MEDPAC | Medicare Payment Advisory Commission

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September 1, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244–8010

Attention: CMS-1793-P

Dear Ms. Brooks-LaSure:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS's) proposed rule entitled "Medicare program; hospital outpatient prospective payment system: Remedy for the 340B-aquired drug payment policy for calendar years 2018–2022," *Federal Register*, no. 131, pp. 44078–44096 (July 11, 2023). We appreciate CMS's ongoing efforts to administer and improve Medicare's outpatient hospital payment policies, particularly given the many competing demands on the agency's staff. We hope that our comments are helpful in these endeavors.

Background

In calendar year (CY) 2018, CMS implemented a policy that reduced the outpatient prospective payment system (OPPS) payment rates for most separately payable non–pass-through drugs that hospitals obtained through the 340B Drug Pricing Program from the default rate of average sales price plus 6 percent (ASP + 6 percent) to ASP – 22.5 percent. The purpose was to more closely align the OPPS payment rates for 340B drugs with the 340B hospitals' drug acquisition costs. To satisfy budget-neutrality requirements under the Social Security Act, CMS increased the payment rates for all covered OPPS nondrug items and services by 3.19 percent. CMS executed the increase in payment rates through a 3.19 percent increase in the OPPS conversion factor.

Hospital stakeholder organizations challenged the policy of reduced payment rates for 340B drugs in court, arguing that it violated parts of Section 1833 of the Social Security Act. The United States Supreme Court agreed to rule on this case. On June 15, 2022, the Supreme Court ruled in the hospitals' favor that the reduced payment rates for the 340B drugs violated parts of the Social Security Act.

The Supreme Court remanded this case to the District Court for the District of Columbia to determine how the reduced payment rates for 340B drugs and the increased payment rates for nondrug items and services that CMS implemented in CY 2018 should be remedied. On September 28, 2022, the District Court vacated the lower payment rates for 340B drugs for the remainder of CY 2022, which meant that most of the drugs obtained through the 340B Program would be paid at a rate of ASP + 6 percent for the remainder of CY 2022. However, the increased payment rates for nondrug items and services remained in place through the end of CY 2022. On January 10, 2023, the District Court issued a second decision that gave CMS the opportunity to determine a remedy that would fully offset the reduced OPPS payment rates for 340B drugs from CY 2018 through September 27, 2022, and the increased OPPS payment rates for nondrug items and services from CY 2018 through CY 2022.

Remedy for the 340B-acquired drug payment policy for CY 2018 through September 27, 2022

In this proposed rule, CMS estimates that, in aggregate, the 340B drug payment policy from CY 2018 through September 27, 2022, lowered OPPS payments to 340B hospitals by $10.5 billion. CMS also estimates that the increased OPPS payment rates for nondrug items and services from CY 2018 through CY 2022 increased payments to all OPPS hospitals by $7.8 billion. Note that when CMS implemented the reduced payment rates for 340B drugs in CY 2018, the agency intended for the magnitude of the aggregate reduced payments for 340B drugs to equal the magnitude of the aggregate increased payments for all nondrug items and services. However, the 340B hospitals provided more 340B drugs than CMS had estimated, so the aggregate reduced payments for the 340B drugs were larger than the aggregate increased payments for nondrug items and services.

In this proposed rule, CMS asserts that the remedy for the reduced payments for 340B drugs must be budget neutral. Therefore, the agency proposes to provide $10.5 billion in remedy payments to 340B hospitals and to reduce OPPS payments by $7.8 billion for nondrug items and services to all OPPS hospitals. The agency proposes to provide the remedy payments for 340B drugs and to reduce payments for all nondrug items and services through two separate, distinct mechanisms.

Remedy for reduced 340B drug payments

CMS has already taken a step to address the $10.5 billion in remedy payments for 340B drugs by reprocessing most OPPS claims for 340B drugs that had dates of service of January 1, 2022, through September 27, 2022. This claims reprocessing has provided 340B hospitals with $1.5 billion in remedy payments.

To address the remaining $9.0 billion in remedy payments for 340B drugs, CMS proposes to provide one-time lump-sum payments to each affected 340B hospital.[1] These lump-sum payments would equal the difference between what the hospitals would have been paid if the 340B payment policy had not been implemented and what the hospitals were actually paid under the 340B policy

[1] CMS estimates that 1,649 340B hospitals were affected.

over the relevant period. CMS emphasized that the lump-sum payments would come entirely from the Medicare program and beneficiaries would have no cost-sharing obligations. CMS also stated that under this proposal the lump-sum payments would occur at the end of CY 2023 or the beginning of CY 2024.

Remedy for overpayments for nondrug items and services

To comply with budget-neutrality requirements in the Social Security Act, CMS proposes a method to offset the $7.8 billion in increased OPPS payments for nondrug items and services from CY 2018 through CY 2022. CMS proposes a 0.5 percent decrease to the OPPS conversion factor that will be in place until the $7.8 billion offset is reached. Important details of this proposal include the following:

- The 0.5 percent reduction to the OPPS conversion factor would begin in CY 2025.
- This would be a one-time reduction rather than a cumulative reduction to the OPPS conversion factor. That is, the applicable OPPS conversion factor will be 0.5 percent lower than it otherwise would have been in each year, until the entirety of the $7.8 billion in overpayments has been recouped.
- CMS estimates it would take 16 years for the 0.5 percent reduction to recoup the budget-neutral amount of $7.8 billion.
- Hospitals that enrolled in Medicare after January 1, 2018, would not be subject to the reduced OPPS payment rates because those hospitals did not receive the full benefits of the increased OPPS payment rates from CY 2018 through CY 2022.

Comment

In addition to the proposed remedy to the 340B policy, CMS considered alternative remedies.[2] All of the remedies considered by CMS raise issues, but in our view, CMS chose the best alternative. Therefore, the Commission supports CMS's proposal. CMS is likely to receive comments against the budget-neutral feature of this proposal but, since the reduced 340B payments were implemented on a budget-neutral basis in CY 2018, we assert that any remedy should likewise be budget neutral.

Although the Commission is supportive of CMS's proposed remedy, we have three concerns. First, CMS's proposed remedy would provide $9.0 billion in remedy payments to 340B hospitals in late CY 2023 or early CY 2024, coupled with a small 0.5 percent reduction in OPPS payment rates for nondrug items and services that will begin in CY 2025 and slowly produce a budget-neutral result after 16 years. The difference between the rate at which CMS proposes to make the lump-sum

[2] Under one alternative that CMS considered, CMS would have reprocessed all OPPS claims from CY 2018 through September 27, 2022. Under a second alternative, CMS would have calculated for each hospital the difference between the additional revenue from the increased payment rates for nondrug items and services and the reduced payment rates for 340B drugs. Depending on whether this difference is positive or negative, the hospital would either make a lump-sum payment to the Medicare program or receive a lump-sum payment from the Medicare program.

remedy payments and the slow rate at which overpayments for nondrug items and services would be recouped could cause an increase in Medicare Part B premiums and put a strain on Medicare Part B's finances in the short term. Eventually, this issue will be resolved as the 0.5 percent reduction in the payment rates for nondrug items and services slowly offsets the increased rates from CY 2018 through CY 2022. However, it would be preferable to set the reduction in payment rates so that it is aligned with the remedy payments such that the effects on the Part B premium and Medicare Part B's finances are mitigated.

A second concern is that CMS's proposal to reduce OPPS payment rates for nondrug items and services beginning in CY 2025 to offset prior overpayments could cause inequities among hospitals. It is likely that, for some hospitals, the drop in revenue from the proposed 0.5 percent reduction in OPPS payment rates will be larger than the additional revenue they received from the increased payments from CY 2018 through CY 2022. For other hospitals, the drop in revenue from the reduced payment rates will be smaller than the additional revenue from the increased payment rates. CMS could consider ways to reduce these inequities if their magnitude is sufficient to warrant it. One possibility is that CMS could require hospitals to include on their cost reports the revenue gained from CY 2018 through CY 2022 and the revenue decrease from the 0.5 percent reduction in OPPS payment rates. CMS could then use the cost reports to make reconciliations. If a hospital's cost report indicates that the reduced payments for nondrug items and services are not lowering a hospital's revenue enough to offset the additional revenue that the hospital received through the increased payment rates from CY 2018 though CY 2022, CMS could require the hospital to make a payment to Medicare. Conversely, if a hospital's cost report indicates that the reduced payments for nondrug items and service are lowering a hospital's revenue by too much, Medicare could make a payment to the hospital. This approach has similarities to the "hold-harmless" payments that are used for the 11 cancer hospitals exempt from the inpatient prospective payment system.

A final concern is that the proposal to exempt hospitals that enrolled in Medicare after January 1, 2018, from the reduced OPPS payment rates will cause more inequities among hospitals. The exempted hospitals derived some financial benefit from the increased payment rates from CY 2018 to CY 2022 but would not face the reduced payment rates that CMS would implement to obtain budget neutrality. The Commission believes these hospitals should be required to face reduced payment rates for a period of time that is commensurate with the period of time they benefitted from the increased payment rates. For example, if a hospital began its Medicare participation on January 1, 2020, the hospital would have benefitted from the increased payment rates for three years (CY 2020, CY 2021, and CY 2022), which is 60 percent of the time that the increased payment rates were in place. For this hospital, CMS could require that the reduced payment rates would apply for 60 percent of the time that CMS expects the reduced payments to be in place (9.6 years if the reduced payments are in place for the proposed 16 years).

Conclusion

MedPAC appreciates your consideration of these issues. The Commission values the ongoing collaboration between CMS and MedPAC staff on Medicare policy, and we look forward to

continuing this relationship. If you have any questions regarding our comments, please contact Paul B. Masi, MedPAC's Executive Director, at 202-220-3700.

Sincerely,

Michael Chernew, Ph.D.
Chair

MC/dz/pm