DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 419

[CMS–1793–P]

RIN 0938–AV18

Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule describes the agency's proposed actions to comply with the remand from the district court to craft a remedy in light of the United States Supreme Court's decision in *American Hospital Association* v. *Becerra,* 142 S. Ct. 1896 (2022), relating to the adjustment of Medicare payment rates for drugs acquired under the 340B Program from calendar year (CY) 2018 through September 27th of CY 2022.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by September 11, 2023.

ADDRESSES: In commenting, please refer to file code CMS–1793–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *https://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1793–P, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1793–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Elise Barringer, (410) 786–9222.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *https://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to the content of comments submitted by other commenters.

I. Background

A. OPPS Payment Policy for Drugs Acquired Through the 340B Program

1. Overview

Under the Hospital Outpatient Prospective Payment System (''OPPS''), we generally set payment rates for separately payable drugs and biologicals (hereinafter referred to collectively as ''drugs'') under section 1833(t)(14)(A) of the Social Security Act (the Act). Section 1833(t)(14)(A)(iii)(II) of the Act provides that, if hospital acquisition cost data are not available, the payment amount is the average price for the drug in a year established under section 1842(o), section 1847A, or section 1847B of the Act, as the case may be. Payment rates for drugs are usually established under section 1847A of the Act, which generally sets a default rate of the average sales price (ASP) plus 6 percent. Section 1833(t)(14)(A)(iii)(II) of the Act also provides that the average price for the drug in the year as established under section 1847A of the Act is calculated and adjusted by the Secretary of the Department of Health and Human Services (Secretary) as necessary for purposes of paragraph (14).

In the calendar year (CY) 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59371), the Centers for Medicare & Medicaid Services (CMS) reexamined the appropriateness of paying the ASP plus 6 percent for drugs acquired through the 340B Drug Pricing Program (hereinafter referred to as the ''340B Program''), a Health Resources and Services Administration (HRSA)-administered program that allows covered entities to purchase certain covered outpatient drugs at discounted prices from drug manufacturers. Based on findings of the Government Accountability Office (GAO),[1] the HHS Office of the Inspector General (OIG),[2] and the Medicare Payment Advisory Commission (MedPAC) [3] that 340B hospitals were acquiring drugs at a significant discount under the 340B Program, CMS adopted a policy beginning in 2018 generally to pay an adjusted amount of ASP minus 22.5 percent for certain separately payable drugs or biologicals acquired through the 340B Program. This adjustment amount was based on our concurrence with an analysis by MedPAC that concluded that the estimated average minimum discount of 22.5 percent of ASP adequately represented the average minimum discount that a 340B participating hospital received for separately payable drugs under the OPPS (82 FR 59354 through 59371). Our intent in implementing this payment reduction was to reflect more accurately the actual costs incurred by participating hospitals in acquiring 340B drugs. We stated our belief that such changes would allow Medicare beneficiaries and the Medicare program to pay a more appropriate amount when hospitals participating in the 340B Program furnished drugs to Medicare beneficiaries that were purchased under the 340B Program (82 FR 59353 through 59371).

2. OPPS Payment for 340B Drugs in CY 2018 Through September 27th of 2022

From January 1, 2018, through September 27, 2022, under the OPPS we generally paid for certain separately payable drugs acquired through the 340B Program at ASP minus 22.5 percent. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370), we finalized our proposal and adjusted the payment rate for separately payable drugs (other than

[1] Government Accountability Office. ''Medicare Part B Drugs: ''Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals.'' June 2015. Available at *https://www.gao.gov/assets/gao-15-442.pdf.*

[2] Office of Inspector General. ''Part B Payment for 340B Purchased Drugs. OEI–12–14–00030''. November 2015. Available at: *https://oig.hhs.gov/oei/reports/oei-12-14-00030.pdf.*

[3] Medicare Payment Advisory Commission. March 2016 Report to the Congress: Medicare Payment Policy. March 2016. Available at Medicare Payment Advisory Commission. March 2016 Report to the Congress: Medicare Payment Policy. March 2016. Available at *https://www.medpac.gov/document/http-www-medpac-gov-docs-default-source-reports-may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program-pdf/.*

drugs with pass-through payment status and vaccines) acquired under the 340B Program from ASP plus 6 percent to ASP minus 22.5 percent. We also noted that critical access hospitals are not paid under the OPPS, and therefore were not subject to the OPPS 340B drug payment adjustment policy (hereinafter referred to as the ''340B payment policy''). We also exempted rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals from the 340B payment adjustment primarily due to these hospitals receiving special payment adjustments under the OPPS. In addition, as stated in the CY 2018 OPPS/ASC final rule with comment period, this policy change did not apply to drugs with pass-through payment status, which are required to be paid based on the ASP methodology, or vaccines, which are excluded from the 340B Program.

Additionally, as discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370), to effectuate the payment adjustment for 340B-acquired drugs, we implemented modifier ''JG,'' effective January 1, 2018. Hospitals paid under the OPPS, other than types of hospitals excluded from the OPPS (such as critical access hospitals), or exempted from the 340B payment policy for CY 2018, were required to report modifier ''JG'' on the same claim line as the drug Healthcare Common Procedure Coding System (HCPCS) code to identify a 340B-acquired drug. For CY 2018, rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals were exempted from the 340B payment adjustment. These hospitals were required to report informational modifier ''TB'' for 340B-acquired drugs, and continued to be paid the full applicable amount, generally ASP plus 6 percent.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58981), we continued the Medicare 340B payment policies that were implemented in CY 2018 and adopted a policy to pay for non-pass-through 340B-acquired biosimilars at ASP minus 22.5 percent of the biosimilar's ASP, rather than the reference biological product's ASP. Additionally, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59015 through 59022), we finalized a policy to pay ASP minus 22.5 percent for 340B-acquired drugs furnished in non-exempted off-campus provider-based departments (PBDs) paid under the Physician Fee Schedule (PFS). We adopted this payment policy for CY 2019 and subsequent years. Also, during the CY 2019 OPPS/ASC rulemaking cycle, we clarified that the 340B payment adjustment applied to drugs priced using either wholesale acquisition cost (WAC) or average wholesale price (AWP), and since the policy was first adopted, we applied the 340B payment adjustment to 340B-acquired drugs priced using these pricing methodologies. The 340B payment adjustment for WAC-priced drugs was WAC minus 22.5 percent. 340B-acquired drugs that were priced using AWP were paid an adjusted amount of 69.46 percent of AWP (83 FR 37125).[4]

For more detailed descriptions of our OPPS payment policy for drugs acquired under the 340B program during this timeframe, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59371); the CY 2019 OPPS/ASC final rule with comment period (83 FR 59015 through 59022); the CY 2020 OPPS/ASC final rule with comment period (84 FR 61321 through 61327); the CY 2021 OPPS/ASC final rule with comment period (85 FR 86042 through 86055); the CY 2022 OPPS/ASC final rule with comment period (86 FR 63640 through 63649); and the CY 2023 OPPS/ASC final rule with comment period (87 FR 71972 through 71973).

3. Payment for Non-Drug Items and Services in CY 2018 Through CY 2022

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59216, 59258), to comply with the statutory budget neutrality requirements under sections 1833(t)(9)(B) and (t)(14)(H) of the Act, we finalized our proposal to redistribute our estimated reduction in payments for separately payable drugs as a result of the 340B payment policy by increasing the conversion factor used to determine the payment amounts for non-drug items and services. As further described in the CY 2018 OPPS/ASC final rule with comment period, we used updated CY 2016 claims data and a list of 340B-eligible providers to calculate an estimated impact of $1.6 billion based on the final CY 2018 policy to pay for OPPS 340B-acquired drugs at a payment rate of generally ASP minus 22.5 percent. In order to effectuate the budget neutrality provisions of the OPPS, the estimated $1.6 billion in reduced drug payments from adoption of the final 340B payment methodology was redistributed in an equal offsetting amount to all hospitals paid under the OPPS by increasing the payment rates by 3.19 percent for nondrug items and services furnished by all hospitals paid under the OPPS for CY 2018. This same conversion factor adjustment applied for CYs 2019 through 2022, increasing payments for non-drug items and services in these CYs as a result of the 340B payment policy.

B. Litigation History of the 340B Payment Policy

The 340B payment policy has been the subject of extensive litigation. On December 27, 2018, in the case of *American Hospital Association* v. *Azar,* 348 F. Supp. 3d 62 (D.D.C. 2018), the United States District Court for the District of Columbia (the District Court) concluded that the Secretary exceeded his statutory authority by adjusting the Medicare payment rates for drugs acquired under the 340B Program to ASP minus 22.5 percent for CY 2018. The District Court subsequently came to the same conclusion for CY 2019. *See Am. Hosp. Ass'n* v. *Azar,* 385 F. Supp. 3d 1 (D.D.C. 2019).

On July 10, 2019, the District Court entered final judgment. *See Am. Hosp. Ass'n* v. *Azar,* No. 18–cv–2084 (RC), 2019 WL 3037306 (D.D.C. July 10, 2019). The agency then appealed to the United States Court of Appeals for the District of Columbia Circuit (the D.C. Circuit), and on July 31, 2020, that court issued an opinion reversing the District Court's judgment. *See Am. Hosp. Ass'n* v. *Azar,* 967 F.3d 818 (D.C. Cir. 2020).

On June 15, 2022, the Supreme Court reversed the decision of the D.C. Circuit, holding that if CMS has not conducted a survey of hospitals' acquisition costs, it may not vary the payment rates for outpatient prescription drugs by hospital group. *See Am. Hosp. Ass'n* v. *Becerra,* 142 S. Ct. 1896 (2022).

The Supreme Court declined to opine on the appropriate remedy and remanded the case to the D.C. Circuit, which in turn remanded it to the District Court. Upon remand to the District Court, the plaintiffs filed motions seeking orders (1) vacating the portion of the CY 2022 final OPPS rule that set the reimbursement rate for 340B drugs at ASP minus 22.5 percent, which was still in effect for the remainder of 2022, and (2) requiring CMS to remedy the reduced payment amounts to 340B hospitals under the final OPPS rules for CY 2018 through CY 2022 by reimbursing them the difference between what they were paid and ASP plus 6 percent. On September 28, 2022, the District Court ruled on the first motion, vacating the 340B

[4] The 69.46 percent of AWP was calculated by first reducing the original 95 percent of AWP price by 6 percent to generate a value that is similar to ASP or WAC with no percentage markup. Then we applied the 22.5 percent reduction to ASP/WAC-similar AWP value to obtain the 69.46 percent of AWP, which was similar to either ASP minus 22.5 percent or WAC minus 22.5 percent.

reimbursement rate for the remainder of 2022. *See Am. Hosp. Ass'n* v. *Becerra,* 18–cv–2084 (RC), 2022 WL 4534617.[5]

On January 10, 2023, the District Court ruled on the second motion, issuing a remand without vacatur to give the agency 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 CY 2018 through CY 2022. *See Am. Hospital Ass'n* v. *Becerra,* 18–cv–2084 (RC), 2023 WL 143337.[6]

C. Payment for 340B-Acquired Drug Claims for September 28, 2022, Through December 31, 2022, and for CY 2023

The agency complied with the District Court's September 28, 2022, decision by uploading revised OPPS drug files to pay the default rate (generally ASP plus 6 percent) for all CY 2022 claims for 340B-acquired drugs paid from September 28, 2022, through the end of CY 2022.[7]

In the CY 2023 OPPS/ASC final rule with comment period, we finalized a policy that drugs acquired through the 340B program would be paid at the default rate (generally ASP plus 6 percent) for CY 2023. Correspondingly, to ensure budget neutrality for CY 2023 OPPS payment rates as required by statute, we finalized a reduction of 3.09 percent to the 2023 OPPS conversion factor. This 3.09 percent reduction for CY 2023 offsets the prior increase of 3.19 percent that was applied to the conversion factor when we implemented the 340B payment policy in CY 2018. This is because a downward adjustment involves a smaller percentage reduction from a larger number to get the same dollar amount as the original upward adjustment from a smaller number. More specifically, in order to achieve the original budget neutrality adjustment for CY 2018, we had to multiply the conversion factor by 1.0319. In order to offset this prior increase for the CY 2023 rule, we had to make a downward adjustment to the conversion factor, which involved dividing 1 by 1.0319, which equals 0.9691. And 1 minus 0.9691 equals 0.0309, which is where we derived the 3.09 percent reduction to the conversion factor for CY 2023. As we explained in the CY 2023 OPPS/ASC final rule, we decreased the OPPS conversion factor to offset the increase the OPPS conversion factor in CY 2018, which originally implemented the 340B policy in a budget neutral manner. We stated: ''This adjustment to the conversion factor is appropriate in these circumstances, including because it removes the effect of the 340B policy as originally adopted in CY 2018, which was recently invalidated by the Supreme Court as explained above, from the CY 2023 conversion factor and ensures it is equivalent to the conversion factor that would be in place if the 340B payment policy had never been implemented'' (87 FR 71975). Additionally, we explained that we agreed with commenters, including the American Hospital Association (AHA), that under these specific circumstances it was appropriate to decrease payments for non-drug items and services by a percentage that would offset the percentage by which they were increased when CMS implemented the 340B policy in CY 2018 (87 FR 71975).

For more detail on the payment rate for drugs acquired under the 340B program for CY 2023 and the corresponding adjustment to the conversion factor to maintain budget neutrality as a result of reversing the 340B adjustment and paying for all separately payable drugs at ASP plus 6 percent (or WAC plus 3 or 6 percent or 95 percent of AWP), we refer readers to the CY 2023 OPPS/ASC final rule with comment period (87 FR 71973 through 71976).

II. Proposal To Remedy Payment Adjustment for 340B-Acquired Drugs From CY 2018 Through September 27th of CY 2022

A. Remedy Options Considered By CMS

We evaluated several options to determine which remedy would best achieve the objective of unwinding the unlawful 340B payment policy while making certain OPPS providers (hereinafter referred to as ''affected 340B covered entity hospitals'')[8] as close to whole as is administratively feasible.

We describe the different remedy options and aspects of those alternative options that we considered below.

1. Make Additional Payments to Affected 340B Covered Entity Hospitals for 340B-Acquired Drugs From CY 2018 Through September 27th of CY 2022 Without Proposing an Adjustment To Maintain Budget Neutrality

We considered calculating the additional amount each affected 340B covered entity hospital would have been paid for 340B-acquired drugs from CY 2018 through September 27th of CY 2022 if not for the 340B payment policy, and then proposing to pay that amount to each hospital without applying a corresponding adjustment to the conversion factor for the increased payments for non-drug items and services that were made from CY 2018 through CY 2022 due to the 340B payment policy. As described in more detail below, we believe that we would have the authority to make remedy payments under sections 1833(t)(2)(E) and 1833(t)(14) of the Act, along with our retroactive rulemaking authority in section 1871(e)(1)(A) of the Act. We note that sections 1833(t)(2)(E) and 1833(t)(14) of the Act require budget neutrality with respect to payment adjustments to the OPPS made under those sections and are not specific to remedy payments. Consequently, we believe the best reading of both of those provisions is that these remedy payments are subject to budget neutrality requirements, at least when the budget neutrality adjustment would not be de minimis. We believe our reading of these provisions is consistent with the statute's general approach of budget neutralizing OPPS payment adjustments, *see, e.g.,* Social Security Act (SSA) section 1833(t)(9)(B), as further explained in the following sections.

Section 1833(t)(2)(E) of the Act straightforwardly requires adjustments made under that provision be made ''in a budget neutral manner.'' (*Accord* 65 FR 18438 (noting (t)(2)(E)'s budget neutrality requirement)) Section 1833(t)(14)(H) of the Act, relating to drug APC payment rates, states that ''Additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but *shall be taken into account for subsequent years.*'' In addition, section 1833(t)(9)(B) of the Act, referenced in section 1833(t)(14)(H), states that ''[i]f the Secretary makes adjustments under subparagraph (A),[9] then the adjustments for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been

[5] *https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2018cv2084-79.*

[6] *https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2018cv2084-86.*

[7] See supra note 4.

[8] Throughout the duration of the policy, the 340B payment adjustment did not apply to critical access hospitals, rural sole community hospitals, children's hospitals, and PPS exempt cancer hospitals.

[9] Section 1833(t)(9)(A) Periodic review.—The Secretary shall review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

made if the adjustments had not been made.''

We believe these statutory requirements require that we maintain budget neutrality when making these remedy payments. To the extent these remedy payments are understood as a payment adjustment under section 1833(t)(2)(E) of the Act, they are subject to that section's budget neutrality constraints. And to the extent these payments are understood as a payment under section 1833(t)(14) of the Act, they are ''[a]dditional expenditures resulting from'' paragraph (t)(14) for years other than 2004 or 2005 and thus are subject to budget neutrality constraints under section 1833(t)(14)(H) of the Act.

This reading of these provisions is consistent with the statute's general approach of budget neutralizing OPPS payment adjustments, *see, e.g.,* SSA section 1833(t)(9)(B), except when expressly exempted, *see* SSA section 1833(t)(7)(I), (t)(14)(H), (t)(16)(D)(iii), (t)(18)(C), (t)(19)(A), (t)(20). Budget neutrality in OPPS serves the important interest of limiting expenditures under Part B and thus protecting the public fisc. *Cf.* H.R. Rep. No. 106–436, at 34 (1999) (noting the goal of prospective payment systems, including the OPPS, is to slow growth rate of Medicare expenditures). The Supplementary Medicare Insurance Trust Fund (hereinafter referred to as the ''Part B Trust Fund'') that makes OPPS payments is mostly financed by premiums from participants and contributions from the general fund of the Treasury. The Trustees of the Part B Trust Fund warn that unexpected increases in Medicare Part B or D expenditures may thus require increases to beneficiary premiums and coinsurance, which already represent a growing share of beneficiaries' total income and are projected to reflect about three-quarters of the average Social Security retired-worker benefit by the end of this century. *See* The 2023 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medicare Insurance Trust Funds at 40–41.[10] Additionally, unexpected increases in Medicare Part B or D expenditures could require tax increases or expenditure reductions elsewhere in the Federal budget; the Trustees already project expenditures to consume more than 30 percent of Federal income tax revenue in just 50 years. *Id.* at 43.

Accordingly, when changes to payment policy are made, we make an adjustment to the OPPS conversion factor in order to maintain budget neutrality. (70 FR 68542 (noting outpatient drugs are included in the budget neutrality calculation beginning in 2006)) We do not believe Congress intended the statute to permit regulated entities to achieve policy outcomes through litigation that would be statutorily unavailable to them through the regular rulemaking process—especially policy outcomes that increase total Medicare expenditures.

We acknowledge that, in the past, not all OPPS payment policy changes based on sections 1833(t)(14) and (t)(2)(E) of the Act have resulted in adjustments to the budget neutrality factor or actual expenditures from the Part B Trust Fund equaling zero in all circumstances. The method CMS uses to account for changes to the ''estimated number of expenditures'' referenced in section 1833(t)(9)(B) and incorporated by section 1833(t)(14)(H) is the OPPS conversion factor (*e.g.,* 71 FR 68193 through 68194). In situations that have not had any estimated impact on the OPPS conversion factor or that would otherwise have a de minimis impact, such as a 0.0001 change to the conversion factor, which would have an inconsequential effect on Medicare payments, CMS has effectively rounded the estimated impact on expenditures to zero.[11] Thus, in circumstances when there would be a de minimis impact on estimated OPPS payment to meet the budget neutrality requirements as a result of a post-rulemaking policy change, we have not changed OPPS payments to reflect the minimal impact of the policy change. When considering whether the estimated amount of expenditures is de minimis, we have taken into account relevant context, such as the size of the change comparable to the OPPS payments overall, the relative number of interested parties and any reliance interests, as well as the anticipated impact on the Part B Trust Fund of the change in payment due to the post-annual rulemaking policy versus the anticipated administrative burden and cost of ratesetting disruption.

In the case of the remedy payments for the 340B payment policy, by contrast, we believe a budget neutrality adjustment is statutorily required and, even if not statutorily required, warranted as a matter of sound public policy. The estimated impact of our one-time lump sum remedy payments is significant and reflects a very substantial fraction of total OPPS spending for any one calendar year, one that goes well beyond any impact of which we have previously rounded to zero. The specifics of the lump sum are discussed in greater detail in the following section, II.B.1. Additionally, we do not believe any reliance interests or administrative burdens outweigh the impact of the remedy payments on the Part B Trust Fund sufficiently to justify disregarding the principle of budget neutrality, if that were statutorily possible. As we explain below, though, the potential reliance interests implicated by the need to recover unwarranted payments made over many years, combined with the unique difficulties in calculating and collecting these payments through retroactive rulemaking, should properly affect the way the budget neutrality principle applies to these unique circumstances.

As noted previously in section I.A.3, we budget neutralized the 340B payment policy from CY 2018 to CY 2022 by increasing the rate for non-drug items and services by 3.19 percent. That resulted in $7.8 billion in additional spending on non-drug items and services during that time period. We note that some OPPS providers are still filing, or re-filing, claims for CY 2022; therefore, our estimate of the total amount of additional spending on non-drug items and services during that time period could change as more claims from CY 2022 are processed, or reprocessed. CMS has repeatedly stated in both litigation and OPPS rules in the **Federal Register** that any remedy payments could be subject to budget neutrality constraints. *See, e.g., Am. Hosp. Ass'n* v. *Becerra,* 142 S. Ct. 1896, 1903 (2022) (acknowledging HHS's position that ''a judicial ruling invalidating the 2018 and 2019 reimbursement rates for certain hospitals would require offsets elsewhere in the program''); 84 FR 61323 (''Recognizing Medicare's complexity in formulating an appropriate remedy, any changes to the OPPS must be budget neutral, and reversal of the policy change, which raised rates for non-drug items and services by an estimated $1.6 billion for 2018 alone, could have a significant

[10] *https://www.cms.gov/oact/tr/2023.*

[11] In the CY 2007 OPPS/ASC final rule with comment period, using our authority under section 1833(t)(2)(E) of the Act, we implemented a quality improvement program which required hospitals eligible to participate in the Inpatient Prospective Payment Systems (IPPS) Reporting Hospital Quality Data for the Annual Payment Update (RHQDAPU) to meet the requirements for receiving the full FY 2007 IPPS payment in order to qualify for the CY 2007 OPPS update. Hospitals failing to meet the requirements would receive a reduced OPPS conversion factor update in CY 2007, the amount of which would then, if not deemed ''negligible,'' be offset by a corresponding increase to the OPPS conversion factor to maintain budget neutrality. See 71 FR 68193 through 68194.

economic impact on the approximate 3,900 facilities that are paid for outpatient items and services covered under the OPPS.''). Additionally, because the 340B payment policy this rule proposes to remedy was itself budget neutralized, failing to budget neutralize the remedy payments would mean that the additional payments for non-drug items and services that were made from CY 2018 through CY 2022 to achieve budget neutrality for the 340B payment policy as described under section I.A.3 of this proposed rule would be a windfall, especially to non-340B hospitals that were not subject to decreased drug payments from CY 2018 through CY 2022. The Trust Fund has a strong interest in recovering that windfall, and those who received it have no legitimate reliance interest in permanently retaining that windfall.

As for the administrative burden specific to maintaining budget neutrality, CMS was already required by the remand order to remedy the 340B policy. The decision to include a budget neutrality component in this remedy does not appreciably change this burden, though of course the burden could be greater or lesser depending on how the remedy is crafted. As set forth more fully below, our proposed budget neutrality adjustment does not directly recoup money already paid to providers; rather, it is a proposed adjustment to future payment rates, allowing hospitals to take such rates into account rather than forcing them to open their bank accounts and disgorge their windfall immediately. On balance, the billions of dollars the proposed payments to affected 340B covered entity hospitals would cost the Part B Trust Fund outweigh the potential administrative expenses or disruption resulting from a broad change in OPPS payment to offset these additional costs.

Finally, even if this remedy rule were exempt from budget neutrality requirements as a matter of statutory interpretation, we would still exercise our authority under section 1833(t)(2)(E) of the Act to offset the extra payments we made for non-drug items and services from 2018 through 2022. As discussed, those payments have proven to be an unwarranted windfall, and the Trust Fund has a strong interest in recovering them. This proposal to avoid a windfall to providers would also be consistent with the agency's longstanding inherent and common-law (and common-sense) recoupment authority, through which ''the Secretary generally has the duty and power to protect against overpayments to providers.'' *Chaves Cnty. Home Health Serv., Inc.* v. *Sullivan,* 931 F.2d 914, 918 (D.C. Cir. 1991); *see also, e.g., United States* v. *Lahey Clinic Hosp., Inc.,* 399 F.3d 1, 16 (1st Cir. 2005) (''Although provisions of the Medicare Act expressly authorize the Secretary to reopen initial payment determinations and to recoup overpayments administratively in certain circumstances, *see* 42 U.S.C. 1395g(a) and 1395gg, the statute does not displace the United States' long standing power to collect monies wrongfully paid through an action independent of the administrative scheme, nor is there any inconsistency.''); *Mount Sinai Hosp. of Greater Miami, Inc.* v. *Weinberger,* 517 F.2d 329, 345 (5th Cir.), *modified,* 522 F.2d 179 (5th Cir. 1975) (similar). For that reason and those discussed above, we would find that unwinding those payments would be necessary to ensure equitable payments, even assuming no statutory budget neutrality requirement applies.

Therefore, we believe that it is required by the statute—but even if not required, that it would be consistent with the statute—and consistent with our past practices, and appropriate, to propose to offset the additional payments for non-drug items and services that were made from CY 2018 through CY 2022 in order to maintain budget neutrality or equitable payments when remedying this policy. But the context of this rule remains unique: We are adjusting payments prospectively in order to provide a remedy for a previous unlawful payment decision. And precisely because that previous payment decision itself followed budget neutrality principles; it provided unwarranted payments to some at the same time it improperly took payments from others. In applying budget neutrality principles to this remedy, we seek to rectify this imbalance and restore matters as closely as possible to where they would have been absent the policy the Supreme Court determined to be unlawful. We solicit comments from the public on our proposed interpretation of our statutory budget neutrality obligations, equitable payment authorities, and recoupment authority.

2. Full Claims Reprocessing From CY 2018 Through September 27th of CY 2022

Perhaps the most perfect measure of achieving budget neutrality in circumstances like this would be to turn back the clock to the day the unlawful payment decision was first made, undo that decision, and start over. To do so here, CMS would have to reprocess all OPPS claims for 340B-acquired drugs and non-drug items and services from CY 2018 through September 27th of CY 2022 using the default payment rate under section (t)(14) of the Act and our retroactive rulemaking authority in section 1871(e)(1)(A) of the Act. This approach would have the benefit of putting providers, beneficiaries, and Medicare back in the same situation they would have been in if CMS had never adopted the ASP minus 22.5 percent rate for 340B-acquired drugs in 2018. But we have previously rejected arguments that remedial rulemaking must necessarily provide this type of precise make-whole relief. *See Shands Jacksonville Med. Ctr., Inc.* v. *Azar,* 959 F.3d 1113, 1118 (D.C. Cir. 2020) (agreeing that the agency need not restore ''each individual hospital . . . at least to the position it would have occupied had the rate reduction never taken effect'').

Reprocessing every single claim might be a potential approach to remedy this situation, if it were administratively achievable. But reprocessing such an unprecedentedly large volume of claims and issuing payment to affected providers in a timely fashion would impose an immense administrative burden on CMS, its contractors, and providers. We accordingly believe that this approach is not feasible in this case. This approach would require the reprocessing of virtually all claims submitted to the OPPS system during the affected period of time, but that system processes more than 100 million claims each year. 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, and leading to widespread beneficiary cost sharing uncertainty, as beneficiaries could be caught by surprise by a significant change in cost sharing responsibility from a claim they thought had been closed many years ago. The large quantity of claims and the amount of time required to reprocess them while continuing normal claims processing likewise would not result in timely payments or adjustments to hospitals. Additionally, reprocessing these claims would lead to the need for significant recoupments of payments for non-drug items and services that would have already been paid at the higher rate based on the budget neutrality adjustment applied as a result of the original 340B payment policy. The D.C. Circuit has held that it is not necessary ''to recalculate each individual claim paid under the reduced rate'' that was the subject of litigation when doing so would have caused significant

administrative burden and delayed payments. *See Shands,* 959 F.3d at 1120. But the expected results of such a calculation can certainly inform an alternative approach to budget neutrality, as we discuss below.

We note that the vast majority of 340B drug claims from CY 2022 have been reprocessed at the higher 340B payment rate, generally ASP plus 6 percent, which we believe was allowable under the District Court's order prospectively vacating the CY2022 340B payment rate and the typical timely filing requirements described at 42 CFR 424.44. We believe this was appropriate for CY 2022 claims given that providers were able to follow the regular claims processing conventions for these claims, and we will ensure CMS does not make duplicate payments for these claims already remedied by the usual claims processing methods. As of this proposed rule, we estimate that for CY 2022, $1.5 billion in remedy payments (including the Medicare and 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, but were held until, or reprocessed after, the 340B rule was vacated and the standard drug payment rates were in effect for 340B-acquired drugs. We consider these reprocessed claims to be partially remedied as 340B providers no longer received the lower 340B drug payment rate for these 340B-acquired drugs. We note that the non-drug item and service payment components of these claims were not remedied, which we discuss in subsequent sections. This $1.5 billion is one component of the total remedy payments accounted for in this proposed rule. We also note that these claims only had the 340B drug portion of the claim adjusted, and that for these claims to be fully remedied the non-drug item and service components of these claims would also need to be adjusted as discussed in subsequent sections.

3. Aggregate Hospital Payments From CY 2018 Through September 27th of CY 2022

We also considered calculating one-time aggregate payment adjustments for each provider for the CY 2018 through September 27th of CY 2022 time-period, including both additional payments for 340B-acquired drugs and reduced payments for non-drug items and services under sections 1833(t)(2)(E) and 1833(t)(14) of the Act, along with our retroactive rulemaking authority in section 1871(e)(1)(A) of the Act. This option would have involved: (1) calculating the total additional payments for each hospital that would have been paid for separately payable non-pass-through 340B-acquired drugs from CY 2018 through September 27th of 2022 in the absence of the 340B payment policy; (2) calculating the additional amount each hospital was paid under the OPPS from CY 2018 through CY 2022 for non-drug items and services as a result of the 340B policy; (3) subtracting (2) from (1); and (4) issuing a payment to, or requiring a recoupment from, each hospital for the 5-year period in which the 340B payment policy was in effect.

While this approach would also have satisfied the statutory budget neutrality concerns discussed above, we do not believe the statute mandates such an inflexible approach in these circumstances. *Cf. Shands Jacksonville Med. Ctr., Inc.,* 959 F.3d at 1120. (For further discussion of this point, see section II.B.1.a.) Such an approach 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. Given these burdens, the financial strain many hospitals experienced during the recent public health emergency, and the amount of time that has transpired since the original payments for these drugs, items, and services were made, we decided not to propose this option and overly burden these hospitals in this way.

B. Proposed Remedy

1. Proposed Methodology for Calculating and Process for Remitting Remedy Payments to Affected 340B Covered Entity Hospitals for 340B-Acquired Drugs Furnished and Paid Adjusted Amounts Under the OPPS in CY 2018 Through September 27th of CY 2022

a. Statutory Authority

CMS believes that the best way to remedy our payment policy for 340B-acquired drugs for the period from CY 2018 through September 27th of CY 2022, which the Supreme Court found unlawful, would be to make one-time lump sum payments to affected 340B covered entities calculated as the difference between what they were paid for 340B drugs (ASP minus 22.5 percent or an adjusted WAC or AWP amount) during the relevant time period (from CY 2018 through September 27th of CY 2022) and what they would have been paid had the 340B payment policy not applied. We believe this approach comes as close to providing 340B covered entities with make-whole relief as CMS can reasonably accomplish, without the massive burden that would be associated with manually reprocessing all claims. Assuming hospitals properly assigned the billing codes discussed below when submitting their CY 2018 through 2022 claims, CMS expects the remedy payment to each 340B covered entity for 340B-acquired drugs to be the same as if CMS manually reprocessed those claims.

We propose to make the remedy payments relying principally on: (1) our rate-setting authority under section 1833(t)(14) of the Act; and (2) our equitable adjustment authority under section 1833(t)(2)(E) of the Act. To the extent this proposed rule is retroactive (in whole or in part), we would rely on our retroactive rulemaking authority in section 1871(e)(1)(A) of the Act.

The Supreme Court has held that if CMS has not conducted a survey of hospitals' acquisition costs, it may not vary the payment rates for outpatient prescription drugs by hospital group. Because we did not use any survey of hospitals' acquisition costs, we believe it is necessary for the remedy to apply the default rate (generally ASP plus 6 percent) to comply with paragraph (14)(A)(iii) of section 1833(t) of the Act for those years, as interpreted by the Supreme Court. Even if a retroactive rule were not necessary to comply with section 1833(t)(14) of the Act, we believe that failing to apply the default rate retroactively would be contrary to the public interest in this specific situation in part because it would leave the plaintiff 340B hospitals paid at a substantially lower rate, due to the magnitude of payment, than we now believe to be proper under the statute and that they have continually pressed in court since we first announced the adjustment. We believe the equities weigh in favor of a partially retroactive remedy here, because a significant number of plaintiff hospitals have been advocating for our current policy in court since we first announced our 340B payment policy for CY 2018 despite our view that there was no administrative or judicial review for such claims, and because the impact on the Part B Trust Fund will be lessened because we are applying budget neutrality principles. We note that the position of those plaintiff hospitals was ultimately vindicated by the Supreme Court.

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.'' Assuming this proposal is viewed as a retroactive remedy (in whole or in part), we believe it would be necessary to use this retroactive rulemaking authority to implement the remedy by revising 340B payment rates for this prior period to comply with the Supreme Court's interpretation of the requirements of section 1833(t)(14) of the Act.

Section 1833(t)(2)(E) of the Act requires the Secretary to, ''establish, in a budget neutral manner, outlier adjustments . . . transitional pass-through payments . . . and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals.'' In this case, we propose that the lump sum payment, calculated as the difference between what an affected 340B covered entity hospital received for 340B-acquired drugs during the time period at issue and what they would have received for 340B-acquired drugs if the 340B adjustment had not been in place, would be an equitable retroactive adjustment. Such an adjustment is necessary to ensure equitable payments to affected 340B covered entity hospitals by making them whole for the decreased payments for 340B-acquired drugs they received from CY 2018 through September 27th of CY 2022 that are no longer proper in light of the Supreme Court's decision. To the extent necessary, we are applying the adjustment retroactively in accordance with the Court's ruling and for the reasons discussed in the above paragraph.

We are proposing to use our authority under 1833(t)(14) of the Act in conjunction with our equitable adjustment authority under 1833(t)(2)(E) of the Act, to accomplish an equitable outcome as we remedy past payments made under the 340B payment policy. To the extent necessary, we also propose to use our retroactive rulemaking authority under section 1871(e)(1)(A) of the Act.

We solicit comment from the public on our proposed use of these authorities in the remedy policies discussed in the rule. We also solicit comment on other possible authorities (including implied authority or common law authority) that might also be applicable to the remedy policies discussed in this rule or on which we could rely to make remedy payments.

b. Estimated Reduction in Drug Payments to Affected 340B Covered Entity Hospitals in CY 2018 Through September 27, 2022

An estimated 1,649 340B covered entity hospitals were paid at the 340B payment rate, which was generally ASP minus 22.5 percent for 340B-acquired drugs for CY 2018 through September 27th of 2022, rather than the default rate, which is generally ASP plus 6 percent, due to the 340B payment policy. CMS estimates that these hospitals received approximately $10.5 billion less in 340B drug payments (including money that would have been paid by Medicare and money that would have come from beneficiaries as copayments) than they would have for drugs provided in CY 2018 through September 27th of 2022 had the 340B policy not been implemented. We will update these estimated figures in the final rule as we continue to receive updated CY 2022 claims data. We expect to have sufficient CY 2022 340B drug claims at issue submitted by September 27, 2023; therefore, by the publication date for the final rule that corresponds to this proposed rule, we should have sufficient claims data to state with more specificity the reduction in drug payments to affected 340B covered entity hospitals in CY 2018 through September 27, 2022. As previously discussed, we estimate that 340B providers have already received $1.5 billion in remedy payments through reprocessed claims for 340B drugs provided from January 1, 2022, through September 27, 2022. Since $1.5 billion of the total $10.5 billion that we calculated affected 340B covered entity hospitals did not receive as a result of this payment policy has already been remedied through reprocessed claims, we estimate the remaining remedy amount that affected 340B covered entity hospitals have not yet received as a result of this policy is $9.0 billion.[12]

We have calculated the estimated aggregate payments by isolating 340B drugs assigned status indicator ''K''(non-pass-through drugs and non-implantable biologicals, including therapeutic radiopharmaceuticals) and billed with modifier ''JG'' (drug or biological acquired with 340B Program discount, reported for informational purposes). We then calculated the difference between these drugs' CY 2018 through 2022 340B payment rate and the 340B rate proposed in this rule, which was generally the difference between ASP minus 22.5 percent and ASP plus 6 percent. We used a similar process to estimate aggregate payments owed for drugs with payment amounts based on WAC or AWP. In particular, for drugs priced using WAC, we calculated the difference between WAC minus 22.5 percent and WAC plus 3 or 6 percent, as applicable, and for drugs priced using AWP, we calculated the difference between 69.46 percent of AWP and 95 percent of AWP. We note that the WAC and AWP based payment rates outlined in this paragraph are the common longstanding default OPPS drug payment rates if ASP data are not available.

We welcome comment on this proposed methodology of estimating the reduction in drug payments to affected 340B covered entity hospitals in CY 2018 through September 27, 2022.

c. Proposed Methodology for Calculating Remedy Payments Owed to Each Affected 340B Covered Entity Hospital

We propose the following process for calculating the amount of payment owed to each affected 340B covered entity hospital and issuing that payment. For each affected 340B covered entity hospital, we propose to calculate the amount the hospital would have been paid under the OPPS from CY 2018 through September 27th of CY 2022 for drugs the hospital acquired through the 340B Program had that 340B policy not been in effect. We would then subtract from this amount the amount each affected 340B covered entity hospital was paid under the OPPS for 340B-acquired drugs during the period of CY 2018 to September 27th of CY 2022.

When added to the adjusted amount paid under the OPPS from CY 2018 through September 27th of CY 2022 for separately payable drugs acquired under the 340B Program, this proposed additional lump sum payment amount would result in the affected 340B covered entity hospital receiving the default ASP plus 6 percent rate (or WAC plus 3 or 6 percent or 95 percent of AWP, as applicable) for drugs acquired

[12] We note that the additional amount CMS pays affected 340B covered entity hospitals through this remedy could decrease if additional CY 2022 claims are processed at the higher payment rate, as discussed under section I.C. As previously explained, the agency complied with the District Court's September 28, 2022, decision by paying the default rate (generally ASP plus 6 percent) for all CY 2022 claims for 340B-acquired drugs paid from September 28, 2022, onward. However, as some affected 340B providers are still filing, or re-filing, claims for CY 2022, we are paying those claims at the higher default payment rate for drugs, which is generally ASP plus 6 percent. Therefore, our estimate of the total amount of additional drug payments that would be made through this remedy could change as more claims from CY 2022 are processed, or reprocessed, at the default payment rate of ASP plus 6 percent.

under the 340B Program for CY 2018 through September 27th of CY 2022.

We illustrate the proposed process for calculating and paying an affected 340B covered entity hospital's additional lump sum OPPS payments for 340B drugs furnished from CY 2018 through September 27th of CY 2022 in the following example. Based on claims data from CY 2018 through September 27th of CY 2022 for which those claims have been processed and OPPS payments already made, we would calculate that a particular 340B-covered entity hospital would have been paid an estimated $10 million for 340B drugs had that 340B payment policy not been in effect during that time period. Then, based on claims data for the same hospital from the same time period, we would calculate that the hospital was actually paid $7.31 million for 340B drugs from CY 2018 through September 27th of CY 2022. The difference between these two amounts—$2.69 million—would be the amount of the additional lump sum payment the 340B covered entity hospital would receive. Another method to estimate the total amount an affected 340B covered entity hospital would have been paid had the 340B payment policy not been in effect (X) is to use the following formula:

$X = (Y/0.775) * 1.06$

Where Y is the total amount received under the 340B policy from CY 2018 to September 27th of CY 2022.

In this example, the Y is $7.31 million. Therefore, ($7.31 million/0.775) * 1.06 = $10 million. The lump sum payment would be $10 million minus $7.31 million, which equals $2.69 million. We solicit comment from the public on our proposed calculation methodology for calculating remedy payments owed to each affected 340B covered entity hospital.

d. Instruction to MACs To Remit Remedy Payments

Consistent with our past practice of remitting payments owed due to litigation, we propose to make additional payments to each 340B covered entity hospital by issuing instructions (such as a Change Request (CR) or a Technical Direction Letter (TDL)) to the 340B covered entity hospital's Medicare Administrative Contractor (MAC), instructing the MAC to issue a one-time lump sum payment to the hospital in the amount calculated using the above described methodology within a specified timeframe, which we propose would be within 60 calendar days of the MAC's receipt of the instruction. For instance, in the example above CMS would issue instructions to the relevant MAC instructing it to issue a payment to the 340B covered entity hospital in the amount of $2.7 million within 60 calendar days of the MAC's receipt of the instructions. (*Note:* MACs will continue to follow normal accounting processes for collecting repayment amounts stemming from provider-specific overpayment obligations, as well as other unique situations such as provider bankruptcy or payment suspension, any of which may impact the provider's net payment amount.) We solicit comment from the public on our proposed approach to remitting remedy payments. We specifically seek comment on the timeframe of 60 calendar days in which we are proposing to have the MACs make the proposed lump sum payments. Given the number of one-time lump-sum payments to hospitals, the size of the payments, and the overall complexity of this remedy, we believe 60 calendar days is necessary for the MACs to accurately and precisely make these payments to individual hospitals. With that being said, we seek comment on this timeframe and if another such timeframe, such as 30 calendar days, is supported by rationale from commenters.

e. Accounting for Beneficiary Cost-Sharing

In most circumstances, beneficiaries would pay in the form of coinsurance approximately 20 percent of any additional 340B drug payments that affected 340B covered entity hospitals would have received, absent the CY 2018 through 2022 340B policy. But as described above, we are proposing to make each remedy payment as a one-time lump sum payment through MAC instructions using a combination of statutory authorities, including, if necessary, our retroactive rulemaking authority under section 1871(e)(1)(A) of the Act and our equitable adjustment authority under section 1833(t)(2)(E) of the Act. Because these payments are remedy payments issued through MAC instructions relying in part on our equitable adjustment authority under section 1833(t)(2)(E) of the Act, we do not believe these payments would be 340B drug payments subject to beneficiary copayments. Rather, we believe that these remedy payments are analogous to the type of cost report adjustments under section 1833(t)(2)(E) of the Act that we have previously found do not authorize providers to seek additional beneficiary copayments.[13]

We acknowledge that we have previously suggested that any remedy might affect beneficiary cost-sharing. *See, e.g.,* 84 FR 61323. But we made that statement in 2019, before the litigation was concluded, and well before we proposed here how to structure any remedy and determine how it should impact beneficiary cost sharing many years later. With the benefit of a concrete proposed remedy, we can clarify that our proposed lump sum payments for the difference in 340B-acquired drug payments due to the 340B payment policy would not affect beneficiary cost-sharing.

We believe that in these unique circumstances, it is appropriate to exercise our authority under section 1833(t)(2)(E) of the Act to make adjustments ''as necessary to ensure equitable payments'' and for Medicare to pay the full $9.0 billion difference between what 340B hospitals were paid for 340B-acquired drugs from CY 2018 through September 27, 2022, and what they would have been paid for 340B-acquired drugs absent the 340B payment policy during this time period, so that affected 340B covered entity hospitals are paid the amount they would have been paid in full without application of the 340B payment policy. While we do not believe it would necessarily be appropriate to make this kind of adjustment under section 1833(t)(2)(E) of the Act to ensure hospitals receive what they would have been paid from Medicare and beneficiaries absent the 340B payment policy every time we make a policy change or lose a lawsuit, we propose finding that such an adjustment is necessary for equitable payments in these unique circumstances in part because of the unprecedented

[13] For example, section 3138 of the Affordable Care Act added a new section 1833(t)(18) to the Social Security Act, providing for an adjustment under section 1833(t)(2)(E) of the Social Security Act to address higher costs incurred by cancer hospitals. Section 1833(t)(2)(E) of the Act, in turn, directs the Secretary to establish, ''in a budget neutral manner,'' payment ''adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals.'' In response to CMS's proposal to implement this adjustment on a per claim basis through increased APC payments, commenters expressed concern that doing so would increase beneficiary copayments since beneficiary copayment is a percentage of the APC payment. These commenters encouraged CMS to implement the adjustment in a way that did not increase beneficiary copayments. Consequently, CMS determined it was appropriate to make the cancer hospital payment adjustment through the form of an aggregate payment to each cancer hospital determined at cost report settlement, as opposed to an adjustment at the APC level, thereby eliminating the higher copayments for beneficiaries associated with providing the adjustment on a claims basis through increased APC payments. *See* CY 2012 OPPS/ASC final rule, 76 FR 74121, 74204 (2011), for our prior use of our equitable adjustment authority under section 1833(t)(2)(E) of the Act to adjust cancer hospital payments.

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.

Accordingly, we believe that here, where we are remedying prior payments, it would be appropriate to set the remedy payment amount under section 1833(t)(2)(E) of the Act so that affected 340B covered entity hospitals would be paid amounts that approximate what they would have been paid for these drugs absent the 340B payment policy, which includes what affected 340B covered entity hospitals would otherwise have been paid by the beneficiary. Therefore, the $9.0 billion payment amount includes $1.8 billion, an amount that is equivalent to what affected 340B covered entity hospitals would have collected from beneficiaries for these 340B-acquired drugs if the 340B payment policy had not been in effect.

We emphasize that, if our proposal is finalized, affected 340B covered entity hospitals may not bill beneficiaries for coinsurance on remedy payments—regardless of this adjustment—because we would issue this remedy payment through MAC instructions relying in part on our equitable adjustment authority under section 1833(t)(2)(E). CMS would consider appropriate administrative action for providers who nevertheless bill beneficiaries for coinsurance. We solicit comments from the public on our proposed approach to accounting for beneficiary cost sharing.

f. Proposed Remedy Payment Amounts

The following data file contains our calculations of the amounts owed under the above-described methodology to each affected 340B covered entity hospital: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps.* We solicit comment from the public on the accuracy of the data in Addendum AAA of this proposed rule, particularly with respect to the estimated amount of remedy payment due to each hospital. This addendum can be found online through the CMS OPPS website.[14]

g. Anticipated Timing of Proposed Remedy Payments

If we finalize the proposal to pay affected 340B covered entity hospitals in the manner described above, we would propose to make these additional payments at the end of CY 2023 or beginning of CY 2024, after this rule has been finalized and the MAC instructions for each affected 340B covered entity hospital have been issued.

h. Eligibility of Proposed Remedy Payments for Interest

CMS also considered its authority to pay interest on the remedy payments but does not believe it has the authority to do so.

2. OPPS Non-Drug Item and Service Payments From CY 2018 Through CY 2022

a. Background

As mentioned earlier in section I.A.3, the 340B payment policy was implemented in a budget neutral manner under sections 1833(t)(9)(B) and 1833(t)(14)(H) of the Act by increasing non-drug item and service payments to all OPPS providers for CY 2018 through CY 2022. To comply with the statutory budget neutrality requirements in sections 1833(t)(9)(B) of the Act and 1833(t)(14)(H) of the Act, as well as section 1833(t)(2)(E), CMS must account for these additional payments, which were made solely due to the 340B payment policy that was in effect from CY 2018 through CY 2022, in determining a remedy for the 340B policy. After the Supreme Court's decision in *American Hospital Association,* those additional payments became a windfall—payments the hospitals should not have received but did anyway. To comply with budget neutrality and restore the situation as closely as reasonably possible to the state that would exist if we simply re-ran all the claims from 2018 to 2022 under the correct payment rules, we must find a means of recovering this windfall.

The reduction in 340B drug payments made to affected 340B covered entity hospitals from CY 2018 through CY 2022 was offset by an increase in non-drug item and service payments made to all hospitals paid under the OPPS during the same time period to comply with statutory budget neutrality requirements. In other words, all hospitals were paid more under the OPPS for non-drug items and services for CY 2018 through CY 2022 than they would have been paid in the absence of the 340B payment policy. Starting in CY 2018, CMS applied an approximate 3.19 percent increase to the OPPS conversion factor to offset the decreased OPPS 340B drug payments in order to maintain budget neutrality in those years. Because we are now making additional payments to affected 340B covered entity hospitals to pay them what they would have been paid had the 340B policy never been implemented, we must correspondingly make an offset to maintain budget neutrality as if the 340B payment policy had not been in effect during CY 2018 through CY 2022. This is consistent with the policy finalized in the CY 2023 OPPS/ASC final rule with comment period (87 FR 71976) where CMS finalized a minus 3.09 percent adjustment to the conversion factor as this adjustment removes the effect of the 340B policy as originally adopted in CY 2018, again, as described in more detail above in section I.C. The CY 2023 adjustment to the conversion factor ensures it is equivalent to the conversion factor that would be in place if the 340B payment policy had never been implemented.

To calculate the additional amount CMS paid for non-drug items and services, we propose to include those assigned the following status indicators, SI = J1, J2, P, Q1, Q2, Q3, R, S, T, U, V. These status indicators generally capture the non-drug items and services impacted by a change in the OPPS conversion factor. For additional details on these status indicators, we refer readers to Addenda D1 of the CY 2023 OPPS/ASC final rule with comment period for the most recent OPPS status indicators and their definitions. This file is available on the CMS website.[15] We calculated the adjusted payment (the payment that would have been made for the non-drug item or service absent the budget neutrality adjustment to the conversion factor due to the 340B payment policy) by taking the amount paid for the non-drug item or service and dividing it by 1.0319 (the amount by which the conversion factor was increased during CYs 2018 through 2022 to budget neutralize the effect of the 340B payment policy). We propose that the amount that would need to be offset to maintain budget neutrality in crafting this remedy would be based on the payments to providers that would have been made for non-drug items and services absent the 340B payment policy during CY 2018 through CY 2022, and the Medicare payment to 340B providers for the amount equivalent to the additional drug payments that would have otherwise been paid as beneficiary cost-sharing. Based on these factors, we are proposing prospectively to offset $7.8 billion in order to maintain budget neutrality. This figure was calculated based on past claims data with 80 percent of this amount based on the Medicare share and 20 percent based on the beneficiary share.

[14] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps.*

[15] *https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient-regulations-and-notices/cms-1772-fc.*

As we explain below, our budget-neutrality adjustment in the 2018 through 2022 OPPS rules reflected a prediction regarding how much we would spend on 340B drugs—a prediction that turned out to be too low. As it turns out, 340B hospitals spent more on drugs than we expected, so our policy ended up saving the Trust Fund (and beneficiaries) more money from cutting the rates paid for 340B drugs than the Trust Fund (and beneficiaries) paid for non-drug services in our budget-neutrality adjustment to offset the savings. Our proposed remedy achieves budget neutrality by reversing that imbalance. In aggregate, the total additional payment that providers will receive as a result of this remedy, $10.5 billion, will be larger than the amount of payment that will be prospectively offset, $7.8 billion. As we explain below, we believe that our proposed remedy, which effectively reverses the imbalance that arose under the policy the Supreme Court deemed unlawful, and reasonably approximates the results that would occur if we simply re-ran the claims after eliminating the 340B adjustment, reflects the best approach to budget neutrality in these unique circumstances. We solicit comments from the public on our proposed approach to implementing budget neutrality.

b. Proposed Prospective Adjustment to Payments for Non-Drug Items and Services To Offset the Increased Payments for Non-Drug Items and Services Made in CY 2018 Through CY 2022

As discussed previously in section II.A.1, we believe that sections 1833(t)(2)(E) and 1833(t)(14) of the Act, under which we propose to make this proposed remedy payment, are properly read to require budget neutrality. Section 1833(t)(2)(E) of the Act provides that adjustments under that provision must be made in a budget neutral manner. Section 1833(t)(14)(H) of the Act states that additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years, while section 1833(t)(9)(B) of the Act states that the adjustments for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made. To implement these requirements, we propose to unwind the additional payments that were made for non-drug items and services to all providers from CY 2018 through CY 2022. In other words, along with reversing the rate change discussed earlier in this rule, we propose to reverse the accompanying increase in the conversion factor for CYs 2018 through 2022 that was solely attributable to the adoption of the 340B payment policy.

In order to reduce the burden on providers of offsetting this amount required to maintain budget neutrality, estimated to be $7.8 billion, we are proposing to implement this adjustment prospectively. We propose to, beginning in CY 2025, reduce all payments for non-drug items and services to all OPPS providers, except new providers as defined later in this section, by 0.5 percent each year until the total offset is reached (approximately 16 years). We believe starting this reduction in CY 2025 would allow CMS time to finalize the appropriate methodology, and then calculate and publish the payment rates derived from this policy in the CY 2025 OPPS/ASC proposed rule, allowing adequate time for impacted parties to assess and prepare for the new payment rates that would be calculated using a reduced conversion factor. Additionally, we believe a 0.5 percent annual reduction in the conversion factor would be appropriate because it would balance the need to address the past payments for non-drug items and services to ensure budget neutrality while also ensuring the offset is not overly financially burdensome on impacted entities, especially those in rural communities, which we believe would be the case if we were to apply an adjustment for the full offset amount in a single year.

We acknowledge that, in litigation, we at one point questioned the American Hospital Association's suggestion that we could achieve budget neutrality by decreasing Medicare payments in future years, noting that section 1833(t)(9) of the Act requires budget neutrality for a particular ''year.'' *See Am. Hosp. Ass'n* v. *Becerra,* Br. for the Respondents, at 30 (U.S. No. 20–1114).[16] At the same time, however, the government pointed to 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.'' *Ibid.* We have now further considered section 1833(t)(9) in light of the Supreme Court's decision holding that judicial review is available and also recognizing the statutory requirement of budget neutrality, and distinct possible ways of approaching the remedy issue have come into focus.

As explained below, we believe that the proposal here is consistent with paragraph (t)(9) of the Act: It would offset the amounts of money that constitute excess payments in past years—which are effectively overpayments for each past year in question (that is, 2018 to 2022) in light of the Supreme Court's decision. In other words, while we propose reducing the conversion factor in future years, we would be doing so not by seeking to budget neutralize payments across a period of years rather than in a particular ''year'', but instead by adjusting payment rates for each year from 2018 to 2022 to account for the Supreme Court's decision. We would then make the requisite additional payments to 340B hospitals for those years, and collect the excess payments from other hospitals in future years. Because the estimated amount of expenditures for each of 2018 to 2022 would still be budget neutralized—indeed, it is our best effort to implement the policy that would have been in effect had the 340B policy never been implemented in the first place—we believe it is consistent with the provision that adjustments may not ''cause the estimated amount of expenditures under this part for the year to increase or decrease.'' *See* SSA section 1833(t)(9)(B). We believe that this interpretation would balance any reliance interests hospitals may have in payments already made while staying consistent with the budget neutrality requirements repeated throughout the OPPS statute in sections 1833(t)(2)(E), 1833(t)(9), and 1833(t)(14)(H). And, as discussed above in section II.A.1, avoiding a windfall to providers is consistent with the agency's recoupment authority. We welcome comments on these aspects of our proposal.

We also acknowledge that under our proposal the Part B Trust Fund would pay out more for remedial payments than it would recover over time based on the reduction in payments for non-drug items and services. That is a consequence of many factors, including our estimate in the CY 2018 OPPS/ASC final rule of the amount that expenditures for 340B-acquired drugs would decrease under the 340B payment policy, which we budget neutralized by applying a corresponding adjustment to the conversion factor to increase expenditures for non-drug

[16] *https://www.supremecourt.gov/DocketPDF/20/20-1114/197027/20211020212647625_20-1114bsUnitedStates.pdf.*

items and services by 3.19 percent. We acknowledged this limitation in Medicare's ability to calculate a precise estimate for purposes of the CY 2018 final rule with comment period in which this original budget neutrality adjustment was made. In the CY 2018 final rule with comment period we discussed that because data on drugs that are purchased with a 340B discount are not publicly available, we did not believe it was possible to more accurately estimate the amount of the aggregate payment reduction and the offsetting amount of the adjustment that was necessary to ensure budget neutrality through higher payment rates for other services. Further we discussed that there were potential offsetting factors, including possible changes in provider behavior and overall market changes that would likely have lowered the impact of the payment reduction (82 FR 52623).

As previously discussed, we now know our estimate of the reduction in expenditures for 340B drugs was lower than the actual amount by which expenditures for 340B drugs were reduced in CYs 2018 through 2022. Therefore, our budget neutrality calculations for those years ended up increasing payments for non-drug services by less than we decreased payments for 340B drugs. In an effort to come as close as is reasonably possible to turning back the clock to restore the position in which we would have been absent the policy the Supreme Court invalidated, we believe the budget neutrality calculation should reverse that result. The total amount of our proposed remedy payments to 340B hospitals for 340B drugs would thus be greater than the prospective reduction to the conversion factor. Given the unique posture of this remedy rule, we do not propose at this time to revise retroactively our estimated expenditures for CY 2018 through 2022, as readjusting our past estimated expenditures in order to prospectively adjust the conversion factor is not our standard practice for budget neutrality, nor is it required by the statute.

While our CY 2018 through 2022 predictions are the primary reasons that our proposed method of budget neutralization would not fully align with the money we predict the Part B Trust Fund would pay out in lump sum payments for 340B-acquired drugs as a result of this remedy, there are additional reasons. Some of these reasons increase the gap between our lump sum payment and our reduction in prospective non-drug spending; others do the opposite. First, as previously discussed, a large portion of the CY 2022 340B drug claims for dates of service between January 1, 2022, and September 27, 2022, have already been remedied as a result of being processed or reprocessed at the default drug payment rate. However, none of the non-drug item and service claims from CY 2022 have been offset yet to account for our proposed method of budget neutralization. Second, as previously noted, during CY 2022 CMS began making payment for 340B drugs at the default drug payment rate, generally ASP plus 6 percent, for claims processed after September 28, 2022; however, no adjustment was made for the increased payment of the non-drug item and service claims that were processed during this time. Therefore, there is over an entire quarter of claims for non-drug items and services that were paid a higher rate due to the 340B payment policy that still need to be offset, while the 340B drug claims for this quarter have already been paid correctly. We note that in aggregate, the total additional payment that providers will receive as a result of this remedy, $10.5 billion ($9 billion in lump sum payments and $1.5 billion for claims in 2022 that were processed or reprocessed at the default drug payment rate), will be larger than the amount of payment that will be prospectively offset, $7.8 billion. All of these figures include the beneficiary co-insurance portion in order to ensure providers receive what they would have absent the unlawful 340B payment policy.

As discussed above at section II.B.1.e, our proposal includes in the remedy payments the amount that affected 340B covered entity hospitals would otherwise have been paid by the beneficiary, so that the payments approximate what the hospitals would have been paid for these drugs absent the previous policy. Because the statute requires that this adjustment be budget neutral, we are proposing to include in the prospective offset calculation an amount to offset this increase in Medicare payments. As also discussed, we are proposing a total prospective offset of $7.8 billion to maintain budget neutrality as if the 340B payment policy had never been in effect and therefore had never adjusted the OPPS conversion factor. That offset encompasses both the money hospitals unwarrantedly received from the Medicare Trust Fund for non-drug services between 2018 and 2022, as well as the additional copayments they received from beneficiaries on those services. And we are using it to offset both the payments we are making to compensate 340B hospitals for the lower amounts Medicare paid them and the equitable adjustment we are making to compensate for the additional beneficiary copayments they would have received.

To avoid potentially overburdening providers with an immediate downward adjustment to the OPPS conversion factor, we believe applying a delayed offset to every non-drug item and service for every hospital is appropriate over a period of time. This is similar to the original 340B payment policy budget neutrality adjustment that increased the payment for every non-drug item and service for CY 2018 through CY 2022 to offset the downward adjustment in the payment rate for drugs acquired under the 340B program. We are 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 in CY 2018 through CY 2022. But there is often some imprecision inherent in budget neutrality calculations, and the alternative would require that we recalculate the additional amount that each hospital received under the prior policy and then apply a specific reduction to that hospital's future non-drug service payment rates to offset that amount. That is very similar to the claims reprocessing alternative that we discussed previously in section II.A.2, which would impose significant burdens and payment delays for 340B providers and it is faster and more certain than prospectively offsetting for all OPPS providers. In addition, it would be administratively unworkable to tailor individual payment reductions for each of the thousands of impacted hospitals for over a decade and a half, meaning we would likely need to collect a lump sum budget neutrality recoupment. That would impose all the burdens of an up-front budget neutrality recoupment we decided against proposing, as explained previously in section II.A.3. Except in the case of truly new hospitals, which we propose to exclude from the prospective offset as described under section II.B.2.c below, we generally do not believe our proposed approach would so significantly undercompensate hospitals to require that outcome, despite these potential distributional consequences. *See Shands Jacksonville Med. Ctr., Inc.* v. *Azar,* 959 F.3d 1113, 1120 (D.C. Cir. 2020) (rejecting challenge to remedy rule even when it left some hospitals

''slightly better off and others slightly worse off than they would have been had the rate reduction never taken effect''). Rather, we believe that our remedy would come as close as reasonably possible to turning back the clock to restore us to the place in which we would have been absent the policy the Supreme Court held unlawful. This remedy applies in truly unique circumstances: we must apply budget neutrality not purely prospectively but in a partially retroactive rulemaking to rectify an adjudicated past violation of law. As previously discussed, re-running all the relevant claims as if the 340B payment policy didn't occur would be close to impossible administratively. In these unique circumstances, we believe our proposed approach properly applies the budget neutrality principle, even if it results in some effectively unavoidable imprecision.

Accordingly, beginning in CY 2025, we propose annually to reduce OPPS payments for non-drug items and services, by decreasing the OPPS conversion factor by 0.5 percent each year until the total offset, estimated to be $7.8 billion, is reached. We recognize this rule is unique and therefore requires a unique prospective offset period. We believe an annual reduction of 0.5 percent would offset this amount in a reasonable amount of time while not imposing too significant of a reduction on hospitals in any particular year. At this time, we estimate that this process would take approximately 16 years (Table 1). This estimate 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. We note that, similar to the original 340B budget neutrality adjustment to the conversion factor, both Medicare payments under the OPPS and beneficiary cost-sharing will be impacted by the change in the conversion factor. In this instance, beneficiaries will generally have lower co-insurance payments for non-drug items and services as a result of this proposed 0.5 percent annual reduction to the OPPS conversion factor for the duration of the required budget neutrality offset. We invite comment on our estimated budget neutrality offset calculations, including the discussion of our method of budget neutralization not fully aligning with the money we predict the Part B Trust Fund would pay out in lump sum payments for 340B-acquired drugs as a result of this remedy, in advance of our application of the 0.5 percent reduction to the conversion factor starting in CY 2025. We would adjust this estimate in future CY annual OPPS rules after CY 2025, based on updated data, such as claims and aggregate OPPS spending estimates, to account for how much of the total additional non-drug item and service payment amount has been offset by the time of each annual rule. In the final CY rulemaking for this process, we propose that when we estimate the remaining amount of Medicare payment that would be needed to be fully offset within the prospective year, we propose that the 0.5 percent reduction amount would be reduced in the final year in which the adjustment applies, if needed, to the percentage estimated to be sufficient to offset the remaining amount by the end of that calendar year. After this final prospective adjustment is made, we propose that we would not make any additional adjustments to the OPPS conversion factor for purposes of offsetting the additional Medicare payments made to remedy the OPPS 340B payment policy, nor would we make any additional future adjustments if the amount of the offset in the final year of this adjustment is more or less than we had estimated in rulemaking for that CY. We propose to codify the 0.5 percent reduction in the OPPS conversion factor effective for CY 2025 in the regulations by adding new paragraph (b)(1)(iv)(B)(*12*) to § 419.32.

TABLE 1—ILLUSTRATION OF THE PROPOSED 0.5 PERCENT CONVERSION FACTOR ADJUSTMENT TO THE OPPS NON-DRUG ITEMS AND SERVICES BEGINNING CY 2025 TO MAINTAIN BUDGET NEUTRALITY

	CY 2024	CY 2025	CY 2026	CY 2027	CY 2028	CY 2029
Total Applicable OPPS Non-Drug Item and Service Spending (millions)	$63,724	$66,910	$70,256	$73,769	$77,457	$81,330
0.5-Percent Payment Reduction Amount (millions)	.....	335	351	369	387	407
Estimated Total Cumulative Offset (millions)	.....	335	686	1,055	1,442	1,849
	CY 2030	CY 2031	CY 2032	CY 2033	CY 2034	CY 2035
Total Applicable OPPS Non-Drug Item and Service Spending (millions)	$85,369	$89,667	$94,150	$98,858	$103,801	$108,991
0.5-Percent Payment Reduction Amount (millions)	427	448	471	494	519	545
Estimated Total Cumulative Offset (millions)	2,276	2,724	3,195	3,689	4,208	4,753
		CY 2036	CY 2037	CY 2038	CY 2039	CY 2040
Total Applicable OPPS Non-Drug Item and Service Spending (millions)		$114,440	$120,162	$126,170	$132,479	$139,102
0.5-Percent Payment Reduction Amount (millions)		572	601	631	662	*581
Estimated Total Cumulative Offset (millions)		5,325	5,926	6,557	7,219	7,800

*Note, 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.

We also note the Total Applicable OPPS Non-Drug Item and Service 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.

We seek comments on the annual percent reduction method described above and whether an alternative option—including those discussed previously in section II.A—would be appropriate. Additional possible alternative timelines for maintaining budget neutrality could be to offset a fixed dollar amount each year over a fixed period of time, such as 5, 10, or 15 years. For example, we could divide the $7.8 billion number by ten in order to offset $780 million per year from CY 2025 through CY 2034 by making an adjustment to the conversion factor to reflect an estimated $780 million reduction in non-drug item and service spending for each year.

We are also considering whether hospitals need additional time to prepare following any finalized policy, and, as such, seek comment on whether delaying the proposed reduction in the conversation factor from CY 2025 to CY 2026 would provide hospitals with additional time to make necessary arrangements.

c. Exclusion of New Providers

CMS recognizes that any hospital that enrolled in Medicare after January 1, 2018, received less than the full amount of the increased non-drug item and service payments made during that time than they otherwise would have received if enrolled prior to that date. This is because the increased non-drug item and service payments were being paid during all of CY 2018 through CY 2022, so any hospital that was not enrolled in Medicare for the full duration of this time period did not receive the full amount of increased non-drug items and service payments. We note that while the 340B drug payments increased to the default rate effective September 28, 2022 following the Supreme Court's decision, the increased conversion factor and associated increased non-drug item and service payments were in effect until December 31, 2022. We are therefore proposing that these providers would not be subject to the prospective rate reduction, which is predominantly designed to offset those non-drug item and service payments made during CY 2018 through CY 2022.

Consequently, we propose to designate any hospital that enrolled in Medicare after January 1, 2018, as a ''new provider'' for purposes of the conversion factor adjustment to offset those additional expenditures by Medicare to remedy the 340B payment policy and to pay these hospitals the rate for non-drug items and services that would apply in the absence of the conversion factor adjustment implemented due to the 340B payment policy remedy. This means that we would calculate payment rates for new providers using the conversion factor before applying the proposed 0.5 percent annual adjustment that would apply for hospitals that are not ''new providers'' for purposes of this policy. For the purpose of designating a new provider, we are proposing the date of enrollment in Medicare as the provider's CMS certification number (CCN) effective date. Providers that would meet this definition, and that we propose would be excluded from the prospective payment adjustment, are listed in the Addendum BBB to this proposed rule. This addendum can be found online through the CMS OPPS website.[17] As reflected in this file, we have determined that approximately 300 providers of the approximately 3,900 OPPS providers meet this definition. We propose to codify the exclusion of new providers from the prospective payment adjustment to the conversion factor for the duration of its application in the regulations by adding new paragraph (b)(1)(iv)(B)(*12*) to § 419.32.

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. Our proposal to exclude ''new providers'' from the prospective rate reduction 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, in part due to the fact that these providers would have received increased non-drug item and service payments for the duration of the 340B payment policy from CY 2018 through CY 2022. We recognize that this approach will exempt some hospitals receiving the 340B lump sum payment from the prospective offset. We considered creating various levels of exclusion from the proposed prospective offset depending on how long the specific hospital received increased non-drug item and service payments as a result of the 340B payment policy. However, we do not think it is feasible for CMS, or likely preferred by providers, to create many different sets of 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 CY 2018 through CY 2022 the provider was enrolled in Medicare for. This is why we are proposing that any hospital that enrolled in Medicare after January 1, 2018, which would have received less than the full amount of the increased non-drug item and service payments made during CY 2018 through CY 2022 due to the 340B payment policy than they otherwise would have received if enrolled prior to that date, would be exempt from the annual adjustment to the conversion factor to offset lump sum payments to affected 340B covered entity hospitals.

We solicit comments on our proposed definition of a ''new provider'' and our proposal to exempt new providers from the annual adjustment to the conversion factor to offset lump sum payments to affected 340B covered entity hospitals. We also solicit comments on whether there are any other easily-identifiable categories of providers who should be similarly exempted from the annual adjustment to the conversion factor.

III. Collection of Information Requirements

This document does not impose information collection requirements; that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Statement of Need

From CY 2018 through September 27th of CY 2022, CMS paid a lower rate (generally ASP minus 22.5 percent) to certain hospitals for drugs acquired through the 340B discount program. The purpose of this policy was to pay these hospitals for 340B drugs at a rate that more accurately reflected the actual costs they incurred to acquire them. This 340B policy was the subject of several years of litigation, which culminated in a decision of the Supreme Court of the United States in *American Hospital Association* v. *Becerra,* 142 S. Ct. 1896 (2022), which held that if CMS has not conducted a survey of hospitals' acquisition costs, it may not vary the payment rates for outpatient prescription drugs by hospital group. The Supreme Court subsequently remanded the case, and the district court ultimately ordered CMS to implement a remedy to address the reduced payment amounts to the plaintiff hospitals from CY 2018 through September 27th of CY 2022.

This proposed rule describes the remedy CMS is proposing to comply with the district court's remand. It would remedy the reduced payment amounts to the affected 340B covered entity hospitals by (1) calculating the amount each hospital would have received for 340B drugs from CY 2018 through September 27th of 2022 had the 340B policy not been in place; (2) subtracting from that total the amount each hospital received for 340B drugs from CY 2018 through September 27th of CY 2022; and (3) paying each affected 340B covered entity hospital the difference between these amounts by issuing instructions to the relevant MAC instructing it to issue a one-time lump sum payment to the hospital. The

[17] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps.*

amount of the lump sum payment would include the portion of the payment amount that would have been paid from the Part B Trust Fund and the portion of the payment amount that would have been paid in the form of beneficiary coinsurance if not for the 340B payment policy.

To comply with statutory budget neutrality requirements, we are proposing to annually reduce OPPS payments for non-drug items and services beginning in CY 2025 by decreasing the OPPS conversion factor by 0.5 percent each year, until a total offset of an estimated $7.8 billion is reached.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 on Modernizing Regulatory Review (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), and Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 14094 amends section 3(f) of the Executive Order 12866 to define a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order.

A regulatory impact analysis (RIA) must be prepared for rules with significant regulatory action(s) and/or with significant effects as per section 3(f)(1) as measured by the $200 million or more in any 1 year. Based on our estimates, the Office of Management and Budget's (OMB's) Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1) as measured by the $200 million or more in any 1 year. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. Therefore, OMB has reviewed these proposed regulations, and the Department has provided the following assessment of their impact. We solicit comments on the regulatory impact analysis provided.

As required by statute, we are implementing this court-ordered remedy in a budget neutral manner, and we estimate that the total increase in Federal Government expenditures, due only to the proposed changes in this proposed rule, would be $2.8 billion. We took into consideration the additional Medicare drug payments of $9.0 billion to the estimated 1,649 340B covered entity hospitals to which the drug payment remedy would apply, and the $6.2 billion in reduced Medicare prospective payments for non-drug items and services beginning in CY 2025 to offset the additional payments that were made for non-drug items and services from CY 2018 through CY 2022 as part of the 340B payment policy and the amount of the 340B drug remedy payments that would otherwise have been paid by the beneficiary. We note that this $6.2 billion figure is the portion of reduced Medicare prospective payments specifically, and this represents approximately 80 percent of the total $7.8 billion offset that we are proposing. Beneficiaries will experience reduced prospective co-insurance 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 drugs that were paid less due to the 340B policy from CY 2018 through September 27, 2022.

While we consider the amount of additional payment made to affected 340B covered entity hospitals for 340B-acquired drug claims with dates of service from January 1, 2022, through September 27, 2022, that were processed or reprocessed at the default drug payment rate after the 340B payment policy was vacated, estimated at $1.5 billion, for purposes of the total aggregate remedy payment to affected 340B covered entity hospitals, we are not including that $1.5 billion in our calculation here, which estimates the total increase in Federal Government expenditures due only to the proposed changes in this proposed rule. This $1.5 billion in remedy payments has already been made after the District Court's order.

The two amounts described above, $9.0 billion and $6.2 billion, are not equal because the separate amounts associated with restoring 340B-acquired drug payments to ASP plus 6 and offsetting the impact of additional Medicare spending to remedy this 340B payment policy are not equal to each other. This is due to many factors, including but not limited to, (1) Medicare's payment policy adjustment for 340B acquired drugs ended on September 27, 2022, while the original conversion factor adjustment of minus 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 payment during this time period have been remedied, (3) Medicare's payment of an amount equivalent to the increased beneficiary cost-sharing 340B providers would have received for 340B-acquired drugs if the 340B payment policy had not been in effect as part of the lump sum payments to providers, and (4) the original budget neutrality adjustment to increase the conversion factor in CY 2018 did not keep pace with the reduction in 340B drug payments for the remainder of the years for which the 340B payment policy previously applied. We note that, in aggregate, the total additional payment that providers will receive as a result of this remedy, $10.5 billion, will be larger than the amount of payment that will be prospectively offset, $7.8 billion.

Most notable of the aforementioned factors is factor (4). From CY 2018 through CY 2022, the actual spending associated with 340B-acquired drugs changed from what was prospectively projected. The actual total reduction in 340B-acquired drug payments during this time period outpaced the corresponding increase in non-drug item and service payments. The proposed changes in this proposed rule are to maintain budget neutrality by undoing the original 340B payment policy. Additionally, this is consistent with our past practice described in the CY 2023 OPPS/ASC final rule with comment period (87 FR 71975), which

had the support of commenters, where we maintained budget neutrality by removing the effect of the 340B policy as originally implemented in CY 2018 from the CY 2023 conversion factor and ensured it was equivalent to the conversion factor that would be in place if the 340B payment policy had never existed, rather than budget neutralizing the increase in 340B drug spending by making a corresponding conversion factor decrease to account for the actual increase in the payment rates for these drugs. This proposed remedy complies with the budget neutrality requirement that Medicare should pay a total amount for the additional 340B-acquired drug payments that is generally offset by the estimated amount that would have paid absent the 340B payment policy. In Table 2 of this proposed rule, we display the impact of these proposed policy changes on drug payments, including aggregate payment by hospital type. Specific proposed additional 340B-acquired drug lump sum payment amounts by individual hospital can be found in Addendum AAA. If we adopt our proposal as proposed, the impact for specific hospital types of the reduced prospective payment for non-drug items and services beginning in CY 2025 would be included in each proposed and final rule for calendar years in which the prospective reduction would apply, beginning in CY 2025.

C. Detailed Economic Analysis

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 2 shows the total number of facilities (1,661), including designated cancer and children's hospitals and Community Mental Health Centers (CMHCs), for which we expect that the remedy payments included in this proposed rule, if finalized, would be made. We excluded all hospitals and CMHCs for which we would not expect any direct effect from the remedy payments in this proposed rule. We show the total number of OPPS hospitals (1,649) for which we expect remedy payments would be made, excluding the PPS-exempt cancer and children's hospitals and CMHCs, on the second line of the table. We excluded cancer and children's hospitals because section 1833(t)(7)(D)(ii) of the Act provides transitional outpatient payments (TOPs) which permanently holds harmless cancer hospitals and children's hospitals to their ''pre-Balanced Budget Act of 1997 (BBA) amount'' as specified under the terms of the statute.

Column 2: Remedy for the 340B Payment Policy (in Millions)

Column 2 shows the estimated remedy payments that would be made under this proposed rule to various categories of affected providers. We note that certain categories of providers may experience limited effects due to either having no providers in the category or limited billing associated with 340B-acquired drugs. We also note that a provider's placement within the categories may vary due to their characteristic information potentially changing across the years in question (CY 2018 through CY 2022).

Column 3 displays the estimated payment impact of any CY 2022 claims that have been reprocessed by the MACs. We note 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.

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

Row		(1) Number of hospitals	(2) Lump sum drug remedy payment (in millions)	(3) CY 2022 reprocessed drug payment remedy (in millions)	(4) Total 340B drug remedy payments (sum of Columns 2 and 3)
1	ALL PROVIDERS *	1,661	9,003.4	1,540.5	10,543.9
2	ALL HOSPITALS (excludes hospitals held harmless and CMHCs)	1,649	9,003.4	1,540.5	10,543.9
3	URBAN HOSPITALS	1,297	8,538.2	1,491.5	10,029.7
4	LARGE URBAN	611	4,326.8	815	5,141.8
5	(GT 1 MILL.).				
6	OTHER URBAN (LE 1 MILL.)	686	4,211.4	676.5	4,887.9
7	RURAL HOSPITALS	324	457.3	47.2	504.5
8	SOLE COMMUNITY	147	95.1	5.9	101.0
9	OTHER RURAL	177	362.2	41.4	403.6
	BEDS (URBAN).				
10	0–99 BEDS	213	258.3	44.4	302.7
11	100–199 BEDS	374	827.1	124.7	951.8
12	200–299 BEDS	252	1,208.8	192.6	1,401.4
13	300–499 BEDS	267	1,982.7	338.9	2,321.6
14	500 + BEDS	191	4,261.3	790.9	5,052.2
	BEDS (RURAL).				
15	0–49 BEDS	124	80.6	7.7	88.3
16	50–100 BEDS	116	104.3	13.3	117.6
17	101–149 BEDS	40	89.4	8.7	98.1
18	150–199 BEDS	21	89.9	8.1	98.0
19	200 + BEDS	23	93.2	9.3	102.5
	REGION (URBAN).				
20	NEW ENGLAND	73	613.4	114.8	728.2
21	MIDDLE ATLANTIC	163	1,173.0	2,36.3	1,409.3
22	SOUTH ATLANTIC	218	1,593.3	280.2	1,873.5
23	EAST NORTH CENT	232	1,318.6	240	1,558.6
24	EAST SOUTH CENT	75	644.2	106	750.2
25	WEST NORTH CENT	79	749.3	129.4	878.7
26	WEST SOUTH CENT	145	610.5	99.6	710.1
27	MOUNTAIN	86	566.2	90.2	656.4
28	PACIFIC	223	1,269.7	195.1	1,464.8
29	PUERTO RICO	3	0.0	0	0.0
	REGION (RURAL).				
30	NEW ENGLAND	11	25.0	1.4	26.4
31	MIDDLE ATLANTIC	22	32.1	3.5	35.6
32	SOUTH ATLANTIC	52	97.1	5.5	102.6
33	EAST NORTH CENT	48	66.9	8	74.9

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

Row		(1) Number of hospitals	(2) Lump sum drug remedy payment (in millions)	(3) CY 2022 reprocessed drug payment remedy (in millions)	(4) Total 340B drug remedy payments (sum of Columns 2 and 3)
34	EAST SOUTH CENT	75	145.5	19.5	165.0
35	WEST NORTH CENT	29	6.8	0.6	7.4
36	WEST SOUTH CENT	54	19.6	1.4	21.0
37	MOUNTAIN	20	28.9	2.7	31.6
38	PACIFIC	13	35.4	4.6	40.0
	TEACHING STATUS.				
39	NON-TEACHING	795	1,682.2	273.2	1,955.4
40	MINOR	514	2,792.9	435.5	3,228.4
41	MAJOR	312	4,520.3	830	5,350.3
	DSH PATIENT PERCENT.				
42	0	0	0.0	0	0.0
43	GT 0–0.10	31	16.5	0.4	16.9
44	0.10–0.16	62	6.9	0.1	7.0
45	0.16–0.23	167	53.7	15.5	69.2
46	0.23–0.35	715	3,819.4	6,71.4	4,490.8
47	GE 0.35	635	5,098.9	8,51.4	5,950.3
48	DSH NOT AVAILABLE**	11	0.1	0	0.1
	URBAN TEACHING/DSH.				
49	TEACHING & DSH	766	7,157.8	1,252	8,409.8
50	NO TEACHING/DSH	521	1,380.3	239.5	1,619.8
51	NO TEACHING/NO DSH	0	0.0	0	0.0
52	DSH NOT AVAILABLE2	10	0.1	0	0.1
	TYPE OF OWNERSHIP.				
53	VOLUNTARY	1,215	7,202.2	1,241.7	8,443.9
54	PROPRIETARY	150	32.2	6.6	38.8
55	GOVERNMENT	256	1,761.1	290.5	2,051.6

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. We note 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.

We estimate that the total proposed monetary transfer in this proposed rule would be approximately $9.0 billion. The $9.0 billion includes the proposed additional lump sum drug payments to the 1,649 affected 340B covered entity hospitals. The $9.0 billion amount is an estimate of the total aggregate additional payments that would need to be made to the affected 340B covered entity hospitals for drugs that were paid less due to the 340B policy from CY 2018 through September 27th of CY 2022. As noted previously, the estimated total amount required to remedy providers is $10.5 billion, which includes the $1.5 billion that has already been paid through 340B drug claims processing and reprocessing that occurred for CY 2022 claims.

We note that in this proposed rule we also describe our proposal to annually reduce OPPS payments for non-drug items and services beginning in the CY 2025 OPPS, by decreasing the OPPS conversion factor by 0.5 percent each year until we have offset the full amount of the additional payments made for non-drug items and services from CY 2018 through CY 2022 due to the increase in the conversion factor in those years in response to the 340B payment policy. This proposed prospective offset will apply to all OPPS providers, including 340B providers, aside from those OPPS providers explicitly excluded as previously discussed. The overall impact of these prospective reductions is estimated to be minus $6.2 billion in Medicare payments alone over the full span of this proposed offset. The estimated impact of this offset for each calendar year for which the offset is estimated to apply is detailed in Table 1 of this proposed rule.[18] The impact of this offset on payments to each provider type for each calendar year in which the offset is in effect would be included in the regulatory impact analysis for the applicable annual OPPS rulemaking, beginning for CY 2025. However, we note that generally the impact of that annual 0.5 percent reduction to the OPPS conversion factor on individual providers as well as categories of providers will depend on the percentage of their OPPS payments that are conversion factor based, and in most cases will be a decrease of slightly less than 0.5 percent relative to overall OPPS payment. Please see Table 3 below for our estimated total impact to the OPPS payments based on the information provided in Table 1.

[18] We note that Table 1 illustrates the prospective reductions of $7.8 billion that represent the reduced Medicare payments as well as reduced cost-sharing paid by the beneficiary. The $6.2 billion of the financial impacts discussed here represents only the Medicare payments over the full span of this proposed offset.

TABLE 3—ESTIMATED ANNUAL IMPACT TO OPPS SPENDING BASED ON 0.5 PERCENT ADJUSTMENT TO THE CONVERSION FACTOR

	CY 2025	CY 2026	CY 2027	CY 2028	CY 2029	CY 2030
0.5-Percent Payment Reduction Amount (millions)	$335	$351	$369	$387	$407	$427
	CY 2031	CY 2032	CY 2033	CY 2034	CY 2035	CY 2036
0.5-Percent Payment Reduction Amount (millions)	$448	$471	$494	$519	$545	$572
	CY 2037	CY 2038	CY 2039	CY 2040		
0.5-Percent Payment Reduction Amount (millions)	$601	$631	$662	$581		
Total Offset			$7.8 billion			

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's CY 2023 OPPS/ASC proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

For the purposes of our estimate we assume that each reviewer reads 100 percent of the proposed rule. We seek comments on this assumption.

Using the mean hourly wage information from the Bureau of Labor Statistics (BLS) for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $123.06 per hour, which is double the BLS hourly rate in order to account for fringe benefits and other indirect costs in addition to the hourly wage itself.[19] Assuming an average reading speed, we estimate that it would take approximately 3 hours for the staff to review this proposed rule. For each entity that reviews the rule, the estimated cost is $369.18 (3 hours × $123.06). Therefore, we estimate that the total cost of reviewing this regulation is $608,778 ($369.18 × 1,649).

D. Alternatives Considered

We evaluated several options to determine which remedy would best achieve the objectives of unwinding the unlawful 340B payment policy while making certain OPPS providers as close to whole as is administratively feasible.

For example, we considered making additional payments to affected 340B covered entity hospitals for 340B-acquired drugs from CY 2018 through September 27th of CY 2022 without implementing a budget neutral adjustment. Additionally, we considered retrospectively reprocessing all claims from CY 2018 through September 27th of CY 2022, which as for the reasons stated in section II.A.2 we determined not to be operationally feasible. We further considered making additional payments to affected 340B covered entity hospitals for 340B-acquired drugs from CY 2018 through September 27th of CY 2022 without proposing an adjustment to maintain budget neutrality, which as for the reasons stated in section II.A.1 we determined not to be operationally feasible.

We also considered calculating one-time aggregate payment adjustments for each provider for the CY 2018 through September 27th of CY 2022 time-period, including both additional payments for 340B-acquired drugs and reduced payments for non-drug items and services under sections 1833(t)(2)(E) and 1833(t)(14) of the Act, along with our retroactive rulemaking authority in section 1871(e)(1)(A) of the Act. This option would have involved: (1) calculating the total additional payments for each hospital that would have been paid for separately payable non-pass-through 340B-acquired drugs from CY 2018 through September 27th of 2022 in the absence of the 340B payment policy; (2) calculating the additional amount each hospital was paid under the OPPS from CY 2018 through CY 2022 for non-drug items and services as a result of the 340B policy; (3) subtracting (2) from (1); and (4) issuing a payment to, or requiring a recoupment from, each hospital for the 5-year period in which the 340B payment policy was in effect, which as for the reasons stated in section II.A.3 we determined not to be feasible or appropriate. Such an approach would require immediate, and in many cases large, 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. Given this burden, the financial strain many hospitals experienced during the recent public health emergency, and the amount of time that has transpired since the original payments for these drugs, items, and services were made, we decided not to propose this option and overly burden these hospitals in this way, making our proposed option much more generous to OPPS providers.

We refer readers to section II.A of this proposed rule for additional discussion of all the alternatives we considered, including our reasons for not proposing them.

As previously discussed, we are proposing the prospective offset to begin in CY 2025, which we believe is appropriate rather than other years, as we believe starting this reduction in CY 2025 would allow CMS time to finalize the appropriate methodology, and then calculate and publish the payment rates derived from this policy in the CY 2025 OPPS/ASC proposed rule, allowing adequate time for impacted parties to assess and prepare for the new payment rates that would be calculated using a reduced conversion factor.

E. Accounting Statement and Table

As required by OMB Circular A–4 (available at *https://*

[19] *https://ww.bls.gov/oes/current/oes_nat.htm.*

www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf), we have prepared an accounting statement in Table 4 showing the classification of the impact associated with the provisions of this proposed rule.

We note readers can find provider-level estimates of proposed Medicare payments in Addendum AAA to this proposed rule. We welcome comment on these payment estimates because, if finalized without further comment by affected providers, these payment amounts will be made by MACs 60 calendar days after receiving relevant instructions from CMS.

TABLE 4—ACCOUNTING STATEMENT

Category	Estimate	Source citation	Year dollar
Transfers			
One-time monetized transfers.	$9.0 billion	Impact table and impact file, based on the respective 2018 through 2022 claims.	CY 2018 through CY 2022.
From whom to whom?	Federal Government to affected 340B covered entity hospitals.		
Previously monetized transfers (occurring before the finalization of this rule).	$1.5 billion	340 drug claims with dates of service from January 1, 2022, through September 27, 2022, that have already been processed or reprocessed at the default drug payment rate, generally ASP plus 6 percent.	CY 2022.
From whom to whom?	Federal Government and beneficiaries to affected 340B covered entity hospitals.		
Total	$10.5 billion.		
Monetized transfers	$7.8 billion	Future reductions to the OPPS conversion factor based on the parameters in this proposed rule (estimated 2025 through 2040).	Estimated to be CY 2025 through CY 2040.
From whom to whom?	Hospitals and other providers who receive payment under the hospital OPPS (other than new providers) to the Federal Government and beneficiaries.		
Total	$7.8 billion.		

We note that the approximately $9.0 billion of expected transfers in this proposed rule is the $9.0 billion in expected additional lump sum drug remedy payments associated with this proposed rule. $1.5 billion of the total $10.5 billion in transfers to providers has already been remedied through processed or reprocessed 340B drug claims for claims with dates of service from January 1, 2022, through September 27, 2022. We also outline the anticipated $7.8 billion offset to Medicare spending and beneficiary cost-sharing to be implemented through a 0.5 percent reduction to the OPPS conversion factor for certain providers.

F. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, many hospitals are considered small businesses either by the Small Business Administration's size standards with total revenues of $41.5 million or less in any single year or by the hospital's not-for-profit status. For details, we refer readers to the Small Business Administration's ''Table of Size Standards'' at *https://www.sba.gov/content/table-small-business-size* standards. As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We believe that this threshold will be reached by the requirements in this proposed rule with comment period. As a result, the Secretary has determined that this rule will have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this proposed rule with comment period would result in approximately $190 million in remedy payments to 240 small rural hospitals. We note that the estimated payment impact for any category of small entity would depend on the degree to which these entities furnished 340B-acquired drugs.

The analysis, together with the remainder of this proposed rule, provides a regulatory flexibility analysis and a regulatory impact analysis. We note that the policies contained in this proposed rule would apply more broadly to OPPS providers and would not specifically focus on small rural hospitals. As a result, the impact on those providers may depend more significantly on their case mix of services provided as well as the extent to which they furnished 340B-acquired drugs.

G. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2023, that threshold is approximately $177 million. This proposed rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications.

We have examined the OPPS and ASC provisions included in this proposed rule in accordance with Executive Order 13132, Federalism, and have determined that they will not have a substantial direct effect on State, local, or tribal governments, preempt State law, or otherwise have a federalism implication. As reflected in Table 2 of this proposed rule, we estimate that payments to impacted governmental hospitals (including State and local governmental hospitals) would increase by approximately $1,800,000,000 if the policies included in this proposed rule

are finalized. Future adjustments to the OPPS conversion factor to offset the additional non-drug item and service payments made from CY 2018 through CY 2022 due to the 340B payment policy would be discussed in the annual rulemaking to which the adjustment would apply. The analyses we have provided in this section of this proposed rule, in conjunction with the remainder of this document, demonstrate that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866 as amended by Executive Order 14094, the RFA, and section 1102(b) of the Act. This proposed rule would affect payments to a small number of small rural hospitals, as well as other classes of hospitals, and some effects may be significant.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on June 15, 2023.

List of Subjects in 42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 419—PROSPECTIVE PAYMENT SYSTEMS FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 1. The authority citation for part 419 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l(t), and 1395hh.

■ 2. Section 419.32 is amended by revising paragraph (b)(1)(iv)(B)(*11*) and adding paragraph (b)(1)(iv)(B)(*12*) to read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv) * * *

(B) * * *

(*11*) For calendar year 2020 through calendar year 2024, a multifactor productivity adjustment (as determined by CMS).

(*12*) Beginning in calendar year 2025, a multifactor productivity adjustment (as determined by CMS) and 0.5 percentage point, except that the 0.5 percentage point reduction shall not apply to hospital outpatient items and services, not including separately payable drugs, furnished by a hospital with a CMS certification number (CCN) effective date of January 2, 2018, or later. This reduction and associated exception to the reduction will be in effect until such time that estimated payment reductions equal $7.8 billion.

* * * * *

Dated: July 6, 2023.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2023–14623 Filed 7–7–23; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

RTID 0648–XD130

Notice of Intent To Prepare an Environmental Impact Statement for Minimizing Non-Chinook Salmon Bycatch in the Bering Sea Pollock Fishery in the Bering Sea/Aleutian Islands Fishery Management Plan Area

AGENCY: National Marine Fisheries Service (NMFS), Alaska Regional Office (AKR), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notification; intent to prepare an environmental impact statement; request for written comments.

SUMMARY: NMFS, in consultation with the North Pacific Fishery Management Council (Council), announces its intent to prepare an Environmental Impact Statement (EIS) on management measures to minimize non-Chinook salmon bycatch, particularly bycatch of chum salmon (*Oncorhynchus keta*) of western Alaska origin (Western Alaska chum), in accordance with the National Environmental Policy Act of 1969 (NEPA). The management measures analyzed in this EIS would apply exclusively to participants in the Bering Sea pollock (*Gadus chalcogrammus*) fishery, managed under the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (BSAI FMP), and consistent with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), National Standards, and other applicable law. The scope of the EIS will be to analyze the impacts to the human environment resulting from alternatives for measures to minimize non-Chinook salmon bycatch. NMFS will accept written comments from the public to identify the issues of concern and assist the Council and NMFS in determining the appropriate range of alternatives for the EIS.

DATES: Written comments will be accepted through September 15, 2023.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2023–0089, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *https://www.regulations.gov* and enter NOAA–NMFS–2023–0089 in the Search box. Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Gretchen Harrington, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS, Attn: Susan Meyer. Mail comments to P.O. Box 21668, Juneau, AK 99802–1668.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *https://www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Bridget Mansfield, (907) 586–7228, *Bridget.Mansfield@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Authority for Action

Under the Magnuson-Stevens Act, the United States has exclusive fishery management authority over all living marine resources found within the exclusive economic zone (EEZ) (*i.e.,* those waters that are 3 to 200 nautical miles (approximately 6 to 370 kilometers) from shore). The management of these marine resources, with the exception of birds and some marine mammals, is vested in the Secretary of Commerce. The Council shares responsibility for preparing FMPs for the fisheries that require conservation and management in the EEZ off Alaska. Management of the Federal groundfish fisheries in the BSAI