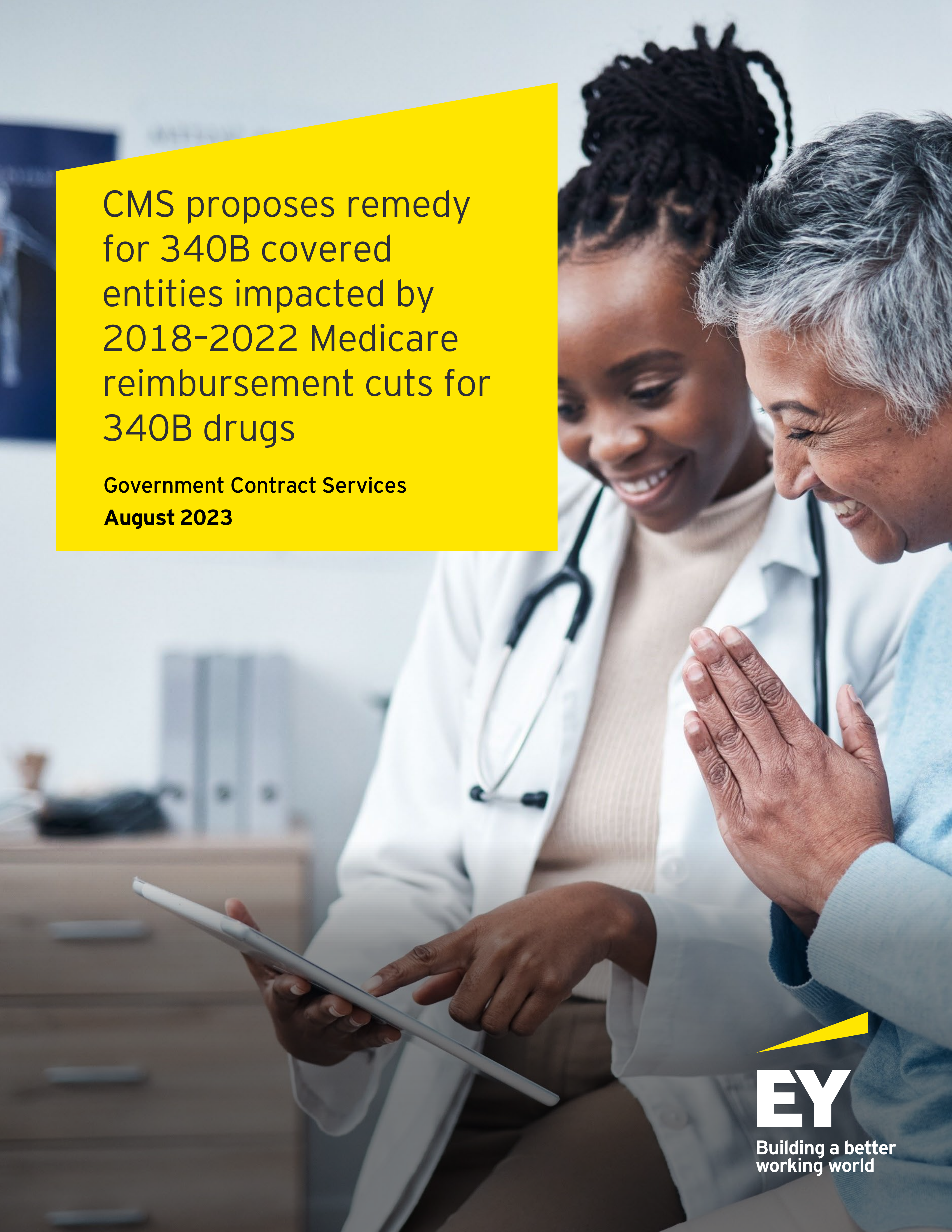

CMS proposes remedy for 340B covered entities impacted by 2018-2022 Medicare reimbursement cuts for 340B drugs

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Building a better working world

Executive summary

The Centers for Medicare & Medicaid Services (CMS) recently released a proposal to compensate 340B covered entities for years of underpayments that were ultimately held unlawful by the federal courts. CMS is proposing to compensate covered entities with lump-sum payments in late 2023 or early 2024, which would be partially offset by modest reimbursement reductions to all Outpatient Prospective Payment System (OPPS) providers over an estimated 16-year period. The CMS proposed rule is open for comments until September 5, 2023, during which time providers have the opportunity to provide feedback to CMS before the rule is finalized.

Detailed discussion

As discussed in the proposed rule, in calendar years (CY) 2018 through 2022, Medicare reimbursement rates were lower for 340B drugs than for non-340B drugs. In 2022, the Supreme Court held that this reimbursement practice was unlawful, and the federal courts subsequently ordered CMS to make restitution. CMS ended its practice of reduced 340B drug reimbursements in 2022, and on July 7, 2023, CMS issued its proposed method for putting 340B covered entities as closely as possible to where they would have been absent the policy the Supreme Court determined to be unlawful.

There are two primary components to CMS's proposal:

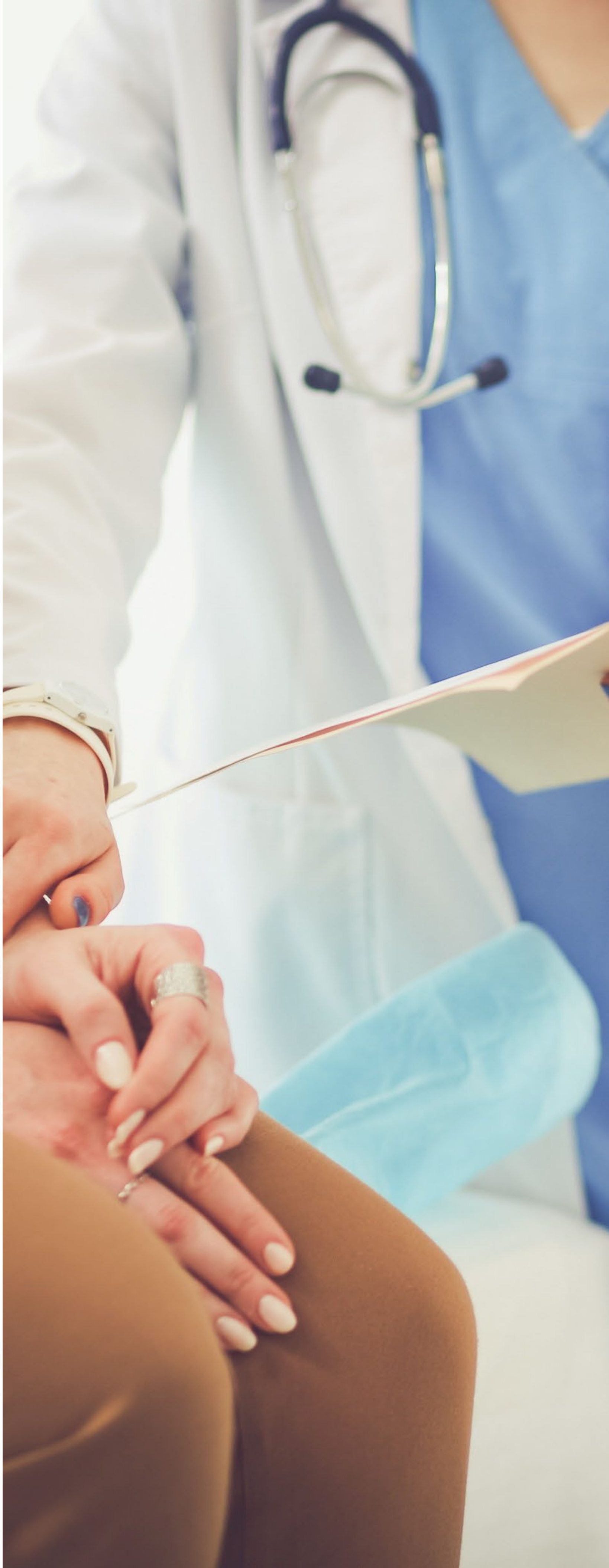
1. Lump-sum payments to 340B hospitals approximately equal to the total outstanding underpayments
2. OPPS rate changes to offset the lump-sum payments

Lump-sum payments

CMS calculated individual lump-sum payments for each affected 340B hospital by identifying drug charges that CMS reimbursed at the reduced rate for each 340B hospital, calculating the amount that the hospitals would have received absent the reduced reimbursement and then subtracting what the hospitals actually received in order to determine the total amount required to make the hospital whole. If the rule goes into effect as proposed, CMS expects to pay affected 340B covered entities these lump-sum payments at the end of CY 2023 or the beginning of CY 2024. CMS has published the individual lump-sum calculations for each covered entity on its website.

Non-drug reimbursement rate decrease

CMS is obligated by statute to maintain budget neutrality for each fiscal year of the Medicare program. In CYs 2018 through 2022, CMS used the savings it realized through reduced reimbursement for 340B drugs to increase the conversion factor it applies to reimbursement rates for non-drug items and services to all OPPS hospitals. Because CMS factored reduced reimbursement for 340B drugs into its budget and used that savings to increase reimbursement for other services, CMS's budget for those years will no longer be neutral once it pays 340B covered entities for drugs charged in those years at the new higher rate. CMS's primary options for achieving neutrality for those years were to (1) claw back that increased reimbursement retroactively or (2) offset it with lowered reimbursement prospectively. To minimize the impact on hospitals, CMS opted to reduce payments by a small amount on a go-forward basis until reduced payments offset the amount of lump-sum repayments. Because CMS used the savings from reduced reimbursement for 340B drugs to increase reimbursement for non-drug items and services, CMS intends to pay for the 340B lump-sum payments by prospectively decreasing reimbursement for non-drug items and services.



CMS estimates that providers received approximately $10.5 billion less in revenue for 340B drugs in CYs 2018 through 2022 than they would have if they had not implemented the reduced reimbursement rate. CMS allowed affected covered entities to resubmit claims with charges for separately reimbursable 340B drugs in 2022 and, as a result of that policy, estimates that CMS has already repaid approximately $1.5 billion of the estimated $10.5 billion. However, in projecting budgets for CYs 2018 through 2022, CMS underestimated the amount it would save on the reduction and, as a result, saved more on 340B drugs than it anticipated. The savings CMS realized from this underestimate exceeded the additional amount CMS spent on non-drug items and services, which CMS estimates to be $7.8 billion. Because CMS spent less than the amount it saved on reduced 340B reimbursement, CMS determined that it needs to realize only $7.8 billion in program savings in order to achieve budget neutrality.

Because CMS wants to minimize the impact of reduced reimbursement for non-drug items and services, CMS is proposing a modest annual reduction in the reimbursement rate for non-drug items and services until such time that this policy has resulted in $7.8 billion in total program savings. CMS is proposing that the reduced non-drug reimbursement go into effect starting calendar year 2025 and projects that it will take approximately 16 years to fully recoup the $7.8 billion. Of note, CMS only proposes to apply the rate decrease to hospitals with CMS certification numbers beginning on or earlier than January 1, 2018.

It is further important to note that the estimated 16-year timeline is only a projection based on the best information available to CMS now. What is of actual importance is recouping the full $7.8 billion, which could take more or fewer than 16 years depending on actual Medicare spending levels. CMS also anticipates that the modest reimbursement rate reduction amount will be more modest still in the final year in which the adjustment applies, needing only to recoup the final balance of the $7.8 billion.

Actions you should consider as a 340B covered entity

- Review the proposed rule and submit any comments to CMS by September 5, the deadline for comment submission.
- Consider how you will pressure test the lump-sum payment amount identified by CMS as owed to your institution.
- Consider as an organization how you will budget for the lump-sum payment and projected reductions in Medicare reimbursement for non-drug items and services in the future.

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