MARKET ACCESS HOT TOPICS NEWSLETTER

A CMS Proposed Rules Special Edition

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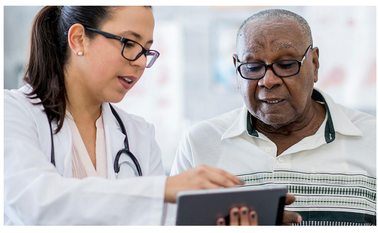

CY 2024 Outpatient Prospective Payment System (OPPS) Final Rule

Background: The Centers for Medicare & Medicaid Services (CMS) issued the calendar year (CY) 2024 OPPS final rule on November 2. This rule includes updates to Medicare payment policies and rates for Hospital Outpatient Departments (HOPDs) and Ambulatory Surgical Centers (ASCs). Additionally, it finalized enhanced procedures for hospitals to publicly disclose hospital charges to improve consumer pricing transparency and compliance. The final rule also included a policy to exclude biosimilars from the OPPS threshold packaging policy when their reference products are separately paid, meaning effective CY 2024, CMS will pay separately for biosimilars even if their per-day cost is below the threshold packaging amount (i.e., $135 per day in CY 2024).

Regeneron's Market Access Take: CMS has updated the OPPS and ASC rates by a 3.1% payment rate for hospitals complying with quality reporting requirements. CMS will continue pass-through payment status in CY 2024 for 42 drugs and biologicals that were approved for pass-through payment status with effective dates beginning between April 1, 2022, and October 1, 2023, while 25 drugs and biologicals, including EVKEEZA®, will have pass-through payment status expire by December 31, 2024. Concurrently, the biosimilar packaging policy finalized in the rule demonstrates CMS' continued interest in implementing payment changes that encourage biosimilar uptake/adoption and cost-effective alternatives to reference biologics.

340B Final Rule to Remedy Underpayment

Background: CMS reduced hospital reimbursement rates for 340B-acquired drugs/biologicals to average sales price (ASP) – 22.5% (as opposed to ASP + 6%) between 2018-2022. In June 2022, the Supreme Court ruled that the 340B payment cuts CMS implemented were invalid as the Agency lacked the appropriate authority to make such payment changes. Accordingly, CMS reverted to its previous payment methodology for 340B-acquired drugs (i.e., ASP + 6%). Additionally, the Supreme Court required CMS to craft a remedy to compensate hospitals for the 2018-2022 time period during which they were reimbursed for 340B-acquired drugs/biologicals at the reduced rate of ASP – 22.5%.

On November 2, the CMS released a final rule detailing how the Agency will remedy 340B underpayments between 2018 and 2022. Under the final rule, CMS finalized the following policies:

- CMS will issue a one-time lump-sum payment to each eligible 340B hospital to reimburse them for the money they were owed due to the 340B reimbursement cut. The total amount CMS will distribute to all eligible 340B hospitals is $9B.
- To maintain budget neutrality, CMS will offset payments for **non-drug items and services** by reducing their reimbursement by 0.5% starting in calendar year (CY) 2026. CMS estimated that hospitals were paid $7.8 billion more for non-drug items and services during the 2018-2022 time period than they would have been paid in the absence of the 340B payment policy. Thus, CMS expects to reduce payment for non-drug items and services by 0.5% starting in 2026 for approximately 16 years, as they estimate that to be the amount of time it will take to offset the $7.8 billion amount in full.

Regeneron's Market Access Take: Although eligible 340B hospitals will benefit from substantial upfront payments, the sustained reduction in reimbursement for non-drug services may prompt changes in hospital expenditure and consequently impact sales and market strategies. While hospital stakeholders were pleased with CMS' decision to issue a one-time lump sum payment to eligible 340B covered hospitals, they were deeply disappointed by CMS's decision to cut hospitals' Medicare payment for non-drug items and services.

Inflation Reduction Act (IRA) "State of the State"

Background: On August 21, CMS issued draft guidance regarding the Medicare Part D Prescription Payment Plan (MPPP), commonly known as out-of-pocket smoothing that allows Part D enrollees to pay their out-of-pocket (OOP) costs throughout a calendar year vs. having to meet their OOP cost obligations in the beginning months of each year. The guidance outlines requirements for Part D plan sponsors, with additional program details expected in early 2024. The following week, on August 29, CMS published a list of 10 Part D drugs earmarked for negotiation during the initial price applicability year (IPAY) in 2026.

Regeneron's Market Access Take: CMS actively guides the implementation of the MPPP, encompassing billing, elections, and the protection of beneficiary interests. CMS will provide final guidance on the operationalization of this program in early 2024 and draft guidance on how stakeholders must engage patients, related to this new benefit option that will first be implemented in the 2025 plan year. In parallel, CMS selected ten drugs, initiating the negotiation phase for IPAY 2026. These drugs span the therapeutic landscape for cardiovascular disease, autoimmune conditions, diabetes, and chronic kidney disease, forming competitive categories. Several manufacturers have filed lawsuits alleging that the drug price negotiation provisions in the IRA violate the manufacturers' First and Fifth Amendments of the US Constitution. Regeneron may want to evaluate access strategies considering how Part D plans and PBMs aim to cover and handle products at the Maximum Fair Price (MFP). In the broader therapeutic area, Regeneron may want to evaluate selected competitors' evolving Part D market strategies, pinpointing access risks or opportunities for non-selected products, which may assist with contracting strategies and broader lifecycle planning.ELP Copays Act, for further clarification on copay accumulator policies. Further, Regeneron should monitor use of accumulator programs against its products as these programs represent significant access and affordability hurdles for patients.

DC District Court Ruling: 2021 Notice of Benefit and Payment Parameters (NBPP) and Copay Accumulators

Background: On September 29, the US District Court nullified a federal rule letting specified plans and Pharmacy Benefit Managers (PBMs) exclude manufacturer copay assistance from beneficiary cost-sharing calculations. The Court struck down the 2021 rule stating the US Department of Health & Human Services (HHS) implemented contradictory interpretations of "cost sharing" in statute and remanded to the agency to provide consistent interpretation. However, on November 28, HHS initiated an appeal to the United States Court of Appeals for the DC Circuit. Concurrently, the federal government also filed a motion seeking clarification on the scope of the Court's September 29 decision. Specifically, HHS stated it did not intend to take corrective action against plans for excluding copay assistance from annual cost-sharing calculations and sought the Court's confirmation that it understood the scope of the decision. HHS also stated its intent to provide clarification of its interpretations of "cost sharing" in future rulemaking

Regeneron's Market Access Take:
The Supreme Court will now address HHS's appeal as the District Court addresses HHS' motion to clarify. HHS indicates that it will fulfill the District Court's request to update the definition of "cost-sharing" in future rulemaking. However, the Court's statement that it will not act against issuers and plans is likely to inform the implementation of copay accumulator programs during the period before such rulemaking is finalized. Regeneron should monitor HHS rulemaking, as well as Congressional discussion of legislation such as the HELP Copays Act, for further clarification on copay accumulator policies. Further, Regeneron should monitor use of accumulator programs against its products as these programs represent significant access and affordability hurdles for patients.

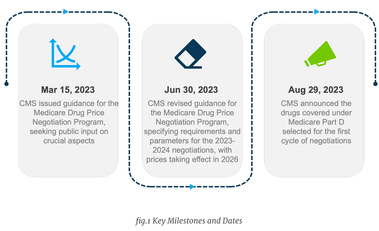

fig.1 Key Milestones and Dates

CMS Releases 2024 Medicare Advantage Plan Star Ratings

Background: CMS publishes the Medicare Advantage (Medicare Part C) and Medicare Part D Star Ratings each year to measure the quality of health and drug services received by consumers enrolled in Medicare Advantage (MA) and Prescription Drug Plans (PDPs or Part D plans). The Star Ratings system helps Medicare consumers compare the quality of Medicare health and drug plans being offered so they are empowered to make the best healthcare decisions for them. CMS released the 2024 Medicare Advantage and Medicare Part D Star Ratings on October 13, which show that the number of MA-PD contracts with a rating of 4 stars or higher decreased from 260 (72.1% of enrollment) in 2023 to 229 (74% of enrollment) in 2024, with the number of 5-star plans falling from 57 (21.87% of enrollment) to 31 (6.96% of enrollment).

Regeneron's Market Access Take:
The average Star Rating for Medicare Advantage Prescription Drug plans (MA-PDs) was 4.04, slightly below the previous year's 4.14, reflecting the impacts of CMS policies. Of note, 31 MA-PD contracts had five Stars in 2024, nearly half the number of plans that earned five stars in 2023 (i.e., 57 plans). Although the average Star Rating for MA-PDs decreased, the percentage of enrollees in MA-PDs with at least 4 Stars increased from 72% to 74%. Beneficiaries in higher-rated plans typically have better health outcomes and report higher satisfaction. These reduced ratings may impact plan benefits for 2025 because MA-PD plans will use 2024 Star Ratings in their 2025 bids to determine eligibility for quality bonus payments. We anticipate that plans, especially ones facing a Star rating decline, will be evaluating value-based contracts to ensure incentives for performance are aligned with Star measures, as well as reviewing plan benefit design to ensure adequate return on investment (ROI) on benefits offered to patients. In addition, the decrease in the Star Ratings tied to changes in CMS' methodology may lead to calls for policy changes, particularly concerning how CMS addresses outliers in determining the cut points used to assign Star Ratings.

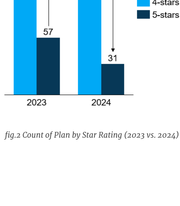

fig.2 Count of Plan by Star Rating (2023 vs. 2024)