



Summary: Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly

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Comments Due: April 6, 2020

On February 5, 2020, the Centers for Medicare & Medicaid Services (CMS) released the [CY 2021 and 2022 Medicare Advantage and Medicare Prescription Drug Benefit Program Policy and Technical Rule](#), outlining proposed programmatic changes to the MA and Part D programs for two upcoming contract years. In a break from historic precedent, many of the program and policy changes that historically had been included in the Draft Call Letter were included in this proposed rule. The Part D Bid Instruction and the [Annual Calendar](#) were also pulled out of the Draft Call Letter and are available separately on CMS' website. The proposed rule implements many of the programmatic changes resulting from recently passed legislation, including the Bipartisan Budget Act of 2018, the 21st Century Cures Act, and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act.

Major provisions in the proposed rule include:

- Proposed establishment of pharmacy performance measure reporting requirements.
- Permitting Part D plan sponsors to offer a second, "preferred" specialty tier.
- Requirement that Part D plans implement a beneficiary real-time benefit tool in 2022.
- Continued implementation of the SUPPORT Act provisions around opioid management.

Comments on proposed rule must be submitted to CMS by April 6, 2020. You may provide feedback via email to advocacy@amcp.org on any provisions included in the proposed rule. AMCP's final comments will be available on the AMCP website and included in the Legislative-Regulatory Briefing Newsletter that is distributed to all AMCP members.

The following is a summary of key sections in the proposed rule that may be of interest to AMCP members:

A. Establishing Pharmacy Performance Measure Reporting

- a. CMS proposes to establish new reporting requirements to require Part D plan sponsors to disclose the pharmacy performance measures they use to evaluate pharmacy performance in their network pharmacy agreements.
 - Plans currently do not have to disclose the pharmacy performance measures to CMS. With this proposal, the agency will be able to report this information publicly in order to increase transparency. CMS encourages the industry to

continue to work to establish a consensus set of pharmacy performance measures.

- b. CMS also seeks comments on Part D pharmacy performance measures more broadly, including recommendations for potential Part D Star Ratings measures to incentivize utilization of a standard set of pharmacy performance measures.

B. Second, “Preferred” Specialty Tier

- a. CMS proposes to allow Part D plan sponsors to establish up to two specialty tiers, with sponsors having the flexibility to determine which drugs are placed on each specialty tier.
 - CMS proposes that if a plan has two specialty tiers, one must be a preferred tier with lower cost sharing.
 - CMS declined to limit the lower cost specialty tier to generic drugs and biosimilar products, but the agency solicits comment on whether it should impose such a restriction.
- b. CMS proposes that the plan sponsor may design its exceptions process so that Part D drugs on specialty tiers are not eligible for a tiering exception to non-specialty tiers.
 - This exemption would apply only to exceptions to non-specialty tiers; plan sponsors would be required to permit tiering exception requests for drugs on the higher cost sharing specialty tier to the lower one.
- c. The maximum allowable cost sharing (25% or 33%, depending on the plan structure) would be maintained and would be applicable to the higher specialty tier (or single tier if there is only one). CMS also solicits comments on allowing the higher cost sharing specialty tier to have a higher coinsurance and/or on adopting a maximum allowable cost sharing of 25% for any specialty tier, regardless of whether the plan has a deductible.
- d. CMS proposes to revise the methodology for determining the specialty tier cost threshold to be based on a 30-day equivalent supply and based on the ingredient cost reported on the Prescription Drug Event (PDE) data.
 - The current methodology uses the negotiated price reflected on the PDE.
- e. CMS proposes to codify the policy of maintaining a specialty-tier cost threshold that reflects Part D drugs with monthly costs in the top 1%, now utilizing the ingredient costs.
- f. CMS proposes to begin applying the new methodology to the CY 2020 specialty tier cost threshold of \$670 and will announce a new threshold in the Final Rule if a change is required based on updated data.
 - Based on the newly proposed methodology and CY 2019 PDE data that CMS has to date, CMS proposes increasing the specialty tier cost threshold for CY 2021 to \$780.

C. Beneficiary Real Time Benefit Tools (RTBT)

- a. CMS proposes to add a requirement that Part D plan sponsors implement a beneficiary RTBT that would allow enrollees to view accurate, timely, and clinically appropriate, patient-specific, real-time formulary and benefit information, effective January 1, 2022.

- In a May 2019 Final Rule on Part, CMS had finalized a requirement, effective January 1, 2021, that plan sponsors support a prescriber RTBT that was capable of integrating with at least one electronic health records or e-prescribing system.
- b. The RTBT will be required to present real-time values for the enrollee's cost-sharing information as well as clinically appropriate formulary alternatives (including the formulary status of these alternatives). The beneficiary RTBT would include any utilization management requirements (step therapy, prior authorization, quantity limits, etc.) for each alternative drug.
 - c. CMS proposes to allow plan sponsors' P&T committees to evaluate whether some drugs should be excluded from the beneficiary RTBT based on certain criteria.
 - d. CMS encourages, but does not propose to require, plan sponsors to include each drug's negotiated price in the beneficiary's RTBT.
 - e. In order to encourage enrollees to utilize the RTBT, CMS proposes to allow plans to offer rewards and incentives to enrollees using the tool.
 - Plans must offer the rewards and incentives to all enrollees who use the tool (or seek access to this information over the phone). Rewards and incentives must be of only nominal value (for example gift cards that are not cash equivalents) and do not encourage enrollees to further patronize the plan or any corporate affiliates of the plan.
 - Plans are not permitted to make eligibility for the rewards and incentives contingent on the type of medication the beneficiary is taking or on the enrollee switching medications. Plans will also be expressly prohibited from including any "enrollee remuneration," including waivers of copays or deductibles, transfer of items or services for free, etc. under the guise of these rewards and incentives.
 - Plans are required to include expenses for any rewards and incentives as administrative costs in the plan bids (i.e. they cannot be considered a drug cost).

D. Continued Implementation of the SUPPORT Act

- a. Per the SUPPORT Act statute, CMS proposes to require Part D plan sponsors to implement Drug Management Programs (DMPs) designed to engage in targeted care management for beneficiaries at-risk for abuse or misuse of frequently abused drugs, beginning on January 1, 2022.
 - DMPs were established by the Comprehensive Addiction and Recovery Act (CARA) and allow plan sponsors to limit a potentially at-risk beneficiary's access to coverage of opioids and/or benzodiazepines to a single prescriber, a limited network of pharmacies, or through a specific point-of-sale edits. Previously, DMPs have been voluntary for plan sponsors.
- b. CMS seeks to modify the definition of a potentially at-risk beneficiary to include a Part D eligible individual who is identified as having a history of opioid-related overdose. A "history of opioid-related overdose" is defined by CMS as a beneficiary for whom a recent claim has been submitted containing a principal diagnosis reflecting an opioid overdose, regardless of the type of opioid, and at least one PDE for an opioid dispensed to the beneficiary has been submitted.

- The current definition involves an individual identified as potentially at-risk by “clinical guidelines” or who has previously been identified as potentially at-risk by another plan.
 - This definition modification is mandated by the SUPPORT Act.
- c. CMS proposes to implement provisions of the SUPPORT Act requiring automatic forwarding of an enrollee’s appeal of an at-risk determination to the Independent Review Entity (IRE).
- Previously, an enrollee appealing an at-risk determination or the implementation of a POS edits or other access limitations, would use existing Part D appeals channels (i.e. the case only goes to the IRE when requested by a beneficiary or if the plan fails to make a timely adjudication).
 - Under this proposal, the case would automatically be sent to the IRE if a plan sponsors affirms its denial of the enrollee’s appeal.
- d. CMS proposes to implement the provision of the SUPPORT Act requiring Part D plans to implement payment suspensions for credible allegations of fraud in the same way CMS implements payment suspensions in the FFS program. Plans will be required to notify the Secretary of the imposition of a payment suspension based on a credible fraud allegation through a new HPMS module.

E. Other Provisions

- a. CMS proposes to increase the weight of the patient experience complaints and access measures in the MA and Part D program quality rating system from a weight of 2 to a weight of 4.