Issue Brief

FEDERAL ISSUE BRIEF

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CMS Proposes "Remedy" for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022

The Centers for Medicare & Medicaid Services (CMS) have issued a proposed rule that "describes the agency's proposed actions to comply with the remand from the district court to craft a remedy in light of the United States Supreme Court's decision in American Hospital Association v. Becerra, 142 S. Ct. 1896 (2022), relating to the adjustment of Medicare payment rates for drugs acquired under the 340B Program from calendar year (CY) 2018 through September 27th of CY 2022."

A copy of the 60-page proposal is currently available at: https://public-inspection.federalregister.gov/2023-14623.pdf. The rule is scheduled for publication on July 11. A 60-day comment period ending September 5, 2023 is provided.

In the CY 2018 outpatient prospective payment system (OPPS) final rule, CMS finalized its proposal to adjust the payment rate for separately payable drugs (other than drugs with pass-through payment status and vaccines) acquired under the 340B Program from Average Sales Price (ASP) plus 6% to ASP minus 22.5%.

CMS noted that critical access hospitals are not paid under the OPPS, and therefore were not subject to the OPPS 340B drug payment adjustment policy. CMS also exempted rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals from the payment adjustment change.

Proposal to Remedy Payment Adjustment for 340B-Acquired Drugs from CY 2018 through September 27th of CY 2022

CMS describes different remedy options and aspects of alternative options.

Proposed Remedy (Page 19)

CMS says it "believes that the best way to remedy our payment policy for 340B-acquired drugs for the period from CY 2018 through September 27th of CY 2022, which the Supreme Court found unlawful, would be to make one-time lump sum payments to affected 340B covered entities calculated as the difference between what they were paid for 340B drugs (ASP minus 22.5% or an adjusted WAC or AWP amount) during the relevant time period (from CY 2018 through September 27th of CY 2022) and what they would have been paid had the 340B payment policy not applied."

Estimated Reduction in Drug Payments to Affected 340B Covered Entity Hospitals in CY 2018 through September 27, 2022 (Page 22)

CMS estimates 1,649 340B covered entity hospitals were paid at the 340B payment rate for CY 2018 through September 27th of 2022, rather than the default rate, which is generally ASP plus 6%. CMS estimates that these hospitals received approximately $10.5 billion less in 340B drug payments (including money that would have been paid by Medicare and money that would have come from beneficiaries as copayments) than they would have for drugs provided in CY 2018 through September 27th of 2022 had the 340B policy not been implemented.

CMS estimates that 340B providers have already received $1.5 billion in remedy payments through reprocessed claims for 340B drugs provided from January 1, 2022, through September 27, 2022. Since

$1.5 billion of the total $10.5 billion. CMS estimates the remaining remedy amount that affected 340B covered entity hospitals have not yet received as a result of this policy is $9.0 billion

CMS illustrates the proposed process for calculating and paying an affected 340B covered entity hospital's additional lump sum OPPS payments furnished from CY 2018 through September 27th of CY 2022 in the following example.

Based on claims data from CY 2018 through September 27th of CY 2022 for which those claims have been processed and OPPS payments already made, CMS would calculate that a particular 340B-covered entity hospital would have been paid an estimated $10 million for 340B drugs had that 340B payment policy not been in effect during that time period.

Then, based on claims data for the same hospital from the same time period, CMS would calculate that the hospital was actually paid $7.31 million for 340B drugs from CY 2018 through September 27th of CY 2022. The difference between these two amounts – $2.69 million – would be the amount of the additional lump sum payment the 340B covered entity hospital would receive.

Another method to estimate the total amount an affected 340B covered entity hospital would have been paid had the 340B payment policy not been in effect (X) is to use the following formula:
$X = (Y/0.775)*1.06$

Where Y is the total amount received under the 340B policy from CY 2018 to September 27th of CY 2022. In this example, the Y is $7.31 million. Therefore, ($7.31 million/0.775)*1.06 = $10 million. The lump sum payment would be $10 million minus $7.31 million, which equals $2.69 million. CMS solicits comment from the public on its proposed calculation methodology.

OPPS Non-Drug Item and Service Payments from CY 2018 through CY 2022 (Page 28)

To ensure budget neutrality for CY 2023 OPPS payment rates as required by statute, CMS finalized a reduction of 3.09% to the 2023 OPPS conversion factor. "This 3.09% reduction for CY 2023 offsets the prior increase of 3.19% that was applied to the conversion factor when CMS implemented the 340B payment policy in CY 2018.

In order to offset "this prior increase for the CY 2023 rule, we had to make a downward adjustment to the conversion factor, which involved dividing 1 by 1.0319, which equals 0.9691."

"And 1 minus 0.9691 equals 0.0309, which is where we derived the 3.09% reduction to the conversion factor for CY 2023."

CMS proposes to reverse the accompanying increase in the conversion factor for CYs 2018 through 2022 that was solely attributable to the adoption of the 340B payment policy. In order to reduce the burden on providers of offsetting this amount required to maintain budget neutrality, estimated to be $7.8 billion, CMS is proposing to implement this adjustment prospectively. (Page 31)

Beginning in CY 2025, CMS would reduce all payments for non-drug items and services to all OPPS providers, except new providers, by 0.5% each year until the total offset is reached (approximately 16 years). (Page 37)

Comment

While this is a relatively short rule, it is still complex and presumes many assumptions and estimates. CMS' budget neutrality adjustments in the proposed CY 2024 Home Health PPS shows how CMS estimates do not always reflect actual results.

What is peculiar is the method CMS proposes to recapture the budget neutrality increase that was made to the OPPS conversion factor in 2018 to increase payments for non-drug items and services as a result of the decrease in 340B payments. On one hand recapturing payments over 16 years is certainly helpful, but 16 years is an awful long-time to keep playing with this item.