

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Part 419**

[CMS–1793–F]

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: Final rule.

SUMMARY: This final rule describes the agency's actions on remand from the United States (U.S.) District Court for the District of Columbia to craft a remedy in light of the U.S. 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: This rule is effective January 8, 2024.

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SUPPLEMENTARY INFORMATION:**I. Background***OPPS Payment Policy for Drugs Acquired Through the 340B Program*

1. Overview

Under the Hospital Outpatient Prospective Payment System (hereinafter referred to as 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 (hereinafter referred to as “the Act”) (42 U.S.C. 1395l(t)(14)(A)). Section 1833(t)(14)(A)(iii)(II) of the Act (42 U.S.C. 1395l(t)(14)(A)(iii)(II)) 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 sections 1842(o), 1847A, or 1847B of the Act (42 U.S.C. 1395u(o), 42 U.S.C. 1395w–3a, & 42 U.S.C. 1395w–3b), as the case may be. Payment rates for drugs are usually established under section 1847A of the Act (42 U.S.C. 1395w–3a), 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 (42 U.S.C. 1395l(t)(14)(A)(iii)(II)) also provides that the average price for the drug in the year as established under section 1847A of the Act (42 U.S.C. 1395w–3a), 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 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 modifiers “JG” and “TB” 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

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/>.

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 (42 U.S.C. 1395(t)(9)(B) and (t)(14)(H)), 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 non-drug 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.

For ease of reference, we refer to the adjustments we made to payment rates for 340B-acquired drugs and the corresponding rate adjustment for non-drug services and items as the 340B Payment Policy.

B. Litigation History of the 340B Payment Policy

The 340B Payment Policy has been the subject of extensive litigation. See the 340B Remedy proposed rule for a more comprehensive summary of the litigation history (88 FR 44079 through 44080).

On June 15, 2022, the Supreme Court held that because CMS had not conducted a survey of hospitals' acquisition costs, it could not vary the payment rates for outpatient prescription drugs by hospital group. See *Am. Hosp. Ass'n v. Becerra*, 142 S. Ct. 1896, 1906 (2022).

The Supreme Court declined to opine on the appropriate remedy, *id.* at 1903, and remanded the case to the U.S. Court of Appeals for the D.C. Circuit, *id.* at 1906, which in turn remanded it to the U.S. District Court for the District of Columbia, see *Am. Hosp. Ass'n v. Becerra*, No. 19–5048, 2022 WL 3061709, at *1 (D.C. Cir. Aug. 3, 2022).⁵ On 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. See *Am. Hosp. Ass'n v. Becerra*, 1:18–cv–02084–RC, Dkts.67, 69 (D.D.C. Aug. 3, 2022).⁶ On September 28, 2022, the district court ruled on the first motion, vacating the reimbursement rate for 340B-acquired drugs for the remainder of 2022. See *Am. Hosp. Ass'n v. Becerra*, 1:18–cv–2084–RC, 2022 WL 4534617, at *5.⁷

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*, 1:18–cv–2084–RC, 2023 WL 143337, at *6.⁸ Both courts and the Departmental Appeals Board have stayed pending challenges to payments made under the 340B Payment Policy. See, for example, *Vanderbilt Univ. Med. Ctr. v. Azar*, 1:20–cv–01582 (D.D.C. May 23, 2023).⁹

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.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 71970), we finalized a policy reversing the 340B Payment Policy. To do so, we first provided that drugs acquired through the 340B Program would be paid at the default rate (generally ASP plus 6 percent) for CY 2023. Second, 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

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.

⁵ <https://ecf.cadc.uscourts.gov/n/beam/servlet/TransportRoom>.

⁶ <https://ecf.dcd.uscourts.gov/doc1/04519382229;https://ecf.dcd.uscourts.gov/doc1/04509382365>.

⁷ https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2018cv2084-79.

⁸ https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2018cv2084-86.

⁹ https://ecf.dcd.uscourts.gov/cgi-bin/DktRpt.pl?145369228216471-L_1_0-1.

that was applied to the conversion factor by 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 in 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, 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 by the 340B Payment 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. Summary of and Responses to Public Comments on Remedy Payment Adjustment for 340B-Acquired Drugs From CY 2018 Through September 27th of CY 2022

A. Remedy Options Considered By CMS

In the proposed rule (88 FR 44080), 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”¹⁰) as close to whole as is administratively feasible.

We describe the different proposed remedy options and aspects of those alternative options that we considered in the proposed rule 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 an Adjustment To Maintain Budget Neutrality

In the proposed rule (88 FR 44080), 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 considered paying 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 we described, 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 (42 U.S.C. 1395l(t)(2)(E) and (t)(14)), along with our retroactive rulemaking authority in section 1871(e)(1)(A) of the Act (42 U.S.C. 1395hh(e)(1)(A)). We noted that sections 1833(t)(2)(E) and (t)(14) of the Act (42 U.S.C. 1395l(t)(2)(E) and (t)(14)) require budget neutrality with respect to payment adjustments to the OPPS made under those sections and there are no exceptions with respect to remedy payments. Consequently, we stated that 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*. That was consistent with the statute’s general approach of

budget neutralizing OPPS payment adjustments. *See, for example*, section 1833(t)(9)(B) of the Act (42 U.S.C. 1395l(t)(9)(B)).

We explained that section 1833(t)(2)(E) of the Act (42 U.S.C. 1395l(t)(2)(E)) straightforwardly requires adjustments made under that provision to be made “in a budget neutral manner.” (*Accord* 65 FR 18438 (noting (t)(2)(E)’s budget neutrality requirement).) And section 1833(t)(14)(H) of the Act (42 U.S.C. 1395l(t)(14)(H)), 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.*” (Emphasis added.) In addition, section 1833(t)(9)(B) of the Act (42 U.S.C. 1395l(t)(9)(B)), referenced in section 1833(t)(14)(H) of the Act (42 U.S.C. 1395l(t)(14)(H)), states in relevant part [i]f the Secretary makes adjustments under subparagraph (A),¹¹ 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 made if the adjustments had not been made.

We explained that these statutes require us to account for budget neutrality in these remedy payments. To the extent these remedy payments are understood as a payment adjustment under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395l(t)(2)(E)), 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 (42 U.S.C. 1395l(t)(14)), we explained that they are “[a]dditional expenditures resulting from” paragraph (t)(14) of the Act for years other than 2004 or 2005 and thus are subject to budget neutrality constraints under section 1833(t)(14)(H) of the Act (42 U.S.C. 1395l(t)(14)(H)).

We noted that this reading of these provisions is consistent with the statute’s general approach of budget neutralizing OPPS payment adjustments, *see, for example*, section 1833(t)(9)(B) of the Act (42 U.S.C. 1395l(t)(9)(B)), except when expressly

¹⁰ 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.

¹¹ Subparagraph (A) reads: 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.

exempted, *see* sections 1833(t)(7)(I), (t)(14)(H), (t)(16)(D)(iii), (t)(18)(C), (t)(19)(A), (t)(20) of the Act (42 U.S.C. 1395l(t)(7)(I), (t)(14)(H), (t)(16)(D)(iii), (t)(18)(C), (t)(19)(A), (t)(20)). Budget neutrality in OPSS serves the important interest of limiting expenditures under Part B and thus protecting the public fisc. *Cf.* H.R. Rep. No. 106–436, at 33–34 (1999) (noting the goal of prospective payment systems, including the OPSS, is to slow growth rate of Medicare expenditures).¹² The Supplementary Medicare Insurance Trust Fund (hereinafter referred to as the Part B Trust Fund) that makes OPSS payments is mostly financed by premiums from participants and contributions from the general fund of the Treasury. We pointed to the Trustees’ of the Part B Trust Fund warning that unexpected increases in Medicare Part B or D expenditures may 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 40–41.¹³ 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, we summarized that when changes to payment policy are made, we generally make an adjustment to the OPSS conversion factor in order to maintain budget neutrality. (*See* 70 FR 68542 (noting outpatient drugs are included in the budget neutrality calculation beginning in 2006).) We do not believe the 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 acknowledged that, in the past, not all OPSS payment policy changes based on sections 1833(t)(14) and (t)(2)(E) of the Act (42 U.S.C. 1395l(t)(14) and (t)(2)(E)) have resulted in adjustments to the budget neutrality factor or actual expenditures from the

Part B Trust Fund equaling zero in all circumstances. We stated that the method CMS uses to account for changes to the “estimated number of expenditures” referenced in section 1833(t)(9)(B) of the Act (42 U.S.C. 1395l(t)(9)(B)) and incorporated by section 1833(t)(14)(H) of the Act (42 U.S.C. 1395l(t)(14)(H)) is the OPSS conversion factor (for example, 71 FR 68193 through 68194). We explained that in situations that have not had any estimated impact on the OPSS 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.¹⁴ Thus, in circumstances when there would be a *de minimis* impact on estimated OPSS payment to meet the budget neutrality requirements as a result of a post-annual-rulemaking policy change, we have not changed OPSS 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 OPSS 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.

We then applied these principles to the remedy payments for the 340B Payment Policy, concluding that 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 substantial fraction of total OPSS 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 of this final rule. Additionally, we noted that reliance interests or administrative burdens would not outweigh the impact of the remedy payments on the Part B Trust Fund sufficiently to justify disregarding the principle of budget neutrality, even if that were statutorily possible. We further explained that 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.

We noted that 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. *See also* section I.A.3 of this final rule. That resulted in \$7.8 billion in additional spending on non-drug items and services during that time period. We acknowledged that some OPSS providers were 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. As of this final rule, that number still rounds to \$7.8 billion, but is more precisely \$7,768,568,239. To assist readers, we will refer to this number as \$7.8 billion throughout this document. We cited our consistent statements in both litigation and OPSS rules in the **Federal Register** that any remedy payments could be subject to budget neutrality constraints. *See, for example, Am. Hosp. Ass’n*, 142 S. Ct. at 1903 (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 OPSS 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 economic impact on the approximate[ly] 3,900 facilities that are paid for outpatient items and services covered under the OPSS.”). Additionally, because the 340B Payment Policy this rule proposed to remedy was itself budget neutralized, failing to budget neutralize the remedy payments would

¹² <https://www.govinfo.gov/content/pkg/CRPT-106hrpt436/pdf/CRPT-106hrpt436-pt1.pdf>.

¹³ <https://www.cms.gov/oact/tr/2023>.

¹⁴ In the CY 2007 OPSS/ASC final rule with comment period, using our authority under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395l(t)(2)(E)), 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 OPSS update. Hospitals failing to meet the requirements would receive a reduced OPSS conversion factor update in CY 2007, the amount of which would then, if not deemed “negligible,” be offset by a corresponding increase to the OPSS conversion factor to maintain budget neutrality. *See* 71 FR 68193 through 68194.

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 final 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.

We also considered the administrative burden specific to maintaining budget neutrality noting CMS was already obliged on remand to remedy the 340B policy. We concluded that 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 OPSS 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 noted that we would still exercise our authority under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395(t)(2)(E)) to offset the extra payments we made for non-drug items and services from 2018 through 2022. Those payments have proven to be an unwarranted windfall, and the Trust Fund has a strong interest in recovering them. We identified that avoiding 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, for example, 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, 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." (internal citations omitted)); *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, unwinding those payments is necessary to ensure equitable payments under these circumstances.

Therefore, we concluded 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 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, we clarified, remains unique: We are adjusting payments prospectively in order to provide a remedy for a previous unlawful payment decision. 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 solicited comments from the public on our proposed interpretation of our statutory budget neutrality obligations, equitable payment authorities, and recoupment authority.

Comment: We received many comments on our proposed interpretation of our statutory budget neutrality obligations, equitable payment authorities, and recoupment authority.

Response: These comments are addressed in section II.B.2.b of this final rule.

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

In the proposed rule (88 FR 44082), we explained that 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. We identified that CMS would

have to reprocess all OPSS 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 (42 U.S.C. 1395(t)(14)) and our retroactive rulemaking authority in section 1871(e)(1)(A) of the Act (42 U.S.C. 1395hh(e)(1)(A)). 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 remedial rulemaking need not 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").

We acknowledged that reprocessing every single claim might be a potential approach to remedy this situation if it were administratively achievable. But we feared that reprocessing such an unprecedentedly large volume of claims and issuing payment to affected 340B covered entity hospitals in a timely fashion would impose an immense administrative burden on CMS, its contractors, and providers. We accordingly concluded that this approach is not feasible in this case. It would require the reprocessing of virtually all claims submitted to the OPSS system during the affected period of time, but that system processes more than 100 million claims each year. We remarked that reprocessing almost 5 years' worth of OPSS claims could take several years, resulting in some affected 340B covered entity hospitals 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, we indicated that 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 cause significant administrative burden and delayed payments. *See Shands*, 959 F.3d at 1120. But we did allow that the expected results of such a calculation can certainly inform an alternative approach to budget neutrality, as we discuss below.

We noted 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 CY 2022 340B payment rate and the typical timely filing requirements described at 42 CFR 424.44. We confirmed this was appropriate for CY 2022 claims given that providers were able to follow the regular claims processing conventions for these claims, and clarified that we will ensure CMS does not make duplicate payments for these claims already remedied by the usual claims processing methods. As part of this final rule, we estimate that for CY 2022, \$1.6 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 of 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. This \$1.6 billion is one component of the total remedy payments accounted for in this final 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.

We thank commenters for their input on our policy proposals. We have summarized the comments received and our responses to those comments in the following section.

Comment: Commenters generally agreed with CMS’s conclusion that reprocessing all claims is not administratively feasible. Commenters appreciated that CMS considered this option but did not formally propose it in the proposed rule.

Response: We appreciate commenters’ concurrence with our conclusion.

Comment: One commenter requested that CMS pay providers that elected to submit adjusted claims for dates of service between January 1, 2022, through September 27, 2022, the beneficiary copayment amount for those claims. The commenter points out that providers who elected not to submit adjusted claims for those dates of service will receive both the Medicare portion and the beneficiary copayment portion through the remedy payment. Failing to pay the beneficiary copayment amounts for providers that elected to submit adjusted claims, the commenter argues, results in different remedies for the beneficiary portion for providers that submitted adjustment claims and those that did not submit adjustment claims, which is an inequitable outcome.

Response: We do not agree that CMS should pay providers that elected to submit adjusted CY 2022 claims additional payment for beneficiary cost sharing. We are paying amounts equal to *lost* beneficiary cost sharing amounts providers are not otherwise legally entitled to collect based on a finding that, under the unique circumstances of this rule, it is necessary to ensure equitable payments under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395l(t)(2)(E)). (See *infra* at II.B.1.e.) Because CY 2022 adjustments followed regular claims processing conventions, providers are legally entitled to collect cost sharing from beneficiaries on those claims. If providers are unable to do so, such payments would be subject to our usual standards governing payments to which providers are legally entitled but unable to collect. *See, for example*, 42 CFR 413.89. We thus do not believe the same rationale applies to reprocessed claims.

Permitting providers to submit adjustment claims also allowed for prompt payment to providers and partially approximated how the claim would have been processed and paid absent the 340B Payment Policy. Indeed, many of these claims have already been finalized and the beneficiaries have paid their cost sharing obligation. Because providers can collect cost sharing for reprocessed CY 2022 claims from beneficiaries and potentially under our bad medical debt regulations, we do not believe it would be equitable under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395l(t)(2)(E)) to make additional, potentially duplicative payments to reflect lost cost sharing.

As described in the proposed rule, we considered these reprocessed claims to be partially remedied as 340B providers no longer received the lower 340B drug payment rate. These claims will be fully

remedied when we address the non-drug item and service payment portion of these claims.

Comment: CMS received several comments requesting a mass reprocessing of all CY 2022 claims and instructions to the Medicare Administrative Contractors (MACs) to make one mass adjustment for claims going back to January 1, 2022.

Response: We do not have an existing procedure to make the mass adjustment commenters proposed for CY 2022 claims without reprocessing each individual claim, and we believe that our proposed lump sum payment achieves a very similar result. While reprocessing just the remaining CY 2022 claims would be less burdensome than reprocessing all claims back to 2018, it would still impose a large administrative burden on CMS, our contractors, and providers. Approximately two hundred million dollars worth of payments would have to be reprocessed, and, importantly, such an undertaking could cause an additional delay in making payments relative to the proposed lump sum payment methodology. Otherwise, the main practical difference between reprocessing the remaining CY 2022 claims or including them in the lump sum payment is whether providers can seek cost sharing payments from beneficiaries, as discussed above. But because we have increased the lump sum payment under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395l(t)(2)(E)) to cover lost beneficiary cost sharing, we do not view that as a material difference between the options. Because including remaining CY 2022 claims in the one-time lump sum payment will provide nearly equivalent remedy funds to affected 340B covered entity hospitals, and will do so more quickly and efficiently than a mass reprocessing of all CY 2022 claims, we decline to treat remaining CY 2022 claims differently from other claims years.

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

In the proposed rule (88 FR 44083), we 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 (42 U.S.C. 1395l(t)(2)(E) and (t)(14)), along with our retroactive rulemaking authority in section 1871(e)(1)(A) of the Act (42

U.S.C. 1395hh(e)(1)(A)), to the extent the policy would be retroactive. 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 OPSS 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. This is similar to the approach we ultimately adopt in this rule, except that it would have effectively implemented budget neutrality requirements through an immediate lump sum *recoupment* that would mirror the lump sum remedy *payment*.

While this approach would also have satisfied the statutory budget neutrality concerns discussed above, we did not read the statute to mandate 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 of this final rule.) Such an approach would require immediate, and in many cases large, retroactive recoupments from the majority of OPSS hospitals and would impose a substantial, immediate burden on these hospitals as well as an uncertain impact on beneficiaries. After accounting for these burdens, the financial strain many hospitals experienced during the recent COVID-19 public health emergency (hereinafter referred to as the “PHE”), 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 as our suggested approach.

Comment: Several commenters expressed general support for our decision not to propose a one-time aggregate payment adjustment for each provider.

Response: We thank commenters for their support.

B. Remedy

1. 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 OPSS in CY 2018 Through September 27th of CY 2022

a. Statutory Authority

In the proposed rule (88 FR 44083), we stated that CMS believes that the best way to remedy our 340B Payment Policy 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 entity hospitals 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 explained that this approach comes as close to providing 340B-covered entities with make-whole relief as CMS can reasonably accomplish, without the 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, as they were required to do, CMS noted that it expects the remedy payment to each 340B covered entity for 340B-acquired drugs to be approximately the same as if CMS manually reprocessed those claims. Calculating the approximate repayment amount based on claims data is relatively straightforward administratively as it involves only an aggregated analysis of the claims in question, whereas reprocessing all claims requires significantly more administrative effort as the claims actually have to be individually reprocessed through the claims processing system. This is practically infeasible for the reasons discussed earlier in this rule. Please see the previous section titled “Full Claims Reprocessing from CY 2018 through September 27th of CY 2022” for additional detail.

We proposed to make the remedy payments relying principally on (1) our rate-setting authority under section 1833(t)(14) of the Act (42 U.S.C. 1395l(t)(14)); and (2) our equitable adjustment authority under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395l(t)(2)(E)). To the extent this rule is retroactive (in whole or in part), we explained that we would rely on our

retroactive rulemaking authority in section 1871(e)(1)(A) of the Act (42 U.S.C. 1395hh(e)(1)(A)).

First, we evaluated our authority under section 1833(t)(14) of the Act (42 U.S.C. 1395l(t)(14)). We pointed to the Supreme Court’s holding that if CMS has not conducted a survey of hospitals’ acquisition costs, the agency may not vary the payment rates for outpatient prescription drugs by hospital group. We acknowledged that because we did not use any survey of hospitals’ acquisition costs when setting rates for 340B-acquired drugs between CY 2018 and September 27, 2022, 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 (42 U.S.C. 1395l(t)(14)(A)(iii)) for those years, as interpreted by the Supreme Court.

We then considered our authority to adjust the prior payment rate. We explained that section 1871(e)(1)(A) of the Act (42 U.S.C. 1395hh(e)(1)(A)) prohibits 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.” We explained that, assuming this remedy is viewed as a retroactive remedy (in whole or in part), it would also 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 (42 U.S.C. 1395l(t)(14)).

But even if a retroactive rule were not necessary specifically to comply with section 1833(t)(14) of the Act (42 U.S.C. 1395l(t)(14)), we found 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 understand to be proper under the statute. We found that the equities weigh in favor of a partially retroactive remedy here, because a significant number of plaintiff hospitals have been advocating for this 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. The equities further align with a partially retroactive remedy, to the extent required, because the impact on the Part B Trust Fund will be

lessened as we are applying budget neutrality principles. We noted that the position of those plaintiff hospitals was ultimately vindicated by the Supreme Court.

We proceeded to consider our authority under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395(t)(2)(E)), which 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 proposed 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 adjustment. We found that 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 explained we would apply the adjustment retrospectively in accordance with the Court’s ruling and for the reasons discussed in the above paragraph.

We therefore proposed to use our authority under section 1833(t)(14) of the Act (42 U.S.C. 1395(t)(14)) in conjunction with our equitable adjustment authority under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395(t)(2)(E)), to accomplish an equitable outcome as we remedy past payments made under the 340B Payment Policy. To the extent necessary, we also proposed to use our retroactive rulemaking authority under section 1871(e)(1)(A) of the Act (42 U.S.C. 1395hh(e)(1)(A)).

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

We thank commenters for their input on our policy proposals. We have summarized the comments received and our responses to those comments in the following section.

Comment: Nearly all commenters supported our proposal to pay via a one-time lump sum payment.

Response: We appreciate commenters’ support.

Comment: Several commenters encouraged CMS and MACs to agree on documentation and treatment of these funds on cost reports, cost report audits, and subsequent Medicare payment adjustments and reviews.

Response: We agree that it is important to coordinate with MACs to ensure consistent documentation and treatment of the one-time lump sum payments. These payments will not be made on cost reports. To ensure timely payment for all impacted providers, CMS shall issue guidance to all MACs to allow consistent documentation and tracking of the 340B payments.

Comment: Two commenters opposed our proposal to pay via a one-time lump sum payment due to concerns that a massive influx of funds to 340B hospitals would enable those hospitals to further dominate local markets by purchasing independent community clinics and other hospitals. One of these commenters requested that repayments be spread out over time, suggesting 5 years for this time-period or, alternatively, 16 years to align it with the budget neutrality adjustment schedule discussed later in this rule. The other commenter suggested that CMS provide remedy funds for 2018 to 2020 and use a 340B drug acquisition cost survey to determine the remedy payments for subsequent years.

Response: We appreciate commenters’ concerns. As previously discussed, the aim of this rule is to situate all OPPTS providers as closely as possible to the financial situation they would have been in if the 340B OPPTS Payment Policy had never existed. Had we never implemented the 340B Payment Policy, hospitals would already have these payments. We thus believe the fairest policy is to pay hospitals as promptly as administratively feasible. We acknowledge that this means that until the budget neutrality adjustment is fully implemented, hospitals will temporarily have additional funds from our payments for non-drug services and items they would not otherwise have had. But commenters have not identified authority requiring us to withhold payments based on competition concerns once we have determined the amount due from Medicare. As such, we believe the payment timeline described in this rule is appropriate.

We acknowledge that we previously suggested that we might use our survey of CY 2018 and 2019 cost data to inform

the remedy as discussed in the CY 2020 OPPTS/ASC final rule with comment period (84 FR 61322). But as we subsequently noted, we received many comments on the survey data, and using that data, which surveyed only 340B hospitals, might not comport with the Supreme Court’s decision. Using it would introduce new complexities into the rate calculation, for instance, by requiring consideration of adjustments to the data and other factors as discussed in the CY 2021 OPPTS/ASC final rule with comment period (85 FR 86052). We do not believe it is worth delaying the remedy payments to allow for such considerations or for us to conduct a new survey many years after the fact.

Comment: We received many comments on the statutory authority we proposed to rely upon to make lump sum payments. While nearly all commenters supported our proposal to implement this remedy via a one-time lump sum payment, industry commenters disagreed with our proposal to rely on sections 1833(t)(14) and (t)(2)(E) of the Act (42 U.S.C. 1395(t)(14) and (t)(2)(E)) to do so. Many of these commenters argued that these statutory provisions do not apply to the remedy payments. These commenters stated that CMS is attempting to rely on statutes designed for, and limited to, making prospective adjustments to spending estimates, or discretionary adjustments based on equity to make remedy payments required by the Supreme Court’s decision.

With respect to section 1833(t)(14) of the Act (42 U.S.C. 1395(t)(14)), these commenters maintained that the expenditures to which the statute applies do not contemplate court-ordered remedy payments. Referencing the text of section 1833(t)(14) of the Act (42 U.S.C. 1395(t)(14)), “[a]dditional 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,” these commenters argue that the proposed lump-sum payment is neither an “additional” expenditure nor an expenditure “resulting from this paragraph.” In their view, there is nothing additional about the lump sum payment, it is what 340B hospitals should have been paid in the first place and the payment is not being made as a result of this paragraph but rather the agency’s loss of a court case. One commenter argued that the additional expenditures are those that could result from CMS electing to refine its payment methodology as permitted

under section 1833(t)(14) of the Act (42 U.S.C. 1395l(t)(14)). The commenter shared that this means performing a survey and changing the drug payment methodology or refining the overhead cost payment. In this case, they stated that the additional expenditures are neither of these and are instead “a loss at the Supreme Court, not a payment methodology refinement.”

With respect to section 1833(t)(2)(E) of the Act (42 U.S.C. 1395l(t)(2)(E)), which provides the Secretary with the authority to establish, “in a budget neutral manner, outlier adjustments . . . and transitional pass-through payments . . . and other adjustments as determined to be necessary to ensure equitable payments,” commenters argued that this provision is not applicable to the remedy payments because, in their view, CMS is not exercising any payment discretion (but is required to make the payments) and the payments are not being made for equitable reasons (but to comply with a court judgment) and, like section 1833(t)(14) of the Act (42 U.S.C. 1395l(t)(14)), the provision is purely prospective in nature. Commenters suggested that in the introductory text of subsection section 1833(t)(2)(E) of the Act (42 U.S.C. 1395l(t)(2)(E)), “under the payment system” refers to the prospective payment system addressed in section (t) as a whole: “Prospective Payment System for Hospital Outpatient Department Services” and section 1833(t)(2)(E) of the Act’s inclusion within that system prohibits its use for recoupments. One commenter argued that CMS construes “adjustment” too broadly and that its meaning under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395l(t)(2)(E)) refers to outliers and transitional pass-through payments, which the commenter characterizes as “cornerstone features” of the outpatient prospective payment system.

Many commenters argued that if section 1833(t)(2)(E) of the Act (42 U.S.C. 1395l(t)(2)(E)) did apply to the proposed lump sum payments, that the amount of the payments is too large to qualify as an adjustment under the statute. In support of this position, these commenters referenced *Biden v. Nebraska*, 143 S. Ct. 2355, 2368 (2023), which interpreted the term “modify” in a different statute to mean “to change moderately and in minor fashion.” According to the commenters, the D.C. Circuit has interpreted HHS’s adjustment authority to have the same limits that the Supreme Court found in the word “modify” in other contexts, and the remedy payment here is too large to qualify. See *Amgen, Inc v. Smith*, 357 F.3d 103, 117 (D.C. Cir.

2004). These commenters agreed that CMS may use section 1833(t)(2)(E) of the Act (42 U.S.C. 1395l(t)(2)(E)) to increase the remedy payments by \$1.8 billion (the amount of beneficiary cost sharing).

Response: We continue to believe that we should rely on sections 1833(t)(14) and (t)(2)(E) of the Act (42 U.S.C. 1395l(t)(14) and (t)(2)(E)) to make these remedy payments. No commenter identified any alternate statutory authority on which we could rely, and we disagree with commenters’ arguments that these provisions are inapplicable. While we agree that section 1833(t) creates a prospective payment system, see section 1833(t)(1)(A) of the Act (42 U.S.C. 1395l(t)(1)(A)), the Supreme Court declined to find this fact foreclosed all retrospective review. Cf. *Am. Hosp. Ass’n v. Becerra*, Br. for Respondents at 21–22 (government brief arguing the statute foreclosed “administrative or judicial review of the prospective payment system,” and noting invalidation of an OPPTS component “could result in the retroactive ordering of payment adjustments” (quoting H.R. Rep. No. 149, 105th Cong., 1st Sess. 724 (1997) (House Report) and *Amgen, Inc.*, 357 F.3d at 112)). Indeed, at least one court has rejected an argument that CMS lacks the authority to make retroactive adjustments when required to comply with other provisions in section 1833(t) of the Act (42 U.S.C. 1395l(t)). See *H. Lee Moffitt Cancer Ctr. & Rsch. Inst. Hosp., Inc. v. Azar*, 324 F. Supp. 3d 1, 16 (D.D.C. 2018) (“HHS has not shown that such a retroactive adjustment would be incompatible with the generally prospective nature of OPPTS.”).

We disagree with commenters that stated that a court has “ordered” payments, or that court-ordered payments necessarily fall outside of section 1833(t)(14) of the Act (42 U.S.C. 1395l(t)(14)). No court has yet weighed in on the appropriate remedy, much less ordered any particular payment. See, for example, *Am. Hosp. Ass’n*, 2023 WL 143337, at *3 (rejecting argument that court should order agency to “repay[] those hospitals that were unlawfully underpaid, from 2018 to the present, the difference between what they were paid and ASP plus 6%”).

We also disagree that our remedy payment is not “equitable” within the meaning of section (t)(2)(E) of the Act (42 U.S.C. 1395l(t)(2)(E)) simply because it remedies legal error. Ensuring that providers are paid according to Congress’ policy judgments is a legitimate way to ensure fairness, in the most common meaning of the term

“equitable.” Indeed, to the extent the term “equitable” under section (t)(2)(E) of the Act (42 U.S.C. 1395l(t)(2)(E)) might be informed by courts’ historic equitable authority, the fact that we are seeking to restore parties to as close a state as they would have been without the now-invalidated 340B Payment Policy makes the rule analogous to historic equitable remedy of recession and restitution. See Restatement (Third) of Restitution and Unjust Enrichment section 54 (2011) (“[T]he expression “rescission and restitution” aptly describes cases in which the claimant may be restored to the status quo ante by obtaining the fungible equivalent of personal property previously transferred to the other party.”).

Nor do we agree with commenters that this rule exceeds our statutory authority to make “adjustments” to the payment system “as determined to be necessary to ensure equitable payments” under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395l(t)(2)(E)). Both the Supreme Court and the D.C. Circuit have declined to define the outer bounds of that term. See *Am. Hosp. Assoc’n*, 142 S. Ct. at 1904 (“[W]e need not determine the scope of HHS’s authority to adjust the price up or down.”); *Amgen, Inc.*, 357 F.3d at 117 (“[T]he court has no occasion to engage in line drawing to determine when ‘adjustments’ cease being ‘adjustments.’”). While we acknowledge that the Supreme Court has held that in certain contexts the statutory authority to “modify” a program limits the amount by which an agency can change the program, we believe the statutory term “adjustment” has a different focus here. For example, in *Nebraska*, when construing the term “modify,” the Supreme Court relied in part on Black’s Law Dictionary’s definition of modify which built in “a connotation of increment or limitation.” 143 S. Ct. at 2368 (citing MODIFY, Black’s Law Dictionary (11th ed. 2019) (“To make somewhat different; to make small changes to (something) by way of improvement, suitability, or effectiveness”).) But that same dictionary defines “adjustment” to focus on adapting something to better apply in a particular circumstance. ADJUSTMENT, Black’s Law Dictionary (11th ed. 2019) (“That which adapts one thing to another or to a particular use”). We therefore believe our adjustment authority under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395l(t)(2)(E)) fairly encompasses adapting generally prospective payments to remedy legal errors made in those payments. And even if adjustment carries a connotation

of increment or limitation, the 28.5 percent adjustment this final rule makes to the payments made to hospitals for 340B-acquired drugs would not exceed it. The cases in which the Supreme Court has found that agencies exceeded their modification authority are those where the Court found that there was a change in kind to the affected program, not simply a change in degree. See *Nebraska*, 143 S. Ct. at 2369 (changes exceeded modification authority when agency “created a novel and fundamentally different loan forgiveness program”); *MCI Telecommunications Corp. v. Am. Tel. & Tel. Co.*, 512 U.S. 218, 230 (1994) (changing statute “from a scheme of rate regulation in long-distance common-carrier communications to a scheme of rate regulation only where effective competition does not exist” exceeded modification authority); cf. also *Amgen, Inc.*, 357 F.3d at 117 (adjustment does not include a “total elimination or severe restructuring of the statutory scheme”). Here, CMS is adjusting payment rates back to their default under the statute. Restoring a default payment provision is the opposite of the implementation of “a new regime entirely” that the Supreme Court has invalidated.

We acknowledge that we are in a somewhat unique situation. We have generally operated the OPPS system based on a belief that its prospective payments were insulated from administrative and judicial review. In light of the Supreme Court’s decision, however, we must find a way to reconcile a primarily *prospective* budget neutral rate-setting system with adjudication processes that are generally *retrospective* in nature. Here, it is enough for us to find that sections 1833(t)(14) and (t)(2)(E)—and section 1871(e)(1)(A), to the extent required—authorize us to correct the legal error identified by courts in our prior payments under section 1833(t)(14).

Comment: One commenter argued that CMS could not rely on its retroactive rulemaking authority under section 1871(e)(1)(A) of the Act (42 U.S.C. 1395hh(e)(1)(A)), in conjunction with sections 1833(t)(2)(E) and (t)(14) of the Act (42 U.S.C. 1395l(t)(2)(E) & (t)(14)), to make the remedy payments because section 1871(e)(1)(A) of the Act (42 U.S.C. 1395hh(e)(1)(A)) prohibits retroactive rulemaking except for two limited exceptions, neither of which apply to the remedy payments. The first exception cited by the commenter applies to situations in which “retroactive application is necessary to comply with statutory requirements” (see section 1871(e)(1)(A)(i) of the Act

(42 U.S.C. 1395hh(e)(1)(A)(i)) and the second to situations in which “failure to apply the change retroactively would be contrary to the public interest” (see section 1871(e)(1)(A)(ii) of the Act (42 U.S.C. 1395hh(e)(1)(A)(ii))). Concerning the first exception, the commenter contends that the proposed rule discusses retroactive rulemaking authority only with respect to the drug payment methodology for 340B-acquired drugs and makes no argument that payments for non-drug items and services may be changed retroactively or that CMS may retroactively re-estimate its budgetary projections from 2018. The commenter concludes that because the OPPS is expressly required to be prospective in nature, “retroactive adjustments” to past years’ payment rates are not “necessary to comply” with statutory requirements of the OPPS. Concerning the second exception, the commenter argues that it is not in the public interest to engage in the retroactive adjustment of prospective payment rates (particularly when doing so would upset the reliance interest of all hospitals with respect to payment for non-drug items and services) when make-whole relief can be implemented without revisiting 2018 through 2022 OPPS rates.

Response: We disagree with the commenter that the OPPS’s generally prospective nature implicitly overrides CMS’s retroactive rulemaking authority under section 1871(e) of the Act (42 U.S.C. 1395hh(e)). The Supreme Court held (in 2022) that we lacked authority (in 2018) under section 1833(t)(14) of the Act (42 U.S.C. 1395l(t)(14)) to set a payment rate of ASP–22.5 percent for 340B-acquired drugs absent a drug acquisition cost survey. Thus, to the extent we are acting retrospectively in this rule, conforming payment rules that are still on the books and still contain a payment rate contrary to the requirements of section 1833(t)(14) of the Act (42 U.S.C. 1395l(t)(14)) would be a classic case where retroactive rulemaking would be “necessary to comply” with statutory requirements. As noted above, courts have rejected the argument that because section 1833(t) of the Act (42 U.S.C. 1395l(t)) establishes a prospective payment system, that system is not subject to any retrospective review or amendment. And because the payment *increases* for non-drug items and services for those years were inextricably linked to the illegal payment *decreases* for 340B-acquired drugs, the same reasoning would apply. We are not, as commenter suggests, re-estimating our budget projections—a point we also discuss

below in section II.B.2. Rather, we are unwinding a payment rate that courts held was illegal.

We also disagree with the commenter’s public interest argument. As noted above, commenters have not identified any authority through which we could implement make-whole relief without relying on sections 1833(t)(14) or (t)(2)(E) of the Act (42 U.S.C. 1395l(t)(14) and (t)(2)(E)). And we disagree that hospitals’ reliance interest undermines our interpretation here. Hospitals were aware that we believed their increased payments for non-drug items and services hinged on the payment decreases for 340B-acquired drugs. (No one, for example, has suggested we could retain the 3.19 percent payment increase in CY 2023 once we reverted to an ASP plus 6 percent payment rate for 340B acquired drugs.) Hospitals successfully convinced courts that those payment decreases are illegal, and it thus follows that the intertwined payment increases were unwarranted under the statute, as well. If the payment increases were not removed, the remedy payments would ultimately come from beneficiaries, taxpayers, or some combination of the two. The commenter’s suggestion would effectively involve at least a \$9 billion transfer from beneficiaries and taxpayers to hospitals, which would be inappropriate especially in a system where budget neutrality requirements generally prevent such transfers.

Comment: Many commenters claimed that CMS does not require any statutory authority to make the remedy payments and that it can make the payments using an “acquiescence authority.” Commenters point to past instances in which CMS has allegedly exercised the posited acquiescence authority, including Administrator rulings,¹⁵ manual updates,¹⁶ settlements with hospitals¹⁷ and the processing and reprocessing of CY 2022 340B drug claims at the default drug rate for dates

¹⁵ See CMS Ruling No. 1498–R.(Apr. 28, 2010). <https://www.cms.gov/regulations-and-guidance/guidance/rulings/downloads/cms1498r.pdf>.

See also CMS Ruling No. 1355–R.(Apr. 14, 2011). <https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/downloads/cms1355r.pdf>.

¹⁶ See CMS Pub. 100–20, Transmittal No. 10520 (Dec. 14, 2020). <https://www.cms.gov/files/document/r10520otn.pdf>.

¹⁷ See *HealthAlliance Hospitals, Inc. v. Azar*, 346 F. Supp. 3d 43 (D.D.C. 2018); see also Clerk’s Orders Granting Extensions To Accommodate Pending Mediation, dated March 26, 2019, April 18, 2019, and June 13, 2019, *HealthAlliance Hosps., Inc. v. Azar*, No. 18–5372 (D.C. Cir.); Joint Stipulation of Dismissal dated August 29, 2019, *HealthAlliance Hosps., No. 18–5372 (D.C. Cir.)*.

See *Cape Cod Hospital v. Sebelius*, 630 F.3d 203 (D.C. Cir. 2011); see also 76 FR 51476, 51799 (Aug. 18, 2011).

of service between January 1, 2022, and September 27, 2022, described in the proposed rule (“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.”).¹⁸ Commenters argue that we are ignoring this acquiescence authority in order to justify the budget neutrality policy we discuss later in section II.B.2 of this final rule.

Response: We have previously explained that acquiescence is a choice by an agency, when faced with a lower court decision disagreeing with the agency’s legal interpretation, to “recognize that court’s interpretation and apply the court’s interpretation uniformly, thereafter, within the jurisdictional bounds of the interpreting court.” *In the Case of: St. Vincent Mercy Medical Center Provider v. Blue Cross Blue Shield Association/national Government Services—Ohio Intermediary*, 2008 WL 6468508, at *9 (CMS Adm’r) (acquiescing to circuit court’s interpretation of law for providers within the jurisdictional bounds of the deciding court). That makes the acquiescence doctrine an awkward fit here because it is most often applied to rulings from circuit courts, whose precedential authority is geographically limited and whose legal interpretations are subject to further review. The Supreme Court is not so limited, and its statutory interpretations are generally binding on parties with pending claims. *See Harper v. Virginia Dep’t of Tax’n*, 509 U.S. 86, 97 (1993) (“When this Court applies a rule of federal law to the parties before it, that rule is the controlling interpretation of federal law and must be given full retroactive effect in all cases still open on direct review.”).

Regardless, we do not understand acquiescence to be an independent source of authority or one that frees us from otherwise applicable statutory constraints, as commenters believe. Commenters’ examples do not suggest otherwise. The cited Administrator rulings were routine applications of judicial precedent to pending administrative appeals. *See CMS Ruling No. 1498–R*, at 6 (Apr. 28, 2010) (limiting relief to providers with “properly pending DSH appeal of the SSI fraction data matching process issue” under section 1869 of the Act (42 U.S.C. 1395ff)); *CMS Ruling 1355–R*, at 8 (limiting relief to providers with “properly pending appeals” under

section 1878 of the Act (42 U.S.C. 1395oo)). Such actions are contemplated by the agency’s authority to “affirm, modify, or reverse” in pending adjudications. *See* section 1869(b)(1) of the Act (42 U.S.C. 1395ff(b)(1)) (incorporating authority under section 205(b) of the Act (42 U.S.C. 405(b)); 1878(f)(1) of the Act (42 U.S.C. 1395oo(f)(1) (same)). The decisions cited by commenters never suggest that we could issue payments that violate statutory limitations, nor have commenters identified any statutory limitations those decisions allegedly violated.¹⁹ Neither payment adjustment in the two cited rulings, for example, were subject to a budget neutrality requirement. *See, for example*, 2014 IPPS Final Rule, 78 FR 50496, 50507 (2013) (noting statutory amendments resulting in reductions to DSH payments “are not budget neutral”); Medicare Program; Hospice Wage Index for Fiscal Year 2010, 74 FR 39384, 39390–91 (2009) (rejecting notion that “Medicare insists on budget neutrality in all of its payment systems”). To the contrary, several of the cited examples show that CMS enforces payment limits in prospective payment systems, even when acting retroactively or in response to disagreement by a court. *See CMS Pub. 100–20*, Transmittal No. 10520 (Dec. 14, 2020) (instructing contractors to recalculate graduate medical education payments to comply with annual payment caps under section 1886(l) of the Act (42 U.S.C. 1395ww(l));²⁰ 76 FR 51476, 51788 (addressing payment issue relating to application of budget neutrality adjustment after court decision in *Cape Cod Hospital v. Sebelius*, 630 F.3d 203 (D.C. Cir. 2011) by “remodel[ing] the recalibration/wage index budget neutrality factor for the years at issue”); *accord* Medicare Program; Changes to the Inpatient Hospital Prospective Payment System and Fiscal Year 1991 Rates, 55 FR 35990, 36043 (1990) (“Absent a retroactive budget neutrality adjustment at the beginning of next fiscal year, we believe that we would be precluded from making mid-year

¹⁹ We understand our approach to remedies to be consistent with how courts view their own remedy authority. *See, for example*, *Off. of Pers. Mgmt. v. Richmond*, 496 U.S. 414, 426 (1990) (“[J]udicial use of the equitable doctrine of estoppel cannot grant respondent a money remedy that Congress has not authorized.”); *Am. Hosp. Ass’n v. Price*, 867 F.3d 160, 167 (D.C. Cir. 2017) (“[I]f the necessary means [to remedy a legal violation by an agency] were unlawful, the Court could not have mandated them.”).

²⁰ We continued to enforce retroactively the payment limitations in section 1886(l) of the Act (42 U.S.C. 1395ww(l)) until Congress stepped in to relieve us of that requirement. *See CAA 2023*, sec. 4143.

corrections to the wage index since they could not be accomplished in a budget neutral fashion as required by law.”).

To be sure, the court in *H. Lee Moffitt Cancer Center v. Azar*, 324 F. Supp. 3d 1 (D.D.C. 2018), noted one prior instance where we had missed a small number of hospitals in our first year implementing budget neutral payment adjustments for certain rural hospitals and did not clearly budget neutralize a retroactive adjustment. *Id.* at 15 (citing 71 FR 67960, 68010). That court acknowledged that CMS had previously “temporarily raised prospective rates in order to make up for reductions applied in prior years” and so saw “no reason why HHS could not do the converse here if it believed offsets were required: make a slight reduction in prospective rates for a future year to accommodate a retroactive adjustment” for the single plaintiff hospital. *Id.* at 17 n.5. In any event, both the rural hospital adjustment issue and the cancer hospital issue involved relatively small adjustments to a single year of payments to a very limited number of providers, and one situation involved resolution through settlements with individual providers that had properly appealed the issue. When the additional rural hospitals (rural essential access community hospitals) were included in the rural hospital adjustment, the entire adjustments changed the budget neutrality factor by approximately 0.00002, which is so small of a change that it would only change payment rates by a fraction of a cent, and likely not change payment rates by a penny. (71 FR 68003). And while all eleven cancer hospitals impacted the budget neutrality factor by 0.0022 the year they were added—reflecting a total of \$71 million of payment impact (76 FR 76,190)—only a few ultimately sued over the payments and the government resolved the matters through settlements with individual providers. *See H. Lee Moffitt*, 324 F. Supp. 3d at 9 (estimating \$7.4 million payment impact for plaintiff hospital). These are the types of *de minimis* impacts that CMS has rounded to zero. We do not believe these two much smaller examples relieve us of our statutory obligations here, which involve several billion dollars and more than 3,600 hospitals, restructuring Medicare Part B payments for these drugs payments across 5 years-worth of claims. As we noted in the proposed rule, we are particularly concerned that adopting providers’ position would allow them to use litigation as a workaround to otherwise applicable constraints on Medicare payments and

¹⁸ See proposed rule at 88 FR 44088 (Nov. 13, 2017).

threaten Congress' control of the Federal budget.

Adhering to the usual statutory constraints on our rulemaking authority under section 1833(t) of the Act (42 U.S.C. 1395f(t)) is particularly appropriate here when we are implementing a remedy through rulemaking rather than adjudication or resolving a matter through settlement. Following judicial interpretations does not necessarily entitle parties without jurisdictionally proper active challenges to have that interpretation applied to prior years' payments. *See* 42 CFR 405.986(b) (change in legal interpretation based on judicial decision not good cause to reopen adjudications); *see also Baptist Mem'l Hosp. v. Sebelius*, 603 F.3d 57, 64 (D.C. Cir. 2010) (denying mandamus to party who sought application of favorable judicial interpretation to prior payment years without pending appeals). Parties who chose to sit on the sidelines might benefit *prospectively* from a change in legal interpretation based on a court ruling, but nothing requires an agency affirmatively to reach back and disturb the finality of payment determinations that providers never properly challenged. *See Grant Med. Ctr. v. Hargan*, 875 F.3d 701, 707 (D.C. Cir. 2017) (“[W]e never require agencies to apply rules retroactively even where it would be permissible for them to do so.” (emphasis in original)); *see also See Your Home Visiting Nurse Servs., Inc. v. Shalala*, 525 U.S. 449, 455 (1999) (holding that “agency’s refusal to reopen a closed case is generally ‘committed to agency discretion by law’ and therefore exempt from judicial review”); 42 CFR 405.986.

Despite these well-established principles, Congress has recognized that sometimes an agency might decide that finality should yield to other policy considerations, including by giving the agency the flexibility to issue retroactive rules in certain circumstances. *See* section 1871(e) of the Act (42 U.S.C. 1395hh(e)). As we explained in the proposed rule, that threshold has been met here, at least to the extent this rule is retroactive. We add that the same principles that sometimes justify acquiescing to a circuit court outside of that court’s jurisdictional bounds also supports our choice to apply the Supreme Court’s interpretation of section 1833(t)(14) of the Act (42 U.S.C. 1395f(t)(14)) to parties who lack pending claims for those payment years and thus are outside the bounds of the Supreme Court’s judgment. Doing so in this case will help to promote uniform treatment of parties under the law and save the government and regulated

parties from uncertainty and litigation costs. We find particularly compelling the fact that we repeatedly stated our view that the preclusion provisions in section 1833(t)(12) of the Act (42 U.S.C. 1395f(t)(12)) foreclosed any administrative or judicial review, a position with which the Supreme Court ultimately disagreed. Given the unique circumstances of this case, we believe extending the remedy to the entire industry through rulemaking properly balances the agencies and parties’ interest in finality and Congress’ control of the Federal budget with uniformity and litigation costs.

Comment. One commenter suggested we view the payment through the lens of monetary damages to make 340B providers whole, suggesting that this is an inevitable consequence of losing a court case.

Response. We appreciate this commenter’s transparency in identifying that the make-whole payments that many commenters are requesting are in fact money damages. But we disagree that money damages are appropriate here. Providers sued under section 1869 (42 U.S.C. 1395ff) of the Social Security Act, which authorizes both courts and the agency to “affirm[], modify[], or revers[e]” administrative decisions on individual requests for payment under section 205(b) or (g) of the Act (42 U.S.C. 405(b) or (g)). Because the Social Security Act does not authorize money damages, we do not believe that is the correct framework to understand the remedy here. *Cf. Schweiker v. Chilicky*, 487 U.S. 412, 424 (1988) (“[T]he [Social Security] Act, however, makes no provision for remedies in money damages against officials responsible for unconstitutional conduct that leads to the wrongful denial of benefits.”). Indeed, even when money damages are appropriate, courts have suggested the goal is to place plaintiffs in the same position as they would have been absent any breach, suggesting the windfall payments for non-drug items and services would need to be deducted from any recovery, regardless. *See Cmty. Health Choice, Inc. v. United States*, 970 F.3d 1364, 1375–1376 & n.10 (Fed. Cir. 2020) (“[W]hen the non-breaching party indirectly benefits from the defendant’s breach, ‘in order to avoid overcompensating the promisee, any savings realized by the plaintiff as a result of the . . . breach . . . must be deducted from the recovery.’”).

After consideration of comments received, and for the reasons stated in our proposed rule and in this final rule, we are finalizing our proposed policy as proposed. In particular, we are finalizing our proposal to make lump

sum payments, 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, as detailed further below. We are doing so for the reasons stated in our proposed rule and in this final rule.

We note that because we are finalizing our proposal to remedy the 340B drug payments through lump sum payments, we must also address the non-drug item and services payment made from CY 2018 through CY 2022 as detailed in subsequent sections of this final rule. We note that because OPPS 340B drug payment is directly and inextricably linked to the OPPS payment for non-drug items and services, if the 340B drug payments are invalidated and must be remedied, then the increased payments for non-drug items and services are invalidated and must be remedied as well. But for the reductions in the 340B drug payments, the increased payments for the non-drug items and services would not have been put into effect.

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

An estimated 1,686 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. In the proposed rule, CMS estimated 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. In the proposed rule (88 FR 44084), we stated that we would update these estimated figures in the final rule as we continued to receive updated CY 2022 claims data. In the proposed rule, we expected to have sufficient CY 2022 340B drug claims at issue submitted by September 27, 2023; therefore, by the publication date for the final rule, we estimated we would 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 discussed in the proposed rule, we estimated that 340B

providers had already received \$1.5 billion in remedy payments through reprocessed claims for 340B drugs provided from January 1, 2022, through September 27, 2022. Accordingly, we estimated in the proposed rule that the remaining remedy amount that affected 340B covered entity hospitals had not yet received as a result of this policy was \$9.0 billion.²¹

In the proposed rule, we 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 the proposed 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 invited 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.

We thank commenters for their input on our policy proposals. We have summarized the comments received and our responses to those comments in the following section.

²¹ We noted 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 of this final rule. 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 covered entity hospitals 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, we advised that 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.

Comment: Most commenters generally agreed with our methodology to calculate what 340B covered entity hospitals would have received. Commenters generally requested that we update our calculations for the final rule.

Response: We thank commenters for their support.

As stated in the proposed rule and as requested by commenters, we updated these calculations using claims data available (CMS Common Working File (CWF) CWF2023w38, processed by 09/22/2023) as of the publication of this final rule. Our updated claims data reflects that these hospitals received an estimated \$10.6 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.

Additionally, we now estimate that \$1.6 billion of the total \$10.6 billion that we calculated affected 340B covered entity hospitals did not receive as a result of the 340B Payment Policy has already been remedied through reprocessed claims. Accordingly, we estimate the remaining remedy amount that affected 340B covered entity hospitals have not yet received as a result of this policy is \$9.004 billion, which has changed from the estimated \$9.003 billion amount that was included in the proposed rule. This change is due to additional CY 2022 claims that have been reprocessed as well as an adjustment made based on a comment received as described in section II.B.1.F of this final rule. For simplicity, we refer to this number as \$9.0 billion throughout this document.

After consideration of comments received, and for the reasons stated in our proposed rule and in this final rule, we are finalizing our methodology of estimating the reduction in drug payments to affected 340B covered entity hospitals in CY 2018 through September 27, 2022, as proposed. Accordingly, as described in more detail later and in Addendum AAA, we will make total lump sum payments in the amount of \$9.004 billion as a result of this final rule. We continue to round our lump sum payment to \$9.0 billion for purposes of this final rule discussion for ease of reference, but the exact unrounded amount will be the total amount paid to hospitals.

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

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

We illustrated 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. We explained that using claims data from CY 2018 through September 27th of CY 2022 for which those claims have been processed and OPPS payments already made, we might calculate that a particular 340B-covered entity hospital would have been paid, for example, an estimated \$10 million for 340B drugs had the 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 might calculate that the hospital was actually paid \$7.31 million for 340B drugs from CY 2018 through September 27th of CY 2022. In that circumstance, we explained that the 340B covered entity hospital would receive as a lump sum payment \$2.69 million, *i.e.*, the difference between these two amounts. We noted that another way to illustrate our estimate of 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.

We noted that in the example above, the Y would be \$7.31 million. Therefore, $(\$7.31 \text{ 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 solicited comment on our proposed calculation methodology for calculating remedy payments owed to each affected 340B covered entity hospital.

We thank commenters for their input on our policy proposals. We have summarized the comments received and our responses to those comments in the following section.

Comment: All commenters who addressed the issue supported CMS's proposed methodology for calculating remedy payments. The commenters agreed that the methodology minimizes the administrative burden and complexities of reprocessing claims for hospitals and CMS. In addition, the commenters supported the proposed methodology because the lump sum payment would be an efficient method that could be completed in a shorter timeline than alternatives like an adjustment to prospective payments.

Response: We appreciate commenters' support.

After consideration of comments received, and for the reasons stated in the proposed rule and this final rule, we are finalizing our methodology to calculate the remedy payments owed to each affected 340B covered entity hospital as proposed.

d. Instruction to MACs To Remit Remedy Payments

Consistent with our past practice of remitting payments owed due to litigation, we proposed 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 proposed 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 \$2.69 million within 60 calendar days of the MAC's receipt of the instructions. (We noted that MACs will continue to follow normal accounting processes for

collecting repayment amounts that are the result of 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 solicited comment from the public on our proposed approach to remitting remedy payments. We specifically sought comment on the timeframe of 60 calendar days in which we proposed 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 believed 60 calendar days was necessary for the MACs to make these payments accurately and precisely to individual hospitals. We sought comment on this timeframe and if another timeframe, such as 30 calendar days, was supported by rationale from commenters.

We thank commenters for their input on our policy proposals. We have summarized the comments received and our responses to those comments in the following section.

Comment: Most commenters supported CMS's proposal for MACs to issue a one-time lump sum payment to affected 340B covered entity hospitals within 60 calendar days of the MAC's receipt of the instruction from CMS to make the payment. Many of these commenters emphasized that MACs should begin processing payments upon receipt of CMS instructions rather than waiting until the end of 60 days to start doing so. These commenters also requested that CMS require MACs to submit weekly updates to CMS on the status of the payments.

Response: We thank these commenters for their support of the 60-calendar day payment timeframe. We agree with commenters that MACs should begin processing payments when they receive our instructions, but no payments may be transmitted before this final rule is effective. See 5 U.S.C. 801(a)(3). Additionally, CMS will submit instructions to MACs after the deadline to submit requests for technical corrections under the process detailed in subsequent sections. We also agree that MACs should update us about the status of the payments; however, we will defer to the MACs to make communications to CMS following their standard communication practices.

Comment: A commenter encouraged CMS to clarify with MACs a process to ensure hospitals are paid the full amount provided by CMS without delay, bypassing the normal accounting processes discussed in the proposed

rule. This commenter expressed concern that allowing MACs to withhold payment would result in disputes between providers and MACs and unreasonably delay payments due to providers. The commenter recommended that CMS clarify that MACs must pay the amount specified by the agency and not permit MACs to withhold payment.

Response: We share the commenter's concern with providing the lump-sum payments quickly and efficiently. We make these payments under sections 1833(t)(14), 1833(t)(2)(E), and (as applicable) section 1871(e) of the Act (42 U.S.C. 1395l(t)(14) and (t)(2)(E) and 42 U.S.C. 1395hh(e)(1)(A)); we do not believe they are somehow different in kind from other Medicare payments made under those authorities in a way that justifies exempting them from MACs' usual procedures. As such, MACs will continue to follow normal accounting processes for collecting repayment amounts that follow 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.

Comment: Multiple commenters requested that CMS state in the final rule that hospitals receiving a remedy payment will also receive information detailing how that payment was calculated and that the payment notice constitutes a final determination. These commenters additionally requested that CMS state in the final rule that a hospital will not waive any claims or give up any legal rights by accepting a remedy payment. These commenters emphasized that providing this information is especially important because OPPS payments for drugs were based on pricing data that can change over time, including AWP, WAC, and ASP; and these drugs may have an established or decreased ASP today, which could lead to confusion regarding whether CMS's remedy payment is based on the historic AWP/WAC/ASP figure or the current ASP figure.

Response: We refer readers to the previous section titled: *Methodology for Calculating Remedy Payments Owed to Each Affected 340B Covered Entity Hospital* for additional information regarding the methodology we used to calculate the lump sum payments. We reiterate that we calculated the payment amounts to approximate what 340B covered entity hospitals would have received had it not been for the 340B Payment Policy. This means using the ASP (or WAC or AWP) based payment rate that would have been paid at that

time instead of the reduced ASP (or WAC or AWP) based payment as a result of the 340B Payment Policy. The remedial payments established by this final rule are being made instead of making case-by-case decisions through a claim-by-claim process. If the hospital does not submit any information during the time period for technical corrections, then the amounts listed in Addendum AAA are the final payment amounts due to the hospital pursuant to this rule. If, however, a hospital does submit information during the technical correction period, then the final payment will only be determined after CMS addresses the hospital's submission. That determination or decision will be the final payment amount determined pursuant to the methodology in this final rule.

Comment: Three commenters recommended that CMS require the MACs to make payment within 30 calendar days of the MAC's receipt of the instruction to pay. These commenters emphasized that swiftly finalizing and effectuating the remedy is in the best interests of CMS and the 340B hospitals and argued that CMS already has estimated the repayment amounts it will issue and could begin laying the groundwork for making these repayments by coordinating with MACs and providing education to MACs beforehand.

Response: We agree that swiftly finalizing and effectuating the remedy is in the best interests of CMS and the affected 340B covered entity hospitals, and we have engaged in the "groundwork" activities mentioned by the commenters (estimating the repayment amounts, considering how to operationalize repaying 340B hospitals, and coordinating with the MACs). However, even having done so, we continue to believe that we should give MACs up to 60 calendar days to process payments to minimize the likelihood of payment error. We agree that MACs should begin processing payments upon receipt of our instructions instead of waiting the full 60 days if possible. We believe this timeframe will allow the MACs to make these lump-sum payments accurately and precisely to individual hospitals. Given the number of payments, the size of the payments, and the overall complexity of this remedy, we believe 60 calendar days is a reasonable payment timeframe.

After consideration of comments received, and for the reasons stated in our proposed rule and in this final rule, we are finalizing our policy to instruct the MACs to remit remedy payments to affected 340B covered entity hospitals as proposed. We will make additional

payments to each 340B covered entity hospital by issuing instructions to the 340B covered entity hospital's Medicare Administrative Contractor (MAC) and instructing the MAC to issue a one-time lump sum payment to the hospital in the amount calculated using the above-described methodology within 60 calendar days of the MAC's receipt of the instruction.

e. Accounting for Beneficiary Cost-Sharing

In the proposed rule, we discussed that 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 proposed 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 (42 U.S.C. 1395hh(e)(1)(A)) and our equitable adjustment authority under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395l(t)(2)(E)). 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 (42 U.S.C. 1395l(t)(2)(E)), we explained that these payments would not be 340B drug payments subject to beneficiary copayments. Rather, we stated that these remedy payments are analogous to the type of cost report adjustments under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395l(t)(2)(E)) that we have previously found do not authorize providers to seek additional beneficiary copayments.²²

²² For example, section 3138 of the Affordable Care Act added a new section 1833(t)(18) to the Social Security Act (42 U.S.C. 1395l(t)(18)), providing for an adjustment under section 1833(t)(2)(E) of the Social Security Act (42 U.S.C. 1395l(t)(2)(E)) to address higher costs incurred by cancer hospitals. Section 1833(t)(2)(E) of the Act (42 U.S.C. 1395l(t)(2)(E)), 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

We acknowledged that we have previously suggested that any remedy might affect beneficiary cost-sharing. (*See, for example,* 84 FR 61323.) But we noted that we made that statement in 2019, before the litigation was concluded, and well before we proposed 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 clarified that our proposed lump sum payments for the difference in 340B-acquired drug payments due to the 340B Payment Policy would not affect particular beneficiary cost-sharing responsibilities.

We also explained that in these unique circumstances, it is appropriate to exercise our authority under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395l(t)(2)(E)) 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 caveated that statement—it would not necessarily be appropriate to make this kind of adjustment under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395l(t)(2)(E)) 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 find that such an adjustment is necessary for equitable payments in these unique circumstances in part because of the unprecedented scope of the remedy in terms of the amount of money at issue; the number of services, beneficiaries, and claims affected; and the number of years that have passed between the claims and the remedy.

Accordingly, we concluded 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 (42 U.S.C. 1395l(t)(2)(E)) so that affected 340B covered entity hospitals would be paid amounts that approximate what they would have been paid for these

with providing the adjustment on a claims basis through increased APC payments. *See* CY 2012 OPPI/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 (42 U.S.C. 1395l(t)(2)(E)) to adjust cancer hospital payments.

drugs absent the 340B Payment Policy, which includes what affected 340B covered entity hospitals would otherwise have been paid by the beneficiary. Therefore, we proposed that the \$9.0 billion payment amount would include \$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 emphasized that, if our proposal was finalized, affected 340B covered entity hospitals could 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) of the Act (42 U.S.C. 1395(t)(2)(E)). We cautioned that CMS would consider appropriate administrative action for providers who nevertheless bill beneficiaries for coinsurance. We solicited comments from the public on our proposed approach to accounting for beneficiary cost sharing.

We thank commenters for their input on our policy proposals. We have summarized the comments received and our responses to those comments in the following section.

Comment: Commenters overwhelmingly supported our proposed approach and rationale for accounting for beneficiary cost sharing.

Response: We appreciate commenters' support.

After consideration of comments received, and for the reasons stated in our proposed rule and in this final rule, we are finalizing our policy to account for beneficiary cost sharing as proposed. We will exercise our authority under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395(t)(2)(E)) to make adjustments "as necessary to ensure equitable payments," to pay the full \$9.0 billion difference, including \$1.8 billion, an amount that is approximately 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 from CY 2018 through September 27, 2022, so that affected 340B covered entity hospitals are paid the approximate amount they would have been paid in full without application of the 340B Payment Policy.

f. Remedy Payment Amounts

We published the following data file that contained our calculations of the amounts owed under the above-

described methodology to each affected 340B covered entity hospital for the proposed rule: <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps>. We solicited comment from the public on the accuracy of the data in Addendum AAA of the 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 OPPTS website.²³

We thank commenters for their input on our policy proposals. We have summarized the comments received and our responses to those comments in the following section.

Comment: A small number of commenters had concerns regarding the payment amounts, including a request for increased transparency. Some commenters expressed a general concern that some hospitals would receive very large lump sum payments relative to their usual OPPTS payments. Similarly, one commenter supported the lump sum calculation methodology but requested that CMS share with participating 340B providers more details about the methodology and a list of their 340B claims on which it was used. Additionally, a couple commenters requested CMS verify their individual payment amounts. Specifically, one commenter indicated that the calculation of the amount owed to them was incorrect. This commenter believes that they were owed more than calculated for CYs 2020 and 2021. Another commenter stated that they were owed nearly \$640,000 more than calculated due to claims from CY 2019 that were resubmitted and reprocessed after September 27, 2022, and paid at the ASP minus 22.5 percent rate. This commenter requested that CMS take into account claims that were processed and paid at the lower rate through December 31, 2022.

Response: We appreciate these commenters' concerns and have reviewed the general and specific issues they raised. We also reviewed the payment data for these commenters who stated our calculations were incorrect. As a result of our review, we identified several claims accruing prior to CY 2022 that providers submitted in late CY 2022. Because those claims accrued prior to CY 2022, the MACs correctly processed those claims at the ASP minus 22.5 percent rate; and these claims should be part of the lump-sum payments. We have accordingly adjusted the remedy payment for affected claims. This means that some

hospitals will receive slightly higher payments than in the proposed rule, which slightly increases the aggregate lump sum payments we are making from \$9.003 in the proposed rule to \$9.004 in this final rule. We also note it would be impractical to list the millions of claims used to calculate all of the lump sum payments. For increased transparency, Addendum AAA has been revised to include additional CY 2022 data (please see comment below on this subject). To resolve any lingering concerns by individual providers and provide the opportunity for additional transparency, we are establishing the technical correction process noted later in the rule.

Comment: An additional commenter requested clarification with respect to two of its affiliated hospitals, which were identified on Addendum AAA as eligible for payment but did not participate in the 340B Program during the years in question.

Response: We appreciate the commenter's transparency. Our calculations are based on the information that hospitals originally used when submitting claims with the 340B billing modifier, "JG." These two hospitals used the 340B billing modifier "JG" for some claims during the time period in which the 340B Payment Policy was in effect, and so they received reduced payments under the 340B Payment Policy. The overall remedy payments for these entities are small relative to other remedy payments for other hospitals, which suggests they may have erroneously included the "JG" modifier when initially submitting claims. We will make remedy payments even to providers who submitted the "JG" modifier incorrectly, because they would have received reduced payments under the 340B Payment Policy.

Comment: One commenter stated that providers are unable to accurately verify estimates because the paid through date for claims used by CMS to create the estimates has not been documented and communicated to providers. The commenter requested that CMS disclose the paid through date to providers so that they can verify the accuracy of the calculations. Since the same issue will arise for any final settlement, the commenter additionally requested that CMS document and communicate to providers the paid through date used to arrive at a final settlement and give providers time to accept or refute that amount.

Response: We processed (or, in some cases, reprocessed) any claims paid on or after September 28, 2022, using the default rate (generally ASP plus 6

²³ <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps>.

percent). In order to ensure we captured all claims appropriately for this analysis, we included all claims with a Claims Process Date (the date the fiscal intermediary completes processing and releases the institutional claim to the CMS common working file) prior to October 12, 2022, or Date of Service on or before September 27, 2022, in our analysis to determine which claims needed to be remedied while ensuring we excluded those claims that were processed or reprocessed at the higher payment rate (generally ASP plus 6 percent).

Comment: Several commenters requested that CMS add an additional column to Addendum AAA displaying the total amount withheld from each 340B hospital for the period from January 1, 2022, through September 27, 2022, before claims were reprocessed to allow hospitals to calculate and confirm the CY 2022 reprocessed claims amounts. These commenters additionally requested that CMS identify the data sets that it used, as well as the cut-off date for any claims data it used, to calculate the amount of the reprocessed CY 2022 claims, even if those data sets were not publicly available.

Response: We concur with the commenters that additional information regarding the process we used to calculate the remedy payment amounts for CY 2022 would be helpful for providers to calculate their CY 2022 reprocessed claims amounts. Our calculations used data from the CMS Common Working File (CWF) OPPS data, CWF2023w38. We also included two additional columns on Addendum AAA: "CY 2022 (January 1 to September 27) 340B Drugs Payment Withheld" and "CY 2022 (January 1 to December 31) 340B Remedy Payment Already Paid."

Comment: One commenter, referencing the proposed rule's acknowledgment that the \$1.5 billion estimated amount for CY 2022 claims through September 27 might change by the time the final rule is issued, requested that CMS include with the final rule an updated addendum of hospital-specific payments to ensure that all activity since the proposed rule was issued has been accounted for.

Response: We agree. The final rule Addendum AAA has been updated with new hospital-specific payment amounts and accounts for all payment activity that has happened since the proposed rule was issued. Our updated claims data reflects that these hospitals received approximately \$10.6 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 27, 2022, had the 340B policy not been implemented.

Additionally, our updated analysis estimates that \$1.6 billion of the total \$10.6 billion that affected 340B covered entity hospitals did not receive as a result of the 340B Payment Policy has already been remedied through reprocessed claims. Accordingly, we estimate the remaining remedy amount that affected 340B covered entity hospitals have not yet received as a result of this policy is \$9.004 billion (rounded to \$9.0 billion for purposes of discussion in this final rule).

Comment: One commenter requested clarification as to whether the amounts listed in Addendum AAA would be the actual amounts paid, or if those amounts would be subject to sequestration. If subject to sequestration, the commenter requested clarification as to the percentage of the reduction. Another commenter requested that CMS not impose sequestration on the repayments since the sequestration adjustment was suspended during the PHE when most of the payments occurred.

Response: The calculated amounts in Addendum AAA are based on original claims that already included any applicable sequestration. We do not need to apply any additional adjustments for sequestration. The sequestration percentage, when applicable, that applied to the original claim will also apply to the remedy payment because the remedy amount is calculated from the sequestration reduced amount. For instance, if the original claim did not have any sequestration adjustment because the claim was paid during the COVID-19 PHE when the sequestration adjustment was suspended, then remedy payment calculation for that claim would not reflect any sequestration adjustment. The lump sum payments were calculated to provide a payment amount as close as possible to what hospitals would have received if not for the 340B Payment Policy, including any sequestration adjustment that would have applied. The amounts included in Addendum AAA are the amounts that hospitals will receive, except that payment amounts may be affected by MACs continuing to follow normal accounting processes for collecting repayment amounts stemming from provider-specific overpayment obligations, adjustments resulting from errors identified through the lump-sum technical correction process described below, as well as other unique

situations such as provider bankruptcy or payment suspension, any of which may impact the provider's net payment amount.

Comment: Many commenters requested a process for affected 340B covered entity hospitals to challenge CMS's calculation of their remedy payment. One commenter requested that CMS provide hospitals with additional time, beyond the 60-day proposed rule comment period, to review the repayment amounts listed in the data file and submit data to CMS justifying an alternative repayment amount. Another commenter suggested that hospitals be provided with 120 days from the date of payment of the lump sum payment to file a dispute, with supporting evidence, that CMS underpaid the hospital for 340B claims for separately payable drugs provided from 2018–2022. One commenter requested that CMS establish a quick, collaborative method for addressing any miscalculation of the remedy payments due. Specifically, the commenter recommended a method with clear, short timelines and a requirement for MACs to respond and resolve any issues quickly.

Response: We agree with commenters that there should be a prompt process for affected 340B covered entity hospitals to request the correction of any errors that hospitals identify in CMS's calculation of the specific remedial payment. Consequently, we are establishing a technical correction process. An affected 340B covered entity hospital can alert CMS to potential errors in the calculation of their lump sum payment amount in Addendum AAA by emailing CMS at the following address, outpatientpps340b@cms.hhs.gov, no later than 11:59 p.m. Eastern Standard Time (EST) on November 30, 2023. Submissions must include (1) a description of the nature of the error; (2) a designated contact person for the purposes of addressing the error; and (3) relevant supporting documentation such as claim numbers, total units, payment amount received, date of payment. We will pay the lump sum to an affected 340B covered entity hospital using this process after the alleged calculation error has been reviewed and resolved by CMS. We will work as diligently as possible to resolve any potential technical corrections submitted promptly. Depending on the complexity of the potential technical correction submitted, and the volume of overall technical corrections submitted, processing technical corrections could take us substantial additional time, and hospitals submitting technical

correction requests may be paid after other hospitals.

Comment: Multiple commenters requested that CMS clarify that the final rule does not affect the procedural stature of any open or stayed administrative appeals and that it intends the final rule to be subject to judicial review. These commenters specifically requested that CMS state that reliance on section 1833(t)(2)(E) of the Act (42 U.S.C. 1395l(t)(2)(E)) as authority for these adjustments is not intended to create any implication that the adjustments are not subject to judicial review.

Response: Because this rule fully compensates providers for the amounts they claimed they are owed on the 340B payment issue, we believe this action moots any pending appeals on that specific issue. Accordingly, if a provider were to proceed with a pending appeal that would, in effect, be seeking double recovery for the same service. A court's jurisdiction to review all or part of this rule is outside the scope of this rulemaking.

The following updated data file contains the final amounts owed under the previously described finalized methodology to each affected 340B covered entity hospital for the final rule: <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps>.

g. Anticipated Timing of Remedy Payments

In the proposed rule (88 FR 44086), we stated that, if we finalized 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 the rule had been finalized and the MAC instructions for each affected 340B covered entity hospital had been issued.

We received the following comments on our proposals.

Comment: Commenters were nearly universally supportive of our proposal to make the remedy payments at the end of CY 2023 or the beginning of 2024.

Response: We appreciate commenters' support.

Comment: One commenter, expressing concern about the financial situation of safety-net and rural hospitals, requested that, prior to CMS finalizing its rule related to the 340B remedy, CMS authorize the MACs to make an initial payment to hospitals that request it in the amount listed in the proposed rule Addendum AAA. Then, in the final rule, the commenter suggests that CMS would instruct the MACs to make an incremental payment

to any hospitals that elected to receive funds immediately based on the final rule and any additional claims that were processed through September 27, 2022. In other words, this commenter requests that CMS instruct the MACs to pay hospitals that ask for immediate payment the amount listed in the proposed rule Addendum AAA prior to the effective date of the final rule and then, in the final rule, instruct the MACs to pay any additional amount due based on the final rule Addendum AAA.

Response: While we appreciate the commenter's concerns, we are unable to authorize any payments until this rule and policy is finalized and effective. As stated above, payments will not be made until this rule is effective, which will occur 60 days after the rule is displayed at the Office of the Federal Register. As additionally noted above, to ensure payments are made accurately, there may be an additional delay for hospitals requesting a technical correction.

After consideration of comments received, for the reasons stated in the proposed rule and this final rule, subject to our clarification above and the technical corrections procedure discussed earlier, we are finalizing our proposal to make these additional payments at the end of CY 2023 or beginning of CY 2024. In summary, we intend to issue instructions for hospitals who do not request any correction to MACs as soon as possible after the technical corrections submission deadline has passed. MACs will be instructed to pay providers as soon as possible after the rule is effective, and payments will be made no later than 60 days after the MAC's receipt of the instructions. We will issue instructions to pay hospitals who submit technical correction requests after those requests are resolved.

h. Eligibility of Remedy Payments for Interest

In the proposed rule (88 FR 44086), CMS also considered its authority to pay interest on the remedy payments but concluded that we did not believe we had the authority to do so.

We received the following comments on our proposals.

Comment: Many commenters disagreed that CMS lacks the authority to pay interest on the remedy payments, pointing to various statutes discussed in the following paragraphs. The majority of these commenters relied on section 1833(j) of the Act (42 U.S.C. 1395l(j)), which provides that whenever a final determination is made that the amount of payment made under this part either to a provider of services or to another person pursuant to an assignment under

section 1842(b)(3)(B)(ii) of the Act was in excess of or less than the amount of payment that is due, and payment of such excess or deficit is not made (or effected by offset) within 30 days of the date of the determination, interest shall accrue on the balance of such excess or deficit not paid or offset (to the extent that the balance is owed by or owing to the provider) at a rate determined in accordance with the regulations of the Secretary of the Treasury applicable to charges for late payments. Instead, these commenters ask us to construe the Supreme Court's decision in *American Hospital Association* as a "final determination."

Response: As described here and in the following several responses, we do not agree that any provision identified by commenters provides CMS with authority to pay interest. Commenters do not identify any administrative "final determination" that would trigger the interest provision in section 1833(j) of the Act (42 U.S.C. 1395l(j)). And our regulations foreclose commenters' suggestion to treat the Supreme Court's decision as a "final determination." Our regulations define "final determination" in section 1833(j) of the Act (42 U.S.C. 1395l(j)) to mean "[a] written determination of an underpayment." 42 CFR 405.378(c)(1)(i)(B). We have previously explained that this definition refers to "administrative, not judicial, determinations; therefore, there is no interest obligation under these regulations for judicial determinations." Medicare Program; Changes Concerning Interest Rates Charged on Overpayments and Underpayments, 56 FR 31332, 31335 (1991).

That interpretation is reinforced by the specific litigation interest provisions in the Medicare statute. Congress provided that cost reports appealed to the Provider Reimbursement Review Board are generally subject to interest beginning 180 days after an intermediary's or the Secretary's final determination. See section 1878(f)(2) of the Act (42 U.S.C. 1395oo(f)(2)). And in the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Congress amended the judicial review process for individual appeals and authorized litigation interest only in cases granted expedited judicial review under section 1869(b)(2) of the Act (42 U.S.C. 1395ff(b)(2)). See Medicare Prescription Drug, Improvement and Modernization Act of 2003, Public Law 108-173, section 931(a), 117 Stat. 2066, 2399 (2003). By providing interest provisions that apply specifically to judicial determinations, Congress confirmed our reading that section 1833(j) of the Act (42 U.S.C. 1395l(j))

applies only to administrative determinations.

Additionally, changing our interpretation of administrative determination may cause the various interest statutes to conflict. For example, if a cost report appeal is denied by an intermediary and a court ultimately finds that payment should have been made, would interest run from 180 days after the intermediary's decision under section 1878(f)(2) of the Act (42 U.S.C. 1395oo(f)(2)), or from 30 days after the court's decision, under commenter's interpretation of section 1833(j)? We decline to construe section 1833(j) of the Act (42 U.S.C. 1395l(j)) in a way that could conflict with other provisions of the Act.

We also disagree that the Supreme Court's decision would be a qualifying "final determination" under section 1833(j) of the Act (42 U.S.C. 1395l(j)), even assuming judicial decisions could sometimes qualify. Interest under this statute runs from a "final determination" that the payment made "was in excess of or less than the amount of payment that is due." But the Supreme Court never calculated how much less the plaintiff hospitals were paid than due, declining to consider remedies in the first instance and instead focusing on the purely legal issue of whether the payment rates in the CY 2018 and 2019 OPSS rules exceeded CMS's authority under section 1833(t)(14) of the Act (42 U.S.C. 1395l(t)(14)). *Am. Hosp. Ass'n*, 142 S. Ct. at 1903, 1906. On remand, the district court similarly rejected the plaintiff hospitals' invitation to calculate the amount owed, whether to the parties before the court or to the entire industry. *See Am. Hosp. Ass'n*, 2023 WL 143337, at *3 (declining to issue "order commanding HHS to repay each underpaid claim to the penny, [because] that cannot possibly be the only rational choice available to the agency"). Because the Supreme Court never determined the amount of underpayment on which interest would run, its decision is not a "final determination" of the "amount" of underpayment under section 1833(j) of the Act (42 U.S.C. 1395l(j)).

Because commenters have not identified a final administrative determination of an underpayment, we do not believe that section 1833(j) of the Act (42 U.S.C. 1395l(j)), as construed by 42 CFR 405.378(c)(1), would authorize CMS to pay interest on the proposed remedy payments.

Comment: Two commenters argued that even if CMS is correct that interest is not due on the amount owed to all hospitals that will receive lump sum

payments, interest is due to plaintiffs in several cases pending before the United States District Court for the District of Columbia that were stayed pending the outcome of CMS's remedy discussed in the proposed rule. These plaintiffs, the commenters contend, are entitled to prevailing party interest under 42 CFR 405.990(j)(2). These commenters argue that, in appealing CMS's initial determination to pay 340B drug claims at the unlawful rate, these plaintiffs clearly communicated to CMS that the rate of ASP minus 22.5 percent exceeded the Secretary's authority and should instead have been paid at ASP plus 6 percent as required by law. When CMS refused to remit payment of ASP plus 6 percent through these administrative proceedings, the plaintiffs thus sufficiently exhausted the administrative appeals process, giving them standing for judicial review under 42 U.S.C. 405(g), and entitling them to the usual interest awarded to prevailing parties that seek an expedited path to judicial review.

Response: 42 CFR 405.990(j)(2) implements section 1869(b)(2)(C)(iv) of the Act (42 U.S.C. 1395ff(b)(2)(C)(iv)). That provision allows a reviewing court to award interest to a prevailing party in litigation where a provider of services or supplier was granted expedited judicial review pursuant to section 1869(b)(2) of the Act (42 U.S.C. 1395ff(b)(2)). We are not aware of any providers who received expedited judicial review pursuant to subparagraph (b)(2), and so, even assuming that provision authorizes CMS to pay interest under section 1869(b)(2) of the Act (42 U.S.C. 1395ff(b)(2)) without a court order, it would not authorize interest payments on the remedy payments here.

To the extent that commenters mean to suggest that section 1869(b)(2)(C)(iv) of the Act (42 U.S.C. 1395ff(b)(2)(C)(iv)) also applies when a court excuses the usual exhaustion requirements contained in section 1869(b)(1) of the Act (42 U.S.C. 1395ff(b)(1)), we disagree. Litigation interest is the exception to cases filed under section 1869, not the rule. No statute authorizes interest for litigants who follow the usual administrative appeal procedures contained in subsection (b)(1). And courts have held that it is subsection (b)(1)'s reference to section 205(g) that authorizes courts to excuse subsection (b)(1)'s exhaustion requirement. *See Tataranowicz v. Sullivan*, 959 F.2d 268, 272 (D.C. Cir. 1992). Subsection (b)(2) contains no such reference to section 205(g), and so we doubt the same reasoning would apply. *Cf.* 1869(b)(2) of the Act (42 U.S.C. 1395ff(b)(2)) (limiting review to the "civil action described in

this subparagraph"). If Congress wanted to extend litigation interest to cases where courts had waived exhaustion under subsection (b)(1), it could have done so when amending that statute to add subsection (b)(2). Because Congress did not, we decline any invitation to extend section 1869(b)(2)(C)(iv) (42 U.S.C. 1395ff(b)(2)(C)(iv)) beyond its plain text, especially considering implications litigation interest has on the United States' sovereign immunity and Congress's control of the public fisc. *See, for example, Libr. of Cong. v. Shaw*, 478 U.S. 310, 316 (1986) ("For well over a century, this Court, executive agencies, and Congress itself consistently have recognized that federal statutes cannot be read to permit interest to run on a recovery against the United States unless Congress affirmatively mandates that result.").

Comment: One commenter stated that the Federal Tort Claims Act provides for post-judgment interest (28 U.S.C. 2674) and requested post-judgment interest from June 15, 2022, the date of the Supreme Court's decision, to the date of final payment. Another commenter argued that the remedy payments are subject to the Prompt Payment Act, as amended, and its rules, which state that "the temporary unavailability of funds does not relieve an agency from the obligation to pay these interest penalties or the additional penalties required under § 1315.11." *See* 5 CFR 1315.10(b)(4). This commenter additionally notes that the failure of CMS to make interest payments could result in additional litigation. Similarly, another commenter stated that section 1815(d) of the Act (42 U.S.C. 1395g(d)) and common law provide for the payment of interest on underpayments to Medicare providers.

Response: We do not agree with commenters that the authorities cited would provide CMS the ability to include interest as part of these lump sum remedy payments. No lawsuit has been filed under the Federal Tort Claims Act, and so its interest provisions are irrelevant. *See* 28 U.S.C. 2674 (limiting section to "the provisions of this title relating to tort claims"). Nor do we believe Medicare providers are subject to the Prompt Payment Act's terms. *Cf.* 5 CFR 1315.1 (limiting applicability to procurement contracts and vendors). Even if they were, that statute does not apply to instances where, as here, "payment that is not made because of a dispute between the head of an agency and a business concern over the amount of payment." 31 U.S.C. 3907(c). Section 1815 of the Act (42 U.S.C. 1395g(d)) governs Part A payments, not Part B, and so is similarly irrelevant. *See* SSA

section 1815(d) (42 U.S.C. 1395g(d)) (limiting applicability to payments “under this part”).

Comment: A couple commenters directed CMS to the Medicare Claims Processing Manual (100–04, Chapter 1, Section 80.2.2) for instructions for assessing and calculating interest due on non-periodic interim (PIP) claims not paid in a timely manner by fiscal intermediaries and carriers. Another commenter referenced MLN Matters No. MM3557 and argued that the 340B claims were clean and unpaid, therefore, based on CMS regulations, interest should be paid from the date of receipt of the claim. These commenters assert that these claims were not processed in a timely manner, rendering them eligible for interest accrual.

Response: We appreciate commenters highlighting these instructions. Our clean claims regulations are found at 42 CFR 405.922 and implement section 1842(c)(2)(C) of the Act (42 U.S.C. 1395u(c)(2)(C)). Section 1842(c)(2)(B)(i) of the Act (42 U.S.C. 1395u(c)(2)(B)(i)) defines a clean claim as a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under this part. Section 1842(c)(2)(C) of the Act (42 U.S.C. 1395u(c)(2)(C)) provides that if payment is not issued, mailed, or otherwise transmitted within an applicable number of calendar days after a clean claim is received, interest shall be paid at the rate used for purposes of section 3902(a) of title 31, United States Code for the period beginning on the day after the required payment date and ending on the date on which payment is made. Our longstanding position has been that section 1842(c)(2)(C) of the Act (42 U.S.C. 1395u(c)(2)(C)) does not apply in situations like this one where a payment regulation was properly applied by the contractor to deny a claim that is ultimately held unlawful by a court. No contractor has the authority to ignore CMS’s binding regulations and make a payment at odds with the regulations within 30 days or otherwise, and so we believe this is a “particular circumstance requiring special treatment.” *Accord* Medicare Program: Changes to the Medicare Claims Appeal Procedures, 74 FR 65296, 65302 (2009) (“Claims initially denied and subsequently paid following a favorable appeal decision, or revised following a reopening action are, by their nature, claims that require special treatment.”). As noted above, the Act speaks expressly to the issue of litigation

interest. And reading section 1842(c)(2)(C) of the Act (42 U.S.C. 1395u(c)(2)(C)) to apply to litigation interest raises a similar conflict as reading section 1833(j) of the Act (42 U.S.C. 1395l(j)) to apply to litigation interest. For example, if a claim denied by a contractor under CMS’s regulations was later certified for expedited judicial review under section 1869(b)(2) of the Act (42 U.S.C. 1395ff(b)(2)), would interest run from 30 days after receipt by the contractor under section 1842(c)(2)(C) of the Act (42 U.S.C. 1395u(c)(2)(C)), or from 60 days after certification under section 1869(b)(2)(C)(iv) of the Act (42 U.S.C. 1395ff(b)(2)(C)(iv))? We decline to construe section 1842(c)(2)(C) of the Act (42 U.S.C. 1395u(c)(2)(C)) in a way that could conflict with other provisions of the Act.

Comment: One commenter requested that CMS share the citations for the authority prohibiting the payment of interest.

Response: As noted above, the Supreme Court has clarified that “[f]or well over a century, this Court, executive agencies, and Congress itself consistently have recognized that Federal statutes cannot be read to permit interest to run on a recovery against the United States unless Congress affirmatively mandates that result.” *Libr. of Cong. v. Shaw*, 478 U.S. 310, 316 (1986). The proper analysis is thus whether there is legal authority affirmatively mandating the payment of interest here. CMS’s inability to pay interest is a consequence of a lack of authority authorizing it to pay interest, not any authority prohibiting it from paying interest.

Comment: One commenter recommended that CMS work with Congress to allow the remedy to include interest.

Response: We appreciate the commenter’s recommendation. As noted, a legislative change would require Congressional action.

Comment: One commenter asked if CMS has considered adjusting future budget neutrality provisions to account for the amount of interest reasonably owed 340B providers.

Response: Since we are not adopting a policy to pay interest in this rule, we have not examined whether doing so would require changes to the budget neutrality adjustments discussed below. We agree with the commenter that if we were to pay interest, we would need to evaluate what, if any, impact such interest would have on budget neutrality requirements.

After a consideration of comments received, and for the reasons discussed

above, we continue to believe that we do not have the authority to include interest as part of the lump sum payments. We therefore are finalizing our proposal that the lump sum remedy payments would not include interest as proposed.

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

a. Background

As described in the proposed rule, 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 (42 U.S.C. 1395l(t)(9)(B) & (t)(14)(H)) by increasing non-drug item and service payments to all OPSS providers for CY 2018 through CY 2022. As we explained in the proposed rule, to comply with the statutory budget neutrality requirements in sections 1833(t)(9)(B) and 1833(t)(14)(H) of the Act (42 U.S.C. 1395l(t)(9)(B) and (t)(14)(H)), as well as section 1833(t)(2)(E) of the Act (42 U.S.C. 1395l(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. As described in the proposed rule, 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. We noted that 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 recover this windfall.

As summarized in the proposed rule, 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 OPSS during the same time period to comply with statutory budget neutrality requirements. In other words, all hospitals were paid more under the OPSS for non-drug items and services for CY 2018 through CY 2022 than they would have been paid absent the 340B Payment Policy. As we explained, starting in CY 2018, CMS applied an approximate 3.19 percent increase to the OPSS conversion factor to offset the decreased OPSS 340B drug payments. And, as we also explained, because we proposed to make 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 were required to correspondingly propose to make an offset to maintain budget neutrality as if the 340B Payment Policy had not been in effect during CY 2018 through CY 2022. As detailed in the proposed rule, this is consistent with the policy finalized in the CY 2023 OPPTS/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 in section I.C. of the proposed rule. 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.

As we described in the proposed rule, to calculate the additional amount CMS paid for non-drug items and services, we proposed 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 OPPTS conversion factor. For additional details on these status indicators, we refer readers to Addenda D1 of the CY 2023 OPPTS/ASC final rule with comment period for the most recent OPPTS status indicators and their definitions. This file is available on the CMS website.²⁴ As we noted in the proposed rule, 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 proposed 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 proposed 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. As we explained, our budget-neutrality adjustment in the 2018 through 2022 OPPTS rules reflected a prediction regarding how much we would spend on 340B drugs—a prediction that turned out to be too low. As it turned out, 340B hospitals spent more on 340B 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. We explained that our proposed remedy would achieve budget neutrality by reversing that imbalance. We proposed that in aggregate, the total additional payment that providers would receive as a result of this remedy, \$10.5 billion, would be larger than the amount of payment that would be prospectively offset, \$7.8 billion. As we explain below and stated in the proposed rule, we believe that our proposed remedy, which would effectively reverse the imbalance that arose under the policy the Supreme Court deemed unlawful and would reasonably approximate 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 solicited comments from the public on our proposed approach to implementing budget neutrality.

Comment: We received many comments on our proposed approach to implementing budget neutrality.

Response: These comments are addressed in Section II.B.2.b of this final rule.

b. 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 described in the proposed rule (88 FR 44087), we believe that sections 1833(t)(2)(E) and (t)(14) of the Act (42 U.S.C. 1395j(t)(2)(E) and (t)(14)) are properly read to require budget neutrality. As we explained in the proposed rule, section 1833(t)(2)(E) of the Act (42 U.S.C. 1395j(t)(2)(E)) provides that adjustments under that provision must be made in a budget neutral manner. Section 1833(t)(14)(H) of the Act (42 U.S.C. 1395j(t)(14)(H)) 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 (42 U.S.C. 1395j(t)(9)(B)) 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 proposed 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 we discussed in the proposed rule, we proposed 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.

As described in the proposed rule, to reduce the burden on providers of offsetting the \$7.8 billion offset required to maintain budget neutrality, we proposed to implement the adjustment prospectively. We proposed to, beginning in CY 2025, reduce all payments for non-drug items and services to all OPPTS providers—except any hospital that enrolled in Medicare after January 1, 2018—by 0.5 percent each year until the total offset was reached (which we estimated to be approximately 16 years). As stated in the proposed rule, starting this reduction in CY 2025 would allow CMS time to finalize its methodology, and then apply its methodology to calculate and publish the payment rates in the CY 2025 OPPTS/ASC proposed rule. We stated it would also allow adequate time for impacted parties to assess and prepare for the new payment rates that would be calculated using a reduced conversion factor. Additionally, as we remarked in the proposed rule, we believed 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 that the offset was not immediately, in the short-term, overly financially burdensome on impacted entities, especially those in rural communities, which we believed would be the case if we were to apply an adjustment for the full offset amount in a single year.

In the proposed rule, we acknowledged that, in litigation, we at

²⁴ <https://www.cms.gov/medicare/medicare-fee-service-payment/hospitaloutpatientpps/hospital-outpatient-regulations-and-notice/cms-1772-fc>.

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 (42 U.S.C. 1395l(t)(9)) 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).²⁵ At the same time, however, the government's briefing 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.* In the proposed rule, we indicated that we had further considered section 1833(t)(9) of the Act (42 U.S.C. 1395l(t)(9)) in light of the Supreme Court's decision holding that judicial review was available and also recognizing the statutory requirement of budget neutrality, and that consequently different ways of approaching the remedy had come into focus.

As we explained in the proposed rule, our proposal was consistent with section 1833(t)(9) of the Act: It would offset the amounts of money that constitute excess payments in past years—which are effectively overpayments for those years (that is, 2018 to 2022) in light of the Supreme Court's decision. In other words, while we proposed 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 proposed that 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. We also explained that because the estimated amount of expenditures for each of 2018 to 2022 would still be budget neutralized—indeed, we stated that it was 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 believed it would be 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 section 1833(t)(9)(B) of the Act (42 U.S.C. 1395l(t)(9)(B)). As noted in the proposed

rule, we believed that this interpretation would account for reliance interests hospitals may have in payments already made while staying consistent with the budget neutrality requirements repeated throughout the OPSS statute in sections 1833(i)(2)(E), (t)(9), and (t)(14)(H) (42 U.S.C. 1395l(i)(2)(E), (t)(9) and (t)(14)(H)). And, as discussed in the proposed rule, we concluded that avoiding a windfall to providers was consistent with the agency's recoupment authority. We invited comments on these aspects of our proposal.

We also acknowledged 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. As we explained, that is a consequence of many factors. The most significant factor is our estimate in the CY 2018 OPSS/ASC final rule of the amount that expenditures for 340B-acquired drugs would decrease under the 340B Payment Policy. As part of the 340B Payment Policy, we budget neutralized the decreased payments for 340B-acquired drugs by applying a 3.19 percent adjustment to the conversion factor to increase expenditures for non-drug items and services. In the proposed rule, we acknowledged that Medicare could not perfectly have calculated a precise estimate when it first made the budget neutrality adjustment in the CY 2018 final rule with comment period. 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, it was not possible to estimate more accurately the amount of the aggregate payment reduction. That imprecision impacted the budget neutrality adjustment we calculated. We discussed that other potential offsetting factors included possible changes in provider behavior and overall market changes that may have lowered the impact of the payment reduction in the CY 2018 OPSS/ASC final rule with comment period (82 FR 52623).

We now know that CMS underestimated the growth in expenditures for 340B drugs in CYs 2018 through 2022. Therefore, as we stated in the proposed rule, our budget neutrality calculations for those years ended up increasing payments for non-drug services by less than we decreased payments for 340B drugs. As we explained, we followed our standard approach not to propose to re-calculate what the budget neutrality offset would have been beginning in 2018 if we had used more accurate assumptions.

Rather, we proposed simply to unwind the 3.19 percent budget neutrality adjustment we set beginning in 2018. Because of our flawed assumptions in 2018, however, the total amount of our proposed remedy payments to 340B hospitals for 340B drugs would thus be greater than the future reduction to payments.

As we explained in the proposed rule, there were other reasons for the difference between the lump-sum payment and our future reductions to non-drug spending. Some of these reasons increase that gap; others do the opposite. First, 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, during CY 2022 CMS began making payment for 340B drugs at the default drug payment rate, generally ASP plus 6 percent, for claims processed on or 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, as we explained, there was 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 needed to be offset, while the 340B drug claims for that quarter had already been paid correctly.

Additionally, as we remarked in the proposed rule, our proposal included in the remedy payments the amount that affected 340B covered entity hospitals would otherwise have been paid by beneficiaries. This, we explained, would approximate what the hospitals would have been paid for these drugs absent the 340B Payment Policy. Because the statute requires that this adjustment be budget neutral, we proposed to include in the prospective offset calculation an amount to offset this increase in Medicare payments.

In sum, we proposed in the proposed rule 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 OPSS conversion factor. That offset encompasses both the windfall providers 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 proposed to use it to offset both the payments we are making

²⁵ https://www.supremecourt.gov/DocketPDF/20/20-1114/197027/20211020212647625_20-1114bsUnitedStates.pdf.

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 proposed to decrease future payments for every non-drug item and service for every hospital. As we explained, this approach was similar to the original budget neutrality adjustment in the 340B Payment Policy 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 acknowledged in the proposed rule that, depending on how a hospital's future mix of drug and non-drug services compared 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 might ultimately receive slightly more (or less) of a payment reduction than the payment increase they received in CY 2018 through CY 2022. We additionally acknowledged that there is often some imprecision inherent in budget neutrality calculations, and being more precise 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. As we explained, that alternative was very similar to the claims reprocessing alternative that we discussed in section II.A.2 of the proposed rule, which would impose significant burdens and payment delays for 340B providers. We also explained that because 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. We noted that it would impose all the burdens of an up-front budget neutrality recoupment that we decided against proposing, as explained in section II.A.3 of the proposed rule. We indicated that, except in the case of truly new hospitals, which we proposed to exclude from the prospective offset

described under section II.B.2.c of the proposed rule, we did not believe our proposed approach would so significantly undercompensate hospitals to require that kind of precision, 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 explained that we believed 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. As we emphasized in the proposed rule, this remedy applies in truly unique circumstances: we must apply budget neutrality in a way that may not be purely prospective, but may be partially retroactive to rectify an adjudicated past violation of law. As discussed in the proposed rule, re-running all the relevant claims as if the 340B Payment Policy did not occur would be close to impossible administratively. Consequently, given these unique circumstances, we explained that we believed our proposed approach properly applied the budget neutrality principle, even if it resulted in some effectively unavoidable imprecision.

Accordingly, as described in the proposed rule, beginning in CY 2025, we proposed to reduce OPPS payments for non-drug items and services annually by decreasing the OPPS conversion factor by 0.5 percent each year until the total offset, estimated to be \$7.8 billion in the proposed rule, was reached. We explained that we recognized that the proposed rule was unique and therefore required a unique prospective offset period. We also explained that we believed 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 the time of the proposed rule, we estimated that this process would take approximately 16 years (Table 1). As detailed in the proposed rule, this estimate was based on current OPPS payments that were made through the OPPS conversion factor and typical year-over-year

increases in OPPS payments over the past ten years. We noted that, similar to the original 340B budget neutrality adjustment to the conversion factor, both Medicare payments under the OPPS and beneficiary cost-sharing would be impacted by the change in the conversion factor. As described in the proposed rule, in this instance, beneficiaries would generally have lower co-insurance payments for non-drug items and services as a result of the proposed 0.5 percent annual reduction to the OPPS conversion factor for the duration of the required budget neutrality offset.

We invited comment on our estimated budget neutrality offset calculations described in the proposed rule, including the discussion of our method of budget neutralization not fully aligning with the money we predicted the Part B Trust Fund would pay out in lump sum payments for 340B-acquired drugs. In the proposed rule, we stated that 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 had been offset by the time of each annual rule. In the proposed rule, we stated that in the final CY rulemaking for this process, when we estimated the remaining amount of Medicare payment that would need to be offset fully within the prospective year, the 0.5 percent reduction amount would be reduced in the final year in which the adjustment applied, 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 was made, we proposed 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 was more or less than we had estimated in rulemaking for that CY. We proposed 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.

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TABLE 1: ILLUSTRATION OF THE PROPOSED 0.5 PERCENT CONVERSION FACTOR ADJUSTMENT TO THE OPPTS 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 OPPTS 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)	\$0	\$335	\$351	\$369	\$387	\$407
Estimated Total Cumulative Offset (millions)	\$0	\$335	\$686	\$1,055	\$1,442	\$1,849

	CY 2030	CY 2031	CY 2032	CY 2033	CY 2034	CY 2035
Total Applicable OPPTS 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 OPPTS 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 OPPTS 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.

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We sought comments on the annual percent reduction method described in the proposed rule and whether an alternative option—including those discussed in section II.A of the proposed rule—would be appropriate. We suggested that an additional possible alternative timeline 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. By way of an example, we suggested that we could divide the \$7.8 billion number by 10 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.

As described in the proposed rule, we also considered whether hospitals needed additional time to prepare following any finalized policy, and, as

such, sought 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.

We received the following comments on our proposals.

Comment: Many commenters argued that since, in their view, sections 1833(t)(14) and (t)(2)(E) of the Act (42 U.S.C. 1395l(t)(14) and (t)(2)(E)) do not apply to the remedy payments (for the reasons described under section II.B.1), the budget neutrality requirements of those statutes also do not apply to the remedy payments.

Response: We explain at length above why sections 1833(t)(14) and (t)(2)(E) of the Act (42 U.S.C. 1395l(t)(14) and (t)(2)(E)) are the proper authorities to make these remedy payments. We therefore disagree with commenters that budget neutrality requirements in those provisions would not also apply. And even if a budget neutrality adjustment is not statutorily required, it is an appropriate exercise of the agency's statutory and common-law or inherent recoupment authorities as a policy matter, as we explain further later in this section.

Comment: Some commenters argued that section 1833(t)(14)(H) of the Act (42 U.S.C. 1395l(t)(14)(H)) cannot authorize our unwinding of the non-drug item and service payments from the 340B Payment Policy. That provision reads, as relevant: "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 their view, there is nothing "additional" about the lump sum payment, because it is what 340B hospitals should have been paid in the first place. And the payment is not being made "as a result of this paragraph" but rather the agency's loss of a court case. These commenters further disagreed with our reading of section 1833(t)(14)'s reference to paragraph (9), which directs CMS to adjust the groups, relative payment weights, and wage indices in the OPPTS "for a year." These commenters argued that this provision is prospective in nature and therefore cannot be relied upon to require or authorize what they characterize as a corresponding retrospective recoupment from hospitals. One commenter interpreted "additional expenditures" in section 1833(t)(14)(H) of the Act (42 U.S.C. 1395l(t)(14)(H)) to refer only to expenditures from CMS electing to refine its drug payment methodology as

permitted under section 1833(t)(14) of the Act (42 U.S.C. 1395l(t)(14)). The commenter asserted that this means performing a survey and changing the drug payment methodology or refining the overhead cost payment, and that, in this case, the additional expenditures are neither of these and are instead "a loss at the Supreme Court, not a payment methodology refinement."

Response: We disagree with commenters' interpretation of sections 1833(t)(14)(H) and (t)(9)(B) of the Act (42 U.S.C. 1395l(t)(14)(H) & (t)(9)(B)). As an initial matter, commenters overlook that we are not adjusting future payments by the \$9 billion lump sum payment or by the \$10.5 billion total cost of this remedy rule. Rather, we are unwinding the payment increases for non-drug services and items in the 340B Payment Policy (82 FR 59482) in order to place providers in as close to a situation as they would have been if the 340B Payment Policy never existed.

Additionally, the Supreme Court stated it would "not address potential remedies." *Am. Hosp. Ass'n*, 142 S. Ct. at 1903. We are using section 1833(t)(14) of the Act (and sections 1871(e) and 1833(t)(2)(E) of the Act, as relevant) to unwind the 340B Payment Policy. Any increased expenditures are therefore a result of paragraph (14). Section 1833(t)(14) of the Act (42 U.S.C. 1395l(t)(14)) does not contain an exception to the budget neutrality requirement when unwinding the agency's past interpretations. Ultimately, we are responding to the Supreme Court's decision for CY 2018 through CY 2022 the same way as we responded to the Supreme Court's decision in the CY 2023 OPPTS final rule: unwinding both the payment decrease for 340B-acquired drugs and the payment increase for non-drug items and services. No one objected to the 3.09 percent decrease to payments for non-drug items and services, despite it responding to the same Supreme Court decision and restoring payments for 340B-acquired drugs to what they should have been all along. We believe our approach here is analogous.

We also disagree that the reference in section 1833(t)(9)(B) of the Act (42 U.S.C. 1395l(t)(9)(B)) to adjustments "for a year" diminishes our ability to return providers to the situation they would have been absent the 340B Remedy Policy. We previously explained that the OPPTS's generally prospective nature does not prevent us from remedying legal errors identified by courts. We believe we should apply section 1833(t)(9)(B) consistent with that instruction; if a court decision invalidates a policy that impacts

payments "for a" particular past "year," we can account under section 1833(t)(9) for the impact the legally correct policy would have had for that same year. That is especially true when, as here, the cut to 340B-acquired drugs was so inextricably intertwined with the 3.19 percent increase to payments for non-drug items and services budget neutralized. Because we are making adjustments to payments for CY 2018 through CY 2022, section 1833(t)(9)(B) of the Act (42 U.S.C. 1395l(t)(9)(B)) requires us to make corresponding budget neutralizing adjustments to the "estimated amount of expenditures" for each of those years. To the extent necessary, this final rule can be viewed as a retroactive adjustment to the payment rates for each of 2018 through 2022, as authorized by section 1871(e)(1)(A) of the Act ((42 U.S.C. 1395hh(e)(1)(A)). We could have, for example, increased the payment rate for 340B-acquired drugs for CY 2018, and decreased the payment rate for non-drug items and services by 3.09 percent for CY 2018 and reprocessed all affected claims. While that solution was not generally supported by the commenters for different reasons, all payment adjustments would have been made in the same year. The fact that we are accomplishing nearly the same result (that is, unwinding the payment decreases and increases for 2018–2022) through the reconciliation process described above and implementing the proper payment or offset amounts does not, in our view, relieve us of the budget neutrality requirements in the statute nor does it render our proposed remedy unreasonable or unsupported by the statutory scheme as a whole.

Comment: One commenter posited that the proposed offsets are not budget neutral because there is no "budget" for the period spanning from 2018 to 2041.

Response: The term "budget neutrality" is a term of art and does not reference a particular "budget." And even if the term "budget" should be construed separately from the rest of the term, a budget does not necessarily have to apply to a defined time frame. See BUDGET, Black's Law Dictionary (11th Ed. 2019) ("A sum of money allocated to a particular purpose or project."). Here, we understand budget neutrality in section 1833(t)(2)(E) (and, to the extent relevant, the title of section 1833(t)(9)(B)) generally to refer to the impact of our policies on OPPTS and the Part B Trust Fund—not to any particular written document.

Comment: Some commenters argue that section 1833(t)(2)(E) of the Act (42 U.S.C. 1395l(t)(2)(E)) similarly cannot be used to unwind the payment increases

for non-drug payments and services, both because the provision is prospective in nature and because its reference to “equitable payments” refers to “payments,” not recoupments or reductions. They argue the surrounding statutory language supports this payment-only reading, as “outlier adjustments under paragraph (5) and transitional pass-through payments under paragraph (6)” should be read to refer to “additional payment[s],” not funding that CMS seeks to recoup from hospitals.

Response: We addressed above why we believe OPPS’s prospective nature does not make it inapplicable to this remedy rule. Just as section 1833(t)(2)(E) of the Act (42 U.S.C. 1395l(t)(2)(E)) is broad enough to encompass individual payments for cancer hospitals (76 FR 74204), it is broad enough to encompass the adjustments to future payments for non-drug items and services we finalize here. Indeed, adjusting future payment years to ensure providers are paid fairly falls comfortably inside the plain text of section 1833(t)(2)(E) of the Act (42 U.S.C. 1395l(t)(2)(E)). We disagree with commenters that the term “equitable payments” can never include reductions. The statute authorizes “adjustments to ensure equitable payments”—not just *upward* adjustments to ensure equitable payments. Similarly, we disagree with the assertion that “equitable payments” excludes adjustments to recoup money that should not have been paid; as explained above, restoring parties to the situation they should have been in is equitable in every sense of the term.

Comment: A few commenters argued that the retroactive rulemaking authority in section 1871(e)(1)(A) of the Act (42 U.S.C. 1395hh(e)(1)(A)) (or anywhere else) does not authorize budget neutrality. One commenter argued that CMS only discussed its retroactive rulemaking authority in the proposed rule with respect to the authority to make the remedy payments, not to budget neutralize the remedy payments. The commenter argues that this is for good reason because CMS cannot rely upon any general retroactive rulemaking statutes to implement an offset because it would rely upon paragraph (9) which is prospective only.²⁶ Another commenter referenced “. . . the risk that HHS may lack authority to recoup these funds at all because of the presumption against retroactive rulemaking,” quoting the district court’s

remand decision. *See Am. Hosp. Ass’n*, 2023 WL 143337, at *5.

Response: We disagree that our retroactive rulemaking authority would not encompass budget neutrality adjustments. To the extent our proposed rule could be construed to disclaim reliance on section 1871(e)’s retroactive rulemaking authority to our budget neutrality adjustment, we clarify here that we intend to rely on that authority to the extent our budget neutrality adjustment is retroactive.

We read the quoted statement from the district court in *American Hospital Association* simply to acknowledge that the plaintiffs argued that CMS lacked retroactive rulemaking authority. That court did not resolve the question one way or another. By contrast, when Congress passed section 1871(e) of the Act (42 U.S.C. 1395hh(e)), it expressly acknowledged the general presumption against retroactive rulemaking, suggesting it intended to depart from that general rule. *See* H.R. Rep. 108–391 at 756.²⁷ And when it did so, Congress had already instructed CMS to set up many prospective payment systems, including OPPS. We believe we should harmonize section 1833(t)(9) of the Act (42 U.S.C. 1395l(t)(9)) and the other prospective payment statutes with section 1871(e) of the Act (42 U.S.C. 1395hh(e)), not read them to conflict. Such a reading would also be inconsistent with courts’ holding that the fact that section 1833(t) of Act (42 U.S.C. 1395l(t)) sets up a general prospective system does not mean it implicitly precludes retrospective review.

Comment: Two commenters argued that budget neutrality does not apply to the payments made to plaintiffs in several cases pending before the U.S. District Court for the District of Columbia that were stayed pending the outcome of CMS’s remedy discussed in the proposed rule. According to these commenters, these plaintiffs’ entitlement to remedial payments is based on judicial review of their individual 340B drug claims under section 205(g) of the Act (42 U.S.C. 405(g)), and therefore the plaintiffs do not rely on associational standing or seek relief that would apply to a broad class of members, which CMS argues implicates budget neutrality. These commenters argue that the plaintiffs’ challenge to CMS’s 340B Payment Policy under section 205(g) of the Act (42 U.S.C. 405(g)) in no way implicates the budget neutrality provisions referenced by CMS in the proposed rule

and that CMS must recognize that the plaintiffs have preserved their rights to seek relief under section 205(g). In their view, section 205(g) provides a process for all hospitals to pursue relief of their own underpaid claims and does not impose or require a single “one size fits all” remedy or require budget neutrality recoupment on favorable payment decisions under that process. For this narrow class of hospitals, the commenters maintain, the appropriate remedy is to make the hospitals whole in the same manner that would otherwise occur when the claims are decided favorably through the administrative claims appeals process—that is, without a budget neutrality recoupment.

Response: We agree with commenters to the extent they question whether the associational standing doctrine on which some plaintiffs relied can override the presentment requirements in section 205(g) of the Act (42 U.S.C. 405(g)), authorize the type of individualized payment recalculations addressed in this rulemaking, or otherwise allow industry groups to serve as a class representative for their members without complying with the applicable Federal Rules of Civil Procedure. *See Warth v. Seldin*, 422 U.S. 490, 515–16 (1975) (noting associational standing most appropriate for prospective relief and not available for individualized monetary calculations). But we do not believe that difference requires us to treat hospitals with pending cases differently from those without pending cases for the budget neutrality adjustment finalized in this rulemaking.

“One of the earliest principles developed in American administrative law was the idea that ‘the choice made between proceeding by general rule or by individual, *ad hoc* litigation is one that lies primarily in the informed discretion of the administrative agency.’” *Almy v. Sebelius*, 679 F.3d 297, 303 (4th Cir. 2012) (quoting *Sec. & Exch. Comm’n v. Chenery Corp.*, 332 U.S. 194, 203 (1947)). We do not believe that by prescribing an adjudication process in sections 205(b) and (g) of the Act (as incorporated by section 1869), the statute impliedly prohibits us from also addressing through rulemaking interpretative concerns identified by courts or insulates those with pending adjudications from the effects of such rulemaking. Nor do those provisions necessarily exempt pending adjudications from other statutory requirements, such as budget neutrality.

Comment: Many commenters disagreed that, even if budget neutrality was not statutorily required, CMS could

²⁶ See Reply In Support Of Plaintiffs’ Motion to Hold Unlawful And Remedy Defendants’ Past Underpayment of 340b Drugs, *Am. Hospital Ass’n v. Becerra*, Case No. 1:18-cv-2084, Dkt. 78 at 14–17 (Sep. 21, 2022).

²⁷ <https://www.congress.gov/108/crpt/hrpt391/CRPT-108hrpt391.pdf>.

still exercise its authority under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395(t)(2)(E)) and its longstanding inherent and common-law recoupment authority to offset the extra payments. These commenters reiterated that section 1833(t)(2)(E) of the Act (42 U.S.C. 1395(t)(2)(e)) does not authorize CMS to make the lump sum payments and, therefore, the budget neutrality requirements of (t)(2)(E) do not apply to the lump sum payments. These commenters also assert that CMS does not have a common-law duty to seek recoupment, so any reliance on common-law would be voluntary, and no common law power of recoupment authorizes the type of recoupment proposed by CMS. They assert that any common-law authority that the government may have to recoup funds can only be exercised by suing in court.

Response: We respectfully disagree with these commenters. As we have explained, we believe a budget neutrality adjustment is statutorily required and, even if not statutorily required, an appropriate exercise of the agency's statutory and common-law or inherent recoupment authorities as a policy matter. As we explain elsewhere in the rule, we believe it falls within our authority to make adjustments "necessary to ensure equitable payments" under section 1833(t)(2)(E) of the Act (42 U.S.C. 1395(t)(2)(E)) to account for and place hospitals in nearly the same position as they would have been absent the 340B Payment Policy. With respect to commenters' assertion that CMS lacks a common-law duty to seek recoupment, we clarify that we would pursue recoupment even if we were not strictly required to do so by common law; the common law reflects the judgment that the government should avoid funding windfalls to private parties. We agree with that judgment. Finally, courts have not limited the government's authority to recoup funds only to lawsuits; courts have acknowledged that agencies may recoup funds through use of a setoff. *See, for example, Mount Sinai Hosp. of Gr. Miami, v. Weinberger*, 517 F.2d 329, 337 (5th Cir. 1975) ("In some circumstances when government funds are improperly paid out the government has a claim enforceable either by direct suit or by setoff against money owed by the government to the recipient of the illegally dispensed funds." (footnotes omitted)).

Comment: Many of these same commenters disagreed with CMS's reasoning that applying budget neutrality was justified as sound public policy because the payments constitute an unwarranted windfall to hospitals

that the Trust Fund has a strong interest in recovering and that hospitals have no legitimate reliance interest in retaining. These commenters argued that it was inappropriate for CMS to characterize the receipt of these funds as a "windfall" since hospitals had no choice but to accept the funds. Commenters additionally objected to CMS's use of the term because it implies that CMS is taking no responsibility for its own role in creating the situation resulting in the payment of the funds that it is now proposing to recoup. These commenters also argued that the proposed rule's reference to any interest that the Trust Fund may have in recoupment is overstated because, based on the most recent Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medicare Insurance Trust Funds, there is no risk that the SMI Trust Fund will become insolvent in the foreseeable future. These commenters disagreed with CMS's contention that achieving budget neutrality serves an important interest in protecting the public fisc. These commenters argued that applying budget neutrality principles increases risks for the public fisc because CMS knows that it can take "aggressive or unsupported positions at the outset" and then simply recoup funds later to make up for any mistakes. Finally, these commenters also disagreed with CMS's contention that hospitals have no legitimate reliance interest in permanently retaining the funds proposed to be recouped. Many of these commenters stated that hospitals properly relied on and have already spent the payments CMS made between 2018 and 2022 and that this reliance was particularly pronounced given the COVID-19 PHE.

One commenter opined that, to the extent CMS concludes that it is unreasonable to burden the Trust Fund, and given a lack of authority for a budget neutrality adjustment or retroactive rulemaking, CMS can reasonably conclude that it has no available funds (nor specific appropriation) for the remedy payment, and therefore, the U.S. Treasury Department's Judgment Fund, 31 U.S.C. 1304, could be the appropriate vehicle for satisfaction of providers' claims in this case.

Response: While we appreciate the commenter's suggested alternative for funding the remedy payments, we disagree that we lack the authority to make the lump-sum payments, budget neutralize the remedy, or engage in retroactive rulemaking for the reasons stated earlier in this rule. We continue

to believe a budget neutrality adjustment is statutorily required and, even if not statutorily required, an appropriate exercise of the agency's statutory and common-law or inherent recoupment authorities as a policy matter. We also disagree that our approach would encourage aggressive statutory interpretations by the agency or otherwise threaten the public fisc. We of course intend to discharge faithfully our obligation to interpret statutes as best we understand them, and the resources the agency has expended litigating and then unwinding the 340B Payment Policy is itself a significant incentive against departing from that intention. And exempting adjustments that stem from a court's decision in litigation from the budget neutrality principles that would otherwise apply in rulemaking distorts incentives for litigants in a way that would itself encourage strategic behavior. Allowing litigants to escape otherwise applicable budget neutrality constraints might encourage potential litigants to press aggressive statutory interpretations in court. We believe the best policy is the one that returns all parties as close as we can to the situation they would have been in if the 340B Payment Policy had never been adopted. That policy best ensures that the only money actually spent is money authorized to be spent by the statute, independent of any strategic behavior.

While there is no immediate solvency crisis in the Part B Trust Fund, as its stewards we have an obligation to preserve the Fund for future generations. And while we acknowledge that our budget neutrality will affect hospitals' medium-term revenue, we have moderated that effect by spreading out our recovery of unwarranted payments over a period of many years.

We disagree that any reliance on our previous payment increases was reasonable under the circumstances here or that we are wrong to characterize those payment increases as windfalls, regardless of whether hospitals could decline the payments or not. Finally, we are not wrong to characterize those prior payments as windfalls, regardless of whether hospitals could decline the payments or not. No one suggests we could have increased payments for non-drug items and services if we had not decreased payments for 340B drugs, PHE or not. Now that the legal justification for the payments cuts has fallen short, so has any legal justification for the payment increases. We take full responsibility for the legal error ultimately found by the Supreme Court. But agency error does not expand hospitals' statutory

entitlement to Medicare payments. Cf. *Heckler v. Community Health Services*, 467 U.S. 51, 62 (1984) (“There is no doubt that respondent will be adversely affected by the Government’s recoupment of the funds that it has already spent . . . [but] respondent [may not] claim any right to expand its services to levels greater than those it would have provided had the error never occurred.”) We repeatedly emphasized to the hospital community that we may need to revisit budget neutrality if the 340B Payment Policy were found to be unlawful; it was clear that the payment increases for non-drug items and services were potentially conditioned on the legality of that policy. To that end, the industry filed multiple briefs disputing our budget neutrality position in court.

Comment: Several commenters stated that CMS’s approach to budget neutrality is inconsistent with its past practices. These commenters argue that CMS did not budget neutralize past changes made to budget neutral systems, such as the OPPI clinical diagnostic laboratory services (citing 80 FR 70354),²⁸ as well as changes to the Inpatient Prospective Payment System wage index (citing § 412.64(e)(1)(ii)) and outlier adjustments (citing 88 FR 27222–23).²⁹ They contend that CMS has previously applied budget neutrality retroactively only when expressly authorized to do so by Congress.

Response: Commenters’ past examples are not analogous to the remedy payment in this rule. Most of these adjustments are examples where CMS’s projections of utilization or some other threshold did not meet a projected target. 80 FR 70353 (explaining agency “overestimated the adjustment necessary to account for the new policy to package laboratory tests”); 88 FR 27223 (noting “the percentage of actual outlier payments relative to actual total payments is higher than we projected for FY 2022”). In those cases, CMS declined to make a retroactive budget neutralization adjustment based on updated data. 80 FR 70354 (noting

adjustment “would not recoup ‘overpayments’ made for” past years); 88 FR 27223 (“[W]e do not make retroactive adjustments to outlier payments” to update projections). Commenters correctly point out that CMS also has sometimes corrected past projections when expressly authorized by Congress. (72 FR 47186; 78 FR 50515–16.)

As we previously explained, CMS is not in this rule revising its budget neutrality factor to update its factual assumptions, *i.e.*, the difference between the estimated and actual budget impact of the 340B Payment Policy. Instead, it is unwinding the legal consequences of an unlawful payment policy. Those two changes are different. When we first implemented the 340B Payment Policy, we also underestimated how much hospitals would ultimately dispense those drugs. We thus failed to increase non-drug payments and services by the amount needed fully to offset the payment cuts to 340B-acquired drugs. But under our consistent approach not to update our factual assumptions underlying our projections, we are not updating our estimation in this final rule. Updating that estimation would require *recalculating* the 3.19 percent payment adjustment for non-drug goods and services so that the new rate would reflect the full \$10.6 billion that CMS in fact saved under the cuts for 340B-acquired drugs. Instead, CMS is simply *reversing* that 3.19 percent payment increase it implemented beginning in CY 2018 for non-drug goods and services, unwinding its legal error so that parties are as close as possible to the same position as they would have been in had CMS set the legally correct payment rates back in CY 2018. This approach—unwinding an unlawful payment policy while not updating factual projections—is consistent with CMS’s general approach to budget neutrality.

Commenters are also wrong that the general IPPS wage index budget neutrality regulation they cite exempts adverse wage index judicial decisions from budget neutrality. Instead, it addresses specific statutory exemptions to the general budget neutrality rule. See 86 FR 45176 (discussing § 412.64(h)(4)(vii)) and 75 FR 50160 (discussing § 412.64(e)(4)); see also SSA § 1886(d)(3)(E)(i). The regulation addressing adverse wage index judicial decisions is silent on the issue of budget neutrality. See 42 CFR 412.64(l) (“[I]f a judicial decision reverses a CMS denial of a hospital’s wage data revision request, CMS pays the hospital by applying a revised wage index that

reflects the revised wage data as if CMS’s decision had been favorable rather than unfavorable.”). Commenters point to no wage index decision that is inconsistent with the budget neutrality policy in this rule, even assuming the policy would apply equally to IPPS.

Comment: Several commenters claimed that non-budget neutral remedies are not the result of a *de minimis* exception to a requirement to budget neutralize as claimed by CMS, and that any *de minimis* exception lacks any statutory basis.

Response: We explained in section I.A of this final rule how we have approached budget neutrality when a post-rulemaking payment change would have a *de minimis* impact on estimated OPPI payments, and in section II.B.1 of this final rule why the remedies to which commenters have pointed are consistent with that policy. As an initial matter, we disagree that this interpretation of budget neutrality is not based in the statute. As we explained in the proposed rule, section 1833(t)(9) of the Act (42 U.S.C. 1395l(t)(9)) instructs us to budget neutralize OPPI based on the amount of “estimated expenditures.” Because there is a certain amount of approximation inherent in the term “estimate,” its use authorizes us to round to \$0 payment amounts that would have only a *de minimis* impact on estimated expenditures. See “Estimate,” Merriam-Webster Dictionary (“to judge tentatively or approximately the value, worth, or significance of”).³⁰ It makes sense that a Congress concerned about cost containment, see H.R. Rep. No. 106–436, at 33–34 (1999), would direct the agency to account for significant budgetary impacts, while giving the agency some discretion with how to handle minor payments that would not meaningfully impact the Part B Trust Fund.

Even if commenters were correct, however, that we have not applied our budget neutrality policy precisely as we articulated in the proposed rule and here, we still believe we should adopt this understanding of budget neutrality as the appropriate policy to apply in this case and going forward. It protects the public fisc, the Medicare Trust fund, and beneficiaries against expenditures that prove to not be authorized by law while accounting for the burden and cost to the agency and providers of making after-the-fact changes to a principally prospective payment system.

³⁰ <https://www.merriam-webster.com/dictionary/estimate>.

²⁸ These commenters also return to the example of *H. Lee Moffitt Center & Research Hospital v. Azar*, 324 F. Supp. 3d 1, 15 (D.D.C. 2018), where the court commented that in 2007, HHS retroactively adjusted payment rates to several rural hospitals without offsetting recoupments to achieve budget neutrality. We addressed that example above.

²⁹ One commenter suggested that CMS never updated budget neutrality calculations in the Physician Fee Schedule (PFS) after incorrectly predicting how often certain new PFS codes would be utilized. The commenter failed to cite any source for this comment, but even assuming the commenter is correct that we have mis-projected utilization for certain PFS codes, that is just another example of a factual projection that we routinely do not update, as explained below.

Comment: Some commenters argued that CMS should not budget neutralize since no court ruling has required budget neutrality and no court has found that hospital payments for non-drug items and services in CYs 2018–2022 were unlawfully paid or received (despite the unlawful reduction in 340B payments resulting in increases to those rates). These commenters point out that the Supreme Court only ruled that the Secretary may not vary payment rates for drugs and biologicals among groups of hospitals in the absence of having conducted a survey of hospitals' acquisition costs. The Court explicitly decided not to address arguments regarding budget neutrality. Likewise, the District Court's subsequent order vacating CMS's 340B reimbursement rate for the remainder of 2022 did so without requiring any offset for budget neutrality.

Similarly, one commenter suggested that, as an alternative to offsetting payment, CMS rely on Section 1870 of the Act (42 U.S.C 1395gg) to recover payment. This statute describes when and how CMS may recover incorrect payments it makes on behalf of an individual. The commenter states that, while it does not authorize CMS to offset payments to account for an overpayment, its approach is "far more rational, and limited, than CMS's overbroad proposal." The commenter further encourages CMS to rely on 42 U.S.C 1395gg because, in addition to addressing overpayments on a beneficiary-specific basis, it also permits CMS to forgo recovery where the individual for whom the incorrect payment was made was without fault and making the adjustment would "defeat the purposes of subchapter II or subchapter XVIII or would be against equity and good conscience."

Response: When we implemented the payment reduction for 340B-acquired drugs in CY 2018, we also implemented a corresponding increase to the OPPS conversion factor that increased the OPPS payment for non-drug items and services. When the payment reduction for 340B-acquired drugs was eliminated for CY 2023 after the Supreme Court found the policy unlawful, we increased 340B drug payments and correspondingly decreased the OPPS conversion factor. As we have made clear throughout the litigation and in prior rulemaking, the increases in OPPS payments for non-drug items and services were directly and inextricably linked to the decreases in payments for 340B-acquired drugs. But for the reductions in the 340B drug payments, we would never have increased payments for the non-drug items and

services; therefore, we believe that if the 340B payments are invalid, then the increased payments for non-drug items and services are invalid, too. While we acknowledge that litigants challenged only the payment increase, when we have made clear that two payment adjustments are so closely linked so that they are really part of the same policy, we believe the policies should rise and fall together regardless of artful pleading strategies. While commenters are correct that the increase to non-drug items and services were authorized under our read of the statute at the time they were promulgated, they omit that this statutory authorization hinged on payment reductions that the Supreme Court held exceeded our statutory authority.

We also do not agree with the commenter's invitation to rely on section 1870 of the Act (42 U.S.C. 1395gg) to forego recovery. Section 1870 speaks to the issue of when providers can shift liability to beneficiaries for overpayments, which can in turn be waived in certain circumstances. See section 1870 of the Act. It is silent about the situation here where CMS adjusts future payments through its budget neutrality authority. We believe that given the close connection between the illegal decreased payments for 340B-acquired drugs and the increased payments for non-drug items and services, and the impact of failing to budget neutralize these payments on the public fisc and beneficiaries, section 1833(t) of the Act (42 U.S.C. 1395l(t)) applies rather than section 1870 of the Act (42 U.S.C. 1395gg).

Comment: One commenter recommended that CMS work with Congress to forgo an offset.

Response: We appreciate the commenter's recommendation. As noted, legislative changes would require Congressional action.

Comment: One commenter noted that implementing a prospective adjustment poses challenges due to the varying volumes and services that change from year to year at each facility, and that consequently any prospective payment reduction would lead to inaccuracies in the calculation. Due to the inability to properly match prospective adjustments to prior increased payments, this commenter suggests that CMS not finalize any prospective adjustments.

Response: We recognize that there are challenges to implementing our budget neutrality offsets prospectively and that the amount we collect from hospitals imperfectly offsets the amount by which the 340B Payment Policy increased each hospital's payments for non-drug services and items. We disagree,

however, that the alternative to a prospective budget neutrality adjustment is no budget neutrality adjustment. Rather, to stay consistent with the statute, the alternative is a one-time debit for the increased payments, as discussed in section II.A. We discussed why we did not select that approach above, and given that decision, our proposed approach properly applies the budget neutrality principle as evenly as possible, even if the calculations may not prove to be to-the-penny exact. See *Shands Jacksonville Med. Ctr.*, 959 F.3d at 1119 (agency may weigh "the competing values of finality and accuracy").

Comment: One commenter supported our proposed budget neutrality adjustment and suggested that, if interest cannot be paid on the lump sum payments, CMS withhold the budget neutral payment reductions from 340B providers for the number of years required to equal the value of interest payments.

Response: We appreciate the commenter's suggestion, however, as described earlier in this rule, we lack the authority to pay interest on the lump-sum payments regardless of whatever method or mechanism might facilitate the payment of such interest.

Comment: MedPAC supported our proposed budget neutrality adjustment, arguing that since the reduced 340B payments were implemented in a budget neutral manner in CY 2018, any remedy should likewise be budget neutral. It additionally indicated that, of all of the alternatives CMS considered, CMS selected the best option. However, MedPAC was concerned about the effect of the immediate lump sum payment and 16-year recoupment on the Medicare premium. It requested that the reduction in payment rates be aligned with the remedy payments so that the effects on the Part B premium and Part B finances are mitigated. MedPAC also expressed concern that reducing the payment rates for non-drug items and services could cause inequities because some hospitals will come out net winners or net losers and requested that CMS consider ways to reduce these inequities if they are significant enough. For example, the commenter suggests, CMS could require hospitals to list on their cost reports the revenue gained from 2018 to 2022 and the revenue decrease from the 0.5 percent reduction and then use the cost reports to make reconciliations.

Response: We thank MedPAC for its support for our proposed budget neutrality adjustment. While we appreciate its concern about the remedy's effect on the Medicare Part B

premium, we believe the proposed prospective offset is appropriate in order to minimize the financial burden on hospitals, especially given the difficulties caused by the COVID-19 PHE. On similar issues of concern, such as the prospective offset start date, many commenters argued that hospitals are suffering from financial challenges of unprecedented workforce shortages, inflation, supply chain disruptions, eroding margins, cost increases due to increases in supplies and staffing costs and the lingering effects of the COVID-19 PHE. We believe it is appropriate to take those factors into consideration here as well. And we expect beneficiaries to obtain the benefit of a lower Part B premium in future years as the budget neutrality adjustment is implemented. As acknowledged previously, there is often some inherent imprecision in budget neutrality calculations. However, given these unique circumstances, coupled with the operational challenges posed by the commenter's suggestion, we believe our proposed approach properly applies the budget neutrality principle in a fair, reasonable manner, even if it results in some unavoidable imprecision. See *Shands Jacksonville Md. Ctr.*, 959 F.3d at 1120 (agency need not "precisely compensate each hospital for payments that were reduced").

Comment: Another commenter supported our proposed budget neutrality adjustment but requested that recoupment occur over a shorter timeframe than 16 years. The commenter proposed 5 years as a possible timeframe, which, in their view, would be the same amount of time that the conversion factor was "artificially inflated" as a result of payment to 340B hospitals at ASP minus 22.5 percent. Alternatively, the commenter suggested offsetting a fixed dollar amount each year over a fixed period of time. For example, dividing 7.8 billion by 5 in order to offset \$1.56 billion per year from CY 2024 to CY 2028 by making an adjustment to the conversion factor to reflect an estimated \$1.56 billion reduction in non-drug items and services spending for each year.

Response: We appreciate the commenter's suggestion for the offset to be implemented over a shorter timeframe than 16 years; however, we believe that the proposed 0.5 percent annual reduction properly reverses the increased payments for non-drug items and services to comply with statutory budget neutrality requirements while at the same time accounting for any reliance interests and ensuring that the

offset is not overly burdensome to impacted entities.

Comment: One commenter recommended that CMS increase the budget neutrality adjustment for OPSS non-drug items and services and apply it over a shorter time frame. This commenter agreed with us that some imprecision in calculating budget neutrality adjustments is unavoidable. However, the commenter contends that CMS unnecessarily exacerbates the imprecision by choosing to recoup budget neutrality payments over a 16-year period rather than a shorter time frame. In the commenter's view, this time frame increases the chance that the relative and absolute amounts of non-drug services furnished by hospitals will deviate from what they were under the original budget neutrality adjustment and that the magnitude of these deviations will increase. The commenter argues that it is appropriate to go with a greater reduction rate because (1) the original budget neutrality adjustment increased payment for OPSS non-drug items and services by 3.19 percent per year, over six times higher than the adjustment proposed by CMS; and (2) Part B reimbursement of hospitals has grown at a rate of 5 percent per year on average between 2017 and 2021 (roughly 4 percent when excluding spending on separately payable drugs under the OPSS). The commenter also argues that CMS should recoup \$10.5 billion rather than the proposed \$6.2 billion. The commenter proposes three alternative recoupment scenarios with annual budget neutrality adjustments that are greater than the 0.5 percent proposed reduction in OPSS non-drug items and services. Scenario 1 would impose a 1.25 percent annual reduction, which would recover the \$7.8 billion within 8 years (or 10 years for the commenter's recommended 10.5 billion). Scenario 2 would impose a 2.25 percent annual reduction, which would recover the \$7.8 billion within 5 years (or 7 years for the commenter's proposed 10.5 billion). Scenario 3 would impose a 3 percent annual reduction, which would recover the \$7.8 billion within 4 years (or 5 years for the commenter's proposed 10.5 billion).

Response: We appreciate the commenter's suggestion to increase the budget neutrality adjustment and apply it over a shorter time frame and the detailed examples of how we might do so. However, as we stated previously, we believe that the proposed 0.5 percent annual reduction (and resulting 16-year implementation timeframe) properly reverses the increased payments for non-drug items and services to comply

with statutory budget neutrality requirements while at the same time accounting for any reliance interests and ensuring that the offset is not overly burdensome on impacted entities. Additionally, while we understand the rationale behind prospectively offsetting \$10.6 billion, standard remedial principles and basic fairness support situating hospitals as closely as possible to the financial situation they would have been in absent the 340B Payment Policy. That means ensuring hospitals receive \$10.6 billion (between the one-time lump sum remedy payment of approximately 9.0 billion and the processing, and reprocessing, of CY 340B 2022 claims of approximately 1.6 billion) for 340B drugs and ensuring a corresponding \$7.8 billion is offset in order to maintain budget neutrality.

Comment: One commenter recommended that CMS incorporate recoupment estimates into the calculation of retrospective lump sum payments. Under this suggested arrangement, providers would be paid a "net" lump sum payment. The commenter suggested that, if this results in a significant debt for a provider, then CMS should provide an interest-free, flexible, long term repayment plan.

Response: We thank the commenter for this suggestion. This proposed approach is similar to the option discussed previously in section II.A of this final rule, titled "Aggregate Hospital Payments from CY 2018 Through September 27th of CY 2022." Please see that section for our consideration of this approach.

Comment: One commenter requested clarification regarding the impact of the proposed 16-year OPSS conversion factor reduction on the ASC payment system. The commenter referenced the CY 2023 OPSS final rule in which CMS stated that changes to the OPSS conversion factor do not impact the ASC conversion factor but that there may be an indirect impact on ASC payments for device-intensive procedures. The commenter requests that CMS provide a more detailed assessment of the impact of its proposed 340B remedy on ASC payment rates. Specifically, the commenter requests additional details on the magnitude of the change in payments for device-intensive procedures with and without the OPSS conversion factor reduction. The commenter recognizes CMS's acknowledgement that specific provider types would experience differentiated reimbursement outcomes depending on how much of their payments are based on the OPSS conversion factor, but the commenter believes that CMS should specifically address the impact of its

proposed remedy on the ASC payment system via a regulatory impact analysis.

Response: We thank the commenter for expressing this concern, and we note that all impacts of this prospective offset to the OPPS conversion factor on other payment systems in a particular year will be discussed during that year's applicable rulemaking cycle, including the specific issues that are raised by this commenter.

Comment: Nearly all commenters supported a CY 2026 start date for the initiation of the adjustment to the conversion factor to provide hospitals with additional time to make necessary arrangements. These commenters cited various rationales, including the extraordinary financial challenges caused by unprecedented workforce shortages, inflation, supply chain disruptions, eroding margins, cost increases due to increases in supplies and staffing costs and the lingering effects of the COVID-19 PHE. One commenter supported finalizing the proposed CY 2025 start date, arguing that hospitals do not need additional time to make necessary arrangements since they have known since the date of the Supreme Court decision that they would not be permitted to keep the windfall they received from CY 2018 through CY 2022.

Response: Based on the broad support to start the adjustment to the conversion in CY 2026 among commenters, we believe finalizing a CY 2026 start date for the initiation of the adjustment to the conversion factor is appropriate to provide entities additional time to prepare for the new payment rates. We agree with commenters that an additional year would allow more time for hospitals to recover from the financial challenges described above and to assess and prepare for the new payment rates that will be calculated using a reduced conversion factor. We appreciate the input of the commenter who supported finalizing the start date as proposed. As noted elsewhere in the rule, we agree that hospitals have been on notice about a potential budget neutrality adjustment for quite a while. But hospitals did not know the details of our proposed policy until we issued the proposed rule, and so we believe an additional year to prepare is merited in this unique situation.

Comment: One commenter stated that the proposed rule does not provide sufficient information on the impact of the decreased conversion factor on individual hospitals and requested that CMS provide greater transparency of its calculations by including the budget neutrality calculations related to the

recoupment in each future year's OPPS proposed rules.

Response: We appreciate the commenter's suggestion and intend to take it into consideration in future OPPS/ASC rulemaking cycles. We note that the impact of the 0.5 percent reduction to the OPPS conversion factor will be discussed in each year's calendar year OPPS/ASC calendar year rule, including the financial impact on particular groups of hospitals.

Comment: One commenter requested that CMS provide greater clarity on each individual hospital's repayment obligations during the recoupment period. The commenter observed that changes in utilization could make the estimated recoupment period longer or shorter than CMS estimates and expressed concern that this could result in hospitals refunding more in additional payments than they ever received during the CY 2018 through CY 2022 period. The commenter requested that CMS ensure that hospitals not be required to pay more in the recoupment than what they were initially paid in increased non-drug payments during the CY 2018 through CY 2022 time frame.

Response: We acknowledge that it is possible that some individual hospitals refund more in additional payments than they received in non-drug payments. But that is the consequence of structuring payments through a future payment cut rather than, for example, clawing back or recouping increased payment amounts between 2018 through 2022. Our methodology properly reverses the increased payments for non-drug items and services to comply with statutory budget neutrality requirements while at the same time accounting for any reliance interests and ensuring that the offset is not overly burdensome on impacted entities. In the aggregate, we expect hospitals will be prospectively offset approximately the same amount that they received in increased non-drug item and service spending from CY 2018 through CY 2022 as a result of the 340B Payment Policy. And while changes to utilization and other behaviors will leave "some hospitals slightly better off and others slightly worse off than they would have been had the rate reduction never taken effect," such differences are permissible variations inherent in a prospective remedy. *Shands Jacksonville Med. Ctr., Inc. v. Azar*, 959 F.3d 1113, 1120 (D.C. Cir. 2020). We have tried to mitigate that effect by limiting the future recoupment to providers that did in fact benefit from the increased payments in the past.

Comment: One commenter expressed concern about the application of the 0.5

percent reduction to new non-drug items and services that were not available from January 1, 2018, through September 27, 2022, and which, therefore, were not reimbursed at the higher rate. This commenter requested that CMS create a system that excepts items and services that are new since October 1, 2022, from the 0.5 percent reduction. The commenter suggested that this could be accomplished with the creation of a new status indicator that would alert MACs to the service being new post-October, which could then be adjudicated at the MAC level using the same methods applied to take the adjustment for sequestration. Similarly, one commenter urged CMS to consider other factors that could impact the recoupment and address them in the final rule. The commenter specifically asked for clarification as to how hospital closures during the recoupment period would impact other hospitals' repayment obligations during the recoupment period and if hospitals that remain open would be required to shoulder the debt associated with the closed hospitals.

Response: To begin, if for any reasons the number of hospitals paid under the OPPS that are subject to the prospective offset decrease, that will not impact the total amount of the offset. Otherwise, changes in what items and services providers bill to Medicare is one example of the changes to utilization and other behaviors discussed above in the preceding comment. As we acknowledge here, those changes will inevitably lead to some distributive effects, but we have done what we can to mitigate that effect by limiting the future recoupment to providers that did in fact benefit from the increased payments in the past. Specifically, exempting new items and services from this payment adjustment may distort providers' incentives to prescribe items and services based on whether they existed between CY 2018 and 2022 rather than whether they are medically appropriate, potentially impacting the care providers give to beneficiaries. And the more exceptions we create, the more complicated we make the payment reduction. Complications increase the risk of delays or errors in implementing this final rule.

Comment: Many commenters argued that budget neutrality adjustments will have severe negative impacts on hospitals and might impair hospitals' ability to continue providing services to vulnerable patients/communities. Various commenters requested that rural hospitals, free-standing children's hospitals, free-standing cancer hospitals

and safety-net hospitals be excluded from the prospective offset.

Response: We acknowledge that our proposal to decrease future payments will have a financial impact across all hospitals paid under the OPPS, except for new providers as described below, and we are particularly mindful of the impact on vulnerable patients and communities. But future decreases are, on aggregate, the mirror image of prior payment increases that, as we have repeatedly stated, would otherwise be a windfall to providers. And such windfalls are not cost-free; as we noted previously, the costs are ultimately borne by beneficiaries and taxpayers—including the vulnerable patients and communities to which commenters themselves refer. Additionally, we note that under section 1833(t)(7)(D)(ii) of the Act (42 U.S.C. 1395l(t)(7)(D)(ii)), cancer

and children's hospitals receive transitional outpatient payments (TOPs) which permanently hold them harmless to their "pre-Balanced Budget Act of 1997 (BBA) amount" as specified under the terms of the statute. These hospitals are permanently held harmless to their "pre-BBA amount," and they receive hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS.

After consideration of the comments received, and for the reasons stated in the proposed and in this final rule, we are finalizing our policy largely as proposed. We believe that sections 1833(t)(2)(E) and (t)(14) of the Act (42 U.S.C. 1395l(t)(2)(E) and (t)(14)), under which we proposed to make this

proposed remedy payment, are properly read to require budget neutrality. We are finalizing that budget neutrality will be maintained through a 0.5 percent reduction to the OPPS conversion factor over an estimated 16-year time period until a total of \$7.8 billion is offset. As previously mentioned, we were convinced by commenters that we should start the prospective offset in CY 2026. As such, we are codifying the 0.5 percent reduction in the OPPS conversion factor effective for CY 2026 in the regulations by adding new paragraph (b)(1)(iv)(B)(12) to § 419.32. The exact impact on OPPS payment rates as a result of this reduction will be reflected in the annual OPPS/ASC proposed and final rules. *See* Table 2 for an illustration of this finalized payment mechanism.

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TABLE 2: ILLUSTRATION OF THE FINALIZED 0.5 PERCENT CONVERSION FACTOR ADJUSTMENT TO THE OPPTS NON-DRUG ITEMS AND SERVICES BEGINNING CY 2026 TO MAINTAIN BUDGET NEUTRALITY

	CY 2025	CY 2026	CY 2027	CY 2028	CY 2029	CY 2030
Total Applicable OPPTS Non-Drug Item and Service Spending (millions)	\$66,910	\$70,256	\$73,769	\$77,457	\$81,330	\$85,369
0.5-Percent Payment Reduction Amount (millions)	\$0	\$351	\$369	\$387	\$407	\$427
Estimated Total Cumulative Offset (millions)	\$0	\$351	\$720	\$1,107	\$1,514	\$1,941

	CY 2031	CY 2032	CY 2033	CY 2034	CY 2035	CY 2036
Total Applicable OPPTS Non-Drug Item and Service Spending (millions)	\$89,667	\$94,150	\$98,858	\$103,801	\$108,991	\$114,440
0.5-Percent Payment Reduction Amount (millions)	\$448	\$471	\$494	\$519	\$545	\$572
Estimated Total Cumulative Offset (millions)	\$2,389	\$2,860	\$3,354	\$3,873	\$4,418	\$4,991

	CY 2037	CY 2038	CY 2039	CY 2040	CY 2041
Total Applicable OPPTS Non-Drug Item and Service Spending (millions)	\$120,162	\$126,170	\$132,479	\$139,102	\$114,440
0.5-Percent Payment Reduction Amount (millions)	\$601	\$631	\$662	\$695	\$188*
Estimated Total Cumulative Offset (millions)	\$5,591	\$6,222	\$6,885	\$7,580	\$7,769

**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 (rounded).*

We also note the Total Applicable OPPTS 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.

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c. Exclusion of New Providers

In the proposed rule (88 FR 44080), CMS recognized 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. As we explained in that rule, this was 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 that time period did not receive the full amount of increased non-drug items and service payments. We noted 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 therefore proposed that these providers would not be subject to the prospective rate reduction, which was predominantly designed to offset those non-drug item and service payments made during CY 2018 through CY 2022.

Consequently, in the proposed rule, we proposed 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. As we explained, that meant 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 proposed the date of enrollment in Medicare as the provider's CMS certification number (CCN) effective date. Providers that met this definition, and that we proposed would be excluded from the prospective payment adjustment, were listed in Addendum BBB to the proposed rule. This addendum can be found online through the CMS OPPS website.³¹ As reflected in this file, we determined that approximately 300 providers out of the approximately 3,900 OPPS providers met this definition. We proposed 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.

We also clarified in the proposed rule that the proposed "new provider" designation was 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 recognized in the proposed rule that this approach would exempt some hospitals receiving the 340B lump sum payment from the prospective offset and explained that we considered creating various levels of exclusion from the 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 concluded that it was not administratively feasible for CMS, or likely desired 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. Consequently, we proposed that any hospital that enrolled in Medicare after January 1, 2018, would be exempt from the annual adjustment to the conversion factor to offset lump sum payments to affected 340B covered entity hospitals. We explained that we were proposing to exempt those hospitals because they 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.

We solicited 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 solicited comments on whether there were any other easily identifiable categories of providers who should be similarly exempted from the annual adjustment to the conversion factor.

We received the following comments on our proposals.

Comment: One commenter expressed concern with the breadth of the new provider exemption. This commenter suggested that hospitals should be subject to reduced payment rates for a period of time commensurate with the period of time they benefited from the increased payment rates. For example, the commenter argued, that if a hospital began its Medicare participation on January 1, 2020, the hospital would have benefited from the increased payment rates for 3 years (2020–2022) which is 60 percent of the time that the increased payments were in place. For this hospital, the commenter argued, CMS would require that the reduced payment rates would apply for 60

percent of the time CMS expects the reduced payments to be in place (9.6 years for 16-year timeframe).

Response: We acknowledge that a more individualized application of the exception would lead to more precise adjustments and potentially decrease the distributive effects discussed above. However, consistent with our general approach in this rule of complying with the budget neutrality requirement while avoiding undue administrative burdens, we believe that such an approach is not feasible because it would result in many different lengths of payment or OPPS conversion factor adjustments. The more complicated we make the payment reduction, the closer it approaches re-processing all payments—an approach we rejected previously in section II.A of this final rule. And as noted above, complications increase the risk we will face delays or errors in implementing this final rule.

Comment: Another commenter appreciated the exclusion of new providers but expressed concern that over the long term the exclusion could either be overlooked or reversed due to future rulemaking and reimbursement adjustments.

Response: While there is always the risk of inadvertent error, we believe we have clearly defined the universe of qualifying providers, and so we believe the risk of overlooking them is relatively low. Should we choose to change our policy in the future, we would do so through notice and comment rulemaking, and interested parties would have the opportunity to express their concerns. Hospitals that will be excluded under the prospective payment adjustment are listed in Addendum BBB to this final rule. This addendum can be found online through the CMS OPPS website.³² During subsequent annual rulemaking, an updated addendum of hospitals will be included in that year's calendar year OPPS/ASC rule. Any errors or omissions in the addenda should be addressed through the public notice and comment period for that year's rule.

After considering the comments received, we are finalizing our policy as proposed, and will designate any hospital that enrolled in Medicare on or after January 2, 2018, as a "new provider" and will 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 will calculate payment rates for new

³¹ <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps>.

³² <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps>.

providers using the conversion factor before applying the 0.5 percent annual adjustment that would apply for hospitals that are not “new providers” for purposes of this policy.

We are codifying 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 as proposed, except we are adding “biologicals” to the reference to separately payable drugs. We are adding “biologicals” to the regulation text at 419.32 in order to ensure that the regulation text matches our finalized policy regarding the calculation of prospective payment rates for hospital services and the exclusion of separately payable drugs and biologicals from that prospective payment rate.

d. Additional Comments Received

Comment: We received a couple of comments asking for CMS to use its current drug acquisition survey to inform OPSS 340B payment rates. Similarly, we heard from commenters that we should conduct another survey. Further, commenters requested we make changes to how Medicare pays for 340B-acquired drugs. Similarly, commenters asked for reform to the 340B Program as a whole.

Response: We appreciate these comments but many of them are out of the scope of this rule. HRSA manages the 340B Program more generally, and more broad comments with respect to that program are not the subject of this rulemaking. OPSS payment policy will be included in the appropriate year’s annual rule. As noted above, we previously suggested that we might use our survey of CY 2018 and 2019 cost data to inform the remedy. (84 FR 61322.) But as we subsequently noted, we received many comments on the survey data, and using that data, which surveyed only 340B hospitals, might not comport with the Supreme Court’s decision. Using it would introduce new complexities into the rate calculation, for instance, by requiring consideration of adjustments to the data and other factors (85 FR 86052). We do not believe it is worth delaying the remedy payments to allow for such considerations or for us to conduct a new survey many years after the fact.

Comment: Many commenters expressed concern about Medicare Advantage Organizations (hereinafter referred to as “MAOs”) realizing a “windfall” as a result of reducing outpatient payments without making corresponding repayments to hospitals. Specifically, these commenters argued

that MAOs will see the benefit of reducing outpatient payments to all hospitals for non-drug items and services by 0.5 percent starting in CY 2026 but will not be required to repay affected 340B covered entity hospitals the amounts that were withheld for 340B drugs from 2018 through 2022. These commenters requested that CMS consider several courses of action to ensure MAOs fully comply with the remedy.

Response: We appreciate commenters’ concerns; however, these comments are out of the scope of this final rule. We refer commenters to the Hospital Outpatient Prospective Payment System Update on Payment Rates for Drugs Acquired through the 340B Program—Informational for MAOs memorandum that was issued by CMS on December 20, 2022.³³ In that memorandum, we summarized the issue with the Outpatient Prospective Payment system rule related to payments for 340B acquired drugs and provided references to the relevant CMS-issued materials that were issued after the Supreme Court decision that vacated the differential payment rates. We clarified that for Medicare Advantage, MAOs must pay non-contract providers or facilities for services and items at least the amount they would have received under Original Medicare payment rules, in accordance with section 1852(a)(2) of the Act (42 U.S.C. 1395w–22). In accordance with section 1854(a)(6)(B)(iii) of the Act (42 U.S.C. 1395w–22(a)(6)(B)(iii)), CMS may not require MAOs to contract with a particular healthcare provider or use particular pricing structures with their contracted providers. Therefore, MAOs that contract with a provider or facility eligible for 340B drugs can negotiate the terms and conditions of payment directly with the provider or facility and CMS cannot interfere in the payment rates that MAOs set in contracts with providers and facilities.

Comment: A few commenters alleged Accountable Care Organizations will continue to be unfairly impacted by CMS not addressing the disparity between paying for 340B drugs at the lower price of ASP minus 22.5 percent in ACO benchmarks (that is, between 2018–2022) and the higher price of ASP plus 6 percent in performance years. The commenters urge CMS to correct this disparity by adjusting its calculation of ACOs’ performance year expenditures to correct for this difference without ACOs having to early renew. The commenters argued an

adjustment would help ACOs that include ACO providers/suppliers that are 340B providers, who help underserved patients and address the health disparities CMS wants to eliminate through policymaking.

Response: The Shared Savings Program includes Parts A and B fee-for-service claims and individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program in benchmark and performance year expenditure calculations. Historical benchmark year expenditures are risk-adjusted, and a blend of national and regional growth rates are used to trend forward expenditures for each benchmark year (benchmark year 1 and 2) to benchmark year 3. Benchmark expenditures are further updated by trending forward to the performance year during financial reconciliation. Risk adjustment is applied to account for changes in severity and case mix of the ACO’s assigned beneficiaries between the benchmark period and the performance year, and the use of a blended national and regional trend adjusts an ACO’s historical benchmark expenditures to remain comparable to changes in performance year expenditures including changes in Medicare payment policy and other factors affecting expenditures. The payment rate for 340B-acquired drugs included in Shared Savings Program PY 2023 financial calculations will be ASP plus 6 percent. For ACOs participating in PY 2023 that have historical benchmark years for which payments for 340B-acquired drugs were based on the ASP minus 22.5 percent rate (2018–2022), the differences between the 340B-acquired drug payments included in historical benchmark year and performance year expenditure calculations have the potential to be mitigated when CMS updates the benchmark using a blend of national and regional growth rates. Additionally, for ACOs with agreement periods starting January 1, 2024, we finalized policies through rulemaking that may also support ACOs impacted by the changes in 340B-acquired drug payment rates, such as policies to reduce the impact of the negative regional adjustment, incorporate a prior savings adjustment in historical benchmarks for renewing and re-entering ACOs, and modifying the methodology for updating the historical benchmark to incorporate a prospective, external factor. These policies are expected to encourage new and continued participation from ACOs serving medically complex and high cost of care populations.

³³ Available at <https://www.cms.gov/files/document/cmsopps340bupdate508g.pdf>.

Any adjustments to 340B-acquired drug claims with CY 2022 dates of service that were processed on or before March 31, 2023, are reflected in Medicare Shared Savings Program (Shared Savings Program) expenditure calculations used in Performance Year (PY) 2022 financial reconciliation and will be used to calculate historical benchmarks for ACOs for which CY 2022 is a benchmark year. Any adjustment to claims with CY 2022 dates of service that were processed after March 31, 2023, or that have not yet been submitted or processed are not reflected in PY 2022 Shared Savings Program expenditure calculations and would not be used to calculate historical benchmarks for ACOs for which CY 2022 is a benchmark year.

Additionally, CMS will provide lump-sum payments to providers that received reduced reimbursement for 340B-acquired drugs from CY 2018 through September 27th of CY 2022, such lump sum payments will be adjusted to ensure that CMS does not make duplicate payments for claims that had already been reprocessed at the higher payment rate. These lump sum payments will not be included in Shared Savings Program calculations, as these payments would not be individually beneficiary identifiable.

Comment: One commenter urged CMS to consider recommendations outlined in the ASCO 340B drug pricing reform statement in any future approach to reforming the 340B Program. The commenter requested that when proposing further policy changes and updates, CMS analyze the impact of the policies, including whether the proposals satisfy the original intent of the legislation, the presence or absence of appropriate safeguards for compliance and oversight, and the unique considerations related to cancer patients and other vulnerable patients.

Response: We appreciate the commenter's concerns; however, this comment is out of the scope of this final rule.

Summary of Finalized Policy

As discussed in the preceding sections, after consideration of the public comments we received, and for the reasons stated in our proposed rule and in this final rule, we are finalizing the proposed remedy for the 340B Payment Policy for CYs 2018–2022, with the one exception that we are changing the implementation date of the 0.5 percent adjustment from CY 2025 to CY 2026. Using our authority under sections 1833(t)(14) and (t)(2)(E) of the Act (42 U.S.C. 1395l(t)(14) and (t)(2)(E)) and, to the extent necessary, section

1871(e)(1)(A) of the Act (42 U.S.C. 1395hh(e)(1)(A)), we will make a one-time lump sum payment to each affected 340B covered entity hospital calculated as the difference between what the affected 340B covered entity hospital received for 340B-acquired drugs during the time period at issue and approximately what they would have received for 340B-acquired drugs if the 340B adjustment had not been in place, which includes what the affected 340B covered entity hospital would otherwise have been paid by the beneficiary. The amount of the lump sum payment that has been calculated for each affected 340B covered entity hospital is listed in Addendum AAA. Following the deadline to submit a request for technical correction to the amount listed in Addendum AAA, we will issue instructions to the Medicare Administrative Contractor (MAC) for each affected 340B covered entity hospital that has not submitted a request for technical correction by the deadline discussed in this rule. We will instruct the MAC to issue a one-time lump sum payment to those hospitals in the amount listed in Addendum AAA within 60 calendar days of the MAC's receipt of the instruction. We will instruct MACs to pay hospitals that submit a request for technical correction through a similar process after the technical correction process is completed, and the payment amount for those providers will be based on the result of the technical correction process. The lump sum payments do not include interest. In aggregate, the lump sum payments we calculate here will total \$9.0 billion and will include a portion equivalent to the amount that beneficiaries, through cost-sharing, would have paid hospitals.

To comply with the budget neutrality requirements of the authorities we are relying on to make the one-time lump sum remedy payments, and alternatively relying on our equitable adjustment or common-law and inherent recoupment authorities, beginning in CY 2026, we will reduce all payments for non-drug items and services to all OPPS providers, except new providers (hospitals with a CMS CCN effective date of January 2, 2018, or later), by 0.5 percent each year until the total estimated offset of \$7.8 billion is reached. We currently estimate that the payment decrease will be completed after approximately 16 years. To implement this reduction and exception for new providers, we are finalizing the proposed regulation text changes at § 419.32(b)(1)(iv)(B) as proposed, except for changing the implementation date of

the 0.5 percent reduction from CY 2025 to CY 2026.

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. Regulatory Impact Analysis

Comment: One commenter alleged that there is a significant discrepancy in CMS's total OPPS payments data, which could impact how long it would take for CMS to effectuate any recoupment. Specifically, the commenter argued that there is a \$23 billion dollar discrepancy between the amount of total OPPS payments stated in the proposed 2024 OPPS rule (\$88.6 billion) and the amount of OPPS payments for all providers stated in the OPPS impact file for the proposed 2024 OPPS rule (\$65.65 billion). The commenter expressed concern about this discrepancy and its effect on individual hospitals and the 16-year recoupment period.

Response: We agree that there are differences between the spending numbers in the OPPS impact files versus overall OPPS spending estimates. The OPPS impact file associated with each proposed and final rule primarily displays the effects of current and prospective policies based on historical claims. It also excludes lines from estimated payment that are removed from the ratesetting process for OPPS purposes. In contrast, the overall OPPS spending estimate is based on projections of future spending and include estimated changes in enrollment, utilization, and case mix. We also agree that things may change over the course of the 16-year recoupment period, and we will monitor the impact of these prospective reductions as well as recoupment amounts over the course of that time period.

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 remanded the case to 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 final rule describes the remedy CMS is finalizing to comply with the District Court's remand. It remedies 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 amount of the lump sum payment includes 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 proposed and are finalizing to annually reduce OPPS payments for non-drug items and services beginning in CY 2026 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 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. 96354) (5 U.S.C. 601–612), section 1102(b) of the Act (42 U.S.C. 1302(b)), section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4) (2 U.S.C. 602), 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). The Executive Order 14094 entitled “Modernizing Regulatory Review” (hereinafter referred to as the “Modernizing E.O.”) amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines 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) of Executive Order 12866 (\$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) economic effect. 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.

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 changes in this final rule, will be \$2.8 billion. We took into consideration the additional Medicare drug payments of \$9.0 billion to the estimated 1,700 340B covered entity

hospitals to which the drug payment remedy will apply, and the \$6.2 billion in reduced Medicare prospective payments for non-drug items and services beginning in CY 2026 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 proposed. 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 reprocessed at the default drug payment rate after the 340B Payment Policy was vacated, estimated at \$1.6 billion, for purposes of the total aggregate remedy payment to affected 340B covered entity hospitals, we are not including that \$1.6 billion in our calculation here, which estimates the total increase in Federal Government expenditures due only to the proposed changes in this final rule. This \$1.6 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 percent and unwinding the associated 3.19 percent rate increase for non-drug items and services are not equal to each other. This is due to many factors. Some factors that decreased the gap include the facts that 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, and 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. By contrast, some factors that increased the gap include the facts that this remedy rule pays 340B providers an amount equivalent to the lost 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 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. In aggregate, the total additional payment that providers will receive as a result of this remedy, \$10.6 billion, will be larger than the amount of payment that will be prospectively offset, \$7.8 billion.

To explain the last factor in more detail, from CY 2018 through CY 2022, the actual spending associated with 340B-acquired drugs changed from what we projected in the CY 2018 OPPI/ASC final rule with comment period. As we noted above in section II.B.2 of this final rule, the actual total reduction in 340B-acquired drug payments during this time period outpaced the corresponding increase in non-drug item and service payments. This final rule maintains budget neutrality by undoing the original 340B Payment Policy. This approach is consistent with how we unwound the 340B Payment Policy prospectively, as described in the CY 2023 OPPI/ASC final rule with comment period (87 FR 71975). There, 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. We did not increase the rate we paid for 340B-acquired drugs without making a corresponding change to the conversion factor. Nor did we adjust the conversion factor to account for the actual increase in the utilization for 340B drugs. In Table 3 of this final rule, we display the impact of these proposed policy changes on drug payments, including aggregate payment by hospital type. Specific 340B-acquired drug lump sum payment amounts, by individual hospital, can be found in Addendum AAA. The impact for specific hospital types of the reduced prospective payment for non-drug items and services beginning in CY 2026 would be included in each proposed and final rule for calendar years in which the prospective reduction would apply, beginning in CY 2026.

C. Detailed Economic Analysis

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 3 shows the total number of facilities (1,686), including designated cancer and children's hospitals and Community Mental Health Centers (CMHCs), that will receive remedy payments under this final rule. We excluded all hospitals and CMHCs that we do not expect will experience any direct effect from the remedy payments in this final rule. We show the total number of OPPI hospitals (1,686) that will receive remedy payments, 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 (42 U.S.C. 1395l(t)(7)(D)(ii)) provides transitional outpatient payments (TOPs), which permanently hold 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 will be made under this final 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: CY 2022 Reprocessed Payment Differential (in Millions)

Column 3 displays the estimated payment impact of any CY 2022 claims that have been reprocessed by the MACs. We note that these claims, which include dates of service for services furnished prior to September 28, 2022, were not reprocessed their payments otherwise would have been included as remedy payments in Column 2.

Column 4: Total 340B Drug Remedy Payments

Column 4 includes the total remedy payments, which is the sum of column 2 and column 3.

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TABLE 3: ESTIMATED FINANCIAL IMPACT OF THE LUMP-SUM REMEDY PAYMENTS ON OPps PROVIDERS

Row		(1) Number of Hospitals	(2) Remedy Payment (in millions)	(3) CY 2022 Reprocessed Payment Differential (in millions)	(4) Total 340B Drug Remedy Payments (Sum of Columns 2 and 3)
1	ALL PROVIDERS *	1,686	9,003.8	1,615.6	10,619.4
2	ALL HOSPITALS (excludes hospitals held harmless and CMHCs)	1,655	9,003.5	1,615.5	10,619.0
3	URBAN HOSPITALS	1,324	8,543.8	1,562.8	10,106.6
4	LARGE URBAN (GT 1 MILL.)	625	4,322.7	843.8	5,166.5
5	OTHER URBAN (LE 1 MILL.)	699	4,221.1	719.0	4,940.1
6	RURAL HOSPITALS	331	453.4	51.3	504.7
7	SOLE COMMUNITY	152	94.2	6.1	100.3
8	OTHER RURAL	179	359.2	45.1	404.3
	BEDS (URBAN)				
9	0 - 99 BEDS	224	259.0	46.6	305.6
10	100-199 BEDS	382	823.9	131.3	955.2
11	200-299 BEDS	253	1,197.3	211.5	1,408.8
12	300-499 BEDS	272	1,980.1	355.2	2,335.3
13	500 + BEDS	193	4,283.4	818.3	5,101.7
	BEDS (RURAL)				
14	0 - 49 BEDS	128	80.3	8.3	88.6
15	50- 100 BEDS	117	101.2	15.8	117.0
16	101- 149 BEDS	41	88.8	9.4	98.2
17	150- 199 BEDS	22	89.9	8.3	98.2
18	200 + BEDS	23	93.2	9.5	102.7
	REGION (URBAN)				
19	NEW ENGLAND	73	609.9	123.7	733.6
20	MIDDLE ATLANTIC	165	1,177.2	244.6	1,421.8
21	SOUTH ATLANTIC	225	1,590.3	289.6	1,879.9
22	EAST NORTH CENT.	236	1,315.4	247.8	1,563.2
23	EAST SOUTH CENT.	75	668.0	113.4	781.4
24	WEST NORTH CENT.	80	749.7	135.3	885.0
25	WEST SOUTH CENT.	149	608.8	104.0	712.8
26	MOUNTAIN	90	564.0	96.1	660.1
27	PACIFIC	228	1,260.5	208.2	1,468.7
28	PUERTO RICO	3	0.0	0.0	0.0

REGION (RURAL)					
29	NEW ENGLAND	11	25.1	1.4	26.5
30	MIDDLE ATLANTIC	23	32.2	3.6	35.8
31	SOUTH ATLANTIC	54	94.7	8.0	102.7
32	EAST NORTH CENT.	48	67.1	8.1	75.2
33	EAST SOUTH CENT.	77	145.2	20.0	165.2
34	WEST NORTH CENT.	30	6.8	0.7	7.5
35	WEST SOUTH CENT.	54	19.5	1.4	20.9
36	MOUNTAIN	20	28.1	2.9	31.0
37	PACIFIC	14	34.7	5.3	40.0
TEACHING STATUS					
38	NON-TEACHING	818	1,673.3	291.6	1,964.9
39	MINOR	522	2,780.8	464.0	3,244.8
40	MAJOR	315	4,543.1	858.5	5,401.6
DSH PATIENT PERCENT					
41	0	0	0.0	0.0	0.0
42	GT 0 - 0.10	31	16.5	0.4	16.9
43	0.10 - 0.16	65	6.9	0.1	7.0
44	0.16 - 0.23	178	54.4	15.7	70.1
45	0.23 - 0.35	728	3,832.4	711.4	4,543.8
46	GE 0.35	642	5,086.9	886.4	5,973.3
47	DSH NOT AVAILABLE **	11	0.1	0.0	0.1
URBAN TEACHING/DSH					
48	TEACHING & DSH	775	7,168.4	1,308.8	8,477.2
49	NO TEACHING/DSH	539	1,375.3	254.0	1,629.3
50	NO TEACHING/NO DSH	0	0.0	0.0	0.0
51	DSH NOT AVAILABLE2	10	0.1	0.0	0.1
TYPE OF OWNERSHIP					
52	VOLUNTARY	1,241	7,208.2	1,308.9	8,517.1
53	PROPRIETARY	152	32.1	7.1	39.2
54	GOVERNMENT	262	1,757.0	298.1	2,055.1

Column (1) shows total hospitals that are expected to receive payments related to the 340B policy under this final rule.

Column (2) includes the estimated drug remedy payment made to account for the policies described in this final rule during the time period of CY 2018 through CY 2022. Column (3) displays the estimated payment impact of any CY 2022 claims that have been reprocessed by the MACs. 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 1,686 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs. We note that this also includes 22 providers who are not expected to receive 340b remedy payments but who had reprocessed CY 2022 claims.

** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.

payments to the 1,686 affected 340B covered entity hospitals. The \$9.0 billion amount is an estimate of the total aggregate additional payments that will 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 \$10.6 billion, which includes the \$1.6 billion that has already been paid through 340B drug claims processing and reprocessing that occurred for CY 2022 claims.

We note that, in this final rule, we described our policy to annually reduce OPSS payments for non-drug items and services beginning in CY 2026, by decreasing the OPSS 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 adjustment. This prospective offset will apply to all OPSS providers, including 340B providers, aside from those OPSS 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 2 of this final rule.³⁴ The impact of this offset on

payments to each provider type for each calendar year in which the offset is in effect will be included in the regulatory impact analysis for the applicable annual OPSS rulemaking, beginning for CY 2026. However, we note that generally the impact of that annual 0.5 percent reduction to the OPSS conversion factor on individual providers, as well as categories of providers, will depend on the percentage of their OPSS payments that are conversion factor-based, and in most cases will be a decrease of slightly less than 0.5 percent of overall OPSS payments. Please see Table 4 below for our estimated total impact to the OPSS payments based on the information provided in Table 2.

TABLE 4: ESTIMATED ANNUAL IMPACT TO OPSS SPENDING BASED ON 0.5 PERCENT ADJUSTMENT TO THE CONVERSION FACTOR

	CY 2026	CY 2027	CY 2028	CY 2029	CY 2030	CY 2031
0.5-Percent Payment Reduction Amount (millions)	\$351	\$369	\$387	\$407	\$427	\$448
	CY 2032	CY 2033	CY 2034	CY 2035	CY 2036	CY 2037
0.5-Percent Payment Reduction Amount (millions)	\$471	\$494	\$519	\$545	\$572	\$600
	CY 2038	CY 2039	CY 2040	CY 2041		
0.5-Percent Payment Reduction Amount (millions)	\$631	\$662	\$696	\$188		
	Total Offset:			\$7.8 billion		

³⁴ 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 offset.

D. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final 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 OPPTS/ASC proposed rule will be the number of reviewers of the 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.

For the purposes of our estimate, we assume that each reviewer reads 100 percent of the rule. We welcomed any public comments on the approach in estimating the number of entities that would review the proposed rule. We did not receive any public comments specific to our solicitation.

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.³⁵ Assuming an average reading speed, we estimate that it would take approximately 3 hours for the staff to review this final 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). We received 1,649 comments on the proposed rule, which we estimate to be equivalent to the estimated number of reviewers.

³⁵ https://www.bls.gov/oes/current/oes_nat.htm.

E. Alternatives Considered

As also discussed in section II.A above, we evaluated several options to determine which remedy would best achieve the objectives of unwinding the unlawful 340B Payment Policy while making certain OPPTS 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 proposing an adjustment to maintain budget neutrality, which for the reasons stated in section II.A.1 and II.B.2 we determined not to be supported by the statute or the proper exercise of our equitable adjustment or common-law and inherent recoupment authorities. We further considered retrospectively reprocessing all claims from CY 2018 through September 27th of CY 2022, which, for the reasons stated in section II.A.2, we determined not to be operationally feasible and to delay remedy payments to hospitals.

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 (t)(14) of the Act (42 U.S.C. 1395l(t)(2)(E) and (t)(14)), along with our retroactive rulemaking authority in section 1871(e)(1)(A) of the Act (42 U.S.C. 1395hh(e)(1)(A)). 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 OPPTS 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 appropriate in these circumstances. Such an approach would require immediate, and in many cases large, recoupments from the majority of OPPTS 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 COVID-19 PHE, 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 final option much more generous to OPPTS providers.

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

We are finalizing the prospective offset for reasons previously discussed to begin in CY 2026, which we believe is appropriate rather than other years, as we believe starting this reduction in CY 2026 is responsive to commenter concerns, and will allow CMS time to finalize the appropriate methodology, and then calculate and publish the payment rates derived from this policy in the CY 2026 OPPTS/ASC proposed rule, allowing adequate time for impacted parties to assess and prepare for the new payment rates that will be calculated using a reduced conversion factor.

F. Accounting Statement and Table

As required by OMB Circular A-4 (available at https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf), we have prepared an accounting statement in Table 5 showing the classification of the impact associated with the provisions of this final rule.

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TABLE 5: ACCOUNTING STATEMENT

<i>Category</i>	<i>Estimate</i>	<i>Source Citation</i>		<i>Year Dollar</i>
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)	\$1.6 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:	\$10.6 billion			
	Transfers*	Year Dollar	Discount Rate	Period Covered
Federal Annualized Monetized (\$Millions/Year)	-\$465.0	2023	7%	CYs 2026-2041
	-\$476.9	2023	3%	CYs 2026-2041
From whom to whom?	Federal Government and beneficiaries to Hospitals and other providers who receive payment under the hospital OPPS (other than new providers).			

*The reduction in annualized monetized transfers is reflective of the aggregate \$7.8 billion in future reductions to the OPPS conversion factor based on the parameters of this final rule for calendar years 2026-2041.

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We note readers can find provider-level calculations of lump-sum Medicare payments in Addendum AAA to this final rule. If an affected 340B covered hospital entity believes that the payment amount listed for them in Addendum AAA is inaccurate, they can request that CMS review the amount using the technical correction processes described earlier in this rule.

We note that the approximately \$9.0 billion of expected transfers in this final rule is the \$9.0 billion in expected additional lump sum drug remedy

payments associated with this final rule. Some of this amount, \$1.6 billion of the total \$10.6 billion, 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. Table 5 provides the present value of the prospective offset adjustment using discount rates of

three and seven percent. We note a commenter referenced the present value of the prospective offset adjustment due to the projected long timeframe. We believe the prospective 0.5 percentage annual reduction in the conversion factor is appropriate because it addresses budget neutrality while also ensuring that the offset was not overly financially burdensome on impacted entities.

G. 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 final rule. 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 (42 U.S.C. 1302(b)) 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 604 of the RFA. For purposes of section 1102(b) of the Act (42 U.S.C. 1302(b)), 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 final rule will result in approximately \$185 million in remedy payments to 245 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 final rule, provides a regulatory flexibility analysis and a regulatory impact analysis. We note that the policies contained in this final rule will 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 as well as the extent to which they furnished 340B-acquired drugs. However, small rural hospitals will experience significant effects from this final rule through the 340B remedy payments if they furnished a significant amount of 340B-acquired drugs and used the "JG" modifier.

H. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 602) 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 final rule does not mandate any requirements for State, local, or Tribal governments, or for the private sector.

I. 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 final 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 3 of this final rule, we estimate that payments to impacted governmental hospitals (including State and local governmental hospitals) will increase by approximately \$1.8 billion if the policies included in this final 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 will be discussed in the annual rulemaking to which the adjustment will apply.

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

J. Congressional Review Act

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (the Congressional Review Act), the Office of Information and Regulatory Affairs has determined that this action meets the criteria set forth in 5 U.S.C. 804(2).

The analyses we have provided in this section of this final rule, in conjunction

with the remainder of this document, demonstrate that this final 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 (42 U.S.C. 1302(b)).

This final rule will 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 October 26, 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 amends 42 CFR part 419 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 2025, a multifactor productivity adjustment (as determined by CMS).

(12) Beginning in calendar year 2026, a multifactor productivity adjustment (as determined by CMS), and 0.5 percentage point reduction, except that the 0.5 percentage point reduction shall not apply to hospital outpatient items and services, not including separately payable drugs or biologicals, 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 the estimated

payment reduction reaches \$7.769 billion, as further described in each calendar year's rule.

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Dated: October 31, 2023.

Xavier Becerra,
Secretary, Department of Health and Human Services.

[FR Doc. 2023-24407 Filed 11-2-23; 4:15 pm]

BILLING CODE 4120-01-P