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

The Centers for Medicare & Medicaid Services (CMS) released a final rule (CMS-1793-F) on November 2, 2023 that describes the agency's 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 (Supreme Court) decision in *American Hospital Association v. Becerra*. The final rule will be published in the November 8, 2023 issue of the *Federal Register*.

CMS is adopting the following final rule policies:

- 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, 2026 until such time as the full amount of the additional payment is recouped (currently estimated at 16 years).

Addendum AAA to the final rule is a list of 340B hospitals and the lump sum payment CMS estimates they are owed. Addendum BBB of the final 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' policy. Both addenda may be found at: https://www.cms.gov/medicare/medicare-fee-service-payment/physicianfeesched/pfs-federal-regulation-notices/cms-1793-f.

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 (MedPAC) 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 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

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

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. 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.

CMS acknowledges that it 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 fiscal 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 proposed to adjust payments prospectively in order to provide a remedy for a previous unlawful payment decision.

CMS estimates that Medicare spending for non-drug items and services that received an increase in payment of 3.19 percent from 2018 through September 27, 2022 was $7.8 billion. This estimate has not changed between the proposed and final rule. CMS addresses public comments on this option later in the final rule.

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 noted that the vast majority of 340B drug claims from 2022 have been reprocessed and paid at ASP+6 percent. As of this final rule, CMS estimates that $1.6 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.

Public commenters generally agree that CMS should not reprocess all claims from January 1, 2018 through September 27, 2022. One commenter noted that CMS' proposed remedy will result in hospitals receiving payment for 2022 claims through September 27 not resubmitted to the Medicare Administrative Contractors (MACs) at the full OPPS amount including the beneficiary coinsurance. However, hospitals that resubmitted claims will only receive the Medicare share of payment and must collect coinsurance directly from the beneficiary. This commenter suggested that an equitable outcome would treat all 2022 claims through September 22 the same—with CMS' remedy payments including beneficiary coinsurance.

CMS disagrees. Under its remedy proposal, the agency is paying amounts equal to lost beneficiary cost sharing amounts providers are not otherwise legally entitled to collect. Because the 2022 claims that were resubmitted followed the regular claims processing conventions, providers are legally entitled to collect cost sharing from beneficiaries on those claims.

Several comments requested CMS make one mass adjustment for claims going back to January 1, 2022. CMS indicated it does not have an existing procedure to make the mass adjustment requested by commenters but it indicates that its lump sum payment achieves a very similar result.[8]

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. Public commenters supported CMS not pursuing this approach.

B. Remedy

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

CMS proposed 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 indicated 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.

[8] This statement appears to be inaccurate. At least two MACs announced that they would mass adjust all 2022 claims on October 17, 2022. First Coast Service Options indicated in a bulletin to its providers that "First Coast will be mass adjusting all impacted claims with a 2022 date of service." National Government Services indicated "as per CMS instructions, once the revised 2022 OPPS drugs files (all four quarters in 2022) are loaded into production regions, National Government Services (NGS) shall reprocess/adjustment 2022 date of service claims with the JG modifier…For impacted claims prior to date of service 9/28/2022, providers may contact NGS Customer Care to request a mass adjustment."

With a few exceptions, public comments supported CMS making a one-time lump sum payment to remedy the underpayment to 340B hospitals. However, there were objections to CMS making these additional payments through retroactive rulemaking. These objections raised complex legal arguments in the following areas:

Inapplicability of Section 1833(t)(14) and (t)(2)(E) of the Act: These commenters stated that CMS is attempting to rely on statutes designed for, and limited to, making prospective adjustments to spending estimates, or discretionary adjustments based on equity to make remedy payments required by the Supreme Court's decision.

With respect to section 1833(t)(14) of the Act, commenters indicated that it applies to "[a]dditional expenditures resulting from this paragraph…" Commenters argue CMS' 340B remedy is not an "additional" payment but one that 340B hospitals were always due and the payment is not being made as a result of "this paragraph" but rather the agency's loss of a court case. With respect to section 1833(t)(2)(E) of the Act which provides authority to "ensure equitable payments," commenters argued that the payments are not being made for equitable reasons but to comply with a court judgment. With respect to both provisions, commenters indicate the provisions are intended to be applied prospectively, not to make retrospective payments. Other commenters indicated that CMS construes "adjustment" too broadly. Citing several precedents[9], commenters indicate that "adjustment" means an "increment or limitation." The remedy here is too large to qualify as an adjustment.

CMS disagreed with these commenters arguing that the Supreme Court decision itself is evidence that the fact the OPPS is a prospective payment system does not foreclose all retrospective review.[10] In addition, CMS cites at least one court that has rejected an argument that CMS lacks the authority to make retroactive adjustments when required to comply with other provisions in section 1833(t) of the Act.[11] CMS believes that the adjustments are "equitable" in that CMS is seeking to restore parties to as close a state as they would have been without having applied the 340B adjustment in the first place.

On the term "adjustment", CMS acknowledges precedent that the term implies a limitation or "small changes" but also indicates—citing Black's Law Dictionary—that "adjustment" can also mean "That which adapts one thing to another or to a particular use". CMS, therefore, believes its adjustment authority fairly encompasses adapting generally prospective payments to remedy legal errors made in those payments. It further argues that even if adjustment carries a connotation of increment or limitation, the 28.5 percent adjustment to payments made to hospitals for 340B-acquired drugs would not exceed it.

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[9] Biden v. Nebraska, (143 S. Ct. 2355, 2368 (2023) and Amgen, Inc v. Smith., (357 F.3d 103, 117 (D.C. Cir. 2004)).
[10] The Supreme Court did not make any explicit decision on retroactive rulemaking. CMS cites its own brief as evidence for this point (e.g., CMS' cites its brief arguing that if the Supreme Court rejects its position, it is implicitly authorizing retroactive rulemaking).
[11] See H. Lee Moffitt Cancer Ctr. & Rsch. Inst. Hosp., Inc. v. Azar, 324 F. Supp. 3d 1, 16 (D.D.C. 2018) ("HHS has not shown that such a retroactive adjustment would be incompatible with the generally prospective nature of OPPS.").

Section 1871 of the Act's Authority for Retroactive Rulemaking: One commenter argues that section 1871 of the Act only authorizes retroactive rulemaking when "retroactive application is necessary to comply with statutory requirements" or "failure to apply the change retroactively would be contrary to the public interest." The commenter argues that the first exception does not apply because CMS is only making the refund of reduced 340B drug payments retroactive and not the adjustment for budget neutrality. If CMS believed that both parts of its policy were necessary to comply with the law, it would make both retroactive. Concerning the second exception, the commenter argues that it is not in the public interest to engage in the retroactive adjustment of prospective payment rates when make-whole relief can be implemented without revisiting 2018 through 2022 OPPS rates (e.g., through acquiescence to the court as discussed below).

CMS disagrees arguing it must act retrospectively to conform payment rates with existing statutory requirements. And because the payment increases for non-drug items and services for those years were inextricably linked to the illegal payment decreases for 340B-acquired drugs, the same reasoning would apply even though the recoupment is being applied prospectively. CMS is not re-estimating any budget projects but is "unwinding" a payment rate that courts held was illegal according to the final rule.

The final rule also indicates disagreement that it would not be in the public interest to do retroactive rulemaking. The commenter's suggestion would effectively involve at least a $9 billion transfer from beneficiaries and taxpayers to hospitals, which would be inappropriate especially in a system where budget neutrality requirements generally prevent such transfers. In CMS' view, "equitability" here applies to the Trust Fund, beneficiaries and the taxpayers as well Congress that established budget neutrality statutory provisions.

Acquiescence Authority: Public commenters argue that CMS may acquiesce to the court's decision rather than engage in retroactive rulemaking. Commenters point to past instances in which CMS has acquiesced to court decisions without undertaking retroactive rulemaking (for instance, its policy of allowing reprocessing of 2022 340B drug claims at the default drug rate for dates of service between January 1, 2022, and September 27, 2022 where its 340B rule was not vacated).

CMS argues that acquiescence is a choice by an agency when faced with a lower court decision disagreeing with the agency's legal interpretation where the court's jurisdiction is geographically limited and whose legal interpretations are subject to further review. The Supreme Court is not so limited, and its statutory interpretations are applicable nationally. CMS argues that the precedents cited by the commenters do not apply to this case.[12]

Further, CMS argues that following judicial interpretations does not necessarily entitle parties without jurisdictionally proper active challenges to have that interpretation applied to prior years' payments. Doing so in this case will help to promote uniform treatment of parties under the law and save the government and regulated parties from uncertainty and litigation costs.

[12] The commenters cited to Administrator Rulings. CMS argued those decisions applied to properly pending appeals on the issue under dispute and not the application of national policy where budget neutrality was involved.

Final Rule Decision: CMS is finalizing its proposal to use retroactive rulemaking to make a lump sum payment to 340B hospitals for payments that would otherwise be due to these hospitals had CMS never adopted the 340B hospital payment adjustment. The final rule indicates that 1,686 340B hospitals received approximately $10.6 billion less in payments than had Medicare paid these claims at ASP+6 percent. CMS believes that about $1.6 billion of this amount has already been paid to 340B hospitals for reprocessed claims with dates of service in 2022 leaving approximately $9.0 billion that 340B hospitals are owed for past year payment reductions.

Determining the Amount Due Each Hospital: 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. Public commenters agreed with this approach to determining how much to pay 340B hospitals for reduced payments from January 1, 2018 through September 27, 2022.

Operational Issues: CMS proposed to issue an instruction to the MACs to issue a one-time lump sum payment within 60 calendar days. Public commenters generally agreed with this proposal. CMS indicated that it anticipates making the additional payments to 340B hospitals at the end of 2023 or the beginning of 2024.

Addendum AAA to the final rule found at the hyperlink at the beginning of this summary shows how much each hospital would be due under CMS' policy. A hospital may submit technical corrections if they believe their information is incorrect. To submit technical corrections to Addendum AAA, submissions may be sent to outpatientpps340b@cms.hhs.gov and must be received by November 30, 2023 and include:

(1) a description of the nature of the error;
(2) a designated contact person for the purposes of addressing the error; and
(3) relevant supporting documentation such as claim numbers, total units, payment amount received, and date of payment.

Final payment will only be determined after CMS addresses the hospital's submission. Submitting a technical correction may delay when a hospital receives its lump sum payment. If the hospital does not submit any technical corrections, then the amounts listed in Addendum AAA are the final payment amounts due to the hospital pursuant to this rule. That determination or decision will be the final payment amount determined pursuant to the methodology in this final rule. CMS further notes that this lump sum payment moots any pending appeals on the 340B payment adjustment in the administrative adjudication process.

A number of commenters raised concerns about the accuracy of their data on Addendum AAA. CMS addressed these comments in the final rule. In response to several comments, CMS added a

column to Addendum AAA showing the amount of payment reductions made to 340B hospitals for the period January 1, 2018 through December 27, 2022 to assist hospitals in reconciling the amounts they are owed.

Beneficiary Coinsurance: The proposed rule indicated 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 policy it proposed in this circumstance is appropriate "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." Public commenters supported CMS' proposal that CMS is finalizing without modification.

Interest Payments: 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.

Many commenters indicate that section 1833(j) of the Act provides that whenever a final determination is made that the amount of payment made was in excess of or less than the amount of payment that is due interest shall accrue within 30 days of the date of the determination. The commenters requested CMS consider the date of the Supreme Court's decision the final determination date. CMS disagrees indicating that its regulations refers to "administrative, not judicial, determinations; therefore, there is no interest obligation under these regulations for judicial determinations."[13] The Supreme Court's decision was not a "final determination" as it remanded a decision on a remedy to the District Court and did not make a judgement on the amounts due to the providers.

There were comments indicating that interest was due to the plaintiffs in the case pending before the District Court that were stayed pending the outcome of CMS's remedy discussed in the proposed rule. These plaintiffs, the commenters contend, sufficiently exhausted the administrative appeals process, giving them standing for judicial review, and entitling them to the usual interest awarded to prevailing parties that seek an expedited path to judicial review. CMS disagrees indicating that the provisions cited by the commenter apply only when the providers received expedited judicial review. These plaintiffs did not receive expedited judicial review as the commenters acknowledge that they exhausted the administrative appeals process.

Some commenters argued that CMS must make interest payments under the Federal Tort Claims Act or the Prompt Payment Act which states that "the temporary unavailability of funds does not relieve an agency from the obligation to pay these interest penalties or the additional penalties."[14] Similarly, another commenter stated that section 1815(d) of the Act and common law provide for the payment of interest on underpayments to Medicare providers. CMS responds that no claims have been filed under the Federal Tort Claims Act so it does not apply. It does not believe Medicare providers are subject to the Prompt Payment Act that is limited to procurement

[13] Medicare Program; Changes Concerning Interest Rates Charged on Overpayments and Underpayments, 56 FR 31332, 31335 (1991).
[14] See § 1315.11" and 5 CFR 1315.10(b)(4).

contracts and vendors. Section 1815 of the Act does not apply because it governs Part A not Part B payments.

Some commenters directed CMS to sub-regulatory guidance where interest is due on unpaid "clean" claims 30 days from the date it is received by the MAC. A clean claim is one that does not require any special treatment that prevents timely payment from being made. CMS responds that its longstanding position has been that these provisions do not apply in "situations like this one where a payment regulation was properly applied by the contractor to deny a claim that is ultimately held unlawful by a court."[15] Further, CMS argues that these claims are not clean because they involve a "particular circumstance requiring special treatment."[16]

Final Rule Decision: CMS is finalizing its policy that the lump sum remedy payments made to 340B hospitals would not include interest.

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 proposed 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 proposed to prospectively offset $7.8 billion in payments in order to maintain budget neutrality. The proposed rule indicated 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.

[15] These claims were not denied. Payments were made, just not consistent with a policy CMS established that the courts found to be unlawful.

[16] Medicare Program: Changes to the Medicare Claims Appeal Procedures, 74 FR 65296, 65302 (2009) ("Claims initially denied and subsequently paid following a favorable appeal decision, or revised following a reopening action are, by their nature, claims that require special treatment.").

CMS proposed 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 indicated 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 indicated 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 proposed not to make any additional adjustments irrespective of whether the final adjustment is more or less than what CMS estimates is needed to fully recoup the additional spending. The proposed rule indicated 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.

Inapplicability of Section 1833(t)(14) and (t)(2)(E) of the Act: Several comments in this section were similar to the comments regarding inapplicability of the use of section 1833(t)(14) of the Act for the purposes that it is being invoked by CMS (e.g., there are not "additional expenditures resulting from this paragraph" that must be made budget neutral). These commenters further disagreed that section 1833(t)(14) of the Act's reference to the paragraph (9) budget neutrality requirement can be applied retroactively.

CMS disagrees and states that it is "unwinding" the effect of past policy determinations that were

determined to be unlawful by the Supreme Court (e.g., to offset an increase in payment for drugs acquired under the 340B program with a reduction in payment for all other services as is required under section 1833(t)(9) of the Act). CMS argues that the generally prospective nature of OPPS does not prevent it from remedying legal errors identified by courts to rectify past actions.

Some commenters argue that section 1833(t)(2)(E) of the Act similarly cannot be used to unwind the payment increases for non-drug payments and services, both because its reference to "equitable payments" refers to "payments," not recoupments or reductions. CMS disagrees arguing that "the statute authorizes "adjustments to ensure equitable payments"—not just upward adjustments to ensure equitable payments.

Section 1871 of the Act's Authority for Retroactive Rulemaking: A few commenters argued that the retroactive rulemaking authority in section 1871(e)(1)(A) of the Act (or anywhere else) does not authorize budget neutrality. One commenter argued that CMS only discussed its retroactive rulemaking authority in the proposed rule with respect to remedy payments, not making them budget neutral. The commenter argues that CMS cannot rely upon any general retroactive rulemaking statutes to implement an offset because it would rely upon paragraph (9) which is prospective only.

CMS disagrees arguing that its proposed rule intended to rely on section 1871(e) of the Act's retroactive rulemaking authority for the budget neutrality adjustment as well as the repayment of additional funds to 340B hospitals. Further, CMS argues section 1871 of the Act generally precludes retroactive rulemaking but recognizes that even with prospective payment systems there may be exceptions to this general rule. CMS states that its policy will harmonize section 1833(t) of the Act's prospectivity provisions with the need, on occasion, to apply policy retroactivity as authorized by section 1871 of the Act. To read these provisions as being in conflict would be "inconsistent with courts' holding that the fact that section 1833(t) of Act sets up a general prospective system does not mean it implicitly precludes retrospective review."[17]

Request for Differential Treatment of Plaintiffs: Some commenters indicated that a narrow set of plaintiffs with pending cases before the District Court are entitled to judicial review of their individual 340B drug claims. These commenters argue that review does not implicate the budget neutrality provisions referenced by CMS in the proposed rule. While CMS acknowledges the legitimacy of these arguments, it further states the statute does not prohibit CMS from addressing the issues of these plaintiffs through the rulemaking process affecting the larger class.

Common Law Duty: Many commenters assert that CMS does not have a common-law duty to seek recoupment, so any reliance on common-law would be voluntary, and no common law power of recoupment authorizes the type of recoupment proposed by CMS. They assert that any common-law authority that the government may have to recoup funds can only be exercised by suing in court. CMS disagrees indicating that common law reflects the judgment that the government should avoid funding windfalls to private parties.

17 CMS does not source "the courts' holding and in language just prior this excerpted quote states "the court did not resolve the question [regarding retroactive rulemaking] one way or another."

Use of the Term Windfall and Reliance Interests: A number of comments objected to CMS' use of the term "windfall" since hospitals had no choice but to accept the additional payments and it implies a lack of acknowledgement of CMS's role in creating the situation resulting in the payment of the funds that it is now proposing to recoup. These commenters also disagreed with CMS's contention that hospitals have no legitimate reliance interest in permanently retaining the funds proposed to be recouped. Many of these commenters stated that hospitals properly relied on and have already spent the payments CMS made between 2018 and 2022 and that this reliance was particularly pronounced given the COVID-19 PHE.

CMS takes full responsibility for the legal error ultimately found by the Supreme Court and does not believe it has erred in characterizing the additional payments as a "windfall" regardless of whether hospital could decline the payments or not. With respect to reliance interests, CMS indicates that it repeatedly emphasized to the hospital community that it may need to revisit budget neutrality if the 340B payment policy were found to be unlawful.

Inconsistency with Past Practices: Several commenters stated that CMS's approach to budget neutrality is inconsistent with its past practices with respect to an underestimate of packaging the cost of clinical diagnostic laboratory services into OPPS payments (80 FR 70354); mid-year corrections to the IPPS wage index (§412.64(e)(1)(ii) in combination with (§412.64(k)(2)); and outlier adjustments. These commenters indicate that CMS has previously applied budget neutrality retroactively only when expressly authorized to do so by Congress.

CMS does not find the examples with respect to clinical diagnostic laboratory services and outliers to be analogous to the 340B situation. In those cases, CMS declined to make a retroactive budget neutrality adjustment based on updated data (80 FR 70354 noting the adjustment "would not recoup 'overpayments' made for" past years and 88 FR 27223 ("[W]e do not make retroactive adjustments to outlier payments" to update projections). CMS is not revising estimates in this situation based on updated data. With respect to wage index regulation, CMS says "it addresses specific statutory exemptions to the general budget neutrality rule." However, CMS also says "the regulation addressing adverse wage index judicial decisions is silent on the issue of budget neutrality."[18]

No Court Order Requiring Budget Neutrality: Some commenters argued that since no court ruling has found that hospital payments for non-drug items and services in CYs 2018-2022 were unlawfully paid or received, CMS should not apply budget neutrality for the increase in payments to 340B hospitals. Another commenter suggested CMS reply on section 1870 of the Act that addresses recovery of overpayments made on behalf of an individual. This statutory provision describes when and how CMS may recover incorrect payments it makes on behalf of an individual. The provision authorizes CMS to forgo recovery where the individual for whom the incorrect payment was made was without fault.

[18]CMS' statement is technically correct but § 412.64(l) does state "***judicial decision.*** If a judicial decision reverses a CMS denial of a hospital's wage data revision request, CMS pays the hospital by applying a revised wage index that reflects the revised wage data as if CMS's decision had been favorable rather than unfavorable." (Bold and italics in the original). CMS' practice has not been to make any wage index changes applied as a result of judicial decision budget neutral.

CMS acknowledges that litigants challenged only the payment increase and no court has ruled on the recoupment aspect of the remedy but states that it has made clear that "the policies should rise and fall together regardless of artful pleading strategies" (e.g., the increase to non-drug items and services hinged on payment reductions the Supreme Court held to be unlawful and one cannot be done without the other). As section 1870 of the Act speaks to when providers can shift liability to beneficiaries for overpayments, which can in turn be waived in certain circumstances, CMS does not believe it applies to this circumstance.

Payment Inaccuracies from Staggered Timing of the Additional Payments and Budget Neutrality Offsets: One commenter noted that implementing a prospective adjustment poses challenges due to the varying volumes and services that change from year to year at each facility, and that consequently it would lead to inaccuracies in the calculation. Due to the inability to properly match prospective adjustments to prior increased payments, this commenter suggests that CMS not finalize any prospective adjustments.

CMS agrees that its prospective budget neutrality offset imperfectly offsets the amount by which the 340B policy increased each hospital's payments for non-drug services and items but does not agree that the alternative is not applying the adjustment at all. The alternative is a one-time debit for the increased payments that CMS earlier explained it did not propose and is not adopting in this final rule.

MedPAC made a similar comment to the one above and asked CMS to reverse the increases and decreases to individual hospitals through cost report reconciliation. CMS did not directly address this comment but as indicated elsewhere it has adopted the best payment offset policy given myriad concerns.

MedPAC and the Part B Premium: Comment: MedPAC supported CMS' proposal but indicated that offset for budget neutrality should be aligned with the remedy payments to avoid the potential for an increase in the Part B premium. CMS responded that it believes the prospective offset is appropriate in order to minimize the financial burden on hospitals given the difficulties caused by the COVID-19 PHE, financial challenges of unprecedented workforce shortages, inflation, supply chain disruptions, and eroding margins among other factors. Any change to the Part B premium in the near term would be offset with lower Part B payments in the future.

Alternative Policies: Several commenters requested that CMS apply the recoupment adjustment over a shorter time period and that the adjustment be designed to recoup a fixed dollar amount per year rather than be applied a percentage reduction to the OPPS conversion factor.[19] These commenters indicated that these alternatives would result in a more precise recoupment relative to the remedy payment to the 340B hospitals. CMS responded that it believes the 0.5 percent annual reduction properly reverses the increased payments for non-drug items and services to comply with statutory budget neutrality requirements while at the same time accounting for any reliance interests and ensuring that the offset is not overly burdensome to impacted entities.

[19] These suggestions would be analogous to the $11 billion recoupment required by the American Tax Relief Act of 2012 over 4 years for increases in payment for documentation and coding under the IPPS that occurred in 2008 and 2009 that were not previously recovered.

Ambulatory Surgical Center (ASC) Payment: One commenter requested clarification regarding the impact of the proposed 16-year OPPS conversion factor reduction on the ASC payment system. While CMS indicates that the 0.5 percent adjustment to the OPPS update will not affect ASCs, this statement is only accurate in the context of non-device intensive procedures where the OPPS relative weights but not the OPPS payments are used in setting the ASC payment. For device intensive procedures, CMS "passes-through" the device portion of the OPPS payment and then uses the normal methodology to value the remainder of the ASC payment making the commenter concerned that in this specific instance, CMS' policy will affect the ASC payment. CMS responds that the issue will be addressed in future rulemaking.

Start Date for the Prospective Adjustment: Nearly all commenters supported a 2026 start date for the initiation of the adjustment to the conversion factor to provide hospitals with additional time for hospitals to recover from the extraordinary financial challenges caused by unprecedented workforce shortages, inflation, supply chain disruptions, eroding margins, cost increases due to increases in supplies and staffing costs and the lingering effects of the COVID-19 PHE. CMS agreed and will start the prospective adjustment beginning in 2026.

Other Issues: Public commenters raised concerns about a number of other issues such as the impact on payment for new non-drug items and services that never received an increase in payment while the 340B payment policy was in effect and how the recoupment would be affected when hospitals close (e.g., would a hospital closure increase the recoupment obligation for remaining hospitals?). CMS responds that it acknowledges the potential redistributive impact of staggering the 340B remedy payments from the recoupment adjustments but indicates it has done what it can to mitigate that effect by limiting the future recoupment to providers that did in fact benefit from the increased payments in the past.

Final Rule Decision: CMS is finalizing a budget neutrality adjustment of 0.5 percent reduction to the OPPS conversion factor over an estimated 16-year time period until a total of $7.8 billion is offset beginning in 2026. The exact impact on OPPS payment rates as a result of this reduction will be reflected in the annual OPPS/ASC proposed and final rules. See Table 2 reproduced below from the final rule for an illustration of the payment recoupment over 16 years beginning in 2026.

Table 2: Illustration of the 0.5 Percent Adjustment to OPPS Non-Drug Spending			
Calendar Year	**OPPS Non-Drug Spending ($ in millions)**	**0.5 Percent Reduction ($ in millions)**	**Cumulative Offset ($ in millions)**
2025	$66,910	$0	$0
2026	$70,256	$351	$351
2027	$73,769	$369	$720
2028	$77,457	$387	$1,107
2029	$81,330	$407	$1,514
2030	$85,369	$427	$1,941
2031	$89,667	$448	$2,389
2032	$94,150	$471	$2,860
2033	$98,858	$494	$3,354
2034	$103,801	$519	$3,873
2035	$108,991	$545	$4,418
2036	$114,440	$572	$4,991
2037	$120,162	$601	$5,591
2038	$126,170	$631	$6,222
2039	$132,479	$662	$6,885
2040	$139,102	$695	$7,580
2041	$114,440	$188*	$7,769

*The final year's offset is estimated to be less than 0.5 percent in order to meet the total estimated offset of $7.8 billion (rounded).
Non-Drug spending are estimates based on an assumption of 5 percent annual growth. The 5 percent annual growth is determined from a 10-year baseline percentage increase.

New Providers: CMS proposed 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 proposed 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 final 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 "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 estimated 16-year offset period depending on how much of the period of 2018 through 2022 the provider was enrolled in Medicare.

One comment on this proposal indicated that it is overly broad in that it will benefit a hospital that enrolled in Medicare as early as 2020 and received three years of increased payment without having to be subject to the recoupment. CMS acknowledged that point in both the proposed and final rule but indicated that any alternative policy it considered that would be more precise would be overly complex and burdensome. CMS is finalizing its proposal without modification. Addendum BBB available at the hyperlink at the beginning of this summary includes a list of hospitals that will be exempt from the 0.5 percent reduction to the annual OPPS update.

Other Comments: CMS received a number of comments that were out-of-scope to the proposed rule. Of particular interest are comments on the following issues:

Medicare Advantage: Many commenters expressed concern about Medicare Advantage Organizations (MAOs) realizing a "windfall" as a result of reducing outpatient payments without making corresponding repayments to hospitals for 340B drugs. CMS responded referencing this memorandum that was issued December 20, 2022: https://www.cms.gov/files/document/cmsopps340bupdate508g.pdf. In accordance with section 1854(a)(6)(B)(iii) of the Act, CMS may not require MAOs to contract with a particular healthcare provider or use particular pricing structures with their contracted providers. Therefore, MAOs that contract with a provider or facility eligible for 340B drugs can negotiate the terms and conditions of payment directly with the provider or facility and CMS cannot interfere in the payment rates that MAOs set in contracts with providers and facilities.

Accountable Care Organizations (ACOs). Some commenters indicated that ACOs will be unfairly impacted in their benchmark calculation because 340B drugs will be paid at the lower price of ASP minus 22.5 percent and the higher price of ASP plus 6 percent in performance years. CMS responded that for ACOs participating in payment year 2023 that have historical benchmark years for which payments for 340B-acquired drugs were based on the ASP minus 22.5 percent rate (2018-2022), the differences between the 340B-acquired drug payments included in historical benchmark year and performance year expenditure calculations have the potential to be mitigated when CMS updates the benchmark using a blend of national and regional growth rates.

III. Regulatory Impact Analysis

CMS estimates that the total increase in Federal Government expenditures due only to this final rule will be $2.8 billion. This estimate reflects additional Medicare drug payments of $9.0 billion to an estimated 1,700 340B covered entities and an offsetting reduction of $6.2 billion for non-drug items and services beginning in 2026. 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 $1.6 billion in additional drug payments that were already made to 340B hospitals for all of 2022. The additional 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 is including 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 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 3 below, reproduced from the final rule, shows the impact of these policy changes on drug payments, including aggregate payments by hospital type. Specific 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 2026 will be included in each proposed and final rule for calendar years in which the prospective reduction would apply.

TABLE 3:
ESTIMATED FINANCIAL IMPACT OF THE 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 *	1,686	$9,004	$1,615	$10,619
ALL HOSPITALS (excludes hospitals held harmless and CMHCs)	1,655	$9,003	$1,615	$10,619
URBAN HOSPITALS	1,324	$8,544	$1,563	$10,107

	(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)**
LARGE URBAN (GT 1 MILL.)	625	$4,323	$844	$5,166
OTHER URBAN (LE 1 MILL)	699	$4,221	$719	$4,490
RURAL HOSPITALS	331	$453	$51	$504
SOLE COMMUNITY	152	$94	$6	$100
OTHER RURAL	179	$359	$45	$404
BEDS (URBAN)				
0-99 BEDS	224	$259	$47	$306
100-199 BEDS	382	$824	$131	$955
200-299 BEDS	253	$1,197	$211	$1,409
300-499 BEDS	272	$1,980	$355	$2,335
500 + BEDS	193	$4,283	$818	$5,102
BEDS (RURAL)				
0 - 49 BEDS	128	$80	$8	$87
50- 100 BEDS	117	$101	$16	$117
101- 149 BEDS	41	$89	$9	$98
150- 199 BEDS	22	$90	$8	$98
200 + BEDS	23	$93	$9	$103
Region (URBAN)				
NEW ENGLAND	73	$610	$124	$734
MIDDLE ATLANTIC	165	$1,177	$245	$1,422
SOUTH ATLANTIC	225	$1,590	$290	$1,880
EAST NORTH CENT	236	$1,315	$248	$1,563
EAST SOUTH CENT	75	$668	$113	$781
WEST NORTH CENT	80	$750	$135	$885
WEST SOUTH CENT	149	$609	$104	$713
MOUNTAIN	90	$564	$96	$660
PACIFIC	228	$1,260	$208	$1,469
PUERTO RICO	3	$0	$0	$0
Region (RURAL)				
NEW ENGLAND	11	$25	$1	$26
MIDDLE ATLANTIC	23	$32	$4	$36
SOUTH ATLANTIC	54	$95	$8	$103
EAST NORTH CENT	48	$67	$8	$75
EAST SOUTH CENT	77	$145	$20	$165
WEST NORTH CENT	30	$7	$1	$7
WEST SOUTH CENT	54	$20	$1	$21
MOUNTAIN	20	$28	$3	$31
PACIFIC	14	$35	$5	$40
TEACHING STATUS				
NON-TEACHING	818	$1,673	$292	$1,965
MINOR	522	$2,781	$464	$3,245
MAJOR	315	$4,543	$858	$5,402
DSH PATIENT PERCENT				
0	0	$0	$0	$0

	(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)**
GT 0-0.10	31	$16	$0	$17
0.10-0.16	65	$7	$0	$7
0.16-0.23	178	$54	$16	$70
0.23-0.35	728	$3,832	$711	$4,544
GE 0.35	642	$5,087	$886	$5,973
DSH NOT AVAILABLE**	11	$0	$0	$0
URBAN TEACHING/DSH				
TEACHING & DSH	775	$7,168	$1,309	$8,477
NO TEACHING/DSH	539	$1,375	$254	$1,629
NO TEACHING/NO DSH	0	$0	$0	$0
DSH NOT AVAILABLE	10	$0	$0	$0
TYPE OF OWNERSHIP				
VOLUNTARY	1,241	$7,208	$1,309	$8,517
PROPRIETARY	152	$32	$7	$39
GOVERNMENT	262	$1,757	$298	$2,055

Column (1) shows total hospitals that are expected to receive payments related to the 340B policy under this final rule.
Column (2) includes the estimated drug remedy payment made to account for the policies described in this final 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 1,686 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.