Two Guidance includes a summary of significant comments (and CMS's responses to those comments) that CMS received in response to the Draft Part Two Guidance. It also builds on the Final Part One Guidance, issued by CMS on February 29, 2024, which focuses on operational requirements for the program. Some of the key changes in the Final Part Two Guidance include:

- A requirement for Part D sponsors to still establish reasonable criteria (i.e., procedures and mechanisms) for identifying Part D enrollees likely to benefit from the M3P program throughout the plan year; **however**, Part D sponsors are no longer required to base their criteria on prior authorization or other utilization management edits in place for a drug with out-of-pocket (OOP) costs at or above the pharmacy point of sale (POS) notification threshold. Instead, Part D sponsors may develop their own criteria/methodology to fulfill this M3P program requirement.
- A clarification that while CMS intends for Part D sponsors to comply with the M3P program requirements, CMS does **not** expect Part D plans that exclusively charge \$0 cost sharing for covered Part D drugs to all plan enrollees to comply with the Final Part One Guidance or this Final Part Two Guidance.
- A requirement for Part D sponsors to send the program election request form either via the membership ID card mailing or in a separate mailing sent out during the same timeframe.
- Specific content requirements for communications materials Part D sponsors must send to Part D enrollees regarding election into, participation in, and termination from the M3P program. If Part D sponsors choose not to use CMS-developed model materials and instead develop their own notices, they must meet these same content requirements.

What Part D Plans Should Be Doing Now

The Final Part Two Guidance and Final Part One Guidance provide clear requirements Part D plans must meet under the M3P program, including member outreach and enrollment, billing and claims processing, and certain reporting requirements. Part D plans are encouraged to review their current pharmacy benefit management (PBM) agreements to consider whether any contract changes are necessary to ensure that both the Part D plan and their PBM are prepared to implement the M3P program beginning in 2025. Check out our recent alert which details specific contract terms in your PBM agreement to look out for as your plan considers the impact of the M3P on its Part D program.

Wiley's multidisciplinary Medicare Drug Pricing team of experienced attorneys and advisors is closely monitoring the M3P program and is available to assist with contract review, contract amendments or change orders, or any questions regarding implementation of the program. For more information about the M3P or the IRA generally, please contact one of the attorneys listed on this alert.