No. 20-1114

In the Supreme Court of the United States

AMERICAN HOSPITAL ASSOCIATION, ET AL., PETITIONERS

v.

XAVIER BECERRA,
SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE RESPONDENTS

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QUESTIONS PRESENTED

Under Medicare's Outpatient Prospective Payment System (OPPS), 42 U.S.C. 1395*l*(t), the Department of Health and Human Services (HHS) reimburses hospitals for outpatient services at predetermined rates based on the average cost that hospitals incur for particular services. The OPPS statute provides direction to HHS on how to calculate, review, and adjust reimbursement rates, and it generally precludes "administrative or judicial review" of the agency's rate determinations or adjustments. 42 U.S.C. 1395*l*(t)(12).

For a "specified covered outpatient drug," the OPPS statute directs HHS to set a reimbursement rate equal to either (I) the drug's "average acquisition cost" (which may vary by hospital group) "as determined by the Secretary taking into account" certain hospital cost survey data, or (II) "if hospital acquisition cost data are not available," the average sales price of the drug as determined by a cross-referenced provision, "as calculated and adjusted by the Secretary as necessary for purposes of this paragraph." 42 U.S.C. 1395*l*(t)(14)(A)(iii).

Beginning in 2018, HHS has adjusted downward the reimbursement rate for specified covered outpatient drugs acquired by hospitals at substantial discounts through Section 340B of the Public Health Service Act, 42 U.S.C. 256b. The adjustments ensure that Medicare reimbursements—and beneficiary copayments—more accurately reflect the amount hospitals pay for the covered drugs. The questions presented are as follows:

1. Whether judicial review of the challenged rate adjustments is precluded by 42 U.S.C. 1395*l*(t)(12).

2. If judicial review is not precluded, whether HHS had authority to adopt the challenged rate adjustments under 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II).

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-43a) is reported at 967 F.3d 818. The opinion of the district court addressing the merits (Pet. App. 44a-86a) is reported at 348 F. Supp. 3d 62. The opinion of the district court addressing the appropriate remedy (Pet. App. 87a-112a) is reported at 385 F. Supp. 3d 1. The opinion of the district court directing entry of final judgment (Pet. App. 113a-117a) is not published in the Federal Supplement but is available at 2019 WL 3037306.

JURISDICTION

The judgment of the court of appeals was entered on July 31, 2020. A petition for rehearing was denied on October 16, 2020 (Pet. App. 118a). The petition for a writ of certiorari was filed on February 10, 2021, and

was granted on July 2, 2021. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

Pertinent statutory provisions are reproduced in an appendix to this brief. App., *infra*, 1a-78a.

STATEMENT

Petitioners are hospitals and hospital associations with members that participate in both Medicare and the drug-discount program created by Section 340B of the Public Health Service Act (PHSA), 42 U.S.C. 256b. Pet. App. 7a-8a. Beginning in 2018, the Department of Health and Human Services (HHS) has issued annual rules adjusting downward the Medicare reimbursement rate for certain drugs obtained through the Section 340B discount program, so that reimbursement rates and beneficiary copayments more closely track hospitals' drug-acquisition costs. *Id.* at 6a-8a. Petitioners challenged those adjustments as beyond the agency's statutory authority. *Id.* at 8a. The district court agreed and remanded to HHS to determine a remedy. *Ibid.* The court of appeals reversed, upholding the validity of the rate adjustments. *Id.* at 17a-31a.

A. Statutory Background

1. The Medicare program

The "largest federal program after Social Security," Medicare spends roughly "$700 billion annually to provide health insurance for nearly 60 million" Americans, principally those above 65 years old or with specified disabilities. *Azar* v. *Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019). Medicare Part A provides coverage for inpatient hospital care, home health care, and hospice services. 42 U.S.C. 1395c *et seq.* Part B provides optional supplemental coverage—supported in part by

beneficiary premiums and coinsurance—for other services, including those provided by a physician's office or hospital outpatient department. 42 U.S.C. 1395j *et seq.*

"Under the Medicare program, health care providers are reimbursed by the Government for expenses incurred in providing medical services to Medicare beneficiaries." *Bowen* v. *Georgetown Univ. Hosp.*, 488 U.S. 204, 205 (1988). This case involves medical services covered by Medicare Part B—specifically, drugs used in hospital outpatient departments. As explained further below, reimbursements and beneficiary copayments for those drugs are based on rates adjusted annually by HHS. See Pet. App. 2a-7a.

2. The Outpatient Prospective Payment System (OPPS)

For many years, Medicare reimbursed providers for "reasonable costs * * * actually incurred." *Good Samaritan Hosp.* v. *Shalala*, 508 U.S. 402, 405 (1993) (citation omitted). Over time, sharp increases in medical costs and demographic changes threatened the program with insolvency. See H.R. Rep. No. 436, 106th Cong., 1st Sess. Pt. 1, at 33 (1999). Congress responded by significantly revising Medicare reimbursement policies in the Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251, to better control costs. As relevant here, the Act directed HHS to establish the Outpatient Prospective Payment System (OPPS), under which hospitals are reimbursed—and beneficiaries are charged copayments—for outpatient services covered by Medicare Part B based on predetermined rates that reflect the median (or mean) costs of providing those services. *Id.* Tit. IV, Subtit. F, Ch. 2, § 4523(a), 111 Stat. 445-449 (codified at 42 U.S.C. 1395*l*(t)).

Specifically, paragraph (2) of the OPPS statute directs HHS to establish classifications for services (or

groups of services) that are comparable clinically and in terms of cost; to establish relative payment weights for each classification based on historical cost data; and to make, in a budget-neutral manner, adjustments to account for differences in cost and other relevant factors. 42 U.S.C. 1395*l*(t)(2). Those components are used to determine hospital reimbursement rates, see 42 U.S.C. 1395*l*(t)(3)(D) and (4), which are also the basis for calculating copayment amounts for Medicare Part B beneficiaries, see 42 U.S.C. 1395*l*(t)(3)(B) and (8). Paragraph (9) requires HHS to review OPPS components annually and adopt (through notice-and-comment rulemaking) budget-neutral adjustments that account for new cost data and other relevant factors. 42 U.S.C. 1395*l*(t)(9); see *Allina*, 139 S. Ct. at 1810. Paragraph (12) provides that "[t]here shall be no administrative or judicial review" of OPPS components, including "the establishment of groups and relative payment weights for covered [outpatient] services, of wage adjustment factors, other adjustments, and methods described in paragraph (2)(F)," and "periodic adjustments made under paragraph" (9). 42 U.S.C. 1395*l*(t)(12)(A) and (C).[1]

3. OPPS rates for specified covered outpatient drugs

In 2003, Congress added paragraph (14) to the OPPS statute. Medicare Prescription Drug, Improvement,

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[1] Subparagraph (12)(C) refers to "periodic adjustments made under paragraph (6)," 42 U.S.C. 1395*l*(t)(12)(C), but "all agree[d]" in the lower courts "that the reference contains a scrivener's error and that Congress in fact intended to refer to paragraph (9)." Pet. App. 9a. In the initial OPPS statute, subparagraph (C) of the preclusion provision cross-referenced paragraph (6), which required annual adjustment of the OPPS components. 111 Stat. 449. Paragraph (6) became paragraph (9) after later statutory amendments, but Congress did not update the cross-reference in the preclusion provision.

and Modernization Act of 2003, Pub. L. No. 108-173, Tit. VI, Subtit. C, § 621(a), 117 Stat. 2066, 2307. Paragraph (14) governs reimbursement rates for "specified covered outpatient drug[s]" (covered drugs)—certain drugs for which HHS has created a separate payment classification group, meaning that providers are reimbursed for the drugs separately from related services. 42 U.S.C. 1395*l*(t)(14)(B)(i). Covered drugs are typically used to treat serious illnesses such as cancer. See Government Accountability Office (GAO), GAO-06-372, *Medicare Hospital Pharmaceuticals: Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS* 1-2, 6-7 (Apr. 2006), https://go.usa.gov/xHwje.

For the first two years of the covered-drug program (2004 and 2005), paragraph (14) instructed HHS to set reimbursement rates within certain limits based on a drug's price. 42 U.S.C. 1395*l*(t)(14)(A)(i)-(ii). It also directed the GAO to conduct surveys to determine hospital acquisition costs for each covered drug. 42 U.S.C. 1395*l*(t)(14)(D)(i). And it instructed HHS to conduct subsequent surveys to determine updated hospital acquisition costs. 42 U.S.C. 1395*l*(t)(14)(D)(ii)-(iii).

Of central relevance here, paragraph (14) provides two ways for HHS to determine reimbursement rates for covered drugs beginning in 2006. First, it directs HHS to set the rate at "the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group * * *), as determined by the Secretary taking into account the hospital acquisition cost survey data" that the GAO and HHS are directed to collect under subparagraph (14)(D). 42 U.S.C. 1395*l*(t)(14)(A)(iii)(I) (subclause (I)). Alterna-

tively, "if hospital acquisition cost data are not available," paragraph (14) directs HHS to set the reimbursement rate at "the average price for the drug in the year established under" certain cross-referenced provisions, "as calculated and adjusted by the Secretary as necessary for the purposes of this paragraph." 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II) (subclause (II)). As relevant here, subclause (II) cross-references 42 U.S.C. 1395w-3a, which prescribes a mechanism for determining drug reimbursement rates under Medicare Part B generally (*e.g.*, for drugs used in physicians' offices, not just hospital outpatient departments subject to the OPPS).[2]

The alternative methods of reimbursement in subclauses (I) and (II) are both "subject to subparagraph [(14)](E)," 42 U.S.C. 1395*l*(t)(14)(A)(iii), which allows HHS to adjust the covered-drug reimbursement rate to account for "overhead and related expenses," 42 U.S.C. 1395*l*(t)(14)(E)(i).

B. Regulatory Background

1. Reimbursement rates for covered drugs

As directed, the GAO conducted and published in 2005 a survey to determine hospital acquisition costs for covered drugs. See GAO-06-372, at 2. The survey, however, failed to "obtain data that would permit calculation of hospitals' acquisition costs, because, in general, hospitals were unable to report accurately or comprehensively on rebates" that they received. *Id.* at 7. In addition, the survey "created a considerable burden for

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[2] Subclause (II) cross-references two other provisions that are not directly relevant here: 42 U.S.C. 1395u(*o*) generally applies to drugs furnished before 2004, and 42 U.S.C. 1395w-3b establishes a competitive-bidding program that has since been suspended, see 73 Fed. Reg. 69,726, 69,753 (Nov. 19, 2008).

hospitals," which informed the GAO that "they had to divert staff from their normal duties." *Id.* at 5. The GAO accordingly advised HHS that conducting routine hospital surveys "would not be practical for collecting the data needed to set and update" reimbursement rates for covered drugs. *Ibid.*

In part for those reasons, HHS declined to rely on the GAO survey data in setting reimbursement rates for covered drugs in 2006. See 70 Fed. Reg. 68,516, 68,639-68,641 (Nov. 10, 2005). Instead, HHS determined that average-sales-price data reported by drug manufacturers and used as the basis for reimbursements under the relevant provision cross-referenced by subclause (II), 42 U.S.C. 1395w-3a, would yield a more reliable "estimate of average acquisition costs." 70 Fed. Reg. at 68,640; see *id.* at 68,639. HHS accordingly adopted the rate prescribed by that provision—106% of average sales price (ASP+6%)—as the reimbursement rate for covered drugs. *Id.* at 68,640. The agency reiterated that, although that rate was derived from *price*, it represented "the best proxy for the combined acquisition and overhead *costs*" of covered drugs. *Id.* at 68,642 (emphasis added); see *ibid.* ("our intent is to pay for drugs * * * based on their hospital acquisition costs"). "Many commenters[,] including * * * hospital associations," supported that rate as "the best available estimate of average hospital acquisition cost." *Id.* at 68,641.

Over the ensuing 15 years, HHS has continued to set reimbursement rates for covered drugs by using a price-based rate as a proxy for hospitals' drug-acquisition costs. See Pet. App. 21a-22a. In the initial years, HHS did so under subclause (I), taking account of the 2005 GAO survey data and other potential acquisition-

cost measures before adopting a price-based rate between ASP+4% and ASP+6% that the agency determined would "reflect[] hospitals' acquisition costs for drugs." 77 Fed. Reg. 68,210, 68,385 (Nov. 15, 2012); see *id.* at 68,383-68,388. Beginning in 2013, the agency set reimbursement rates for covered drugs under subclause (II), determining that the rate of ASP+6% prescribed by the applicable cross-referenced provision, 42 U.S.C. 1395w-3a, would "represent[] [hospitals'] combined acquisition and pharmacy overhead" costs. 77 Fed. Reg. at 68,386; see 82 Fed. Reg. 52,356, 52,490, 52,501 (Nov. 13, 2017).

Over the years, the relationship between an average-sales-price-based methodology and acquisition costs has been examined and confirmed. In a 2010 report, for example, HHS's Office of Inspector General (OIG) found that Medicare payments calculated using ASP were generally within one percent of the providers' reported acquisition costs for the drugs analyzed. See HHS, OIG, *Memorandum Report: Payment for Drugs Under the Hospital Outpatient Prospective Payment System* 1, 3, 9 (Oct. 22, 2010) (2010 OIG Report).

2. Reimbursements for covered drugs acquired by hospitals through the Section 340B discount program

Although ASP serves as a good proxy for the acquisition costs of most covered drugs, that is not universally true. The provision that HHS relied on in determining ASP incorporates many "price concessions," such as "volume discounts, prompt pay discounts, [and] cash discounts," 42 U.S.C. 1395w-3a(c)(3), but does not account for discounts obtained by hospitals under the program established by Section 340B of the PHSA, 42 U.S.C. 256b; see 42 U.S.C. 1395w-3a(c)(2)(A) (cross-referencing 42 U.S.C. 1396r-8(c)(1)(C)(i), which excludes

sales under the 340B program); 82 Fed. Reg. at 52,494; Pet. App. 22a.

Adopted in 1992, the 340B program "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health-care facilities." *Astra USA, Inc.* v. *Santa Clara County*, 563 U.S. 110, 113 (2011); see 42 U.S.C. 256b(a)(1). Facilities that participate in a "prime vendor program," 42 U.S.C. 256b(a)(8), can obtain even deeper discounts on some drugs, see 82 Fed. Reg. at 52,494. The 340B program is not directly linked to Medicare, nor does it speak directly to Medicare payment amounts; the program instead provides that "manufacturers participating in *Medicaid* must offer discounted drugs to covered entities, dominantly, local facilities that provide medical care for the poor" pursuant to federal grants. *Astra*, 563 U.S. at 115 (emphasis added); see 42 U.S.C. 256b(a)(3) and (4).

In 2005, only about 10% of participants in the 340B program were hospitals. See GAO, GAO-11-836, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 27 (Sept. 2011), https://go.usa.gov/xMGRA. Because those hospitals' 340B discounts were not taken into account when calculating the average-sales-price data that HHS used to set reimbursement rates for covered drugs, hospitals participating in the 340B program received payments that substantially exceeded their drug-acquisition costs. See 82 Fed. Reg. at 52,494. A 2010 estimate by the HHS OIG found that the relevant payments exceeded the 340B hospitals' drug-acquisition costs by at least 31%. 2010 OIG Report 1 & n.1.

By 2015, the number of hospitals participating in the 340B program had more than tripled. 82 Fed. Reg. at 52,495. Subsequent studies found that the Medicare

payments they received for covered drugs exceeded their acquisition costs by even more than initially thought. A 2015 HHS OIG report, for example, found that Medicare payments were "58 percent more than the statutorily based 340B ceiling prices [for 2013], which allowed covered entities to retain approximately $1.3 billion" in profit. OIG, HHS, *Part B Payments for 340B-Purchased Drugs*, *Executive Summary* (Nov. 2015), https://go.usa.gov/xV2jK. For some drugs, the difference between the Medicare payment amount and the 340B ceiling price was so large that, in at least one quarter of 2013, "the beneficiary's coinsurance alone (i.e., 20 percent) was greater than the amount a covered entity spent to acquire the drug." *Id.* at 9.

A 2015 GAO report similarly found that "[t]he amount of the 340B discount ranges from an estimated 20 to 50 percent off what the entity would have otherwise paid" to purchase the drug. GAO, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals* 8 (June 2015), https://go.usa.gov/xHvpp. And a 2016 report by the Medicare Payment Advisory Commission (MedPAC) found that "the aggregate discount on Part B drugs received by covered entities equaled 33.6 percent of the average sales price * * * in 2013." *Report to the Congress: Medicare Payment Policy* 79 (Mar. 2016), https://go.usa.gov/xV2jj.

3. The rate adjustments at issue here

In its annual rule adjusting OPPS reimbursement rates for 2018, HHS addressed the gap between reimbursements and acquisition costs for hospitals that purchase covered drugs through the 340B discount program. See 82 Fed. Reg. at 52,490-52,509.

The agency began by determining that "hospital acquisition cost data are not available," and that it must accordingly set the reimbursement rate for covered drugs under the price-based methodology in subclause (II). 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II); see 82 Fed. Reg. at 52,492. The agency calculated a rate of ASP+6% under the relevant cross-referenced provision, 42 U.S.C. 1395w-3a, and set that as the reimbursement rate for most covered drugs, 82 Fed. Reg. at 52,509. For covered drugs obtained through the 340B program at steep discounts, however, HHS determined that it was "necessary for the purposes of" paragraph (14) to "adjust[]" that rate, 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II), so that reimbursements for those drugs would "better, and more appropriately, reflect the resources and acquisition costs that [340B] hospitals incur," 82 Fed. Reg. at 52,495, 52,501; see *id.* at 52,362, 52,509.

After reviewing studies on the excessive payments that 340B hospitals had received for covered drugs (see pp. 9-10, *supra*), HHS determined that a reimbursement rate of average sales price minus 22.5% (ASP-22.5%) reflected the "'lower bound'" of the "minimum" average discount for 340B hospitals. 82 Fed. Reg. at 52,496; see *id.* at 52,494-52,495. HHS explained that, in most cases, the average discount for 340B hospitals may be "significantly higher, than * * * 22.5 percent," *id.* at 52,496 (citation omitted), but that it had selected the "conservative" figure of 22.5% to ensure that 340B hospitals would not be reimbursed below their acquisition costs, *id.* at 52,402. HHS emphasized that it had not received any comments during the rulemaking indicating that a different figure would better reflect drug-acquisition costs for 340B hospitals, which was "notable because hospitals have their own data regarding their

own acquisition costs, as well as data regarding OPPS payment rates for drugs." *Id.* at 52,500.

HHS also explained that, because beneficiary copayments are directly linked to reimbursement rates, the adjustment to the covered-drug reimbursement rate for 340B hospitals would reduce "drug costs for Medicare beneficiaries for drugs acquired by hospitals under the 340B Program." 82 Fed. Reg. at 52,362. The agency noted that the benefits of that reduction would be particularly meaningful for cancer patients, who often face especially high outpatient drug costs. *Id.* at 52,497. For example, the agency observed, one commenter had noted that the adjustment would save a Medicare beneficiary approximately $500 per month on a drug that is reimbursed at $10,000 per month, "which may be the difference between getting treatment and foregoing it for financial reasons." *Id.* at 52,497-52,498. HHS explained that its adjustment would also address concerns raised by studies that excessive reimbursement rates for covered drugs acquired by 340B hospitals had resulted in "unnecessary utilization of [those] drugs" without any apparent health benefits. 82 Fed. Reg. at 52,624; see *id.* at 52,494.

In all, HHS estimated that its adjustment would reduce excessive Medicare payments to 340B hospitals by $1.6 billion in 2018. See 82 Fed. Reg. at 52,509. Pursuant to the OPPS statute's budget-neutrality requirement, see 42 U.S.C. 1395*l*(t)(9)(B) and (14)(H), HHS redistributed those savings by making an offsetting 3.2% increase in the reimbursement rates for non-drug outpatient items and services provided by all hospitals, see 82 Fed. Reg. at 52,623. HHS later adopted the same adjusted rate and offsetting increase in the rulemakings for 2019, 2020, and 2021, and recently proposed to do

the same for 2022. See 83 Fed. Reg. 58,818, 58,975-58,977 (Nov. 21, 2018); 84 Fed. Reg. 61,142, 61,321-61,327 (Nov. 12, 2019); 85 Fed. Reg. 85,866, 86,042-86,055 (Dec. 29, 2020); 86 Fed. Reg. 42,018, 42,134-42,137 (Aug. 4, 2021).[3]

C. Proceedings Below

1. On the day HHS published its rate adjustment for 2018, petitioners challenged it in federal district court. See Pet. App. 7a-8a. The government contended that the suit was barred by the express preclusion-of-review provision in 42 U.S.C. 1395*l*(t)(12) and the general statutory requirement that a claim arising under the Medicare Act be raised before HHS in the context of a concrete request for reimbursement, see 42 U.S.C. 405(g)-(h), 1395ii. The district court dismissed the suit on the latter ground without addressing preclusion, 289 F. Supp. 3d 45, 50-55, and the court of appeals affirmed on the same basis, 895 F.3d 822, 825-828.

2. The hospital petitioners subsequently presented reimbursement claims for covered drugs they had administered in 2018 and 2019, and then sought administrative review of the adjusted rate used to reimburse them. Pet. App. 8a. HHS denied those requests on the ground that the rate adjustments are unreviewable under the OPPS preclusion provision, 42 U.S.C. 1395*l*(t)(12), which bars both administrative and judicial review of generally applicable rates used to determine

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[3] In keeping with its longstanding "policy to apply the same treatment to all separately payable drugs," HHS applies the methodology discussed above to determine reimbursements rates not only for covered drugs within paragraph (14) but also for separately payable drugs generally—including those not subject to paragraph (14). 82 Fed. Reg. at 52,490; see 77 Fed. Reg. at 68,383.

reimbursement of hospitals' individual claims. See Pet. App. 8a.

Petitioners then brought this action. The district court concluded that the OPPS preclusion provision does not apply to a claim that the HHS Secretary "acted in excess of his statutory authority" (*i.e.*, "that he acted *ultra vires*"), and thus that the preclusion and merits inquiries overlap. Pet. App. 68a. On the merits, the court held that HHS had exceeded its authority under subclause (II) in making the challenged rate adjustment. *Id.* at 70a-79a. The court reasoned that, to bring Medicare rates in line with hospital acquisition costs for the drugs at issue here, HHS must collect hospital survey data pursuant to subclause (I) and cannot "achieve under subsection (II) what" it "could not do under subsection (I) for lack of adequate data." *Id.* at 76a.

The district court declined to impose a remedy. The court stated that, as a result of the OPPS budget-neutrality requirement, the "retroactive OPPS payments" that petitioners sought "would presumably require similar offsets elsewhere," resulting in "a quagmire that may be impossible to navigate considering the volume of Medicare Part B payments made in 2018." Pet. App. 84a-85a; see *id.* at 101a. The court also noted that the Federation of American Hospitals—appearing as an amicus curiae on behalf of more than 1000 non-340B hospitals—had argued that HHS "lacks authority to recoup any or all of the 3.2[%] budget neutrality adjustment" made in prior years. *Id.* at 111a (citation omitted; brackets in original). The court declined to resolve that issue, instead remanding the matter to HHS with instructions that the agency devise a remedy. *Id.* at 101a-112a.

3. The court of appeals reversed, upholding HHS's rate adjustments on the merits. Pet. App. 1a-43a.

a. The court of appeals first concluded that judicial review is not precluded. In the court's view, it was "at least possible, if not probable, that Congress conceived of the [covered drug] rate-setting program as entirely distinct from the general paragraph (2) and (9) program" referenced in the OPPS preclusion provision. Pet. App. 17a. Because HHS's contrary interpretation was, in the court's assessment, "not *clearly* correct," the court held that the agency had "failed to 'overcom[e] the strong presumption that Congress did not mean to prohibit' review." *Ibid.* (citation omitted).

b. On the merits, the court of appeals held that HHS's rate adjustments permissibly implemented Congress's delegation of authority for the agency to "adjust[ ]" the price-based rate prescribed by subclause (II) "as necessary for purposes of" paragraph (14). 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II); see Pet. App. 17a-31a. The court emphasized that several important points were undisputed, including that (1) "the 'hospital acquisition cost data' contemplated by subclause (I) was unavailable, such that HHS needed to determine payment rates in accordance with subclause (II)'s fallback reliance on average drug prices"; (2) the adjustment selected by HHS was "a fair, or even conservative, measure of the reduction needed to bring payments" to 340B hospitals "into parity with their costs to obtain the drugs"; and (3) the adjustments would reduce out-of-pocket costs for Medicare beneficiaries and allow hospitals that were not receiving large discounts on covered drugs through the 340B program to benefit from larger reimbursement payments. Pet. App. 19a-20a.

The court of appeals explained that the "central" statutory "question is whether HHS permissibly conceived of the 'purposes of this paragraph,' i.e., paragraph (14), in exercising its subclause (II) authority to 'adjust' payment rates 'as necessary for the purposes of this paragraph.'" Pet. App. 20a-21a (brackets and citation omitted). The court agreed with HHS that paragraph (14)'s "core purposes include reimbursing hospitals for their costs to acquire" covered drugs. *Id.* at 21a. HHS's interpretation, the court explained, was supported by subclause (I)'s express reference to cost-based reimbursement, other OPPS provisions focusing on aligning reimbursement with costs, and HHS's longstanding approach of setting reimbursement rates based on a price-based rate that it regarded as a good proxy for drug-acquisition costs. *Id.* at 21a-23a. By contrast, the court observed that petitioners had identified "no other 'purpose' that could permissibly support an adjustment." *Id.* at 24a. In particular, the court rejected petitioners' argument that only a hospital's "overhead costs" may be taken into account when HHS adjusts rates under subclause (II). *Id.* at 25a.

The court of appeals likewise rejected petitioners' contention that subclause (I)—which requires HHS to set rates based on hospital acquisition cost, taking into account survey data—implicitly prohibits HHS from using reliable cost data to make rate adjustments under subclause (II). Pet. App. 24a. The court explained that nothing in the statutory text or structure "foreclose[s] an adjustment to ASP under subclause (II) that is based on reliable cost measures" or "obligate[s HHS] to continue reimbursing 340B hospitals for [covered drugs] in amounts substantially exceeding their costs" if HHS does not conduct a cost survey. *Id.* at 20a.

The court of appeals similarly rejected petitioners' contention that the rate adjustment was "simply too large and sweeping to qualify as an 'adjustment.'" Pet. App. 29a. The court explained that, "[e]ven if there are limits to what HHS could permissibly consider an 'adjustment,' that line has not been crossed here," given that HHS "acted on a conservative estimate drawn from data of undisputed reliability." *Id.* at 29a-30a.

c. Judge Pillard dissented on the merits. She concluded that HHS lacks authority to bring the rate paid to 340B hospitals in line with their acquisition costs unless HHS collects the hospital survey data described in subclause (I). See Pet. App. 31a-36a. She indicated that she would interpret the adjustment authority in subclause (II) "as primarily cross-referencing incremental modifications like the overhead-cost adjustment described in subparagraph (E)." *Id.* at 36a.

SUMMARY OF ARGUMENT

The decision below should be affirmed for either of two reasons. First, judicial review is precluded by the OPPS statute, 42 U.S.C. 1395*l*(t)(12). Alternatively, if the Court reaches the merits, the rate adjustments adopted by HHS were within its express statutory authority under 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II).

I. In adopting the OPPS, Congress revised Medicare Part B reimbursement in several significant ways. It tied reimbursement rates for outpatient services to the average costs of providing those services—determined by HHS in advance—which gives hospitals incentives to provide services more efficiently and control costs. It required HHS to make annual adjustments to OPPS components in a budget-neutral manner. And to protect those key features of the program, it precluded review of generally applicable OPPS components.

Both the text and rationale of the OPPS preclusion provision apply with full force to the rate adjustments at issue here. In applying paragraph (14)'s methodology to adjust the annual reimbursement rates for covered drugs, HHS necessarily engaged in both "development of the classification system under paragraph (2)" of the OPPS statute and "periodic adjustments made under paragraph [(9)]." Review is accordingly precluded by 42 U.S.C. 1395*l*(t)(12)(A) and (C). Allowing judicial invalidation of those adjustments would directly undermine hospitals' reliance on the predetermined rates, and it would raise the prospect of highly disruptive retroactive adjustments to other OPPS rates to achieve budget neutrality. That is precisely the sort of unmanageable "quagmire" Congress adopted the preclusion provision to prevent. Pet. App. 84a.

II. If the Court reaches the merits, it should uphold the rate adjustments. Under the relevant statutory provisions, HHS must set reimbursement rates equal to drug-acquisition costs if it has specified survey data—or, if such data are not available, based on average price "as calculated and adjusted by the Secretary as necessary for purposes of" paragraph (14). 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II). It is undisputed that survey data were not available here, so the agency proceeded under subclause (II). HHS then "calculated" the reimbursement rate based on average price, and "adjusted" it to reflect the substantial discounts that 340B hospitals receive. *Ibid.* As the court of appeals correctly held, that approach fully complies with the text of subclause (II).

Petitioners contend that aligning reimbursement rates with drug-acquisition costs is not among the "purposes of" paragraph (14) that HHS may pursue under subclause (II), but that argument has numerous flaws.

It is difficult to accept that cost-based reimbursement is not among the "purposes of" paragraph (14), when that is the payment method that paragraph (14) expressly prescribes in subclause (I). Moreover, as the agency has long recognized and independent studies have confirmed, subclause (II) is designed so that it too generally produces a reimbursement rate that approximates acquisition cost—a result that makes sense given that Congress created subclause (II) as a fallback mechanism for HHS to use when survey data are not available and it cannot proceed under subclause (I).

Petitioners contend that subclause (I) sets forth the exclusive mechanism for cost-based reimbursement. But that is not what the statute says, and petitioners accept that subclause (II) aligns reimbursements with acquisition costs in most circumstances. Petitioners' position is that Congress compelled HHS to make reimbursements *less* accurate—and far above hospitals' costs—in this circumstance by ignoring the effect of 340B discounts, even though HHS has reliable data supporting a cautious downward adjustment that would align reimbursements with costs and enable Medicare beneficiaries to save on copayments. Petitioners identify nothing in the text, structure, history, or purpose of the OPPS to support that result.

The most natural and straightforward reading of the statutory text supports HHS's position, and the Court can resolve the case on that basis. It would also be appropriate to defer to the agency's interpretation under *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), as the Court previously has done in upholding HHS's interpretations of the Medicare Act. HHS adopted the rates at issue here through notice-and-comment rulemaking pursuant to

an express delegation of statutory authority, and the agency thoroughly addressed a matter within its expertise under the complex Medicare program. The ultimate question is whether HHS permissibly considered drug-acquisition costs in setting the challenged reimbursement rates. The agency did, and the decision below should accordingly be affirmed.

ARGUMENT

I. THE OPPS STATUTE PRECLUDES REVIEW OF THE CHALLENGED RATE ADJUSTMENTS

A. Congress Precluded Review Of OPPS Components To Ensure A Workable Reimbursement Scheme

In enacting the OPPS, Congress revamped the hospital outpatient reimbursement process with the "goal of controlling Medicare Part B costs." *American Hosp. Ass'n* v. *Azar*, 964 F.3d 1230, 1234 (D.C. Cir. 2020) (*AHA*), cert. denied, 141 S. Ct. 2853 (2021). The OPPS advances that objective principally "in two ways." *Ibid.* First, it requires reimbursement for covered services at predetermined rates, set annually by HHS based on the average cost of providing those services. See *ibid.* That approach "encourages hospital efficiency," which limits costs. *Ibid.* Second, the OPPS directs that adjustments to predetermined rates be made in a budget-neutral manner. See *ibid.* Thus, if HHS adjusts rates upward for one class of services, it must correspondingly adjust rates downward for others. That requirement further limits Medicare's "expenditure growth." *Id.* at 1235.

The OPPS did not eliminate the statutory right of a hospital to contest a reimbursement determination with HHS and then in court. 42 U.S.C. 1395ff(b); see, *e.g.*, *Shalala* v. *Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 7-9 (2000). Congress did, however, limit the

issues that a hospital can raise in such a challenge. Of central relevance here, Congress provided that "[t]here shall be no administrative or judicial review" of OPPS components, including:

> (A) the development of the classification system under paragraph (2), including the establishment of groups and relative payment weights for covered OPD [*i.e.*, outpatient] services, of wage adjustment factors, other adjustments, and methods described in paragraph (2)(F);
>
> (B) the calculation of base amounts under paragraph (3); and
>
> (C) periodic adjustments made under paragraph [(9)].

42 U.S.C. 1395*l*(t)(12). Congress thus allowed hospitals to challenge *individualized* determinations (such as a finding that a hospital's documentation did not support its reimbursement request), while prohibiting "administrative or judicial review of *the prospective payment system*." H.R. Rep. No. 149, 105th Cong., 1st Sess. 724 (1997) (House Report). HHS's regulations have accordingly long provided that a hospital cannot seek review of "[a]ny issue regarding the computation of the payment amount * * * *of general applicability* for which [HHS] * * * has sole responsibility under Part B." 42 C.F.R. 405.926(c) (emphasis added).

By protecting the central determinations underlying the OPPS—the predetermined rates that must be adjusted annually in budget-neutral fashion—the preclusion provision enables a workable reimbursement scheme. See *Amgen Inc.* v. *Smith*, 357 F.3d 103, 112-113 (D.C. Cir. 2004). The provision reflects the reality that, if thousands of hospitals could sue to invalidate the

hundreds of OPPS determinations or adjustments that HHS makes every year, the "efficient operation of the complex prospective payment system" that Congress designed would be practically impossible. *Id.* at 112.

Specifically, because judicial review would often take more than a year, invalidation of an OPPS component "could result in the retroactive ordering of payment adjustments after hospitals have already received their payments for the year." *Amgen*, 357 F.3d at 112. In addition, because of the budget-neutrality requirement, "judicially mandated changes in one payment rate would affect the aggregate impact of the Secretary's decisions by requiring offsets elsewhere." *Ibid.* The agency would have to figure out how to make those offsets while simultaneously revising the OPPS components for the coming year—a Herculean task that could turn into a Sisyphean one. All the while, hospitals would lack clarity about the governing reimbursement rates, thereby undercutting the premise that they will pursue efficiency based on knowledge of predetermined rates. See *AHA*, 964 F.3d at 1234. As Congress recognized, preclusion is necessary to avoid "the havoc that piecemeal review of OPPS payments could bring about." *Amgen*, 357 F.3d at 112.

Importantly, precluding judicial review of OPPS components does not leave HHS unsupervised in implementing the program. In making the required annual adjustments, see 42 U.S.C. 1395*l*(t)(9), HHS proceeds through notice-and-comment rulemaking, see 42 U.S.C. 1395hh(a)(2), which affords "affected parties fair warning of potential changes in the law and an opportunity to be heard on those changes," *Azar* v. *Allina Health Servs.*, 139 S. Ct. 1804, 1816 (2019). In addition, Congress itself attends closely to implementation of the

OPPS, regularly making amendments at a minute level of detail. In 2013, for example, Congress added a "[s]pecial payment rule" to the OPPS statute explaining when HHS should reduce the payment rate "for stereotactic radiosurgery, complete course of treatment of cranial lesion(s) consisting of 1 session that is multi-source Cobalt 60 based." 42 U.S.C. 1395*l*(t)(16)(D)(i)(I); see American Taxpayer Relief Act of 2012, Pub. L. No. 112-240, § 634, 126 Stat. 2313, 2355. Such extensive legislative supervision underscores that, in precluding judicial review of OPPS components, Congress ensured that review would be "reserved solely for [itself]." *Painter* v. *Shalala*, 97 F.3d 1351, 1356 (10th Cir. 1996) (discussing a Medicare preclusion provision).

B. The OPPS Preclusion Provision Applies To The Rate Adjustments At Issue Here

Whether "a particular statute precludes judicial review" depends on "its express language," as well as "the structure of the statutory scheme, its objectives, its legislative history, and the nature of the administrative action involved." *Block* v. *Community Nutrition Inst.*, 467 U.S. 340, 348 (1984); see, *e.g.*, *Thryv, Inc.* v. *Click-To-Call Techs., LP*, 140 S. Ct. 1367, 1373-1374 (2020) (finding judicial review precluded). Here, those sources of meaning demonstrate that Congress barred "administrative or judicial review" of the rate adjustments that petitioners challenge. 42 U.S.C. 1395*l*(t)(12).

1. First, as a textual matter, the rate adjustments at issue are covered by the preclusion-of-review provision because they are part of HHS's "development of the classification system under paragraph (2), including the establishment of groups and relative payment weights for covered OPD services." 42 U.S.C. 1395*l*(t)(12)(A). A covered drug under paragraph (14) is defined as one

"for which a separate ambulatory payment *classification group* (APC) has been established." 42 U.S.C. 1395*l*(t)(14)(B)(i) (emphasis added). The authority to make those classification groups comes from paragraph (2), which authorizes HHS to "develop a classification system for covered OPD services" and "establish groups of covered OPD services[] within th[at] classification system." 42 U.S.C. 1395*l*(t)(2)(A)-(B). In setting the rates at issue, HHS thus necessarily developed "the classification system under paragraph (2)." 42 U.S.C. 1395*l*(t)(12)(A); see Pet. App. 38a (Pillard, J., dissenting) (recognizing that HHS had "established a *new subclassification* for drugs purchased by 340B providers") (citation omitted). Review is accordingly precluded by subparagraph (12)(A).

Second, and independently, the challenged rate adjustments are covered by the preclusion-of-review provision because they are "periodic adjustments made under paragraph" (9), 42 U.S.C. 1395*l*(t)(12)(C)—the provision requiring HHS to annually review and adjust OPPS components, 42 U.S.C. 1395*l*(t)(9). HHS expressly relied on paragraph (9) in promulgating the annual adjustments at issue, see 82 Fed. Reg. at 52,361-52,362, and no other provision requires annual revision of the rates for covered drugs. The cross-references between paragraphs (9) and (14), moreover, mandate that rates set by applying paragraph (14)—including those at issue here—are subsidiary parts of adjustments "under paragraph (9)." 42 U.S.C. 1395*l*(t)(14)(H); see 42 U.S.C. 1395*l*(t)(9)(B). Review is accordingly barred by subparagraph (12)(C).

2. The structure, "purpose[,] and design" of the OPPS "strongly reinforce [that] conclusion." *Thryv*, 140 S. Ct. at 1374; see *Block*, 467 U.S. at 349; *United*

States v. *Erika, Inc.*, 456 U.S. 201, 206-211 (1982) (finding preclusion under Medicare statute).

The OPPS preclusion provision ensures that hospitals can rely on the predetermined rates HHS sets, and it avoids "the havoc that piecemeal review of OPPS payments could bring about." *Amgen*, 357 F.3d at 112. Those considerations apply with full force to rates set for covered drugs. Preventing such "disrupt[ion of a] complex and delicate administrative scheme" is precisely the kind of objective this Court has recognized in upholding the statutory preclusion of judicial review. *Block*, 467 U.S. at 348; see, *e.g.*, *Thryv*, 140 S. Ct. at 1376 (preclusion to avoid retroactively "nullifying" an agency's "thoroughgoing determination" in a complex statutory scheme); *Cuozzo Speed Techs., LLC* v. *Lee*, 136 S. Ct. 2131, 2140 (2016) (preclusion to prevent complex agency determinations from being "unwound").

This case illustrates the disruption that judicial review of annual rates for covered drugs could unleash. As noted above, HHS—acting pursuant to the budget-neutrality requirement—redistributed the $1.6 billion per year in savings that resulted from the rate adjustments at issue by increasing other OPPS payment rates by 3.2%. In this suit, petitioners sought an order requiring HHS to "pay 340B hospitals the full" $1.6 billion per year, *without* recouping the payments made as the result of the offsetting 3.2% rate increase. D. Ct. Doc. 37, at 8-11 (Feb. 14, 2019); see Pet. Br. 28-29. Meanwhile, the Federation of American Hospitals explained that the hospitals that received the 3.2% rate increase had "relied on [it] and were properly paid." D. Ct. Doc. 38, at 6 (Feb. 8, 2019). For its part, the district court declined to order any remedy, declaring the issue "a quagmire that may be impossible to navigate." Pet.

App. 84a. Although the court recognized the problem, it neglected the solution that Congress provided: rather than trying to navigate a quagmire, the court should have dismissed the suit as precluded.

C. The Preclusion Analysis Advanced By Petitioners And The Court Of Appeals Is Mistaken

Petitioners contend (Br. 16-31) that the OPPS preclusion provision does not apply to the rate adjustments at issue here. That analysis is mistaken.

1. Petitioners begin by emphasizing the "'presumption' favoring judicial review of administrative action." Br. 16 (quoting *Mach Mining, LLC* v. *EEOC*, 575 U.S. 480, 486 (2015)); see Pet. App. 8a-9a. But that presumption "is just that—a presumption." *Block*, 467 U.S. at 349. "[L]ike all presumptions used in interpreting statutes," it "may be overcome by specific language." *Ibid.; s*ee, *e.g.*, *Thryv*, 140 S. Ct. at 1373-1376; *Cuozzo*, 136 S. Ct. at 2139-2142. And here, Congress used language that is unmistakably specific and clear: "[t]here shall be no administrative or judicial review," 42 U.S.C. 1395*l*(t)(12), of OPPS components.

This is accordingly not a case in which the Court is asked to infer preclusion from statutory silence. Cf. *Mach Mining*, 575 U.S. at 487-489 (declining to make such an inference). Instead, preclusion is mandated by "the plain text of § (t)(12)." *Amgen*, 357 F.3d at 112. The court of appeals' extensive and seemingly dispositive reliance on a presumption in favor of review, see, *e.g.*, Pet. App. 17a (reasoning that it is "at least possible, if not probable, that Congress" permitted judicial review, and that the government "at a minimum, is not *clearly* correct"), was thus mistaken.

2. Petitioners assert (Br. 17) that, if Congress had meant to preclude review of HHS's determination of the

OPPS components, it "could easily have precluded judicial review across the board in Section 1395*l*." But a flat bar on review of all determinations under Section 1395*l* would have eliminated review of the individual reimbursement determinations that Congress sought to preserve. See pp. 20-21, *supra*. Precluding "administrative or judicial review of the prospective payment *system*," while allowing review of individual reimbursement determinations, required drafting a preclusion provision that covered only the systemic components of the OPPS. House Report 724 (emphasis added). That is what Congress did, which is why HHS has always understood the preclusion provision to bar review only of OPPS determinations "of general applicability." 42 C.F.R. 405.926(c).

Petitioners portray paragraph (14) as a "self contained" provision that does not have "anything to do" with the determinations under paragraphs (2) and (9) of which Congress precluded review. Pet. Br. 20, 23; see Pet. App. 15a, 17a. But paragraph (14) is not an island. Neither petitioners nor the courts below have explained how HHS could carry out the direction in paragraph (14) outside the "classification system under paragraph (2)." 42 U.S.C. 1395*l*(t)(12)(A). Nor does any provision other than paragraph (9) require annual adjustment of the rates at issue here. Petitioners suggest (Br. 21) that paragraph (14) itself includes such a requirement, but the language they cite refers only to the "year" in which HHS sets the relevant rate. 42 U.S.C. 1395*l*(t)(14)(A)(iii). Petitioners may be correct that paragraph (14) reflects an assumption that HHS will adjust the rate every "year." *Ibid.* But that assumption comes from the annual-adjustment direction in *paragraph (9)*—which confirms that review is precluded.

For similar reasons, it is immaterial that the preclusion directive in paragraph (12) does not explicitly mention paragraph (14). See Pet. Br. 24-27. Although Congress has on some occasions included express-preclusion language in adding certain other provisions to the OPPS statute, see *ibid.*, it had no need to so when it added paragraph (14). As discussed above, paragraph (14) provides specific instructions to HHS on how to carry out its paragraph (2) and (9) authorities. Moreover, paragraph (14) grew out of the pass-through payment system for drugs previously established by paragraph (6). See 42 U.S.C. 1395*l*(t)(14)(B)(i)(II). As petitioners observe (Br. 25), paragraph (6) is one of the provisions for which Congress had previously established preclusion. See 42 U.S.C. 1395*l*(t)(12)(E). That legislative backdrop reinforces that Congress expected review of determinations applying paragraph (14) to be precluded as well.[4]

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[4] The court of appeals relied on the fact that HHS did not make the adjustments at issue here under 42 U.S.C. 1395*l*(t)(2)(E), which provides authority to make "adjustments as determined to be necessary to ensure equitable payments." See Pet. App. 15a. It is true that the agency did not rely on that authority here, because it had ample authority under 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II). See Part II, *infra*. But to the extent the court concluded that HHS *could not* adjust the rates at issue here pursuant to subparagraph (2)(E), the court was mistaken. Nothing in either that provision or the relevant provisions of paragraph (14) prevents HHS from using the equitable-adjustment authority in subparagraph (2)(E) to make an adjustment equivalent to the one it made here. And if HHS had proceeded in that manner, review of its adjustment would have been precluded by 42 U.S.C. 1395*l*(t)(12)(A), which expressly refers to "other adjustments" under paragraph (2). See *Amgen*, 357 F.3d at 107, 114-116; see also *AHA*, 964 F.3d at 1244. That judicial review of an equivalent adjustment would have been precluded in that scenario underscores that it is precluded here too.

3. Petitioners similarly have no persuasive explanation for why Congress, having generally precluded judicial review of OPPS components, would allow review of the rates for covered drugs. Petitioners note (Br. 18) that paragraph (14) includes highly specific directions that affect billions of dollars in reimbursements. But the same is true of many OPPS determinations that petitioners apparently accept are unreviewable. See, *e.g.*, 42 U.S.C. 1395*l*(t)(3) (providing detailed instructions on the calculation of reimbursement base amounts).

Petitioners also downplay the disruption that would result from judicial invalidation of years-old reimbursement rates for covered drugs. They acknowledge (Br. 23) that the rates HHS sets for covered drugs must "be taken into account" when the agency makes budget-neutral adjustments under paragraph (9). See 42 U.S.C. 1395*l*(t)(14)(H). But in their view (Br. 23-24), that express *inclusion* of paragraph (14) determinations in the budget-neutrality requirement suggests that adjustments to rates for covered drugs should be treated as *separate* from the budget-neutral adjustments made under paragraph (9). That logic does not follow; the textual interconnections between paragraphs (14) and (9) instead demonstrate that invalidating the rates at issue here would unleash the "havoc" that Congress adopted the preclusion provision to avoid. *Amgen*, 357 F.3d at 112.

Petitioners contend (Br. 29) that "courts have approved judicial review of similar determinations in the past—and the sky has not fallen." But some of the cases they cite (Br. 29-30) *upheld* the agency's determinations, and in the 24-year history of the OPPS, the D.C. Circuit has *never* invalidated an OPPS rate. See, *e.g.*, *AHA*, 964 F.3d at 1246; *Amgen*, 357 F.3d at 118. Other

cited cases did not implicate the budget-neutrality requirement, see *Shands Jacksonville Med. Ctr., Inc.* v. *Azar*, 366 F. Supp. 3d 32, 62 (D.D.C. 2018), or did not order any additional payments, see *H. Lee Moffitt Cancer Ctr. & Research Inst. Hosp., Inc.* v. *Azar*, 324 F. Supp. 3d 1, 19 (D.D.C. 2018). And while petitioners briefly assert (Br. 28-29) that the budget-neutrality requirement would not compel retrospective adjustments to offset the payments they seek, that is not how the district court understood the case. See Pet. App. 108a ("if the Secretary were to retroactively raise the 2018 and 2019 340B rates, budget neutrality would require him to retroactively lower the 2018 and 2019 rates for other Medicare Part B products and services").

Petitioners relatedly suggest (Br. 29) that HHS could devise a remedy that achieves budget neutrality by reducing payments in future years. But the statute requires budget-neutrality in a particular "year." 42 U.S.C. 1395*l*(t)(9)(B). And petitioners' position would undermine hospitals' reliance on predetermined reimbursement rates, which is central to the OPPS's objective of increasing cost-efficiency. See p. 20, *supra*.

4. Finally, petitioners briefly contend (Br. 30-31) that, even if the OPPS preclusion *does* cover the rate adjustments at issue, judicial review would *still* be available because the adjustment exceeded HHS's statutory authority. That suggestion—that review of an agency's action on the merits is barred only if a court concludes that the agency is correct on the merits—effectively erases the preclusion provision. This Court has squarely rejected such efforts, explaining that an express preclusion provision cannot be overcome merely by alleging that the agency's action "exceeded the agency's statutory authority." *Board of Governors*

of the Fed. Reserve Sys. v. *MCorp Fin., Inc.*, 502 U.S. 32, 43 (1991); see, *e.g.*, *Fresno Cmty. Hosp. & Med. Ctr.* v. *Cochran*, 987 F.3d 158, 162 (D.C. Cir. 2021) (concluding, in a case under the Medicare statute, that an argument that courts may "'disregard statutory bars on judicial review' when the agency has violated the underlying statute * * * would essentially remove the statutory bar against judicial review") (citation omitted). To the extent earlier circuit decisions treat the scope of an express preclusion provision as coterminous with the merits, see *Amgen*, 357 F.3d at 114, they are irreconcilable with both Congress' and this Court's direction. "[N]o administrative or judicial review," 42 U.S.C. 1395*l*(t)(12), means no administrative or judicial review.

II. THE CHALLENGED RATE ADJUSTMENTS ARE WITHIN THE AGENCY'S STATUTORY AUTHORITY

If the Court reaches the merits, it should uphold the challenged rate adjustments because they are within HHS's authority under the OPPS statute.

A. HHS Permissibly Exercised Its Statutory Authority To Adjust The Price-Based Drug Reimbursement Rate "As Necessary For Purposes Of" Paragraph (14)

1. The OPPS statute generally requires HHS to set Medicare payment rates based on the average cost of providing a particular service. 42 U.S.C. 1395*l*(t)(2)(C). Congress followed that model when it added paragraph (14) in 2003. After giving one-time directions for calculating the reimbursement rates for covered drugs in 2004 and 2005, see 42 U.S.C. 1395*l*(t)(14)(A)(i)-(ii), Congress provided instructions for HHS to use beginning in 2006. Those instructions are central to this case.

Congress's primary instruction, in subclause (I), requires HHS to set the reimbursement rate for covered

drugs at "the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group * * *), as determined by the Secretary taking into account the hospital acquisition cost survey data" that Congress directed GAO and HHS to collect. 42 U.S.C. 1395*l*(t)(14)(A)(iii)(I); see 42 U.S.C. 1395*l*(t)(14)(D) (elaborating survey directions).

Congress also anticipated that such acquisition cost data might not always be available, see, *e.g.*, GAO-06-372, at 5-7 (describing shortcomings in initial survey and advising HHS that regular surveys "would not be practical"), so it established subclause (II) as a backup mechanism for HHS to set reimbursement rates for covered drugs without survey data. Subclause (II) directs HHS to set the rate at "the average price for the drug in the year established under" a cross-referenced provision that takes into account many drug discounts. 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II); see 42 U.S.C. 1395w-3a(c)(2)(A). As noted, that provision prescribes a rate of ASP+6%, which is generally a good proxy for hospital acquisition costs. 42 U.S.C. 1395w-3a(b)(1)(A); see pp. 7-8, *supra*. That rate can then be "adjusted by the Secretary as necessary for the purposes of" paragraph (14). 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II).

By directing HHS to set reimbursement rates at slightly above covered drugs' average price, taking into account many discounts, Congress in subclause (II) established a backup mechanism for setting reimbursement rates that closely approximated its primary mechanism—paying hospitals for covered drugs' "average acquisition cost." 42 U.S.C. 1395*l*(t)(14)(A)(iii)(I). Further highlighting Congress's focus on hospital costs, subclauses (I) and (II) are both "subject to subpara-

graph [(14)](E)," 42 U.S.C. 1395*l*(t)(14)(A)(iii), which allows HHS to adjust the reimbursement rate to account for "overhead and related expenses," 42 U.S.C. 1395*l*(t)(14)(E)(i).

2. The rate adjustments at issue here represent a straightforward application of paragraph (14)'s text. Because the "hospital acquisition cost data" referenced in subclause (I) "[were] not available," HHS proceeded under subclause (II). As directed by that provision, HHS "calculated" the average price for covered drugs as "established" under 42 U.S.C. 1395w-3a: ASP+6%. The agency set that as the reimbursement rate for most covered drugs, reiterating its longstanding explanation that an ASP+6% rate generally represents the best proxy for "average hospital acquisition costs." 82 Fed. Reg. at 52,501; see *id.* at 52,509.

HHS then "adjusted" the rate from ASP+6% to ASP-22.5% for covered drugs acquired by 340B hospitals at substantial discounts not taken into account under 42 U.S.C. 1395w-3a. The agency determined that such an adjustment was "necessary for purposes of" paragraph (14), 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II), to more accurately reflect those hospitals' acquisition costs, see 82 Fed. Reg. at 52,362, 52,494-52,509. The agency explained that the adjustment would lower out-of-pocket copayments for Medicare beneficiaries who receive covered drugs from 340B hospitals and reduce the incentive for those hospitals to overutilize covered drugs. See *ibid.*

3. The central statutory question is whether the "purposes of" paragraph (14) that HHS may pursue under subclause (II) include accurately reflecting hospitals' costs of acquiring covered drugs. 42 U.S.C.

1395*l*(t)(14)(A)(iii)(II). As the court of appeals explained, the statutory text, structure, and purpose—as well as the agency's longstanding practice and common sense—all demonstrate that paragraph (14) includes such a purpose. See Pet. App. 21a-28a.

First, the text of paragraph (14) makes clear that one of its primary "purposes" is to ensure that reimbursement rates reflect drug-acquisition costs. 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II). Congress's lead instruction under paragraph (14) directs HHS to set rates equal to "the acquisition cost" after taking into account "the hospital acquisition cost survey data" that Congress directed the GAO and HHS to collect. 42 U.S.C. 1395*l*(t)(14)(A)(iii)(I). That statutory text "alone indicates that Congress's primary goal is to reimburse providers for their acquisition costs." Pet. App. 21a. And while subclause (II) does not expressly prescribe reliance on acquisition costs, it cross-references a provision that sets drug reimbursement at 106% of ASP, adjusted for many discounts—a rate that has long been understood as a good proxy for acquisition costs. Thus, Congress's primary and secondary reimbursement directions in paragraph (14) both demonstrate the "purposes of th[at] paragraph" to tie reimbursement to acquisition costs. 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II).

Congress's focus on ensuring that reimbursement rates reflect hospital costs is evident throughout the OPPS. See Pet. App. 22a. Paragraph (2)—which sets forth the "[s]ystem requirements" for the OPPS—instructs HHS to use "data from the most recent available *cost reports*" to establish relative payment weights for covered services "based on median (or, at the election of the Secretary, mean) *hospital costs*." 42 U.S.C. 1395*l*(t)(2)(C) (emphasis added). Paragraph (2) further

instructs HHS to adjust reimbursement rates in light of differences in "*labor-related costs* across geographic regions." 42 U.S.C. 1395*l*(t)(2)(D) (emphasis added). It also instructs HHS to make "outlier adjustments" in certain circumstances to "approximate the *marginal cost of care*" beyond the otherwise-applicable limit. 42 U.S.C. 1395*l*(t)(2)(E) and (5)(B) (emphasis added). Likewise, paragraph (9)—which requires HHS to adjust OPPS rates not less than annually—instructs the agency to take into account "*new cost data*." 42 U.S.C. 1395*l*(t)(9)(A) (emphasis added).

Broader principles of Medicare reimbursement further support the agency's conclusion that the "purposes of" paragraph (14) include aligning hospital payments with drug-acquisition costs. Even before enactment of the OPPS, an "overriding purpose in the Medicare scheme" was to ensure "reasonable (not excessive or unwarranted) cost reimbursement." *Regions Hosp.* v. *Shalala*, 522 U.S. 448, 460 (1998). Indeed, the very concept of reimbursement is linked to cost. An employee who submits an expense report expects to be reimbursed for costs incurred. If an employer adopted a policy under which reimbursement was based principally on costs incurred as demonstrated by a hotel receipt—or, if a receipt is unavailable, on the average nightly hotel price as adjusted for relevant discounts—it would be clear that the purpose of the policy is to reimburse employees for costs. HHS's determination that paragraph (14)'s "purposes" encompass the objective of aligning drug reimbursements with drug-acquisition costs is thus supported by statutory—and ordinary—meaning.

B. Petitioners' Contentions That The Rate Adjustments Exceeded HHS's Statutory Authority Lack Merit

Petitioners advance a different and strained view of the statute, in which aligning reimbursement rates with drug-acquisition costs is not one of the "purposes of" paragraph (14) that HHS can permissibly pursue under subclause (II). Petitioners' position is thus that Congress *compelled* HHS, when proceeding under subclause (II), to knowingly and dramatically overpay hospitals for drugs acquired through the 340B program, even when the agency has reliable data that would support a lower rate. Petitioners offer no account of paragraph (14)'s purposes that would justify that counterintuitive result. Their recognition (Br. 43-44) that improving price accuracy using "information at the agency's disposal" is among the valid "purposes of" paragraph (14) *supports* the adjustments adopted here. And petitioners' alternative contention (Br. 36-39) that the adjustments at issue here are too big to be considered adjustments has no foundation in the statute or precedent.

1. Aligning reimbursement rates with drug-acquisition costs for 340B hospitals is a "purpose[] of" paragraph (14) that HHS may pursue under subclause (II)

As the court of appeals emphasized, petitioners do not dispute many key aspects of HHS's statutory interpretation. Pet. App. 19a-20a. To begin, it is undisputed that hospital acquisition cost survey data were not available when HHS set rates for the covered drugs for 2018 and 2019, so HHS accordingly had to set reimbursement rates under subclause (II). See *ibid.*; Pet. Br. 32-34. Petitioners also do not contest the price-based rate that HHS set for non-340B hospitals under subclause (II) or the agency's conclusion that it reflected "average

hospital acquisition costs." 82 Fed. Reg. at 52,501. Nor do petitioners dispute that a downward adjustment to that rate for 340B hospitals would reflect the substantial discounts that they receive. Pet. App. 20a.[5]

Instead, petitioners' principal argument (Br. 32-36, 41-46) is that bringing reimbursements into line with acquisition costs for 340B hospitals is not among the "purposes of" paragraph (14) that HHS may pursue under subclause (II). That argument is mistaken. In short, aligning reimbursement rates with drug-acquisition costs is central among the "purposes of" paragraph (14). And nothing in that paragraph or any other statutory provision prevents HHS from pursuing that purpose for 340B hospitals under subclause (II).

a. The "purposes of" paragraph (14) include aligning reimbursement rates with drug-acquisition costs

i. As an initial matter, it is difficult to accept that aligning reimbursement rates with drug-acquisition costs is not among the "purposes of" paragraph (14), when the lead reimbursement mechanism prescribed by paragraph (14) is setting rates at "average acquisition cost," 42 U.S.C. 1395*l*(t)(14)(A)(iii)(I), and the backup mechanism begins with setting rates at ASP+6%—a measure that generally approximates acquisition costs.

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[5] In a footnote, petitioners question (Br. 43 n.14) whether the data that HHS relied on accurately captured the size of their 340B discounts. But as HHS emphasized when it finalized the OPPS rule for 2018, it did not receive any comments arguing that a figure different from ASP-22.5% would better reflect the acquisition costs for drugs acquired by 340B hospitals. 82 Fed. Reg. at 52,500. That rate, moreover, is a "lower bound estimate" of the 340B discount's size. *Id.* at 52,498. The court of appeals accordingly limited its holding to "specific circumstances" in which HHS bases an adjustment on "reliable" data of the kind that it used here. Pet. App. 24a, 28a.

Petitioners' account of paragraph (14)'s purposes is thus contrary to its text—in addition to the structure of the OPPS and Medicare's design more generally. See Pet. App. 21a; pp. 33-35, *supra*.

Moreover, petitioners acknowledge (Br. 42) that at least one "purpose of paragraph (14) is * * * ensuring accuracy in carrying out Congress's specific reimbursement-rate instructions." In petitioners' view (Br. 43), "if the required cost-survey data is not available and the agency therefore must use" subclause (II) to set reimbursement rates, HHS should "make th[e] average-price amount as accurate as possible given the information at the agency's disposal and the instructions in the statutory provisions that subclause (II) cross-references." That proposal, however, is not meaningfully different from what HHS did here; the agency calculated average price for covered drugs under the cross-referenced provision (42 U.S.C. 1395w-3a), which takes into account many discounts, and then adjusted it downward based on reliable information at the agency's disposal to more accurately reflect the discounts received by 340B hospitals that were not taken into account by the cross-referenced provision.

The implication of petitioners' position thus appears to be that an adjustment to account for 340B discounts would have been consistent with the "purposes of" paragraph (14) if HHS had simply described it entirely in terms of price. But in this context (the effect of a discount on the amount that hospitals pay for covered drugs), no meaningful difference exists between price and cost. See Pet. App. 28a. Petitioners' own position thus underscores that aligning reimbursement rates with the amount hospitals pay for covered drugs is a

"purpose[] of" paragraph (14) that HHS may pursue under subclause (II).

ii. Petitioners also make little effort to defend the narrow reading of the "purposes of" paragraph (14) identified by the dissent below: to make only "incremental modifications" to reflect considerations like overhead costs. Pet. App. 36a. The central flaw in that reading is that subclause (II) refers to "the purposes of this paragraph"—paragraph (14)—as a whole. 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II). And it is not plausible to conclude that the "purposes of" paragraph (14) as a whole are limited to accounting for overhead-cost adjustments and the like. See, *e.g.*, *Cyan, Inc.* v. *Beaver Cty. Emps. Ret. Fund*, 138 S. Ct. 1061, 1070 (2018) (explaining that a statutory reference to a provision "as a whole" should be read as covering the whole provision, not just one part).

Notably, petitioners do not contend that the "purposes of" paragraph (14) referenced in subclause (II) are *limited* to making overhead-cost adjustments. They instead dispute (Br. 43-45) the court of appeals' conclusion that reading subclause (II) to have such a purpose would make it superfluous, given that paragraph (14) separately specifies that subclause (II) is "subject to subparagraph [(14)](E)," 42 U.S.C. 1395*l*(t)(14)(A)(iii), which expressly allows adjustments for "overhead and related expenses," 42 U.S.C. 1395*l*(t)(14)(E)(i). The court's analysis on that point was correct; the dissent's position would "leave subclause (II)'s adjustment authority duplicative of authority already conferred by subparagraph (14)(E)." Pet. App. 25a. But in any event, petitioners fall far short of establishing that overhead and similar cost-based adjustments are the *sole* "purpose[] of" paragraph (14), to

the exclusion of aligning reimbursement rates with the amount that hospitals pay for covered drugs.

b. HHS has authority to align reimbursement rates with drug-acquisition costs under subclause (II)

Because aligning reimbursement rates with hospital acquisition costs is among the "purposes of" paragraph (14), petitioners' position comes down largely to their contention (Br. 32-36, 39-41, 45-46) that HHS cannot rely on that purpose *under subclause (II)*. That is, petitioners suggest that the statute implicitly limits HHS to setting reimbursement rates to reflect acquisition costs if the agency proceeds *under subclause (I)*, by taking into account cost survey data. But that is not what the statute says; it contradicts the agency's consistent and unchallenged practice; and it makes little sense as an account of the statutory scheme.

i. First, and most significantly, the statute does not limit HHS to aligning reimbursement rates with acquisition costs *only* when it proceeds under subclause (I). In the two subclauses at issue, Congress provided alternative directions for two different scenarios: one in which HHS has "hospital acquisition cost survey data" (subclause (I)), and one in which such data "are not available" (subclause (II)). In the first scenario, HHS must take the survey data "into account" when setting rates based on "average acquisition cost." 42 U.S.C. 1395*l*(t)(14)(A)(iii)(I). In the second scenario, HHS must set reimbursements rates based on price, as "adjusted by the Secretary as necessary for purposes of" paragraph (14). 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II). Nothing in the statute says or implies that aligning reimbursements with acquisition costs is not among the "purposes of [paragraph (14)]" that HHS may consider in "adjust[ing]" rates under subclause (II). *Ibid.* As

this Court recognized in interpreting a similar statutory scheme, Congress "by expressly making cost relevant to" regulation under one provision did not "implicitly make[] cost irrelevant to" regulation under a related provision of the same statute. *Michigan* v. *EPA*, 576 U.S. 743, 755 (2015).

Contrary to petitioners' contention (Br. 39), moreover, HHS's decision to set a reimbursement rate that reflects acquisition costs without using survey data does not "break[] sharply from years of agency rate-setting under" this statutory scheme. To the contrary, as outlined above, HHS has set a reimbursement rate that is expressly designed to reflect acquisition costs every year since the beginning of the program in 2006, regardless of whether it proceeded under subclause (I) or subclause (II). See pp. 7-8, *supra*; Pet. App. 21a-22a (explaining that the adjustments here are consistent with the agency's interpretation "all along").

ii. Petitioners' reading depends heavily (Br. 35-36, 45) on the premise that allowing HHS to adjust reimbursement rates to track hospital acquisition costs under subclause (II) would render superfluous subclause (I) and the related survey directions in subparagraph (D). But it would not. Subclause (I) would continue to govern HHS's setting of reimbursement rates when the agency has survey data. And subparagraph (D) would continue to supply the requirements for obtaining that data. Statutory provisions are, of course, "not superfluous" if they still "serve a[] purpose" in the statutory scheme. *Nielsen* v. *Preap*, 139 S. Ct. 954, 969 (2019). All the provisions at issue here do.

As a practical matter, moreover, a survey may be the best and most accurate way to obtain certain information relevant to acquisition costs. In this case, HHS

had an unusually extensive amount of data about acquisition costs incurred by hospitals under the 340B program—a statutorily mandated program run by an agency within HHS. But that will not always (or even often) be the case in other contexts. In those circumstances, a survey may be the only way to ascertain the prices that certain classes of hospitals pay for drugs. See, *e.g.*, GAO-06-372 (reporting survey results for teaching, urban, and large hospitals).

In addition, even when other reliable cost information is available, a survey may allow additional refinement to the reimbursement rate. For example, while the appeal in this case was pending, HHS conducted a survey of 340B hospitals—consistent with the requirements of subparagraph (D)—to determine their acquisition costs of covered drugs. See 85 Fed. Reg. at 86,044-86,045, 86,050. The survey revealed that 340B hospitals are acquiring drugs even more cheaply than the challenged rate of ASP-22.5% anticipates. See *id.* at 86,045 (noting survey results indicating that the average discount is at least 34.7%). As required by subclause (I), HHS took that survey data "into account" when adopting the 2021 rule, 42 U.S.C. 1395*l*(t)(14)(A)(iii)(I), but ultimately decided to continue the ASP-22.5% rate as an appropriate measure of acquisition costs, see 85 Fed. Reg. at 86,045-86,055. Petitioners now suggest (Br. 34 n.11) that the 2020 survey did not comply with subparagraph (D) and that the agency's 2021 rule did not comply with subclause (I). Those allegations highlight that HHS's interpretation does not render those provisions superfluous.

iii. Ultimately, petitioners' position is not driven by a preference for price-based rates over cost-based rates as a matter of policy or statutory interpretation. As

noted, rates set under either subclause (I) or subclause (II) will typically approximate acquisition costs, and petitioners generally accept as much. Petitioners' contentions are instead driven by the fact that the provision cross-referenced by subclause (II) excludes a particular category of steep discounts that benefit petitioners. Their position thus amounts to a claim that that Congress forced HHS to make reimbursement rates less accurate, by dramatically overcompensating one category of hospitals if survey data are unavailable—even though other reliable cost measures are available, and even though the overpayments drive up copayments for Medicare beneficiaries and create incentives to overutilize costly drugs. At bottom, that reading is not a plausible account of the statutory scheme.

c. HHS has authority to vary reimbursement rates by hospital group under subclause (II)

To the extent petitioners make an independent argument (Br. 33, 35-36, 46) that HHS's actions here are unlawful because the agency lacks authority under subclause (II) to vary reimbursement rates by hospital group, that claim also fails. Petitioners observe (Br. 33) that subclause (I) expressly provides authority to vary by hospital group and suggest that the absence of such an express statement in subclause (II) should be understood as an intentional "choice to withhold" similar authority under that provision. But as the court of appeals explained and petitioners do not refute, Congress had no need to specify authority to vary by hospital group in subclause (II) given that it provided broader authority in that subclause (but not subclause (I)) to make adjustments "as necessary for the purposes of" paragraph (14). See Pet. App. 30a-31a; see also 42 U.S.C. 1395*l*(t)(14)(B)(i) (defining a covered drug as one for

which a *separate classification group* is established) (emphasis added).

Petitioners' argument regarding HHS's authority to vary by hospital group thus collapses into their argument about the scope of the "purposes of" paragraph (14). See Pet. Br. 34 (explaining that the several limitations they would impose on HHS's authority "have the same rationale"). For the reasons explained above, the "purposes of" paragraph (14) include aligning reimbursement rates with acquisition costs. Petitioners identify no reason in the statute (or common sense) why Congress would have prevented HHS from tailoring adjustments under subclause (II) to accurately align reimbursements with the acquisition costs of particular hospital groups. Pet. App. 30a-31a.

d. Section 340B does not foreclose the adjustment to reimbursement rates at issue here

Petitioners appear to suggest (Br. 9-10, 40) that the 340B program itself limits HHS's discretion under subclause (II) to make adjustments "as necessary for purposes of" paragraph (14). As explained above, however, the 340B program is not a Medicare program; there is no requirement that drugs purchased through the program be used to treat Medicare beneficiaries; and many entities covered by the program are not hospitals but rather federally funded local clinics or health centers. See *Astra USA, Inc.* v. *Santa Clara County*, 563 U.S. 110, 113-115 (2011); p. 9, *supra*. Section 340B accordingly does not compel any particular level of Medicare reimbursement, let alone substantial overpayments for discounted drugs that would raise beneficiary copayments and adversely affect other hospitals. Indeed, petitioners do not appear to dispute that HHS, proceeding

with survey data under subclause (I), could adopt precisely the same reimbursement rate that it did here without violating Section 340B.

Because the rate adjustments that HHS adopted were cautious, moreover, reimbursements for 340B hospitals "continue to exceed the discounted 340B price" that hospitals receive "under the 340B program." 82 Fed. Reg. at 52,499. To take a simplified example, a 340B hospital that purchases a drug with an average sales price of $1000, discounted by 40%, would pay $600 and be reimbursed $775 (ASP-22.5%). That would leave the hospital ahead by $175. By contrast, a non-340B hospital would pay $1000 and be reimbursed $1060 (ASP+6%), which would leave that hospital ahead by $60. Nothing in the 340B program supports petitioners' position that the 340B hospital must be reimbursed the same $1060, thereby putting it ahead by $460 (almost eight times more than a non-340B hospital). To be sure, 340B hospitals play a vital role by providing care to low-income patients, and they rightly receive significant support from Congress and HHS. But while Congress could have framed Section 340B as a guarantee of particular Medicare payments, it did not. HHS thus correctly concluded that "it is inappropriate for Medicare" —and Medicare beneficiaries via copayments —"to subsidize [340B hospitals] through Medicare payments for separately payable drugs." 82 Fed. Reg. at 52,495.

2. HHS's reduction in the reimbursement rate for 340B hospitals to reflect their substantial discounts is an "adjustment" under subclause (II)

Petitioners alternatively contend (Br. 36-39) that HHS's downward adjustment of 28.5% in the reimbursement rate for 340B hospitals (from ASP+6% to ASP-22.5%) to account for 340B discounts is too large

to be an "adjust[ment]" within the meaning of subclause (II). That claim lacks support.

As a matter of ordinary language, it is hardly atypical to call a reduction of 28.5% an adjustment. See Pet. App. 29a (noting dictionary definitions). And in any event, the critical question is not what the word means in the abstract, cf. Pet. Br. 37 (referring to adjustments of ties or computer monitors), but how it is used in this statutory context, see, *e.g.*, *United States* v. *Briggs*, 141 S. Ct. 467, 470 (2020). Subclause (II) authorizes HHS to adjust the price-based rate for covered drugs "as necessary for purposes of" paragraph (14). As explained above, one of those "purposes" is ensuring that reimbursements track drug-acquisition costs.

Petitioners do not seriously dispute that accomplishing that purpose requires a downward reduction of at least the amount that HHS adopted here; indeed, they concede that a rate change to improve the accuracy of drug prices paid by hospitals would be a permissible exercise of HHS's "adjustment" authority. See p. 38, *supra*. Petitioners also do not suggest that, for example, an *upward* adjustment to reimbursement rates to account for higher wages would cease to be an "adjustment" if it exceeded some particular level. See 42 U.S.C. 1395*l*(t)(2)(D) (directing wage adjustments); see also *Amgen*, 357 F.3d at 117 (declining to "engage in line drawing to determine when 'adjustments' cease being 'adjustments'" for purposes of a related OPPS provision). HHS's "conservative" reduction of 28.5%—based on the "lower bound" of the "minimum" average discount for 340B hospitals, 82 Fed. Reg. at 52,496—thus readily qualifies as an "adjust[ment]" as that term is used in subclause (II).

Petitioners rely (Br. 36-37, 49) on this Court's holding in *MCI Telecommunications Corp.* v. *AT&T*, 512 U.S. 218 (1994), that an agency's decision "to eliminate the tariff-filing requirement entirely" for large portions of an industry could not be considered a "modification" within the meaning of the statute at issue. *Id.* at 229. That comparison instead illustrates the permissibility of HHS's reading. The agency's decision here to reduce a drug reimbursement rate by 28.5% for hospitals receiving even greater discounts on those drugs is not remotely akin to eliminating a statutory requirement entirely—tearing "the heart [out] of" the statutory section, as the *MCI* Court described it. *Ibid.* Because HHS's reduction here served the familiar purpose of aligning rates with costs, it does not even approach such a "radical or fundamental change." *Ibid.*

C. Deference To HHS's Interpretation Is Warranted But Unnecessary To Sustain The Rate Adjustments

1. For the reasons discussed above, the rate adjustments that HHS adopted are proper under the best and most natural reading of subclause (II). Thus, if the Court concludes that review is not precluded and employs "all the standard tools of interpretation," it should sustain the agency's actions. Pet. Br. 47 (quoting *Kisor* v. *Wilkie*, 139 S. Ct. 2400, 2414 (2019)); accord Gov't C.A. Reply Br. 12 ("HHS's interpretation of the statutes that it is charged with administering is * * * correct and, at a minimum, reasonable.").

2. Although the government can prevail without any deference to its interpretation under *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), such deference is warranted.

Petitioners do not dispute that the prerequisites for *Chevron* deference are satisfied. See *United States* v.

Mead Corp., 533 U.S. 218, 229 (2001). HHS adopted the interpretation in question through notice-and-comment rulemaking, as it was required to do. See *Allina*, 139 S. Ct. at 1817. HHS expressly explained why it believed it was acting within its statutory authority. See 82 Fed. Reg. at 52,362, 52,496. And this Court has frequently held that HHS is entitled to deference when interpreting Medicare provisions given the agency's "practical experience in superintending the huge program." *Sebelius* v. *Auburn Reg'l Med. Ctr.*, 568 U.S. 145, 157 (2013); see, *e.g.*, *Regions Hosp.*, 522 U.S. at 457.

This case, moreover, does not present the potential concerns about *Chevron* deference that petitioners and many of their amici assert, because it does not require the Court to "indulge" what petitioners call (Br. 46) "the fiction that Congress implicitly delegated to the agency the power to" resolve a statutory ambiguity. Rather, this case involves an *express* delegation of authority to "the Secretary" to "calculate[] and adjust[]"reimbursement rates "as necessary for purposes of" paragraph (14). 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II); see, *e.g.*, *Cuozzo,* 136 S. Ct. at 2144 (deferring to an agency's decision under an express delegation). As this Court has explained both before and after *Chevron*, the operative question when an agency acts pursuant to such an express delegation is whether the agency's decision is "arbitrary, capricious, or manifestly contrary to the statute," *Auburn Reg'l*, 568 U.S. at 157 (quoting *Chevron*, 467 U.S. at 844), which can occur if (for example) the agency relies on an impermissible factor, see, *e.g.*, *Michigan*, 576 U.S. at 750; *FCC* v. *National Citizens Comm. for Broad.*, 436 U.S. 775, 793 (1978). Here, petitioners' central argument is that HHS relied on an impermissible factor in

making its rate adjustments; the agency's central argument is that it did not. However that dispute is resolved, it presents no occasion to consider any broader issues concerning *Chevron*.

Petitioners assert (Br. 49) that it is "unlikely" that "Congress would have left to the agency's discretion the determination of the shape of the multi-billion-dollar Medicare drug-reimbursement system." But petitioners themselves acknowledge (Br. 2) that "Congress has historically delegated considerable discretion to [HHS] to develop reimbursement methodologies for other services covered by Medicare." Indeed, petitioners accept (Br. 19-20) that Congress has *precluded* judicial review (even deferential review) of HHS's determinations in setting the general components of the OPPS, see 42 U.S.C. 1395*l*(t)(12), which govern massive amounts of Medicare reimbursements. Moreover, as noted above, OPPS rates are interdependent, and they are published in advance of the year in which they will be paid, which allows hospitals to rely on the published rates in determining the mix of services that they will provide. Particularly given Congress's explicit delegation of authority to HHS to "calculate[] and adjust[]" reimbursement rates for purposes of the particular drug program at issue here, 42 U.S.C. 1395*l*(t)(14)(A)(iii)(II), it is difficult to imagine a more unlikely scenario in which to infer that Congress intended for courts to revisit such determinations de novo.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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APPENDIX

1. 42 U.S.C. 256b(a) provides in pertinent part:

Limitation on prices of drugs purchased by covered entities

(a) Requirements for agreement with Secretary

(1) In general

The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs (other than drugs described in paragraph (3)) purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2). Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the "ceiling price"), and shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.

(2) "Rebate percentage" defined

(A) In general

For a covered outpatient drug purchased in a calendar quarter, the "rebate percentage" is the amount (expressed as a percentage) equal to—

(i) the average total rebate required under section 1927(c) of the Social Security Act [42 U.S.C. 1396r-8(c)] with respect to the drug (for a unit of the dosage form and strength involved) during the preceding calendar quarter; divided by

(ii) the average manufacturer price for such a unit of the drug during such quarter.

(B) Over the counter drugs

(i) In general

For purposes of subparagraph (A), in the case of over the counter drugs, the "rebate percentage" shall be determined as if the rebate required under section 1927(c) of the Social Security Act [42 U.S.C. 1396r-8(c)] is based on the applicable percentage provided under section 1927(c)(3) of such Act.

(ii) "Over the counter drug" defined

The term "over the counter drug" means a drug that may be sold without a prescription and which is prescribed by a physician (or other persons authorized to prescribe such drug under State law).

(3) Drugs provided under State medicaid plans

Drugs described in this paragraph are drugs purchased by the entity for which payment is made by the State under the State plan for medical assistance under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.].

(4) "Covered entity" defined

In this section, the term "covered entity" means an entity that meets the requirements described in paragraph (5) and is one of the following:

(A) A Federally-qualified health center (as defined in section 1905(*l*)(2)(B) of the Social Security Act [42 U.S.C. 1396d(*l*)(2)(B)]).

(B) An entity receiving a grant under section 256a[1] of this title.

(C) A family planning project receiving a grant or contract under section 300 of this title.

(D) An entity receiving a grant under subpart II 1 of part C of subchapter XXIV (relating to categorical grants for outpatient early intervention services for HIV disease).

(E) A State-operated AIDS drug purchasing assistance program receiving financial assistance under subchapter XXIV.

(F) A black lung clinic receiving funds under section 937(a) of title 30.

(G) A comprehensive hemophilia diagnostic treatment center receiving a grant under section

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[1] See References in text note below.

501(a)(2) of the Social Security Act [42 U.S.C. 701(a)(2)].

(H) A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988.

(I) An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act [25 U.S.C. 1651 et seq.].

(J) Any entity receiving assistance under subchapter XXIV (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary pursuant to paragraph (7).

(K) An entity receiving funds under section 247c of this title (relating to treatment of sexually transmitted diseases) or section 247b(j)(2) 1 of this title (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to paragraph (7).

(L) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act [42 U.S.C. 1395ww(d)(1)(B)]) that—

(i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low

income individuals who are not entitled to benefits under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] or eligible for assistance under the State plan under this subchapter;

(ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act [42 U.S.C. 1395ww(d)(5)(F)]) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act [42 U.S.C. 1395ww(d)(5)(F)(i)(II)]; and

(iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

(M) A children's hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act [42 U.S.C. 1395ww(d)(1)(B)(iii)], or a freestanding cancer hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(v) of the Social Security Act, that would meet the requirements of subparagraph (L), including the disproportionate share adjustment percentage requirement under clause (ii) of such subparagraph, if the hospital were a subsection (d) hospital as defined by section 1886(d)(1)(B) of the Social Security Act.

(N) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act [42 U.S.C. 1395i-4(c)(2)]), and that meets the requirements of subparagraph (L)(i).

(O) An entity that is a rural referral center, as defined by section 1886(d)(5)(C)(i) of the Social Security Act [42 U.S.C. 1395ww(d)(5)(C)(i)], or a sole community hospital, as defined by section 1886(d)(5)(C)(iii) of such Act, and that both meets the requirements of subparagraph (L)(i) and has a disproportionate share adjustment percentage equal to or greater than 8 percent.

* * * * *

(8) Development of prime vendor program

The Secretary shall establish a prime vendor program under which covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs. If a covered entity obtains drugs directly from a manufacturer, the manufacturer shall be responsible for the costs of distribution.

* * * * *

2. 42 U.S.C. 1395*l*(t) provides:

Payment of benefits

(t) Prospective payment system for hospital outpatient department services

(1) Amount of payment

(A) In general

With respect to covered OPD services (as defined in subparagraph (B)) furnished during a year beginning with 1999, the amount of payment under this part shall be determined under a prospective payment system established by the Secretary in accordance with this subsection.

(B) Definition of covered OPD services

For purposes of this subsection, the term "covered OPD services"—

(i) means hospital outpatient services designated by the Secretary;

(ii) subject to clause (iv), includes inpatient hospital services designated by the Secretary that are covered under this part and furnished to a hospital inpatient who (I) is entitled to benefits under part A but has exhausted benefits for inpatient hospital services during a spell of illness, or (II) is not so entitled;

(iii) includes implantable items described in paragraph (3), (6), or (8) of section 1395x(s) of this title;

(iv) does not include any therapy services described in subsection (a)(8) or ambulance

services, for which payment is made under a fee schedule described in section 1395m(k) of this title or section 1395m(*l*) of this title and does not include screening mammography (as defined in section 1395x(jj) of this title), diagnostic mammography, or personalized prevention plan services (as defined in section 1395x(hhh)(1) of this title); and

(v) does not include applicable items and services (as defined in subparagraph (A) of paragraph (21)) that are furnished on or after January 1, 2017, by an off-campus outpatient department of a provider (as defined in subparagraph (B) of such paragraph).

(2) System requirements

Under the payment system—

(A) the Secretary shall develop a classification system for covered OPD services;

(B) the Secretary may establish groups of covered OPD services, within the classification system described in subparagraph (A), so that services classified within each group are comparable clinically and with respect to the use of resources and so that an implantable item is classified to the group that includes the service to which the item relates;

(C) the Secretary shall, using data on claims from 1996 and using data from the most recent available cost reports, establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B))

based on median (or, at the election of the Secretary, mean) hospital costs and shall determine projections of the frequency of utilization of each such service (or group of services) in 1999;

(D) subject to paragraph (19), the Secretary shall determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner;

(E) the Secretary shall establish, in a budget neutral manner, outlier adjustments under paragraph (5) and transitional pass-through payments under paragraph (6) and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals;

(F) the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services;

(G) the Secretary shall create additional groups of covered OPD services that classify separately those procedures that utilize contrast agents from those that do not; and

(H) with respect to devices of brachytherapy consisting of a seed or seeds (or radioactive source), the Secretary shall create additional groups of covered OPD services that classify such devices separately from the other services (or group of services) paid for under this subsection in a manner reflecting the number, isotope, and radioactive intensity of such devices furnished, including

separate groups for palladium-103 and iodine-125 devices and for stranded and non-stranded devices furnished on or after July 1, 2007.

For purposes of subparagraph (B), items and services within a group shall not be treated as "comparable with respect to the use of resources" if the highest median cost (or mean cost, if elected by the Secretary under subparagraph (C)) for an item or service within the group is more than 2 times greater than the lowest median cost (or mean cost, if so elected) for an item or service within the group; except that the Secretary may make exceptions in unusual cases, such as low volume items and services, but may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 360bb of title 21.

(3) Calculation of base amounts

(A) Aggregate amounts that would be payable if deductibles were disregarded

The Secretary shall estimate the sum of—

(i) the total amounts that would be payable from the Trust Fund under this part for covered OPD services in 1999, determined without regard to this subsection, as though the deductible under subsection (b) did not apply, and

(ii) the total amounts of copayments estimated to be paid under this subsection by beneficiaries to hospitals for covered OPD services in 1999, as though the deductible under subsection (b) did not apply.

(B) Unadjusted copayment amount

(i) In general

For purposes of this subsection, subject to clause (ii), the "unadjusted copayment amount" applicable to a covered OPD service (or group of such services) is 20 percent of the national median of the charges for the service (or services within the group) furnished during 1996, updated to 1999 using the Secretary's estimate of charge growth during the period.

(ii) Adjusted to be 20 percent when fully phased in

If the pre-deductible payment percentage for a covered OPD service (or group of such services) furnished in a year would be equal to or exceed 80 percent, then the unadjusted copayment amount shall be 20 percent of amount determined under subparagraph (D).

(iii) Rules for new services

The Secretary shall establish rules for establishment of an unadjusted copayment amount for a covered OPD service not furnished during 1996, based upon its classification within a group of such services.

(C) Calculation of conversion factors

(i) For 1999

(I) In general

The Secretary shall establish a 1999 conversion factor for determining the medicare OPD fee schedule amounts for each covered

OPD service (or group of such services) furnished in 1999. Such conversion factor shall be established on the basis of the weights and frequencies described in paragraph (2)(C) and in such a manner that the sum for all services and groups of the products (described in subclause (II) for each such service or group) equals the total projected amount described in subparagraph (A).

(II) Product described

The Secretary shall determine for each service or group the product of the medicare OPD fee schedule amounts (taking into account appropriate adjustments described in paragraphs (2)(D) and (2)(E)) and the estimated frequencies for such service or group.

(ii) Subsequent years

Subject to paragraph (8)(B), the Secretary shall establish a conversion factor for covered OPD services furnished in subsequent years in an amount equal to the conversion factor established under this subparagraph and applicable to such services furnished in the previous year increased by the OPD fee schedule increase factor specified under clause (iv) for the year involved.

(iii) Adjustment for service mix changes

Insofar as the Secretary determines that the adjustments for service mix under paragraph (2) for a previous year (or estimates that

such adjustments for a future year) did (or are likely to) result in a change in aggregate payments under this subsection during the year that are a result of changes in the coding or classification of covered OPD services that do not reflect real changes in service mix, the Secretary may adjust the conversion factor computed under this subparagraph for subsequent years so as to eliminate the effect of such coding or classification changes.

(iv) OPD fee schedule increase factor

For purposes of this subparagraph, subject to paragraph (17) and subparagraph (F) of this paragraph, the "OPD fee schedule increase factor" for services furnished in a year is equal to the market basket percentage increase applicable under section 1395ww(b)(3)(B)(iii) of this title to hospital discharges occurring during the fiscal year ending in such year, reduced by 1 percentage point for such factor for services furnished in each of 2000 and 2002. In applying the previous sentence for years beginning with 2000, the Secretary may substitute for the market basket percentage increase an annual percentage increase that is computed and applied with respect to covered OPD services furnished in a year in the same manner as the market basket percentage increase is determined and applied to inpatient hospital services for discharges occurring in a fiscal year.

(D) Calculation of medicare OPD fee schedule amounts

The Secretary shall compute a medicare OPD fee schedule amount for each covered OPD service (or group of such services) furnished in a year, in an amount equal to the product of—

(i) the conversion factor computed under subparagraph (C) for the year, and

(ii) the relative payment weight (determined under paragraph (2)(C)) for the service or group.

(E) Pre-deductible payment percentage

The pre-deductible payment percentage for a covered OPD service (or group of such services) furnished in a year is equal to the ratio of—

(i) the medicare OPD fee schedule amount established under subparagraph (D) for the year, minus the unadjusted copayment amount determined under subparagraph (B) for the service or group, to

(ii) the medicare OPD fee schedule amount determined under subparagraph (D) for the year for such service or group.

(F) Productivity and other adjustment

After determining the OPD fee schedule increase factor under subparagraph (C)(iv), the Secretary shall reduce such increase factor—

(i) for 2012 and subsequent years, by the productivity adjustment described in section 1395ww(b)(3)(B)(xi)(II) of this title; and

(ii) for each of 2010 through 2019, by the adjustment described in subparagraph (G).

The application of this subparagraph may result in the increase factor under subparagraph (C)(iv) being less than 0.0 for a year, and may result in payment rates under the payment system under this subsection for a year being less than such payment rates for the preceding year.

(G) Other adjustment

For purposes of subparagraph (F)(ii), the adjustment described in this subparagraph is—

(i) for each of 2010 and 2011, 0.25 percentage point;

(ii) for each of 2012 and 2013, 0.1 percentage point;

(iii) for 2014, 0.3 percentage point;

(iv) for each of 2015 and 2016, 0.2 percentage point; and

(v) for each of 2017, 2018, and 2019, 0.75 percentage point.

(4) Medicare payment amount

The amount of payment made from the Trust Fund under this part for a covered OPD service (and such services classified within a group) furnished in a year is determined, subject to paragraph (7), as follows:

(A) Fee schedule adjustments

The medicare OPD fee schedule amount (computed under paragraph (3)(D)) for the service or

group and year is adjusted for relative differences in the cost of labor and other factors determined by the Secretary, as computed under paragraphs (2)(D) and (2)(E).

(B) Subtract applicable deductible

Reduce the adjusted amount determined under subparagraph (A) by the amount of the deductible under subsection (b), to the extent applicable.

(C) Apply payment proportion to remainder

The amount of payment is the amount so determined under subparagraph (B) multiplied by the pre-deductible payment percentage (as determined under paragraph (3)(c)) for the service or group and year involved, plus the amount of any reduction in the copayment amount attributable to paragraph (8)(C).

(5) Outlier adjustment

(A) In general

Subject to subparagraph (D), the Secretary shall provide for an additional payment for each covered OPD service (or group of services) for which a hospital's charges, adjusted to cost, exceed—

(i) a fixed multiple of the sum of—

(I) the applicable medicare OPD fee schedule amount determined under paragraph (3)(D), as adjusted under paragraph (4)(A) (other than for adjustments under this paragraph or paragraph (6)); and

(II) any transitional pass-through payment under paragraph (6); and

(ii) at the option of the Secretary, such fixed dollar amount as the Secretary may establish.

(B) Amount of adjustment

The amount of the additional payment under subparagraph (A) shall be determined by the Secretary and shall approximate the marginal cost of care beyond the applicable cutoff point under such subparagraph.

(C) Limit on aggregate outlier adjustments

(i) In general

The total of the additional payments made under this paragraph for covered OPD services furnished in a year (as estimated by the Secretary before the beginning of the year) may not exceed the applicable percentage (specified in clause (ii)) of the total program payments estimated to be made under this subsection for all covered OPD services furnished in that year. If this paragraph is first applied to less than a full year, the previous sentence shall apply only to the portion of such year.

(ii) Applicable percentage

For purposes of clause (i), the term "applicable percentage" means a percentage specified by the Secretary up to (but not to exceed)—

(I) for a year (or portion of a year) before 2004, 2.5 percent; and

(II) for 2004 and thereafter, 3.0 percent.

(D) Transitional authority

In applying subparagraph (A) for covered OPD services furnished before January 1, 2002, the Secretary may—

(i) apply such subparagraph to a bill for such services related to an outpatient encounter (rather than for a specific service or group of services) using OPD fee schedule amounts and transitional pass-through payments covered under the bill; and

(ii) use an appropriate cost-to-charge ratio for the hospital involved (as determined by the Secretary), rather than for specific departments within the hospital.

(E) Exclusion of separate drug and biological APCS from outlier payments

No additional payment shall be made under subparagraph (A) in the case of ambulatory payment classification groups established separately for drugs or biologicals.

(6) Transitional pass-through for additional costs of innovative medical devices, drugs, and biologicals

(A) In general

The Secretary shall provide for an additional payment under this paragraph for any of the following that are provided as part of a covered OPD service (or group of services):

(i) Current orphan drugs

A drug or biological that is used for a rare disease or condition with respect to which the drug or biological has been designated as an orphan drug under section 360bb of title 21 if payment for the drug or biological as an outpatient hospital service under this part was being made on the first date that the system under this subsection is implemented.

(ii) Current cancer therapy drugs and biologicals and brachytherapy

A drug or biological that is used in cancer therapy, including (but not limited to) a chemotherapeutic agent, an antiemetic, a hematopoietic growth factor, a colony stimulating factor, a biological response modifier, a bisphosphonate, and a device of brachytherapy or temperature monitored cryoablation, if payment for such drug, biological, or device as an outpatient hospital service under this part was being made on such first date.

(iii) Current radiopharmaceutical drugs and biological products

A radiopharmaceutical drug or biological product used in diagnostic, monitoring, and therapeutic nuclear medicine procedures if payment for the drug or biological as an outpatient hospital service under this part was being made on such first date.

(iv) New medical devices, drugs, and biologicals

A medical device, drug, or biological not described in clause (i), (ii), or (iii) if—

(I) payment for the device, drug, or biological as an outpatient hospital service under this part was not being made as of December 31, 1996; and

(II) the cost of the drug or biological or the average cost of the category of devices is not insignificant in relation to the OPD fee schedule amount (as calculated under paragraph (3)(D)) payable for the service (or group of services) involved.

(B) Use of categories in determining eligibility of a device for pass-through payments

The following provisions apply for purposes of determining whether a medical device qualifies for additional payments under clause (ii) or (iv) of subparagraph (A):

(i) Establishment of initial categories

(I) In general

The Secretary shall initially establish under this clause categories of medical devices based on type of device by April 1, 2001. Such categories shall be established in a manner such that each medical device that meets the requirements of clause (ii) or (iv) of subparagraph (A) as of January 1, 2001, is included in such a category and no such device is included in more than one category.

For purposes of the preceding sentence, whether a medical device meets such requirements as of such date shall be determined on the basis of the program memoranda issued before such date.

(II) Authorization of implementation other than through regulations

The categories may be established under this clause by program memorandum or otherwise, after consultation with groups representing hospitals, manufacturers of medical devices, and other affected parties.

(ii) Establishing criteria for additional categories

(I) In general

The Secretary shall establish criteria that will be used for creation of additional categories (other than those established under clause (i)) through rulemaking (which may include use of an interim final rule with comment period).

(II) Standard

Such categories shall be established under this clause in a manner such that no medical device is described by more than one category. Such criteria shall include a test of whether the average cost of devices that would be included in a category and are in use at the time the category is established is not insignificant, as described in subparagraph (A)(iv)(II).

(III) Deadline

Criteria shall first be established under this clause by July 1, 2001. The Secretary may establish in compelling circumstances categories under this clause before the date such criteria are established.

(IV) Adding categories

The Secretary shall promptly establish a new category of medical devices under this clause for any medical device that meets the requirements of subparagraph (A)(iv) and for which none of the categories in effect (or that were previously in effect) is appropriate.

(iii) Period for which category is in effect

A category of medical devices established under clause (i) or (ii) shall be in effect for a period of at least 2 years, but not more than 3 years, that begins—

(I) in the case of a category established under clause (i), on the first date on which payment was made under this paragraph for any device described by such category (including payments made during the period before April 1, 2001); and

(II) in the case of any other category, on the first date on which payment is made under this paragraph for any medical device that is described by such category.

(iv) Requirements treated as met

A medical device shall be treated as meeting the requirements of subparagraph (A)(iv), regardless of whether the device meets the requirement of subclause (I) of such subparagraph, if—

(I) the device is described by a category established and in effect under clause (i); or

(II) the device is described by a category established and in effect under clause (ii) and an application under section 360e of title 21 has been approved with respect to the device, or the device has been cleared for market under section 360(k) of title 21, or the device is exempt from the requirements of section 360(k) of title 21 pursuant to subsection (*l*) or (m) of section 360 of title 21 or section 360j(g) of title 21.

Nothing in this clause shall be construed as requiring an application or prior approval (other than that described in subclause (II)) in order for a covered device described by a category to qualify for payment under this paragraph.

(C) Limited period of payment

(i) Drugs and biologicals

Subject to subparagraph (G), the payment under this paragraph with respect to a drug or biological shall only apply during a period of at least 2 years, but not more than 3 years, that begins—

(I) on the first date this subsection is implemented in the case of a drug or biological described in clause (i), (ii), or (iii) of subparagraph (A) and in the case of a drug or biological described in subparagraph (A)(iv) and for which payment under this part is made as an outpatient hospital service before such first date; or

(II) in the case of a drug or biological described in subparagraph (A)(iv) not described in subclause (I), on the first date on which payment is made under this part for the drug or biological as an outpatient hospital service.

(ii) Medical devices

Payment shall be made under this paragraph with respect to a medical device only if such device—

(I) is described by a category of medical devices established and in effect under subparagraph (B); and

(II) is provided as part of a service (or group of services) paid for under this subsection and provided during the period for which such category is in effect under such subparagraph.

(D) Amount of additional payment

Subject to subparagraph (E)(iii), the amount of the payment under this paragraph with respect to a device, drug, or biological provided as part of a covered OPD service is—

(i) subject to subparagraph (H), in the case of a drug or biological, the amount by which the amount determined under section 1395u(*o*) of this title (or if the drug or biological is covered under a competitive acquisition contract under section 1395w-3b of this title, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary for purposes of this paragraph) for the drug or biological exceeds the portion of the otherwise applicable medicare OPD fee schedule that the Secretary determines is associated with the drug or biological; or

(ii) in the case of a medical device, the amount by which the hospital's charges for the device, adjusted to cost, exceeds the portion of the otherwise applicable medicare OPD fee schedule that the Secretary determines is associated with the device.

(E) Limit on aggregate annual adjustment

(i) In general

The total of the additional payments made under this paragraph for covered OPD services furnished in a year (as estimated by the Secretary before the beginning of the year) may not exceed the applicable percentage (specified in clause (ii)) of the total program payments estimated to be made under this subsection for all covered OPD services furnished in that year. If this paragraph is first applied to less than a

full year, the previous sentence shall apply only to the portion of such year. This clause shall not apply for 2018 or 2020.

(ii) Applicable percentage

For purposes of clause (i), the term "applicable percentage" means—

(I) for a year (or portion of a year) before 2004, 2.5 percent; and

(II) for 2004 and thereafter, a percentage specified by the Secretary up to (but not to exceed) 2.0 percent.

(iii) Uniform prospective reduction if aggregate limit projected to be exceeded

If the Secretary estimates before the beginning of a year that the amount of the additional payments under this paragraph for the year (or portion thereof) as determined under clause (i) without regard to this clause will exceed the limit established under such clause, the Secretary shall reduce pro rata the amount of each of the additional payments under this paragraph for that year (or portion thereof) in order to ensure that the aggregate additional payments under this paragraph (as so estimated) do not exceed such limit.

(F) Limitation of application of functional equivalence standard

(i) In general

The Secretary may not publish regulations that apply a functional equivalence standard to a drug or biological under this paragraph.

(ii) Application

Clause (i) shall apply to the application of a functional equivalence standard to a drug or biological on or after December 8, 2003, unless—

(I) such application was being made to such drug or biological prior to December 8, 2003; and

(II) the Secretary applies such standard to such drug or biological only for the purpose of determining eligibility of such drug or biological for additional payments under this paragraph and not for the purpose of any other payments under this subchapter.

(iii) Rule of construction

Nothing in this subparagraph shall be construed to effect the Secretary's authority to deem a particular drug to be identical to another drug if the 2 products are pharmaceutically equivalent and bioequivalent, as determined by the Commissioner of Food and Drugs.

(G) Pass-through extension for certain drugs and biologicals

In the case of a drug or biological whose period of pass-through status under this paragraph ended

on December 31, 2017, and for which payment under this subsection was packaged into a payment for a covered OPD service (or group of services) furnished beginning January 1, 2018, such pass-through status shall be extended for a 2-year period beginning on October 1, 2018.

(H) Temporary payment rule for certain drugs and biologicals

In the case of a drug or biological whose period of pass-through status under this paragraph ended on December 31, 2017, and for which payment under this subsection was packaged into a payment for a covered OPD service (or group of services) furnished beginning January 1, 2018, the payment amount for such drug or biological under this subsection that is furnished during the period beginning on October 1, 2018, and ending on March 31, 2019, shall be the greater of—

(i) the payment amount that would otherwise apply under subparagraph (D)(i) for such drug or biological during such period; or

(ii) the payment amount that applied under such subparagraph (D)(i) for such drug or biological on December 31, 2017.

(I) Special payment adjustment rules for last quarter of 2018

In the case of a drug or biological whose period of pass-through status under this paragraph ended on December 31, 2017, and for which payment under this subsection was packaged into a payment amount for a covered OPD service (or

group of services) beginning January 1, 2018, the following rules shall apply with respect to payment amounts under this subsection for covered a OPD[15] service (or group of services) furnished during the period beginning on October 1, 2018, and ending on December 31, 2018:

(i) The Secretary shall remove the packaged costs of such drug or biological (as determined by the Secretary) from the payment amount under this subsection for the covered OPD service (or group of services) with which it is packaged.

(ii) The Secretary shall not make any adjustments to payment amounts under this subsection for a covered OPD service (or group of services) for which no costs were removed under clause (i).

(J) Additional pass-through extension and special payment adjustment rule for certain diagnostic radiopharmaceuticals

In the case of a drug or biological furnished in the context of a clinical study on diagnostic imaging tests approved under a coverage with evidence development determination whose period of pass-through status under this paragraph concluded on December 31, 2018, and for which payment under this subsection was packaged into a payment for a covered OPD service (or group of services) furnished beginning January 1, 2019, the Secretary shall—

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[15] So in original. Probably should be "a covered OPD".

(i) extend such pass-through status for such drug or biological for the 9-month period beginning on January 1, 2020;

(ii) remove, during such period, the packaged costs of such drug or biological (as determined by the Secretary) from the payment amount under this subsection for the covered OPD service (or group of services) with which it is packaged; and

(iii) not make any adjustments to payment amounts under this subsection for a covered OPD service (or group of services) for which no costs were removed under clause (ii).

(7) Transitional adjustment to limit decline in payment

(A) Before 2002

Subject to subparagraph (D), for covered OPD services furnished before January 1, 2002, for which the PPS amount (as defined in subparagraph (E)) is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount (as defined in subparagraph (F)), the amount of payment under this subsection shall be increased by 80 percent of the amount of such difference;

(ii) at least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.71 and the pre-BBA amount, exceeds (II) the product of 0.70 and the PPS amount;

(iii) at least 70 percent, but less than 80 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.63 and the pre-BBA amount, exceeds (II) the product of 0.60 and the PPS amount; or

(iv) less than 70 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 21 percent of the pre-BBA amount.

(B) 2002

Subject to subparagraph (D), for covered OPD services furnished during 2002, for which the PPS amount is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by 70 percent of the amount of such difference;

(ii) at least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.61 and the pre-BBA amount, exceeds (II) the product of 0.60 and the PPS amount; or

(iii) less than 80 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 13 percent of the pre-BBA amount.

(C) 2003

Subject to subparagraph (D), for covered OPD services furnished during 2003, for which the PPS amount is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by 60 percent of the amount of such difference; or

(ii) less than 90 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 6 percent of the pre-BBA amount.

(D) Hold harmless provisions

(i) Temporary treatment for certain rural hospitals

(I) In the case of a hospital located in a rural area and that has not more than 100 beds or a sole community hospital (as defined in section 1395ww(d)(5)(D)(iii) of this title) located in a rural area, for covered OPD services furnished before January 1, 2006, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount of such difference.

(II) In the case of a hospital located in a rural area and that has not more than 100 beds and that is not a sole community hospital (as defined in section 1395ww(d)(5)(D)(iii) of this title), for covered OPD services furnished on or after January 1, 2006, and before January 1,

2013, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the applicable percentage of the amount of such difference. For purposes of the preceding sentence, the applicable percentage shall be 95 percent with respect to covered OPD services furnished in 2006, 90 percent with respect to such services furnished in 2007, and 85 percent with respect to such services furnished in 2008, 2009, 2010, 2011, or 2012.

(III) In the case of a sole community hospital (as defined in section 1395ww(d)(5)(D)(iii) of this title) that has not more than 100 beds, for covered OPD services furnished on or after January 1, 2009, and before January 1, 2013, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by 85 percent of the amount of such difference. In the case of covered OPD services furnished on or after January 1, 2010, and before March 1, 2012, the preceding sentence shall be applied without regard to the 100-bed limitation.

(ii) Permanent treatment for cancer hospitals and children's hospitals

In the case of a hospital described in clause (iii) or (v) of section 1395ww(d)(1)(B) of this title, for covered OPD services for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount of such difference.

(E) PPS amount defined

In this paragraph, the term "PPS amount" means, with respect to covered OPD services, the amount payable under this subchapter for such services (determined without regard to this paragraph), including amounts payable as copayment under paragraph (8), coinsurance under section 1395cc(a)(2)(A)(ii) of this title, and the deductible under subsection (b).

(F) Pre-BBA amount defined

(i) In general

In this paragraph, the "pre-BBA amount" means, with respect to covered OPD services furnished by a hospital in a year, an amount equal to the product of the reasonable cost of the hospital for such services for the portions of the hospital's cost reporting period (or periods) occurring in the year and the base OPD payment-to-cost ratio for the hospital (as defined in clause (ii)).

(ii) Base payment-to-cost ratio defined

For purposes of this subparagraph, the "base payment-to-cost ratio" for a hospital means the ratio of—

(I) the hospital's reimbursement under this part for covered OPD services furnished during the cost reporting period ending in 1996 (or in the case of a hospital that did not submit a cost report for such period, during the first subsequent cost reporting

period ending before 2001 for which the hospital submitted a cost report), including any reimbursement for such services through cost-sharing described in subparagraph (E), to

(II) the reasonable cost of such services for such period.

The Secretary shall determine such ratios as if the amendments made by section 4521 of the Balanced Budget Act of 1997 were in effect in 1996.

(G) Interim payments

The Secretary shall make payments under this paragraph to hospitals on an interim basis, subject to retrospective adjustments based on settled cost reports.

(H) No effect on copayments

Nothing in this paragraph shall be construed to affect the unadjusted copayment amount described in paragraph (3)(B) or the copayment amount under paragraph (8).

(I) Application without regard to budget neutrality

The additional payments made under this paragraph—

(i) shall not be considered an adjustment under paragraph (2)(E); and

(ii) shall not be implemented in a budget neutral manner.

(8) Copayment amount

(A) In general

Except as provided in subparagraphs (B) and (C), the copayment amount under this subsection is the amount by which the amount described in paragraph (4)(B) exceeds the amount of payment determined under paragraph (4)(C).

(B) Election to offer reduced copayment amount

The Secretary shall establish a procedure under which a hospital, before the beginning of a year (beginning with 1999), may elect to reduce the copayment amount otherwise established under subparagraph (A) for some or all covered OPD services to an amount that is not less than 20 percent of the medicare OPD fee schedule amount (computed under paragraph (3)(D)) for the service involved. Under such procedures, such reduced copayment amount may not be further reduced or increased during the year involved and the hospital may disseminate information on the reduction of copayment amount effected under this subparagraph.

(C) Limitation on copayment amount

(i) To inpatient hospital deductible amount

In no case shall the copayment amount for a procedure performed in a year exceed the amount of the inpatient hospital deductible established under section 1395e(b) of this title for that year.

(ii) To specified percentage

The Secretary shall reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed the following percentage:

(I) For procedures performed in 2001, on or after April 1, 2001, 57 percent.

(II) For procedures performed in 2002 or 2003, 55 percent.

(III) For procedures performed in 2004, 50 percent.

(IV) For procedures performed in 2005, 45 percent.

(V) For procedures performed in 2006 and thereafter, 40 percent.

(D) No impact on deductibles

Nothing in this paragraph shall be construed as affecting a hospital's authority to waive the charging of a deductible under subsection (b).

(E) Computation ignoring outlier and pass-through adjustments

The copayment amount shall be computed under subparagraph (A) as if the adjustments under paragraphs (5) and (6) (and any adjustment made under paragraph (2)(E) in relation to such adjustments) had not occurred.

(9) Periodic review and adjustments components of prospective payment system

(A) Periodic review

The Secretary shall review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. The Secretary shall consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the groups and weights. Such panel may use data collected or developed by entities and organizations (other than the Department of Health and Human Services) in conducting such review.

(B) Budget neutrality adjustment

If the Secretary makes adjustments under subparagraph (A), 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. In determining adjustments under the preceding sentence for 2004 and 2005, the Secretary shall not take into account under this subparagraph or paragraph (2)(E) any expenditures that would not have been made but for the application of paragraph (14).

(C) Update factor

If the Secretary determines under methodologies described in paragraph (2)(F) that the volume of services paid for under this subsection increased beyond amounts established through those methodologies, the Secretary may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year.

(10) Special rule for ambulance services

The Secretary shall pay for hospital outpatient services that are ambulance services on the basis described in section 1395x(v)(1)(U) of this title, or, if applicable, the fee schedule established under section 1395m(*l*) of this title.

(11) Special rules for certain hospitals

In the case of hospitals described in clause (iii) or (v) of section 1395ww(d)(1)(B) of this title—

(A) the system under this subsection shall not apply to covered OPD services furnished before January 1, 2000; and

(B) the Secretary may establish a separate conversion factor for such services in a manner that specifically takes into account the unique costs incurred by such hospitals by virtue of their patient population and service intensity.

(12) Limitation on review

There shall be no administrative or judicial review under section 1395ff of this title, 1395oo of this title, or otherwise of—

(A) the development of the classification system under paragraph (2), including the establishment of groups and relative payment weights for covered OPD services, of wage adjustment factors, other adjustments, and methods described in paragraph (2)(F);

(B) the calculation of base amounts under paragraph (3);

(C) periodic adjustments made under paragraph (6);

(D) the establishment of a separate conversion factor under paragraph (8)(B); and

(E) the determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under paragraph (5) or the determination of insignificance of cost, the duration of the additional payments, the determination and deletion of initial and new categories (consistent with subparagraphs (B) and (C) of paragraph (6)), the portion of the medicare OPD fee schedule amount associated with particular devices, drugs, or biologicals, and the application of any pro rata reduction under paragraph (6).

(13) Authorization of adjustment for rural hospitals

(A) Study

The Secretary shall conduct a study to determine if, under the system under this subsection, costs incurred by hospitals located in rural areas by ambulatory payment classification groups (APCs) exceed those costs incurred by hospitals located in urban areas.

(B) Authorization of adjustment

Insofar as the Secretary determines under subparagraph (A) that costs incurred by hospitals located in rural areas exceed those costs incurred by hospitals located in urban areas, the Secretary shall provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs by January 1, 2006.

(14) Drug APC payment rates

(A) In general

The amount of payment under this subsection for a specified covered outpatient drug (defined in subparagraph (B)) that is furnished as part of a covered OPD service (or group of services)—

(i) in 2004, in the case of—

(I) a sole source drug shall in no case be less than 88 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug;

(ii) in 2005, in the case of—

(I) a sole source drug shall in no case be less than 83 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug; or

(iii) in a subsequent year, shall be equal, subject to subparagraph (E)—

(I) to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); or

(II) if hospital acquisition cost data are not available, the average price for the drug in the year established under section 1395u(*o*) of this title, section 1395w-3a of this title, or section 1395w-3b of this title, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of this paragraph.

(B) Specified covered outpatient drug defined

(i) In general

In this paragraph, the term "specified covered outpatient drug" means, subject to clause (ii), a covered outpatient drug (as defined in section 1396r-8(k)(2) of this title) for which a separate ambulatory payment classification group (APC) has been established and that is

(I) a radiopharmaceutical; or

(II) a drug or biological for which payment was made under paragraph (6) (relating to pass-through payments) on or before December 31, 2002.

(ii) Exception

Such term does not include—

(I) a drug or biological for which payment is first made on or after January 1, 2003, under paragraph (6);

(II) a drug or biological for which a temporary HCPCS code has not been assigned; or

(III) during 2004 and 2005, an orphan drug (as designated by the Secretary).

(C) Payment for designated orphan drugs during 2004 and 2005

The amount of payment under this subsection for an orphan drug designated by the Secretary under subparagraph (B)(ii)(III) that is furnished

as part of a covered OPD service (or group of services) during 2004 and 2005 shall equal such amount as the Secretary may specify.

(D) Acquisition cost survey for hospital outpatient drugs

(i) Annual GAO surveys in 2004 and 2005

(I) In general

The Comptroller General of the United States shall conduct a survey in each of 2004 and 2005 to determine the hospital acquisition cost for each specified covered outpatient drug. Not later than April 1, 2005, the Comptroller General shall furnish data from such surveys to the Secretary for use in setting the payment rates under subparagraph (A) for 2006.

(II) Recommendations

Upon the completion of such surveys, the Comptroller General shall recommend to the Secretary the frequency and methodology of subsequent surveys to be conducted by the Secretary under clause (ii).

(ii) Subsequent secretarial surveys

The Secretary, taking into account such recommendations, shall conduct periodic subsequent surveys to determine the hospital acquisition cost for each specified covered outpatient drug for use in setting the payment rates under subparagraph (A).

(iii) Survey requirements

The surveys conducted under clauses (i) and (ii) shall have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug. With respect to the surveys conducted under clause (i), the Comptroller General shall report to Congress on the justification for the size of the sample used in order to assure the validity of such estimates.

(iv) Differentiation in cost

In conducting surveys under clause (i), the Comptroller General shall determine and report to Congress if there is (and the extent of any) variation in hospital acquisition costs for drugs among hospitals based on the volume of covered OPD services performed by such hospitals or other relevant characteristics of such hospitals (as defined by the Comptroller General).

(v) Comment on proposed rates

Not later than 30 days after the date the Secretary promulgated proposed rules setting forth the payment rates under subparagraph (A) for 2006, the Comptroller General shall evaluate such proposed rates and submit to Congress a report regarding the appropriateness of such rates based on the surveys the Comptroller General has conducted under clause (i).

(E) Adjustment in payment rates for overhead costs

(i) MedPAC report on drug APC design

The Medicare Payment Advisory Commission shall submit to the Secretary, not later than July 1, 2005, a report on adjustment of payment for ambulatory payment classifications for specified covered outpatient drugs to take into account overhead and related expenses, such as pharmacy services and handling costs. Such report shall include—

(I) a description and analysis of the data available with regard to such expenses;

(II) a recommendation as to whether such a payment adjustment should be made; and

(III) if such adjustment should be made, a recommendation regarding the methodology for making such an adjustment.

(ii) Adjustment authorized

The Secretary may adjust the weights for ambulatory payment classifications for specified covered outpatient drugs to take into account the recommendations contained in the report submitted under clause (i).

(F) Classes of drugs

For purposes of this paragraph:

(i) Sole source drugs

The term "sole source drug" means—

(I) a biological product (as defined under section 1395x(t)(1) of this title); or

(II) a single source drug (as defined in section 1396r-8(k)(7)(A)(iv) of this title).

(ii) Innovator multiple source drugs

The term "innovator multiple source drug" has the meaning given such term in section 1396r-8(k)(7)(A)(ii) of this title.

(iii) Noninnovator multiple source drugs

The term "noninnovator multiple source drug" has the meaning given such term in section 1396r-8(k)(7)(A)(iii) of this title.

(G) Reference average wholesale price

The term "reference average wholesale price" means, with respect to a specified covered outpatient drug, the average wholesale price for the drug as determined under section 1395u(*o*) of this title as of May 1, 2003.

(H) Inapplicability of expenditures in determining conversion, weighting, and other adjustment factors

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.

(15) Payment for new drugs and biologicals until HCPCS code assigned

With respect to payment under this part for an outpatient drug or biological that is covered under this part and is furnished as part of covered OPD services for which a HCPCS code has not been assigned, the amount provided for payment for such drug or biological under this part shall be equal to 95 percent of the average wholesale price for the drug or biological.

(16) Miscellaneous provisions

(A) Application of reclassification of certain hospitals

If a hospital is being treated as being located in a rural area under section 1395ww(d)(8)(E) of this title, that hospital shall be treated under this subsection as being located in that rural area.

(B) Threshold for establishment of separate APCS for drugs

The Secretary shall reduce the threshold for the establishment of separate ambulatory payment classification groups (APCs) with respect to drugs or biologicals to $50 per administration for drugs and biologicals furnished in 2005 and 2006.

(C) Payment for devices of brachytherapy and therapeutic radiopharmaceuticals at charges adjusted to cost

Notwithstanding the preceding provisions of this subsection, for a device of brachytherapy consisting of a seed or seeds (or radioactive source)

furnished on or after January 1, 2004, and before January 1, 2010, and for therapeutic radiopharmaceuticals furnished on or after January 1, 2008, and before January 1, 2010, the payment basis for the device or therapeutic radiopharmaceutical under this subsection shall be equal to the hospital's charges for each device or therapeutic radiopharmaceutical furnished, adjusted to cost. Charges for such devices or therapeutic radiopharmaceuticals shall not be included in determining any outlier payment under this subsection.

(D) Special payment rule

(i) In general

In the case of covered OPD services furnished on or after April 1, 2013, in a hospital described in clause (ii), if—

(I) the payment rate that would otherwise apply under this subsection for stereotactic radiosurgery, complete course of treatment of cranial lesion(s) consisting of 1 session that is multi-source Cobalt 60 based (identified as of January 1, 2013, by HCPCS code 77371 (and any succeeding code) and reimbursed as of such date under APC 0127 (and any succeeding classification group)); exceeds

(II) the payment rate that would otherwise apply under this subsection for linear accelerator based stereotactic radiosurgery, complete course of therapy in one session (identified as of January 1, 2013, by HCPCS code G0173 (and any succeeding code) and

reimbursed as of such date under APC 0067 (and any succeeding classification group)),

the payment rate for the service described in subclause (I) shall be reduced to an amount equal to the payment rate for the service described in subclause (II).

(ii) Hospital described

A hospital described in this clause is a hospital that is not—

(I) located in a rural area (as defined in section 1395ww(d)(2)(D) of this title);

(II) classified as a rural referral center under section 1395ww(d)(5)(C) of this title; or

(III) a sole community hospital (as defined in section 1395ww(d)(5)(D)(iii) of this title).

(iii) Not budget neutral

In making any budget neutrality adjustments under this subsection for 2013 (with respect to covered OPD services furnished on or after April 1, 2013, and before January 1, 2014) or a subsequent year, the Secretary shall not take into account the reduced expenditures that result from the application of this subparagraph.

(E) Application of appropriate use criteria for certain imaging services

For provisions relating to the application of appropriate use criteria for certain imaging services, see section 1395m(q) of this title.

(F) Payment incentive for the transition from traditional X-ray imaging to digital radiography

Notwithstanding the previous provisions of this subsection:

(i) Limitation on payment for film X-ray imaging services

In the case of an imaging service that is an X-ray taken using film and that is furnished during 2017 or a subsequent year, the payment amount for such service (including the X-ray component of a packaged service) that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 20 percent.

(ii) Phased-in limitation on payment for computed radiography imaging services

In the case of an imaging service that is an X-ray taken using computed radiography technology (as defined in section 1395w-4(b)(9)(C) of this title)—

(I) in the case of such a service furnished during 2018, 2019, 2020, 2021, or

2022, the payment amount for such service (including the X-ray component of a packaged service) that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 7 percent; and

(II) in the case of such a service furnished during 2023 or a subsequent year, the payment amount for such service (including the X-ray component of a packaged service) that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 10 percent.

(iii) Application without regard to budget neutrality

The reductions made under this subparagraph—

(I) shall not be considered an adjustment under paragraph (2)(E); and

(II) shall not be implemented in a budget neutral manner.

(iv) Implementation

In order to implement this subparagraph, the Secretary shall adopt appropriate mechanisms which may include use of modifiers.

(17) Quality reporting

(A) Reduction in update for failure to report

(i) In general

For purposes of paragraph (3)(C)(iv) for 2009 and each subsequent year, in the case of a subsection (d) hospital (as defined in section 1395ww(d)(1)(B) of this title) that does not submit, to the Secretary in accordance with this paragraph, data required to be submitted on measures selected under this paragraph with respect to such a year, the OPD fee schedule increase factor under paragraph (3)(C)(iv) for such year shall be reduced by 2.0 percentage points.

(ii) Non-cumulative application

A reduction under this subparagraph shall apply only with respect to the year involved and the Secretary shall not take into account such reduction in computing the OPD fee schedule increase factor for a subsequent year.

(B) Form and manner of submission

Each subsection (d) hospital shall submit data on measures selected under this paragraph to the Secretary in a form and manner, and at a time, specified by the Secretary for purposes of this paragraph.

(C) Development of outpatient measures

(i) In general

The Secretary shall develop measures that the Secretary determines to be appropriate for

the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.

(ii) Construction

Nothing in this paragraph shall be construed as preventing the Secretary from selecting measures that are the same as (or a subset of) the measures for which data are required to be submitted under section 1395ww(b)(3)(B)(viii) of this title.

(D) Replacement of measures

For purposes of this paragraph, the Secretary may replace any measures or indicators in appropriate cases, such as where all hospitals are effectively in compliance or the measures or indicators have been subsequently shown not to represent the best clinical practice.

(E) Availability of data

The Secretary shall establish procedures for making data submitted under this paragraph available to the public. Such procedures shall ensure that a hospital has the opportunity to review the data that are to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures of process, structure, outcome, patients' perspec-

tives on care, efficiency, and costs of care that relate to services furnished in outpatient settings in hospitals on the Internet website of the Centers for Medicare & Medicaid Services.

(18) Authorization of adjustment for cancer hospitals

(A) Study

The Secretary shall conduct a study to determine if, under the system under this subsection, costs incurred by hospitals described in section 1395ww(d)(1)(B)(v) of this title with respect to ambulatory payment classification groups exceed those costs incurred by other hospitals furnishing services under this subsection (as determined appropriate by the Secretary). In conducting the study under this subparagraph, the Secretary shall take into consideration the cost of drugs and biologicals incurred by such hospitals.

(B) Authorization of adjustment

Insofar as the Secretary determines under subparagraph (A) that costs incurred by hospitals described in section 1395ww(d)(1)(B)(v) of this title exceed those costs incurred by other hospitals furnishing services under this subsection, the Secretary shall, subject to subparagraph (C), provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs effective for services furnished on or after January 1, 2011.

(C) Target PCR adjustment

In applying section 419.43(i) of title 42 of the Code of Federal Regulations to implement the appropriate adjustment under this paragraph for

services furnished on or after January 1, 2018, the Secretary shall use a target PCR that is 1.0 percentage points less than the target PCR that would otherwise apply. In addition to the percentage point reduction under the previous sentence, the Secretary may consider making an additional percentage point reduction to such target PCR that takes into account payment rates for applicable items and services described in paragraph (21)(C) other than for services furnished by hospitals described in section 1395ww(d)(1)(B)(v) of this title. In making any budget neutrality adjustments under this subsection for 2018 or a subsequent year, the Secretary shall not take into account the reduced expenditures that result from the application of this subparagraph.

(19) Floor on area wage adjustment factor for hospital outpatient department services in frontier States

(A) In general

Subject to subparagraph (B), with respect to covered OPD services furnished on or after January 1, 2011, the area wage adjustment factor applicable under the payment system established under this subsection to any hospital outpatient department which is located in a frontier State (as defined in section 1395ww(d)(3)(E)(iii)(II) of this title) may not be less than 1.00. The preceding sentence shall not be applied in a budget neutral manner.

(B) Limitation

This paragraph shall not apply to any hospital outpatient department located in a State that receives a non-labor related share adjustment under section 1395ww(d)(5)(H) of this title.

(20) Not budget neutral application of reduced expenditures resulting from quality incentives for computed tomography

The Secretary shall not take into account the reduced expenditures that result from the application of section 1395m(p) of this title in making any budget neutrality adjustments this[16] subsection.

(21) Services furnished by an off-campus outpatient department of a provider

(A) Applicable items and services

For purposes of paragraph (1)(B)(v) and this paragraph, the term "applicable items and services" means items and services other than items and services furnished by a dedicated emergency department (as defined in section 489.24(b) of title 42 of the Code of Federal Regulations).

(B) Off-campus outpatient department of a provider

(i) In general

For purposes of paragraph (1)(B)(v) and this paragraph, subject to the subsequent provisions of this subparagraph, the term "off-campus outpatient department of a provider"

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[16] So in original. Probably should be preceded by "under".

means a department of a provider (as defined in section 413.65(a)(2) of title 42 of the Code of Federal Regulations, as in effect as of November 2, 2015) that is not located—

(I) on the campus (as defined in such section 413.65(a)(2)) of such provider; or

(II) within the distance (described in such definition of campus) from a remote location of a hospital facility (as defined in such section 413.65(a)(2)).

(ii) Exception

For purposes of paragraph (1)(B)(v) and this paragraph, the term "off-campus outpatient department of a provider" shall not include a department of a provider (as so defined) that was billing under this subsection with respect to covered OPD services furnished prior to November 2, 2015.

(iii) Deemed treatment for 2017

For purposes of applying clause (ii) with respect to applicable items and services furnished during 2017, a department of a provider (as so defined) not described in such clause is deemed to be billing under this subsection with respect to covered OPD services furnished prior to November 2, 2015, if the Secretary received from the provider prior to December 2, 2015, an attestation (pursuant to section 413.65(b)(3) of title 42 of the Code of Federal Regulations) that such department was a department of a provider (as so defined).

(iv) Alternative exception beginning with 2018

For purposes of paragraph (1)(B)(v) and this paragraph with respect to applicable items and services furnished during 2018 or a subsequent year, the term "off-campus outpatient department of a provider" also shall not include a department of a provider (as so defined) that is not described in clause (ii) if—

(I) the Secretary receives from the provider an attestation (pursuant to such section 413.65(b)(3)) not later than December 31, 2016 (or, if later, 60 days after December 13, 2016), that such department met the requirements of a department of a provider specified in section 413.65 of title 42 of the Code of Federal Regulations;

(II) the provider includes such department as part of the provider on its enrollment form in accordance with the enrollment process under section 1395cc(j) of this title; and

(III) the department met the mid-build requirement of clause (v) and the Secretary receives, not later than 60 days after December 13, 2016, from the chief executive officer or chief operating officer of the provider a written certification that the department met such requirement.

(v) Mid-build requirement described

The mid-build requirement of this clause is, with respect to a department of a provider, that

before November 2, 2015, the provider had a binding written agreement with an outside unrelated party for the actual construction of such department.

(vi) Exclusion for certain cancer hospitals

For purposes of paragraph (1)(B)(v) and this paragraph with respect to applicable items and services furnished during 2017 or a subsequent year, the term "off-campus outpatient department of a provider" also shall not include a department of a provider (as so defined) that is not described in clause (ii) if the provider is a hospital described in section 1395ww(d)(1)(B)(v) of this title and—

(I) in the case of a department that met the requirements of section 413.65 of title 42 of the Code of Federal Regulations after November 1, 2015, and before December 13, 2016, the Secretary receives from the provider an attestation that such department met such requirements not later than 60 days after such date; or

(II) in the case of a department that meets such requirements after such date, the Secretary receives from the provider an attestation that such department meets such requirements not later than 60 days after the date such requirements are first met with respect to such department.

(vii) Audit

Not later than December 31, 2018, the Secretary shall audit the compliance with requirements of clause (iv) with respect to each department of a provider to which such clause applies. Not later than 2 years after the date the Secretary receives an attestation under clause (vi) relating to compliance of a department of a provider with requirements referred to in such clause, the Secretary shall audit the compliance with such requirements with respect to the department. If the Secretary finds as a result of an audit under this clause that the applicable requirements were not met with respect to such department, the department shall not be excluded from the term "off-campus outpatient department of a provider" under such clause.

(viii) Implementation

For purposes of implementing clauses (iii) through (vii):

(I) Notwithstanding any other provision of law, the Secretary may implement such clauses by program instruction or otherwise.

(II) Subchapter I of chapter 35 of title 44 shall not apply.

(III) For purposes of carrying out this subparagraph with respect to clauses (iii) and (iv) (and clause (vii) insofar as it relates to clause (iv)), $10,000,000 shall be available from the Federal Supplementary Medical

Insurance Trust Fund under section 1395t of this title, to remain available until December 31, 2018. For purposes of carrying out this subparagraph with respect to clause (vi) (and clause (vii) insofar as it relates to such clause), $2,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title, to remain available until expended.

(C) Availability of payment under other payment systems

Payments for applicable items and services furnished by an off-campus outpatient department of a provider that are described in paragraph (1)(B)(v) shall be made under the applicable payment system under this part (other than under this subsection) if the requirements for such payment are otherwise met.

(D) Information needed for implementation

Each hospital shall provide to the Secretary such information as the Secretary determines appropriate to implement this paragraph and paragraph (1)(B)(v) (which may include reporting of information on a hospital claim using a code or modifier and reporting information about off-campus outpatient departments of a provider on the enrollment form described in section 1395cc(j) of this title).

(E) Limitations

There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise of the following:

(i) The determination of the applicable items and services under subparagraph (A) and applicable payment systems under subparagraph (C).

(ii) The determination of whether a department of a provider meets the term described in subparagraph (B).

(iii) Any information that hospitals are required to report pursuant to subparagraph (D).

(iv) The determination of an audit under subparagraph (B)(vii).

(22) Review and revisions of payments for non-opioid alternative treatments

(A) In general

With respect to payments made under this subsection for covered OPD services (or groups of services), including covered OPD services assigned to a comprehensive ambulatory payment classification, the Secretary—

(i) shall, as soon as practicable, conduct a review (part of which may include a request for information) of payments for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there

are not financial incentives to use opioids instead of non-opioid alternatives;

(ii) may, as the Secretary determines appropriate, conduct subsequent reviews of such payments; and

(iii) shall consider the extent to which revisions under this subsection to such payments (such as the creation of additional groups of covered OPD services to classify separately those procedures that utilize opioids and non-opioid alternatives for pain management) would reduce payment incentives to use opioids instead of non-opioid alternatives for pain management.

(B) Priority

In conducting the review under clause (i) of subparagraph (A) and considering revisions under clause (iii) of such subparagraph, the Secretary shall focus on covered OPD services (or groups of services) assigned to a comprehensive ambulatory payment classification, ambulatory payment classifications that primarily include surgical services, and other services determined by the Secretary which generally involve treatment for pain management.

(C) Revisions

If the Secretary identifies revisions to payments pursuant to subparagraph (A)(iii), the Secretary shall, as determined appropriate, begin making such revisions for services furnished on or after January 1, 2020. Revisions under the previous

sentence shall be treated as adjustments for purposes of application of paragraph (9)(B).

(D) Rules of construction

Nothing in this paragraph shall be construed to preclude the Secretary—

(i) from conducting a demonstration before making the revisions described in subparagraph (C); or

(ii) prior to implementation of this paragraph, from changing payments under this subsection for covered OPD services (or groups of services) which include opioids or non-opioid alternatives for pain management.

3. 42 U.S.C. 1395w-3a provides in pertinent part:

Use of average sales price payment methodology

(a) Application

(1) In general

Except as provided in paragraph (2), this section shall apply to payment for drugs and biologicals that are described in section 1395u(*o*)(1)(C) of this title and that are furnished on or after January 1, 2005.

(2) Election

This section shall not apply in the case of a physician who elects under subsection (a)(1)(A)(ii) of section 1395w-3b of this title for that section to apply instead of this section for the payment for drugs and biologicals.

(b) Payment amount

(1) In general

Subject to paragraph (7) and subsections (d)(3)(C) and (e), the amount of payment determined under this section for the billing and payment code for a drug or biological (based on a minimum dosage unit) is, subject to applicable deductible and coinsurance—

(A) in the case of a multiple source drug (as defined in subsection (c)(6)(C)), 106 percent of the amount determined under paragraph (3) for a multiple source drug furnished before April 1, 2008, or 106 percent of the amount determined under paragraph (6) for a multiple source drug furnished on or after April 1, 2008;

(B) in the case of a single source drug or biological (as defined in subsection (c)(6)(D)), 106 percent of the amount determined under paragraph (4); or

(C) in the case of a biosimilar biological product (as defined in subsection (c)(6)(H)), the amount determined under paragraph (8).

(2) Specification of unit

(A) Specification by manufacturer

The manufacturer of a drug or biological shall specify the unit associated with each National Drug Code (including package size) as part of the submission of data under section 1396r-8(b)(3)(A)(iii) of this title or subsection (f)(2), as applicable.

(B) Unit defined

In this section, the term "unit" means, with respect to each National Drug Code (including package size) associated with a drug or biological, the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids. For years after 2004, the Secretary may establish the unit for a manufacturer to report and methods for counting units as the Secretary determines appropriate to implement this section.

(3) Multiple source drug

For all drug products included within the same multiple source drug billing and payment code, the amount specified in this paragraph is the volume-weighted average of the average sales prices reported under section 1396r-8(b)(3)(A)(iii) of this title or subsection (f)(2), as applicable, determined by—

(A) computing the sum of the products (for each National Drug Code assigned to such drug products) of—

(i) the manufacturer's average sales price (as defined in subsection (c)); and

(ii) the total number of units specified under paragraph (2) sold; and

(B) dividing the sum determined under subparagraph (A) by the sum of the total number of units under subparagraph (A)(ii) for all National Drug Codes assigned to such drug products.

(4) Single source drug or biological

The amount specified in this paragraph for a single source drug or biological is the lesser of the following:

(A) Average sales price

The average sales price as determined using the methodology applied under paragraph (3) for single source drugs and biologicals furnished before April 1, 2008, and using the methodology applied under paragraph (6) for single source drugs and biologicals furnished on or after April 1, 2008, for all National Drug Codes assigned to such drug or biological product.

(B) Wholesale acquisition cost (WAC)

The wholesale acquisition cost (as defined in subsection (c)(6)(B)) using the methodology applied under paragraph (3) for single source drugs and biologicals furnished before April 1, 2008, and using the methodology applied under paragraph (6) for single source drugs and biologicals furnished on or after April 1, 2008, for all National Drug Codes assigned to such drug or biological product.

(5) Basis for payment amount

The payment amount shall be determined under this subsection based on information reported under subsection (f) and without regard to any special packaging, labeling, or identifiers on the dosage form or product or package.

(6) Use of volume-weighted average sales prices in calculation of average sales price

(A) In general

For all drug products included within the same multiple source drug billing and payment code, the amount specified in this paragraph is the volume-weighted average of the average sales prices reported under section 1396r-8(b)(3)(A)(iii) of this title or subsection (f)(2), as applicable, determined by—

(i) computing the sum of the products (for each National Drug Code assigned to such drug products) of—

(I) the manufacturer's average sales price (as defined in subsection (c)), determined by the Secretary without dividing such price by the total number of billing units for the National Drug Code for the billing and payment code; and

(II) the total number of units specified under paragraph (2) sold; and

(ii) dividing the sum determined under clause (i) by the sum of the products (for each National Drug Code assigned to such drug products) of—

(I) the total number of units specified under paragraph (2) sold; and

(II) the total number of billing units for the National Drug Code for the billing and payment code.

(B) Billing unit defined

For purposes of this subsection, the term "billing unit" means the identifiable quantity associated with a billing and payment code, as established by the Secretary.

(7) Special rule

Beginning with April 1, 2008, the payment amount for—

(A) each single source drug or biological described in section 1395u(*o*)(1)(G) of this title that is treated as a multiple source drug because of the application of subsection (c)(6)(C)(ii) is the lower of—

(i) the payment amount that would be determined for such drug or biological applying such subsection; or

(ii) the payment amount that would have been determined for such drug or biological if such subsection were not applied; and

(B) a multiple source drug described in section 1395u(*o*)(1)(G) of this title (excluding a drug or biological that is treated as a multiple source drug because of the application of such subsection) is the lower of—

(i) the payment amount that would be determined for such drug or biological taking into account the application of such subsection; or

(ii) the payment amount that would have been determined for such drug or biological if such subsection were not applied.

(8) Biosimilar biological product

The amount specified in this paragraph for a biosimilar biological product described in paragraph (1)(C) is the sum of—

(A) the average sales price as determined using the methodology described under paragraph (6) applied to a biosimilar biological product for all National Drug Codes assigned to such product in the same manner as such paragraph is applied to drugs described in such paragraph; and

(B) 6 percent of the amount determined under paragraph (4) for the reference biological product (as defined in subsection (c)(6)(I)).

(c) Manufacturer's average sales price

(1) In general

For purposes of this section, subject to paragraphs (2) and (3), the manufacturer's "average sales price" means, of a drug or biological for a National Drug Code for a calendar quarter for a manufacturer for a unit—

(A) the manufacturer's sales to all purchasers (excluding sales exempted in paragraph (2)) in the United States for such drug or biological in the calendar quarter; divided by

(B) the total number of such units of such drug or biological sold by the manufacturer in such quarter.

(2) Certain sales exempted from computation

In calculating the manufacturer's average sales price under this subsection, the following sales shall be excluded:

(A) Sales exempt from best price

Sales exempt from the inclusion in the determination of "best price" under section 1396r-8(c)(1)(C)(i) of this title.

(B) Sales at nominal charge

Such other sales as the Secretary identifies as sales to an entity that are merely nominal in amount (as applied for purposes of section 1396r-8(c)(1)(C)(ii)(III) of this title, except as the Secretary may otherwise provide).

(3) Sale price net of discounts

In calculating the manufacturer's average sales price under this subsection, such price shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1396r-8 of this title). For years after 2004, the Secretary may include in such price other price concessions, which may be based on recommendations of the Inspector General, that would result in a reduction of the cost to the purchaser.

(4) Payment methodology in cases where average sales price during first quarter of sales is unavailable

In the case of a drug or biological during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales for the drug or biological is not sufficiently available from the manufacturer to compute an average sales price for the drug or biological, the Secretary may determine the amount payable under this section—

(A) in the case of a drug or biological furnished prior to January 1, 2019, based on—

(i) the wholesale acquisition cost; or

(ii) the methodologies in effect under this part on November 1, 2003, to determine payment amounts for drugs or biologicals; and

(B) in the case of a drug or biological furnished on or after January 1, 2019—

(i) at an amount not to exceed 103 percent of the wholesale acquisition cost; or

(ii) based on the methodologies in effect under this part on November 1, 2003, to determine payment amounts for drugs or biologicals.

(5) Frequency of determinations

(A) In general on a quarterly basis

The manufacturer's average sales price, for a drug or biological of a manufacturer, shall be calculated by such manufacturer under this subsection on a quarterly basis. In making such calculation insofar as there is a lag in the reporting of

the information on rebates and chargebacks under paragraph (3) so that adequate data are not available on a timely basis, the manufacturer shall apply a methodology based on a 12-month rolling average for the manufacturer to estimate costs attributable to rebates and chargebacks. For years after 2004, the Secretary may establish a uniform methodology under this subparagraph to estimate and apply such costs.

(B) Updates in payment amounts

The payment amounts under subsection (b) shall be updated by the Secretary on a quarterly basis and shall be applied based upon the manufacturer's average sales price calculated for the most recent calendar quarter for which data is available.

(C) Use of contractors; implementation

The Secretary may contract with appropriate entities to calculate the payment amount under subsection (b). Notwithstanding any other provision of law, the Secretary may implement, by program instruction or otherwise, any of the provisions of this section.

(6) Definitions and other rules

In this section:

(A) Manufacturer

The term "manufacturer" means, with respect to a drug or biological, the manufacturer (as defined in section 1396r-8(k)(5) of this title), except

that, for purposes of subsection (f)(2), the Secretary may, if the Secretary determines appropriate, exclude repackagers of a drug or biological from such term.

(B) Wholesale acquisition cost

The term "wholesale acquisition cost" means, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

(C) Multiple source drug

(i) In general

The term "multiple source drug" means, for a calendar quarter, a drug for which there are 2 or more drug products which—

(I) are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations"),

(II) except as provided in subparagraph (E), are pharmaceutically equivalent and bioequivalent, as determined under subparagraph (F) and as determined by the Food and Drug Administration, and

(III) are sold or marketed in the United States during the quarter.

(ii) Exception

With respect to single source drugs or biologicals that are within the same billing and payment code as of October 1, 2003, the Secretary shall treat such single source drugs or biologicals as if the single source drugs or biologicals were multiple source drugs.

(D) Single source drug or biological

The term "single source drug or biological" means—

(i) a biological; or

(ii) a drug which is not a multiple source drug and which is produced or distributed under a new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

(E) Exception from pharmaceutical equivalence and bioequivalence requirement

Subparagraph (C)(ii) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (C)(i), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (F).

(F) Determination of pharmaceutical equivalence and bioequivalence

For purposes of this paragraph—

(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity; and

(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence.

(G) Inclusion of vaccines

In applying provisions of section 1396r-8 of this title under this section, "other than a vaccine" is deemed deleted from section 1396r-8(k)(2)(B) of this title.

(H) Biosimilar biological product

The term "biosimilar biological product" means a biological product approved under an abbreviated application for a license of a biological product that relies in part on data or information in an application for another biological product licensed under section 262 of this title.

(I) Reference biological product

The term "reference biological product" means the biological product licensed under such section

262 of this title that is referred to in the application described in subparagraph (H) of the biosimilar biological product.

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