Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022
Proposed Rule Summary

The Centers for Medicare & Medicaid Services (CMS) released a proposed rule (CMS-1793-P) on July 7, 2023 that describes the agency's proposed actions to craft a remedy relating to the adjustment of Medicare payment rates for drugs acquired under the 340B Program from calendar year 2018[1] through September 27, 2022 following a remand from the United States District Court for the District of Columbia (the District Court) and the United States Supreme Court's decision in *American Hospital Association v. Becerra*. The proposed rule will be published in the July 11, 2023 issue of the *Federal Register*. **The public comment period will end on September 5, 2023.** CMS indicates that the final rule will be published by September 27, 2023.

CMS is making the following proposals:

- Repay 340B hospitals for money owed from January 1, 2018 through September 27, 2022 through a lump sum payment less amounts already paid through claims reprocessing that occurred for services furnished between January 1, 2022 through September 27, 2022.
- Provide the repayment amount to hospitals inclusive of any additional beneficiary coinsurance and not allowing hospitals to collect additional coinsurance.
- Maintain budget neutrality for these additional payments to 340B hospitals through a -0.5 percentage point adjustment to the annual outpatient prospective payment system (OPPS) update that applies to non-drug OPPS services beginning January 1, 2025 until such time as the full amount of the additional payment is recouped (currently estimated at 16 years).

Addendum AAA to the proposed rule is a list of 340B hospitals and the lump sum payment they would receive if this rule were to be finalized. Addendum BBB of the proposed rule is a list of hospitals enrolled after January 1, 2018 that would be exempt from the 0.5 percent adjustment to the OPPS update under CMS' proposal. Both addenda may be found at: https://www.cms.gov/medicare/medicare-fee-service-payment/hospitaloutpatientpps/hospital-outpatient-regulations-and/cms-1793-p.

I. Background

CMS provides the regulatory and litigation history regarding its policy to pay for drugs acquired under the 340B program at average sales price (ASP)-22.5 percent rather than ASP+6 percent, its otherwise applicable default methodology. In summary:

- Beginning in 2018, CMS adopted a policy to pay for drugs acquired under the 340B program at ASP-22.5 percent to approximate a minimum average discount for 340B drugs based on findings of the General Accountability Office and the Medicare Payment Advisory Commission that hospitals acquire drugs at a significant discount under the 340B program. CMS made the reduction in payment for drugs acquired under the 340B program budget

[1] Henceforth in this document, a year is a calendar year unless otherwise indicated.

neutral by increasing payments for non-drug OPPS services by 3.19 percent or approximately $1.6 billion. This adjustment remained on the rates paid for non-drug OPPS services through September 27, 2022 and was not updated for changes to utilization of 340B drugs.

- On December 27, 2018, the District Court concluded that the Secretary lacked authority to bring the default rate in line with average acquisition cost.[2] While the initial decision applied only to CMS' 2018 policy, the District Court later made the same finding for CMS' 2019 policy.[3] The policy continued while CMS pursued its appeal.
- On June 15, 2022, the Supreme Court held that the Secretary may not vary payment rates for drugs and biologicals among groups of hospitals in the absence of having conducted a survey of hospitals' acquisition costs.[4]
- On September 28, 2022, the District Court vacated CMS' 340B reimbursement rate for the remainder of 2022 without requiring any offset for budget neutrality.[5] In response to this order, CMS changed its payment systems to make payment at ASP+6 percent for claims received shortly after the District Court's order with a date of service after September 27, 2022. Some of CMS' contractors allowed for reprocessing of ALL 2022 claims at the revised ASP+6 percent rate.
- On January 10, 2023, the District Court issued a remand to CMS giving it the opportunity to determine the proper remedy for the reduced payment amounts to 340B hospitals under the payment rates in the final OPPS rules for 2018 through 2022.[6]

Effective January 1, 2023, CMS is making payments for all 340B acquired drugs at ASP+6 percent. CMS made this policy budget neutral by applying a -3.09 percent adjustment to all non-drug OPPS rates.[7]

II. Proposed Remedy Options for 2018 through September 27, 2022

A. Remedy Options Considered by CMS

1. Additional Payments to 340B Hospitals without a Budget Neutrality Adjustment

CMS considered providing 340B hospitals with additional drug payments for the period from January 1, 2018 through September 27, 2022 without a corresponding offset for budget neutrality. However, CMS believes that budget neutrality is required under sections 1833(t)(2)(E) and 1833(t)(14) of the Act when the budget neutrality adjustment would not be de minimis and is not expressly exempted by statute. CMS does not believe Congress intended the statute to permit regulated entities to achieve policy outcomes through litigation that would be

[2] American Hospital Association v. Azar, 348 F. Supp. 3d 62 (D.D.C. 2018)
[3] Am. Hosp. Ass'n v. Azar, 385 F. Supp. 3d 1 (D.D.C. 2019)
[4] 142 S. Ct. 1896 (2022)
[5] See Am. Hosp. Ass'n v. Becerra, 18-cv-2084 (RC), 2022 WL 4534617.
[6] Am. Hospital Ass'n v. Becerra, 18-cv-2084 (RC), 2023 WL 143337
[7] See 87 FR 71975. The original adjustment multiplied the OPPS conversion factor by 1.0319 (3.19 percent) so reversing the adjustment requires dividing the OPPS conversion factor by 1.0319 or 1/1.0319 or 0.9691 which equals a reduction of 3.09 percent.

statutorily unavailable to them through the regular rulemaking process—especially policy outcomes that increase total Medicare expenditures.

The proposed rule does acknowledge that CMS has not achieved budget neutral changes to OPPS payments in all circumstances. In situations that have not had any estimated impact on the OPPS conversion factor or that would otherwise have a de minimis impact, CMS has effectively rounded the estimated impact on expenditures to zero. In the case of the remedy payments for the 340B payment policy, CMS believes the amount is not de minimis and even if a budget neutrality adjustment is not statutorily required, one is warranted as a matter of sound public policy.

Even if the remedy rule were exempt from budget neutrality requirements as a matter of statutory interpretation, CMS indicates that it would still exercise authority under section 1833(t)(2)(E) of the Act to offset the extra payments made for non-drug items and services consistent with the agency's "longstanding inherent and common-law (and common-sense) recoupment authority." CMS proposes to adjust payments prospectively in order to provide a remedy for a previous unlawful payment decision.

2. Full Claims Reprocessing from 2018 through September 27, 2022

CMS rejects reprocessing of all claims with dates of service from January 1, 2018 through September 27, 2022 as unnecessarily burdensome. Reprocessing almost 5 years' worth of OPPS claims could take several years, resulting in some affected 340B covered entities having to wait multiple years to receive payment.

The proposed rule notes that the vast majority of 340B drug claims from 2022 have been reprocessed and paid at ASP+6 percent. As of this proposed rule, CMS estimates that $1.5 billion in remedy payments (including the Medicare beneficiary portions) have already been made to providers through reprocessed claims, or claims that had dates of service January 1, 2022 through September 27, 2022. CMS considers these reprocessed claims to be partially remedied indicating that for these claims to be fully remedied, payment for the non-drug item and service components would need to be reduced.

3. Aggregate Hospital Payments from 2018 Through September 27, 2022

Under this approach CMS would determine the aggregate amount due to or from each hospital from January 1, 2018 through September 27, 2022 based on the difference between the additional 340B payments owed to the hospital less the amount to be refunded as result of reversing the budget neutrality adjustment originally made in 2018. CMS rejected this approach as it would require immediate, and in many cases large, retroactive recoupments from the majority of OPPS hospitals and would impose a substantial, immediate burden on these hospitals as well as an uncertain impact on beneficiaries.

B. Proposed Remedy

1. Paying 340B Hospitals for the Retroactive Period (January 1, 2018 - September 27, 2022)

CMS proposes to make a one-time lump sum payment to each 340B hospital that would be the same as if CMS manually reprocessed claims for January 1, 2018 through September 27, 2022 at a rate of ASP+6 percent . The proposed rule indicates that CMS is establishing this policy using its rate-setting authority under section 1833(t)(14) of the Act and the equitable adjustment authority under section 1833(t)(2)(E) of the Act. To the extent CMS' proposal is retroactive, CMS is relying on its retroactive rulemaking authority in section 1871(e)(1)(A) of the Act.

Section 1871(e)(1)(A) of the Act prohibits the application of a substantive change in regulations to items and services furnished before the effective date of the substantive change unless, "such retroactive application is necessary to comply with statutory requirements" or the "failure to apply the change retroactively would be contrary to the public interest." Even if a retroactive rule were not necessary to comply with section 1833(t)(14) of the Act, CMS believes that failing to apply ASP+6 percent retroactively would be contrary to the public interest as it would leave the plaintiff 340B hospitals paid at a substantially lower rate.

The proposed rule indicates that 1,649 340B hospitals received approximately $10.5 billion less in payments than had Medicare paid these claims at ASP+6 percent. CMS believes that about $1.5 billion of this amount has already been paid to 340B hospitals for reprocessed claims with dates of service in 2022. The proposed rule indicates that CMS will update these amounts for claims submitted through September 27, 2023; the publication date for the final rule that corresponds to this proposed rule.

To determine the aggregate amount due to 340B hospitals, CMS determined the difference in payment for separately payable drugs at ASP-22.5 percent and ASP+6 percent where the claim included the "JG" modifier that was used to apply the payment adjustment for drugs acquired under the 340B program. Mathematically, CMS indicates this is the equivalent of dividing the ASP-22.5 percent payment by 0.775 (i.e., removing the 22.5 percent reduction in payment) and multiplying the result by 1.06 (i.e., providing the 6 percent additional payment). Where applicable, CMS used an analogous process if the drug was based on wholesale acquisition cost or average wholesale price.

CMS proposes to issue an instruction to the Medicare Administrative Contractors to issue a one-time lump sum payment within 60 calendar days. If this rule is finalized, CMS anticipates making the additional payments to 340B hospitals at the end of 2023 or the beginning of 2024. Addendum AAA to the proposed rule found at the hyperlink at the beginning of this summary shows how much each hospital would be due under CMS' proposal.

The proposed rule indicates that CMS would pay the hospital the full amount owed including additional beneficiary coinsurance while prohibiting the hospital from collecting the additional coinsurance from the beneficiary. CMS cites its equitable adjustment authority as the basis for including the beneficiary coinsurance payments in the amount paid to the hospital. According to CMS, the proposed policy is appropriate in this circumstance "because of the unprecedented

scope of the remedy in terms of the amount of money at issue; the number of services, beneficiaries, and claims affected; and the number of years that have passed between the claims and the remedy."

No interest will be included on the additional payments to 340B hospitals. CMS indicates that it does not have the authority to include interest on the additional payments.

2. OPPS Non-Drug Item and Service Payments from 2018 through 2022

Once it refunds payments to 340B hospitals, CMS indicates that it must recoup the additional payments made for non-drug OPPS services that were intended to make the reduction in drug payments budget neutral. Otherwise, hospitals will receive a windfall from having received these additional payments.

CMS proposes to calculate the amount paid from 2018 through 2022 for non-drug OPPS services by taking the spending in these years associated with HCPCS codes assigned status indicators J1, J2, P, Q1, Q2, Q3, R, S, T, U, V and dividing it by 1.0319 (the amount by which the conversion factor was increased during 2018 through 2022). Based on these factors, CMS is proposing to prospectively offset $7.8 billion in payments in order to maintain budget neutrality. The proposed rule indicates that the offset amount will include not just the money paid to hospitals but also the additional coinsurance paid by beneficiaries.

The $7.8 billion amount is less than the amount CMS will pay back to 340B hospitals because CMS did not update the budget neutrality adjustment from 2018 to 2022 to reflect higher savings from application of the 340B policy (e.g., if CMS had updated the budget neutrality adjustment as public commenters requested, hospitals would have been paid more for non-drug OPPS services during this period). Additionally, CMS' implementation of the District Court's September 27, 2022 order has already resulted in partial remedy for 2022 to 340B hospitals with no offset to non-drug OPPS services. The amount being refunded to 340B hospitals will also differ from the amount being recouped from hospitals through offsetting adjustments to non-drug OPPS services because of the gap between when the lump sum payment is being made and the reduction in prospective non-drug spending is being applied.

CMS proposes beginning in 2025, to reduce payments for non-drug items and services to all OPPS providers (except new providers that enrolled in Medicare beginning in 2018) by 0.5 percent each year until the total offset is reached (approximately 16 years). The proposed rule indicates that 2025 is an appropriate starting point because it will allow CMS to finalize the methodology, calculate and publish the payment rates derived from this policy and allow adequate time for impacted parties to assess and prepare for the new payment rates.

In past litigation, CMS questioned whether budget neutrality could be achieved by decreasing Medicare payments in future years noting that section 1833(t)(9) of the Act requires budget neutrality for a particular "year." However, CMS notes the District Court's conclusion that if the Secretary was to retroactively increase the 2018 and 2019 payments for 340B hospitals, "budget neutrality would require him to retroactively lower the 2018 and 2019 rates for other Medicare

Part B products and services." CMS argues that its proposal would reduce payments for "particular" years (2018 through 2022) just prospectively over a period estimated to be 16 years.

Given the unique posture of this remedy rule, CMS does not propose to retroactively revise expenditure estimates for 2018 through 2022 as it is not standard practice to do so for budget neutrality, nor is it required by the statute. CMS is aware that, depending on how a hospital's future mix of drug and non-drug services compares to its past mix of drug and non-drug services, as well as any absolute growth in a hospital's non-drug services, some hospitals may ultimately receive slightly more (or less) of a payment reduction than the payment increase they received for 2018 through 2022. The alternative would be a lump sum budget neutrality recoupment. That would impose all of the burdens of an up-front budget neutrality adjustment that CMS previously indicated would require immediate, and in many cases large, retroactive recoupments from the majority of OPPS hospitals and would impose a substantial, immediate burden on those hospitals as well as have an uncertain impact on beneficiaries.

CMS' estimate of 16 years for the recoupment process is based on current OPPS payments that are made through the OPPS conversion factor and typical year-over-year increases in OPPS payments over the past ten years. The proposed rule indicates that CMS would adjust this estimate in future years based on updated claims and aggregate OPPS spending estimates. Once sufficient adjustments are made to recoup the additional expenditures for 2018-2022, CMS proposes not to make any additional adjustments irrespective of whether the final adjustment is more or less than CMS estimates is needed to fully recoup the additional spending. The proposed rule indicates that CMS considered alternatives of making a larger recoupment adjustment over a different period of time such as 5, 10, or 15 years or beginning the adjustment in 2026 to give hospitals more time to prepare for the payment change.

CMS proposes to exempt any new provider (i.e., a provider that enrolled in Medicare on or after January 1, 2018) from the -0.5 percent adjustment to non-drug OPPS services on the basis that these hospitals did not receive the full 3.19 percent increase in payments that was applied from January 1, 2018 through September 27, 2022 to offset the payment reductions for 340B acquired drugs. For the purpose of designating a new provider, CMS is proposing the date of enrollment in Medicare as the provider's CMS certification number (CCN) effective date. Providers that meet this definition are listed in Addendum BBB of the proposed rule, which is available through the hyperlink at the beginning of the summary. This policy would affect approximately 300 of 3,900 OPPS providers.

This proposed "new provider" designation is intended to apply only to truly new providers, meaning those that were not enrolled in Medicare as of January 1, 2018. The proposal would not apply to providers that were enrolled in Medicare before January 1, 2018, and subsequently had a change in ownership that resulted in a new CCN. CMS recognizes that this approach will exempt some hospitals receiving the 340B lump sum payment from the prospective offset but rejected creating unique payment rates for different groups of hospitals for the duration of the proposed 16-year offset period depending on how much of the period of 2018 through 2022 the provider was enrolled in Medicare.

III. Regulatory Impact Analysis

CMS estimates that the total increase in Federal Government expenditures due only to the proposed changes in this proposed rule would be $2.8 billion. This estimate reflects additional Medicare drug payments of $9.0 billion and an offsetting reduction of $6.2 billion for non-drug items and services beginning in 2025. The $6.2 billion figure represents Medicare's proportion of the reduced prospective payments after beneficiary coinsurance or approximately 80 percent of the total $7.8 billion offset that CMS proposes to recoup. Beneficiaries will experience reduced prospective coinsurance payments representing approximately the remaining 20 percent of the total $7.8 billion offset.

The $9.0 billion amount is an estimate of the total aggregate additional payments that still need to be made to 340B hospitals for January 1, 2018 through September 27, 2022 exclusive of an estimated $1.5 billion in additional drug payments that were already made to 340B hospitals for all of 2022. The additional proposed Medicare drug payments ($9.0 billion) are different than the amounts being recouped ($7.8 billion) due to:

1. Medicare's payment policy adjustment for 340B acquired drugs ended on September 27, 2022, while the original conversion factor adjustment of +3.19 percent remained in effect until December 31, 2022,
2. Most of the 340B drug claims with dates of service between January 1, 2022, and September 27, 2022, have already been reprocessed at the higher default drug payment rate, while none of the increased non-drug item and service payments during this time period have been reduced,
3. CMS proposes to include beneficiary coinsurance in the amount paid to 340B hospitals as part of the lump sum payments to providers, and
4. The original budget neutrality adjustment to increase the conversion factor in 2018 was not updated annually and resulted in more money being taken away from hospitals through reduced drug payments than was added back to non-drug OPPS items and services through the conversion factor adjustment.

The first two of these factors would make the amount being recouped larger than the amount being paid back to hospitals for reduced drug payments. The last two would make the amount owed to 340B hospitals higher than the amount needing to be recouped. CMS indicates that fourth factor is the most significant in explaining the estimated of difference of $2.8 billion between the amount owed hospitals and the amounts expected to be recouped through prospective reductions to the OPPS update of 0.5 percent per year.

Table 2 below, reproduced from the proposed rule, shows the impact of these proposed policy changes on drug payments, including aggregate payments by hospital type. Specific proposed additional 340B-acquired drug lump sum payment amounts by individual hospital can be found in Addendum AAA. The impact on hospitals of the reduced payments beginning in 2025 would be included in each proposed and final rule for calendar years in which the prospective reduction would apply.

TABLE 2:
ESTIMATED FINANCIAL IMPACT OF THE PROPOSED REMEDY PAYMENTS ON OPPS PROVIDERS

	(1)	(2)	(3)	(4)
	Number of Hospitals	**Lump Sum Drug Remedy Payment ($ in millions)**	**2022 Drug Payments Made (in Millions)**	**Total 340B Drug Remedy Payment (sum of Columns 2 and 3**
ALL PROVIDERS *	1,661	$9,003	$1,540	$1,054
ALL HOSPITALS (excludes hospitals held harmless and CMHCs)	1,649	$9003	$1,540	$1,054
URBAN HOSPITALS	1,297	$8,538	$1,491	$1,003
LARGE URBAN (GT 1 MILL.)	611	$4,326	$815	$5,141
OTHER URBAN (LE 1 MILL)	686	$4,211	$676	$4,887
RURAL HOSPITALS	324	$457	$47	$504
SOLE COMMUNITY	147	$95	$6	$101
OTHER RURAL	177	$362	$41	$403
BEDS (URBAN)				
0-99 BEDS	213	$258	$44	$302
100-199 BEDS	374	$827	$125	$951
200-299 BEDS	252	$1,209	$193	$1,401
300-499 BEDS	267	$1,982	$339	$2,322
500 + BEDS	191	$4,261	$791	$5,052
BEDS (RURAL)				
0 - 49 BEDS	124	$80	$8	$88
50- 100 BEDS	116	$104	$13	$117
101- 149 BEDS	40	$89	$9	$98
150- 199 BEDS	21	$89	$8	$98
200 + BEDS	23	$93	$9	$102
Region (URBAN)				
NEW ENGLAND	73	$613	$114	$728
MIDDLE ATLANTIC	163	$1,173	$236	$1,409
SOUTH ATLANTIC	218	$1,593	$280	$1,873
EAST NORTH CENT	232	$1,318	$240	$1,558
EAST SOUTH CENT	75	$644	$106	$750
WEST NORTH CENT	79	$749	$129	$878
WEST SOUTH CENT	145	$610	$100	$710
MOUNTAIN	86	$566	$90	$656
PACIFIC	223	$1,270	$195	$1,464
PUERTO RICO	3	$0	$0	$0
Region (RURAL)				
NEW ENGLAND	11	$25	$1	$26
MIDDLE ATLANTIC	22	$32	$3	$36
SOUTH ATLANTIC	52	$97	$5	$103
EAST NORTH CENT	48	$67	$8	$75
EAST SOUTH CENT	75	$145	$19	$165
WEST NORTH CENT	29	$7	$1	$7
WEST SOUTH CENT	54	$20	$1	$21
MOUNTAIN	20	$29	$3	$32

	(1)	(2)	(3)	(4)
	Number of Hospitals	**Lump Sum Drug Remedy Payment ($ in millions)**	**2022 Drug Payments Made (in Millions)**	**Total 340B Drug Remedy Payment (sum of Columns 2 and 3**
PACIFIC	13	$35	$5	$40
TEACHING STATUS				
NON-TEACHING	795	$1,682	$273	$1,955
MINOR	514	$2,793	$435	$3,228
MAJOR	312	$4,520	$830	$5,350
DSH PATIENT PERCENT				
0	0	$0	$0	$0
GT 0-0.10	31	$16	$0	$17
0.10-0.16	62	$7	$0	$7
0.16-0.23	167	$54	$15	$69
0.23-0.35	715	$3,819	$671	$4,491
GE 0.35	635	$5,099	$851	$5,950
DSH NOT AVAILABLE**	11	$0	$0	$0
URBAN TEACHING/DSH				
TEACHING & DSH	766	$7,158	$1,252	$8,410
NO TEACHING/DSH	521	$1,380	$239	$1,720
NO TEACHING/NO DSH	0	$0	$0	$0
DSH NOT AVAILABLE	10	$0	$0	$0
TYPE OF OWNERSHIP				
VOLUNTARY	1,215	$7,202	$1,242	$8,444
PROPRIETARY	150	$32	$7	$39
GOVERNMENT	256	$1,761	$290	$2,052

Column (1) shows total hospitals that are expected to receive payments related to the 340B policy under this proposed rule.
Column (2) includes the estimated drug remedy payment made to account for the policies described in this proposed rule during the time period of CY 2018 through CY 2022.
Column (3) displays the estimated payment impact of any CY 2022 claims that have been reprocessed by the MACs. CMS notes that if these claims, which include dates of service for services furnished prior to September 28, 2022, were not reprocessed their payments would otherwise have been included as remedy payments in Column 2.
Column (4) includes the total remedy payments, which is the sum of column 2 and column 3.These 1,661 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.
** Complete disproportionate share hospital (DSH) numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.