

CMS PROPOSES \$9 BILLION LUMP SUM REMEDY FOR HOSPITALS IN THE 340B DRUG PROGRAM

July 12, 2023

On July 11, 2023, the Centers for Medicare and Medicaid Services (“CMS”) released its proposed rule that would provide a \$9 billion lump sum remedy for hospitals in the 340B Drug Pricing Program, a special drug-discount program. This proposal came after the U.S. Supreme Court found that CMS had not obtained enough information to proceed with its reimbursement reductions for Calendar Years 2018-2022 and held those payment rates invalid.

BACKGROUND

Generally, payment rates for drugs are established under section 1847A of the Social Security Act, which typically sets a default rate of the average sales price (“ASP”) plus 6 percent. Under the 340B Drug Pricing Program, participating covered entities may purchase certain covered outpatient drugs at discounted prices from drug manufacturers. The statutory default rate of ASP plus 6 percent was used for Medicare reimbursements to the covered entities who acquired drugs under the 340B Drug Pricing Program until 2018, when CMS adopted a new policy of paying the entities the ASP price minus 22.5 percent.

Extensive litigation over the new policy began in 2018. In the Supreme Court decision, *American Hospital Association v. Becerra*, 14 S. Ct. 1896 (2022), the Court determined that CMS may not vary payment rates for outpatient prescription drugs by hospital group if it has not conducted a survey of hospitals’ acquisition costs. On remand, the District Court held that the reimbursement rate for 340B drugs must be vacated for the remainder of 2022 and tasked CMS with determining the proper remedy for addressing the reduced payment amounts to affected hospitals from 2018 through 2022.

After estimating that the affected hospitals received roughly \$10.5 billion less in drug payments than they would have without the new policy, CMS got moving on a solution. With about \$1.5 billion of the \$10.5 billion in losses already repaid to affected 340B providers, CMS drafted a proposal to repay the remaining \$9 billion to the 1,600 affected hospitals.

THE PROPOSED RULE

CMS has determined that the best remedy is a one-time lump sum payment. The payment will be calculated “as the difference between what the affected 340B covered entity hospitals were paid for 340B drugs during the relevant period (from CY 2018 through September 27 of CY 2022) and what they would have been paid had the payment policy not applied.

If this method of payment and rule is finalized, CMS has noted that 340B covered entity hospitals may expect payment at the end of 2023 or beginning of 2024. CMS has proposed that it will make the appropriate payment to each covered entity by issuing instructions to the entity's Medicare Administrative Contractor ("MAC"). The instructions will likely be in the form of a Change Request or Technical Direction Letter. Within 60 days of receiving the instruction, the MAC will issue payment to the entity.

As part of the policy that went into effect in 2018, CMS also increased payments for non-drug items and services. These increases were made in effort to maintain budget neutrality, which is required by statute. As a result of the increases, CMS estimates that hospitals were paid \$7.8 billion more for non-drug items and services from 2018 through 2022 than they would have without the policy. CMS is now proposing to make a corresponding offset, as if the 2018 policy never went into effect. This goal will be achieved by reducing payments for non-drug items and services by 0.5 percent each year until the total offset is reached. CMS estimates that repaying the roughly \$7.8 billion payment increase for non-drug items and services from 2018 to 2022 will take roughly 16 years. CMS proposes that any hospital enrolled in Medicare after January 1, 2018, be exempt from the prospective rate reduction. This exemption is proposed because these hospitals would not have received the full benefit of the increased payment for non-drug items and services from 2018 through 2022.

CONCLUSION

The proposed rule will have a 60-day comment period ending September 5, 2023. For more information on the proposed remedy repayment amounts for specific hospitals, visit <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps>.

For further background and reasoning for the proposed rule, please read the [proposed rule](#) in its entirety.

CONTACT US

For questions and assistance on CMS's proposed rule, please contact a member of Hancock Daniel's [Compliance](#) team.

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