February 5, 2021

2022 Medicare Advantage and Part D Final Rule Includes Update to Star Ratings System and Implementing Coverage and Transparency Measures

Attorneys
Margaux J. Hall
Mara Sanders
Eliza Pan

On January 15, 2021, the Centers for Medicare & Medicaid Services ("CMS") issued the Contract Year 2022 Medicare Advantage and Part D Final Rule. The final rule was released amidst a flurry of regulations and program updates that the Trump administration's Department of Health and Human Services issued in its final days, and includes a number of measures that touch on access to care, price transparency, and competition, including measures that:

- Allow for Part D formularies to include two specialty tiers;
- Require Part D plans to implement a drug benefit tool that gives beneficiaries and providers real-time information on out-of-pocket costs for prescription drugs;
- Require Medicare Part D plans to report to CMS the measures that plans use to evaluate the performance of network pharmacies;
- Codify sub-regulatory updates to the Star Ratings system for Medicare Advantage ("MA") and Part D plans; and
- Impose requirements that are designed to address the opioid epidemic.

The regulations set forth in the final rule are effective on March 22, 2021, with most requirements taking effect in plan year 2022. We note that, on January 20, 2021, the Biden administration issued a "regulatory freeze," instructing agencies to postpone the effective dates for any rules (which includes both regulations and sub-regulatory guidance) that have been issued but that have not taken effect so as to permit review of any questions of fact, law, and policy, and, where appropriate, to open a 30-day comment period.[1] We do not anticipate that this regulatory freeze will change the effective date of the regulations set forth in the final rule, which occurs after expiration of the 60-day regulatory delay period. It is, however, possible that, following review, aspects of the final rule may be changed or withdrawn.

We also briefly summarize another midnight regulatory change by the Trump Administration—specifically, a Part D Payment Modernization Model that is likely to meaningfully restrict beneficiary access to therapies, including drugs in previously protected therapy classes, if authorization for that Model is not altered or withdrawn by the Biden Administration.

We summarize herein key provisions of the final rule, as well as the Part D model, as they currently stand.

Part D Option for a Second, "Preferred," Specialty Tier

The final rule makes a significant change to rules governing Part D formulary design. Under the Part D program, CMS permits Part D plans to design their own prescription drug formularies, subject to certain requirements, including limitations on cost-sharing obligations that can be imposed on Part D beneficiaries. Currently, CMS permits Part D plans to place drugs that cost over a specified threshold (for contract year 2021, $670) in a single specialty tier. Plans may charge higher co-insurance—up to 25 or 33 percent, depending on the plan's deductible—for drugs in this specialty tier.[2] Under the final rule, starting on January 1, 2022, Part D plans may establish a second specialty tier, splitting specialty drugs between a non-preferred specialty tier and a preferred specialty tier, with the preferred tier carrying lower cost-sharing obligations than the non-preferred tier.[3] Plans will have flexibility to allocate Part D drugs across the two

specialty tiers, subject to CMS's existing formulary review and approval process and the specialty tier cost threshold.[4] By allowing plans to apply differential co-insurance obligations to specialty drugs, this dual specialty tier model is designed to give plans flexibility to incentivize beneficiaries to select lower-cost specialty drugs.

The final rule also codifies updates to the methodologies for calculating of the specialty tier cost threshold and determining whether the drug meets the specialty tier cost threshold. Under the new methodologies, the price of a given drug will be calculated based on ingredient cost for a 30-day supply of the drug (as reported to CMS in prescription drug event records), as opposed to the negotiated price of the drug. CMS will also adjust the specialty tier threshold annually to ensure that the threshold reflects the top one percent of drug prices, rounded up to the nearest $10.[5] This new calculation methodology results in a specialty tier threshold cost of $780 for the 2021 plan year, although the agency has said that—notwithstanding this methodology change—for the current 2021 contract year, it will maintain the specialty tier threshold at $670.[6] CMS intends for these changes to the specialty-tier system to give Part D plans more leverage in negotiating with drug manufacturers for high-cost drugs and, in turn, to reduce out-of-pocket costs for enrollees in exchange for placing certain drugs in the "preferred" specialty tier.[7]

Real-Time Benefit Tool Requirement

The final rule requires Part D plans to offer by January 1, 2023 a beneficiary real-time benefit tool ("RTBT"), which must permit enrollees to access patient-specific, real-time formulary and benefit information, such as cost, formulary alternatives, and utilization management requirements.[8] Plans may choose to offer the tool through existing, online, patient portals, through standalone RTBT portals, or through computer applications.[9] CMS hopes that RTBTs will allow health care providers and enrollees to weigh cost differences among medications prior to the point of purchase.[10] With RTBTs, enrollees may be better equipped to discuss drug therapy options during visits with health care providers and to anticipate out-of-pocket costs before trips to the pharmacy.

The final rule's RTBT requirement builds on a recent push by CMS and Congress to improve price transparency for Part D beneficiaries and health care providers. In May 2019, for instance, CMS finalized a policy that requires each Part D plan to adopt an RTBT that can integrate with at least one e-Prescribing system or electronic health record system by January 1, 2021.[11] CMS has encouraged health care providers to use these RTBTs to identify lower-cost, alternative therapies for enrollees, with the stated goal of lowering out-of-pocket costs for beneficiaries and improving therapy adherence by beneficiaries. CMS's new RTBT requirements come on the heels of the December 27, 2020 enactment of Section 119 of the Consolidated Appropriations Act of 2021 ("Section 119"), which includes a requirement that Part D plans adopt an RTBT that meets technical specifications to be prescribed by CMS.[12] CMS has not yet prescribed technical standards under Section 119 and clarified in the final rule that Section 119's technical requirements will apply only once RTBT technical standards have been promulgated via notice-and-comment rulemaking.[13]

Potential Restricted Access to Part D Drugs Through Part D Payment Modernization Model

While, under the final rule, CMS institutes several Part D program changes intended to improve beneficiary access to drugs, just days after issuing the final rule, the agency announced a CMS Innovation Center Part D Payment Modernization Model Request for Applications ("RFA") that will significantly weaken access protections for beneficiaries. Specifically, the RFA for the voluntary demonstration project would allow participating Part D plan sponsors to significantly limit the scope of drugs covered under Part D formularies and to limit access to protected class drugs, notwithstanding the longstanding access protections that these classes of drugs have been afforded.[14] Part D plans currently are required to include at least two drugs per class on their formularies, and to cover substantially all drugs in six protected classes (immunosuppressants, anticonvulsants, antidepressants, antineoplastics, antipsychotics, and antiretrovirals). Starting in 2022, plans that participate in the Part D Payment Modernization Model would only be required to include one drug per class on their formularies. Additionally, CMS would eliminate special protections for the six protected classes, allowing plans that participate in the model to cover only one drug in each protected class.

Antirretrovirals would retain protections for the first year of the updated demonstration but would lose protections beginning in 2023.

These changes to the Part D Payment Modernization Model rules, which come in the form of sub-regulatory guidance, are subject to review under the Biden administration's regulatory freeze. While it is not yet known whether, under the Biden administration, CMS will ultimately choose to implement these changes, such weakening of beneficiary protections would appear to fit squarely within the category of rules that the Biden administration intends to scrutinize and reconsider. It, therefore, remains to be seen whether these changes to the Part D Payment Modernization Model formulary requirements will ultimately take effect, as currently written.

Pharmacy Performance Measure Reporting Requirements

Starting in plan year 2022, CMS will require Part D plan sponsors to report the pharmacy performance measures that they use to evaluate network pharmacy performance under their network agreements. In instituting this requirement, the agency emphasized the growing magnitude of pharmacy price concessions based on performance measures within the Part D program, and expressed a desire to provide the public with transparency regarding these measures. The agency also said that it believes that "publishing a list of currently used pharmacy performance measures will promote the development of consensus-built standards by the industry that are transparent and equitable across various pharmacy types and patient populations, and support value-based care."[15]

Codification of Updates to the MA and Part D Star Ratings Rating System

CMS measures MA and Part D plan quality and performance through a Star Ratings system that annually assigns and publishes a rating for each plan, based on data collected on a number of measures over the course of previous plan years. The Star Ratings system is the primary means through which beneficiaries can compare and select plans, and the basis of quality-based bonus payments awarded to plans by CMS. As a result, the specific Star Ratings measures that the agency evaluates, as well as the methodology through which Star Ratings are calculated, can have major implications for plans and beneficiaries alike.

While the final rule does not introduce any new Star Ratings quality or performance measures, it codifies updates to CMS's methodology for the Star Ratings system that were previously instituted through sub-regulatory guidance. CMS's decision to subject updates to the Star Rating system to formal, notice-and-comment rulemaking is notable in light of the fact that CMS historically has updated Star Ratings measures and methodologies through annually issued call letters and other sub-regulatory guidance, without a formal notice-and-comment rulemaking process as contemplated under the Administrative Procedure Act. By subjecting updates to the Star Ratings system to formal notice and comment, CMS appears to be signaling a recognition of the importance of Star Ratings to stakeholders and of government payments in connection with the MA and Part D programs, and a strengthened commitment to meaningful consideration of stakeholder input in the design of the Star Ratings system.

The final rule codifies changes to the Star Rating system for data collection occurring in 2022 onward (affecting Star Ratings displayed starting in 2024) that were initially accomplished via sub-regulatory guidance, including finalization of the methodology for calculating ratings that determine Quality Bonus Payments ("QBPs") to MA organizations[16] and implementation of substantive updates to the specifications of two Health Outcomes Survey measures: the Improving or Maintaining Physical Health measure and the Improving or Maintaining Mental Health measure. The final rule also makes changes to the calculation methodology for and delayed implementation of the MA Transition to Care and Follow-Up After ED Visit for People with Multiple High-Risk Chronic Conditions measures, with data now to be collected beginning in 2022 for display starting in 2024.[17]

Additional Measures

The final rule includes a number of other measures, including but not limited to measures designed to implement the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities ("SUPPORT") Act and otherwise take action to address the opioid crisis. These measures, which take effect in 2022, include:

- Implementation of the SUPPORT Act's requirements that:
    - Part D plans establish drug management programs, through which plans and prescribers can monitor opioid overutilization among enrollees and identify potential at-risk beneficiaries whose access to prescription opioids should be restricted;[18] and
    - Part D plans notify the Secretary of Health and Human Services of any imposition of a payment suspension on a pharmacy based on a credible allegation of fraud pursuant to the SUPPORT Act. Plans must report any such payment suspensions via a new secure program integrity portal within CMS's Health Plan Management System;[19]
- Requirements for Part D plans, including MA prescription drug plans and standalone prescription drug plans, to disclose certain information to all enrollees regarding the risks associated with prolonged opioid use and alternative therapies;[20] and
- Requirements for MA plans to disclose information to enrollees regarding the safe disposal of prescription drugs that are controlled substances, with the option for plans to tell enrollees about the availability of in-home drug disposal kits.[21]

---

1. Ronald A. Klain, Assistant to the President and Chief of Staff, Memorandum for the Heads of Executive Departments and Agencies: Regulatory Freeze Pending Review (Jan. 20, 2021), *available at* https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/regulatory-freeze-pending-review/.
2. CMS, Press Release, "Changes to Medicare Advantage and Part D Will Provide Better Coverage, More Access and Improved Transparency for Medicare Beneficiaries" (Jan. 15, 2021), https://www.cms.gov/newsroom/press-releases/changes-medicare-advantage-and-part-d-will-provide-better-coverage-more-access-and-improved.
3. 86 Fed. Reg. at 5867.
4. *Id.*
5. *Id.* at 5946-50.
6. *Id*. at 5950.
7. CMS, "Contract Year 2022 Medicare Advantage and Part D Final Rule (CMS-4190-F2) Fact Sheet" (Jan. 15, 2021), https://www.cms.gov/newsroom/fact-sheets/contract-year-2022-medicare-advantage-and-part-d-final-rule-cms-4190-f2-fact-sheet.
8. 86 Fed. Reg. at 5868.
9. *Id.*
10. *Id.* at 5951.
11. CMS, Fact Sheet, "Medicare Advantage and Part D Drug Pricing Final Rule (CMS-4180-F)" (May 16, 2019), https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-and-part-d-drug-pricing-final-rule-cms-4180-f.
12. Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, § 119 (2021) (to be codified at 42 U.S.C. § 1395w–104).
13. 86 Fed. Reg. at 5950.

14. CMS, "Part D Payment Modernization Model: Request for Applications for CY 2022," https://innovation.cms.gov/media/document/partd-payment-modernization-cy22rfa.
15. 86 Fed. Reg. 5864, 5955 (Jan. 19, 2021).
16. The final rule clarifies that the enrollment-weighted QBP rating calculations use enrollment figures from November in the year that the Star Ratings are released. 86 Fed. Reg. at 5931.
17. *Id.* at 5921-26.
18. *Id.*
19. *Id.* at 5904-12.
20. *Id.* at 5895.
21. *Id.* at 5891-94.